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

Form 10-K

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

For the fiscal year ended December 31, 2025

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

For the transition period from _____ to _____

Commission File Number 000-23186

BIOCRYST PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**62-1413174**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

4505 Emperor Blvd., Suite 200, Durham, North Carolina 27703
(Address of principal executive offices)

(919) 859-1302
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value	**BCRX**	**Nasdaq Global Select Market**

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 Act. Yes ☐ No ☒

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

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

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

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

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

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

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

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

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

The registrant estimates that the aggregate market value of the Common Stock on June 30, 2025 (based upon the closing price shown on the Nasdaq Global Select Market on June 30, 2025) held by non-affiliates was $1,863,392,680.

The number of shares of Common Stock, par value $0.01, of the registrant outstanding as of February 20, 2026 was 250,800,620 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed in connection with the solicitation of proxies for its 2025 annual meeting of stockholders are incorporated by reference into Items 10, 11, 12, 13, and 14 under Part III hereof.

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When used in this report, unless otherwise indicated, "we," "our," "us," the "Company," and "BioCryst" refer to BioCryst Pharmaceuticals, Inc. and, where appropriate, its subsidiaries.

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "report") includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are subject to the "safe harbor" created in Section 21E. In particular, statements about our expectations, beliefs, plans, objectives or assumptions of future events or performance are contained or incorporated by reference in this report. All statements other than statements of historical facts contained herein are forward-looking statements. These forward-looking statements can generally be identified by the use of words such as "may," "will," "intends," "plans," "believes," "anticipates," "expects," "estimates," "predicts," "potential," the negative of these words or similar expressions. Statements that describe our future plans, strategies, intentions, expectations, objectives, goals or prospects are also forward-looking statements. Discussions containing these forward-looking statements are principally contained in the "*Business*," "*Risk Factors*," and "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" sections of this report, as well as any amendments we make to those sections in filings with the Securities and Exchange Commission ("SEC"). These forward-looking statements include, but are not limited to, statements about:

- the preclinical development, clinical development, commercialization, or post-marketing studies of our products and product candidates, including ORLADEYO® (berotralstat), navenibart, BCX17725, avoralstat, STAR-0310 and early-stage discovery programs and our plans and anticipated timing regarding the same;
- our discovery, acquisition and commercialization of best-in-class and first-in-class medicines;
- the timing and success of our commercialization of ORLADEYO in the United States and elsewhere and expectations regarding the commercial market for ORLADEYO;
- additional regulatory approvals, or milestones, royalties or profit from sales of our products by us or our partners;
- the implementation of our business model, strategic plans for our business, products, product candidates and technology;
- our ability to establish and maintain collaborations or out-license rights to our products and product candidates;
- plans, programs, progress and potential success of our collaborations, including, for example, with Torii Pharmaceutical Co., Ltd. ("Torii") for ORLADEYO in Japan and Shionogi & Co., Ltd. ("Shionogi") and Green Cross Corporation ("Green Cross") for peramivir in their territories;
- our and our subsidiary guarantors' ability to satisfy obligations under and to comply with covenants set forth in connection with the Blackstone Loan Agreement (as defined below);
- the scope of protection we are able to establish and maintain for intellectual property rights covering our products, product candidates, and technology;
- our ability to operate our business without infringing the intellectual property rights of others;
- estimates of our revenues, expenses, capital requirements, annual cash utilization, and our needs for additional capital or financing;
- the timing or likelihood of regulatory filings, regulatory agreements, deferrals, approvals, and other decisions;
- our ability to manage our liquidity needs to fund our operations or repay our recourse debt obligations;
- our financial performance;
- statements and projections regarding financial goals, including maintaining sustained profitability or positive cash flow;

- competitive companies, technologies, and our industry; and

- the Merger (as defined below), including, but not limited to, our expectations regarding the cost, benefits and expected synergies of the transaction.

We have based any forward-looking statements on our current expectations about future events or performance. While we believe these expectations are reasonable, forward-looking statements are inherently subject to known and unknown risks and uncertainties, many of which are beyond our control. Actual results may differ materially from those suggested or implied by these forward-looking statements for various reasons, including those discussed in this report under the heading "*Risk Factors*" in Part I, Item 1A, some of which are summarized in the "*Risk Factor Summary*" below. Any forward-looking statement is subject to these and other risks, uncertainties, and assumptions relating to our operations, results of operations, industry, and future growth. Given these risks and uncertainties, you are cautioned not to place undue reliance on our forward-looking statements. The forward-looking statements included in this report are made only as of the date hereof. We do not undertake, and specifically decline, any obligation to update, revise or correct any of these statements or to publicly announce the results of any such revisions to any forward-looking statements to reflect future events or developments, except as may be required by U.S. federal securities laws.

Risk Factor Summary

An investment in the Company involves risks. You should carefully read this entire report and consider the uncertainties and risks discussed in the "*Risk Factors*" section in Part I, Item 1A of this report, which may adversely affect our business, financial condition, or results of operations, along with the other information included in our other filings with the SEC, before making an investment decision in the Company. A summary of the principal factors that make an investment in the Company speculative or risky is set forth below.

- We may not achieve sustained profitability, and we may need to raise additional capital in the future. If we are unable to raise capital or obtain financing if and when needed, we may need to adjust our operations.

- If the benefits of the Merger do not meet the expectations of investors or securities analysts, the market price of our common stock may decline. In addition, combining Astria with our business may be more difficult, costly or time consuming than expected and the combined company may fail to realize the anticipated benefits, cost savings and synergies of the Merger.

- Our success depends in part upon our ability to manage our product candidate pipeline, advance our product candidates through the various stages of development, especially through the clinical trial process, and to receive and maintain regulatory approvals for the commercial sale of our product candidates. The development process and related regulatory processes are complex and uncertain, may be lengthy and expensive, and require, among other things, an indication that our products and product candidates are safe and effective. For example, applicable regulatory agencies could refuse to approve, or impose restrictions or warnings on, our product candidates, require us to conduct additional studies or adopt study designs that differ from our planned development strategies, suspend or terminate our clinical trials, withdraw approval for our products, or take other actions that could materially impact the cost, timing, and success of our planned development and commercialization strategies.

- We rely heavily upon third parties, including development partners, contractors, contract research organizations, and third-party suppliers, manufacturers, and distributors, for many important stages of our product candidate development and in the commercialization of certain of our products and product candidates. Our failure to establish and maintain these relationships, the failure of any such third party to perform its obligations under agreements with us, or the failure of such a relationship to meet our expectations could have a material adverse impact on our business, financial condition, and results of operations.

- If the U.S. Food and Drug Administration or comparable foreign regulatory authorities approve generic versions or biosimilars of any of our products that receive marketing approval, the sales of our products could be adversely affected.

- The commercial viability of any approved product could be compromised if the product is less effective than expected, causes undesirable side effects that either were not previously identified or were worse than expected, or fails to achieve market acceptance by physicians, patients, third-party payors, health authorities, and others.

- There can be no assurance that our or our partners' commercialization efforts, methods, and strategies for our products or technologies will succeed, and our future revenue generation is uncertain.

- We face intense competition, and if we are unable to compete effectively, the demand for our products may be reduced. In addition, developments by others may render our products, product candidates, or technologies obsolete or noncompetitive.

- We are subject to various laws and regulations related to our products and product candidates, and if we or our employees, consultants, or partners do not comply with these laws and regulations, we could face substantial penalties and our reputation could be harmed. In addition, we and our partners may be subject to new legislation, regulatory proposals, and healthcare payor initiatives that may increase our costs of compliance and adversely affect our or our partners' ability to market our products or develop our product candidates.

- If we fail to adequately protect or enforce our intellectual property rights, the value of those rights would diminish. Legal proceedings to protect or enforce our patents, the patents of our partners, or our other intellectual property rights could be expensive, time consuming, and unsuccessful. If we fail to secure the rights to patents of others, this could adversely affect our business.

- We face an inherent risk of liability in the event that the use or misuse of our products or product candidates results in personal injury or death, and our product liability insurance coverage may be insufficient.

- If we fail to reach milestones or to make annual minimum payments or otherwise breach our obligations under our license agreements, our licensors may terminate our agreements with them and/or seek additional remedies.

- The Blackstone Loan Agreement (as defined below) contains conditions and restrictions that limit our flexibility in operating our business.

- International expansion of our business exposes us to business, legal, regulatory, political, operational, financial, and economic risks. For example, our actual or perceived failure to comply with non-U.S. governmental laws and regulations and other obligations related to privacy, data protection, and information security could harm our business.

- If our facilities, or the facilities of our third-party vendors, incur damage or power is lost for a significant length of time, our operations will be disrupted, which will adversely affect our business.

- Cyber incidents and related disruptions in our or our third-party vendors' information technology systems, as well as challenges with properly managing or using artificial intelligence, could adversely affect our business.

- Our ability to maintain global brand uniformity for ORLADEYO may be impacted by the sale of our European ORLADEYO business.

- Our business, operations, clinical development or commercialization plans and timelines, and access to capital could be adversely affected by unpredictable and unstable market and economic conditions.

- If we fail to retain our existing key personnel, or fail to attract and retain additional key personnel, the development of our product candidates, the commercialization of our products, and the related growth of our business may be delayed or stopped.

- Future acquisitions, strategic investments, partnerships, alliances, or divestitures could fail to meet our expectations and/or adversely affect our operating results and financial condition.

- Our existing principal stockholders hold a substantial amount of our common stock and may be able to influence significant corporate decisions, which may conflict with the interests of other stockholders.

- Our stock price has been, and is likely to continue to be, highly volatile, which could cause the value of an investment in our common stock to decline significantly.

- If we fail to maintain effective internal control over financial reporting, we may not be able to produce accurate

and timely financial statements, which may adversely affect investor confidence in us and our financial reporting, adversely affect our business and operating results and negatively impact the trading price of our common stock.

- Natural disasters, epidemic or pandemic disease outbreaks, trade wars, armed conflicts, political unrest, or other events could disrupt our business or operations, or those of our development partners, manufacturers, regulators, or third parties with whom we conduct business now or in the future.

- We are subject to legal proceedings, which could harm our reputation or result in other losses or unexpected expenditure of time and resources.

PART I

ITEM 1. *BUSINESS*

Our Business

We are a global biotechnology company focused on developing and commercializing medicines for hereditary angioedema ("HAE") and other rare diseases, driven by our deep commitment to improving the lives of people living with these conditions. We have built a robust commercial infrastructure to support the successful commercialization of ORLADEYO, an oral, once-daily therapy discovered and developed internally for the prevention of HAE attacks. Our business strategy includes leveraging this established commercial platform to successfully commercialize a pipeline of potential first-in-class or best-in class oral small molecule and injectable protein therapeutics targeting a range of rare diseases. These programs are being pursued through both internal discovery efforts and strategic business development. By utilizing our existing commercial capabilities and focusing on rare disease markets, we believe that we can more effectively optimize costs and strategically allocate resources to support long-term, sustainable growth.

Molecules from our discovery and business development efforts that are commercially available or that are in active development are summarized in the table below and are discussed in further detail under "*Products and Product Candidates*" in this "*Part I—Item 1—Business*" section of this report. For a description of our relationships with third parties regarding our products and product candidates, see "*Business—Collaborations, License and Other Relationships*." In addition to the molecules referenced in the table below, we are pursuing certain pre-clinical medicines directed at other rare disease targets.

Drug/Drug Candidate	Drug Class	Therapeutic Area(s)	Phase
ORLADEYO® (berotralstat)	Oral Serine Protease Inhibitor Targeting Kallikrein (once-daily oral capsule treatment)	Hereditary Angioedema	Approved (United States and multiple global markets)
	Oral Serine Protease Inhibitor Targeting Kallikrein (once-daily oral pellets treatment for patients who are 2 to <12 years of age)	Hereditary Angioedema	Approved (United States)
Navenibart (STAR-0215)	Monoclonal Antibody Plasma Kallikrein Inhibitor	Hereditary Angioedema	Phase 3
BCX17725	Protein Therapeutic	Netherton Syndrome	Phase 1
Avoralstat	Ocular Plasma Kallikrein Inhibitor	Diabetic Macular Edema	Phase 1
STAR-0310	Monoclonal Antibody OX40 Antagonist	Atopic Dermatitis	Phase 1a
RAPIVAB® (peramivir injection)	Intravenous Neuraminidase Inhibitor	Acute Uncomplicated Influenza	Approved (United States, Australia & Canada)
RAPIACTA® (peramivir injection)	Intravenous Neuraminidase Inhibitor	Uncomplicated Seasonal Influenza	Approved (Japan & Taiwan)
PERAMIFLU® (peramivir injection)	Intravenous Neuraminidase Inhibitor	Uncomplicated Seasonal Influenza	Approved (Korea)

Business Strategy

Our business strategy is threefold: to serve patients, create stockholder value and increase profitability by (i) focusing our discovery efforts on potential first-in-class or best-in-class oral small-molecule and injectable protein therapeutics to target rare diseases, (ii) pursuing strategic external business development opportunities focusing on rare disease assets with disciplined and efficient use of capital, and (iii) successfully commercializing these products by leveraging our existing commercial infrastructure. By focusing primarily on rare disease markets, we believe that we can more effectively control the costs of, and our strategic allocation of financial resources toward, post-approval commercialization.

We select disease targets and product candidates in which an orally-administered small-molecule or an injectable protein therapeutic has the potential to be best-in-class or would be the first to market. We strive to advance our product candidate portfolio from internal discovery and development and strategic business initiatives to commercial markets efficiently by utilizing talented and highly-skilled employees working in conjunction with strategic outsource partners. The principal elements of our strategy are:

- *Focusing on High Value-Added Structure-Guided Drug Design Technologies.* We utilize structure-guided drug design in order to most efficiently develop new therapeutic product candidates. Structure-guided drug design is a process by which we design a product candidate through detailed structural analysis of the protein target, which the product candidate must inhibit in order to stop the progression of the disease or disorder. We use X-ray crystallography, computer modeling of molecular structures and advanced chemistry techniques to focus on the three-dimensional molecular structure and active site characteristics of the protein targets that control cellular biology. We believe that structure-guided drug design is a powerful tool for the efficient development of small-molecule and protein therapeutic product candidates that have the potential to be safe and effective. Our structure-guided drug design technologies typically allow us to design and synthesize multiple product candidates that inhibit the same protein target, with the goal of establishing broad intellectual property protection and formulating compounds with competitive advantages.

- *Selecting Inhibitors that are Promising Product Candidates.* We start by selecting disease targets with well-understood biology and characteristics that fit with our ability to utilize structure-guided drug design capabilities to build potent and specific inhibitors. Next, we narrow our selection of these product candidates based on product characteristics, such as initial indications of safety and biologic activity on the target.

- *Expanding our Pipeline Through External Opportunities.* Business development is a key component of our strategy to drive future growth and sustain profitability. Our focus is concentrated on identifying and acquiring rare disease assets with potential for near-term value creation. We prioritize opportunities that can be efficiently integrated into our existing commercial infrastructure, enabling meaningful synergies and operating leverage and enhanced long-term value.

- *Developing our Product Candidates Efficiently.* An important element of our business strategy is to progress our product candidates efficiently through the development process. In order to accomplish this, we typically strive for disease targets with a defined clinical and regulatory pathway for approval or diseases where high unmet needs allow for frequent interactions with regulators. In addition, as we determine such relationships to be appropriate or desirable, we control certain fixed costs and overhead by outsourcing with strategic partners and contractors or entering into license agreements with third parties. By outsourcing certain aspects of our operations, we are able to focus financial resources directly where they provide the most benefit and reduce our business risk.

- *Commercializing our Product Candidates in Key Markets.* A core part of our strategy is to commercialize our rare disease products in targeted, high-value markets to support sustainable growth. We have established commercial teams in the United States and other global markets for the commercialization of ORLADEYO, and we will leverage this structure and expertise to commercialize our products in key markets where we believe we can do this efficiently and effectively. We have also established relationships with licensing, distribution and other partners in certain markets, including Japan, the pan-Latin America region, and parts of Europe and Asia, and will continue to seek such relationships where we determine this to be an effective approach.

Products and Product Candidates

ORLADEYO® (berotralstat)

ORLADEYO is an oral, once-daily therapy discovered and developed by us for the prevention of HAE attacks. HAE is a rare, severely debilitating and potentially fatal genetic condition with an estimated prevalence of between 1 in 33,000 to 1 in 67,000 people. HAE symptoms include recurrent episodes of edema in various locations, including the hands, feet, face, genitalia and airway. Airway swelling is particularly dangerous and can lead to death by asphyxiation. In addition, patients often have bouts of severe abdominal pain, nausea and vomiting caused by swelling in the intestinal wall. By inhibiting plasma kallikrein, ORLADEYO suppresses bradykinin production. Bradykinin is the mediator of acute swelling attacks in HAE patients.

A capsule formulation of ORLADEYO was approved by the U.S. Food and Drug Administration ("FDA") in December 2020 for prophylaxis to prevent attacks of HAE in adults and pediatric patients 12 years and older, and we subsequently received regulatory approvals for ORLADEYO in other global markets. In December 2025, we received FDA approval for the use of an oral pellet formulation of ORLADEYO for prophylactic therapy in pediatric patients with HAE aged 2 to <12 years. ORLADEYO is the first and only targeted oral prophylactic therapy for children with HAE aged 2 to <12 years. We also filed an application for the use of ORLADEYO in patients with HAE aged 2 to <12 years with the European Medicines Agency and the Japan Pharmaceutical and Medical Devices Agency and additional regulatory filings are planned in other global territories.

Our specialty pharmacy provider for ORLADEYO in the United States began shipping ORLADEYO capsules to patients with a prescription in the United States in December 2020. Through EMPOWER Patient Services, administered by our specialty pharmacy provider, we aim to streamline access to therapy by providing each HAE patient and their healthcare provider with a single point of contact for access to ORLADEYO.

Based on proprietary analyses of HAE prevalence and market research studies with HAE patients, physicians, and payors in the United States and Europe, and five full years of commercialization experience with ORLADEYO in the United States from 2021 through 2025, we anticipate that the global commercial market for ORLADEYO has the potential to reach a global peak of $1 billion in annual net ORLADEYO revenues. Based on our commercialization experience with ORLADEYO, we believe there is a seasonal impact to our business in the first quarter of each year due to typical first quarter requirements from payors for prescription reauthorization of specialty products, like ORLADEYO, that can temporarily move patients from paid drug to free product. These expectations are subject to numerous risks and uncertainties that may cause our actual results, performance, or achievements to be materially different. There can be no assurance that our commercialization methods and strategies will succeed, or that the market for ORLADEYO will develop in line with our current expectations. See "*Risk Factors—Risks Relating to Our Business—Risks Relating to Product Development and Commercialization—There can be no assurance that our or our partners' commercialization efforts, methods, and strategies for our products or technologies will succeed, and our future revenue generation is uncertain*" in Part I, Item 1A of this report for further discussion of these risks.

On each of December 7, 2020 and November 19, 2021, we entered into a Purchase and Sale Agreement with RPI 2019 Intermediate Finance Trust ("RPI"), pursuant to which we sold to RPI the right to receive certain royalty payments from us (the "RPI Royalty Purchase Agreements"). On November 19, 2021, we also entered into a Purchase and Sale Agreement (the "OMERS Royalty Purchase Agreement" and, collectively with the RPI Royalty Purchase Agreements, the "Royalty Purchase Agreements") with OCM IP Healthcare Holdings Limited, an affiliate of OMERS Capital Markets ("OMERS"), pursuant to which we sold to OMERS the right to receive certain royalty payments from us. See "*Note 9—Royalty Financing Obligations*" in the Notes to Consolidated Financial Statements in Part II, Item 8 of this report for additional information about our obligations under the Royalty Purchase Agreements.

We have also entered into a number of collaborations and other relationships with commercial partners to help support the global commercialization of ORLADEYO. See "*Collaborations, License and Other Relationships*" below for a description of our relationships with these partners.

On February 24, 2025, we announced that a new market tracking survey of 60 HAE treaters showed that 97 percent are considering prescribing ORLADEYO and 59 percent (up from 26 percent 18 months prior) of current prescribers indicate they are extremely likely to prescribe for more of their patients. We also announced positive results from an interim analysis of the ongoing APeX-P clinical trial evaluating ORLADEYO in children with HAE aged 2 to <12. In addition, we announced that additional real-world studies with ORLADEYO show statistically significant HAE attack rate reductions experienced by patients with C1-inhibitor deficiency and normal C1-inhibitor levels and function. Patient-

reported outcomes also showed willingness to change long-term prophylaxis and improved treatment satisfaction across varying levels of attack frequency and severity after ORLADEYO initiation.

On May 5, 2025, we announced that the percentage of U.S. HAE patients who describe a strong preference for an oral prophylaxis therapy increased to 70 percent, up from 50 percent in 2023, in our latest market survey of HAE patients. We also announced that we submitted an NDA to the FDA to expand the ORLADEYO label to children with HAE aged 2 to <12.

On May 16, 2025, we announced new real-world evidence on the use of ORLADEYO in adolescents and people with severe HAE showing significant and sustained reductions in HAE attack rates through 18 months of follow-up after beginning treatment with ORLADEYO in both patient populations.

On May 30, 2025, we announced new data which highlights the reduction in the percentage of days with HAE symptoms among young children initiating berotralstat in our APeX-P trial. The ongoing APeX-P clinical trial, which is complete through the primary endpoint, is continuing to assess an oral pellet formulation of ORLADEYO in pediatric patients who are 2 to <12 years of age at enrollment. We also announced the broad safety and efficacy outcomes observed across all age groups of patients taking ORLADEYO to prevent HAE attacks.

On June 13, 2025, we announced that the National Institute of Drug and Food Surveillance in Colombia granted approval for ORLADEYO for the prophylaxis of HAE attacks in adults and pediatric patients 12 years of age or older. We have an exclusive collaboration with Pint Pharma GmbH ("Pint Pharma") to register and promote ORLADEYO in the pan-Latin America region. Under the terms of the agreement, Pint Pharma is responsible for obtaining and maintaining all marketing authorizations and for commercializing ORLADEYO in the region.

On June 16, 2025, we announced new data on the long-term efficacy and safety of ORLADEYO for the prophylactic treatment of HAE in patients across all age groups, demonstrating sustained reductions in HAE attacks and consistent safety profile.

On August 4, 2025, we announced that new real-world data from over 350 patients with HAE with normal C1 inhibitor showed substantial reductions in attack rates with ORLADEYO, which we believe reinforces its value for a historically underserved patient segment and provides strong evidence to close gaps in both treatment and reimbursement.

On October 1, 2025, we announced the successful completion of the sale of our European ORLADEYO business to Neopharmed Gentili. See "*Collaborations, License and Other Relationships*" below for a discussion of this sale.

On November 6, 2025, we announced new data demonstrating the early and negative psychosocial impact of HAE and resulting emergency department and hospital visits on pediatric patients and their caregivers, as well as new one-year data from the ongoing APeX-P clinical trial showing early and sustained reductions in monthly attack rates over one year in pediatric patients with HAE aged 2 to <12 years treated with once-daily ORLADEYO.

On December 12, 2025, we announced that the FDA approved our new drug application ("NDA") for the use of an oral pellet formulation of once-daily ORLADEYO for prophylactic therapy in pediatric patients with HAE aged 2 to <12 years.

Navenibart (STAR-0215)

On January 23, 2026 (the "Closing Date"), BioCryst completed the transactions contemplated by the Agreement and Plan of Merger, dated as of October 14, 2025 (the "Merger Agreement"), by and among BioCryst, Axel Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of BioCryst ("Merger Sub") and Astria Therapeutics, Inc., a Delaware corporation ("Astria"). On the Closing Date, Merger Sub merged with and into Astria (the "Merger"), with Astria surviving the Merger as a wholly owned subsidiary of BioCryst. Pursuant to the Merger, on the Closing Date, we acquired Astria's lead product candidate navenibart, a injectable monoclonal antibody designed to inhibit plasma kallikrein for the treatment of HAE. Navenibart is currently in Phase 3 clinical development, and the FDA has granted Fast Track and Orphan Drug designations to navenibart for the treatment of HAE. In addition, the European Commission has granted Orphan Medicinal Product Designation to navenibart for the treatment of HAE. The goal for navenibart is to develop a potentially best-in-class injectable prophylactic therapy with a differentiated every 3- and 6-month administration schedule, which could offer significant improvements over existing injectable options and address key unmet needs in the HAE patient community.

On February 26, 2026, we announced that new positive, interim results from the long-term, open-label ALPHA-SOLAR trial show sustained, robust HAE attack suppression with navenibart administered every three and six months.

BCX17725 (Netherton syndrome)

BCX17725 is a potent and selective investigational protein therapeutic KLK5 inhibitor designed to provide best-in-class, potentially disease-modifying, treatment for people with Netherton syndrome. Netherton syndrome is a serious, rare, lifelong genetic disorder causing disruption of the skin barrier with premature separation of the skin layers, chronic inflammation and vulnerability to serious infections, caused by lack of normal function of a natural inhibitor of KLK5. People with Netherton syndrome often have itchy, red, scaly, inflamed skin, fragile hair, and are more likely to develop severe food allergies, asthma and eczema. Netherton syndrome can be life-threatening, especially during infancy when patients are vulnerable to dehydration and recurrent infections. Currently, there are no approved treatments that target the underlying cause of Netherton syndrome. BCX17725 is designed to replace missing functions of the natural KLK5 inhibitor, which could restore the normal skin barrier and result in improved skin function, including protection from severe inflammatory and infectious complications of the disease.

On May 5, 2025, we announced that the FDA cleared our investigational new drug application, which will enable our clinical trial of BCX17725 to enroll patients in the United States. This Phase 1 trial is also open in Australia.

On July 30, 2025, we were notified that the FDA granted Fast Track designation for BCX17725 for the treatment of Netherton syndrome.

On February 26, 2026, we announced that we expect to report data from the clinical trial of BCX17725 for the treatment of Netherton syndrome in up to 12 patients by the end of 2026.

Avoralstat

Avoralstat, an investigational plasma kallikrein inhibitor, is designed to treat patients with diabetic macular edema (“DME”) through the delivery of avoralstat to the back of the eye through the suprachoroidal space. DME is an important cause of vision loss in diabetes and is due to leakage of fluid from the blood vessels in the retina. While current treatments focus on vascular endothelial growth factor (“VEGF”) inhibition, DME can develop from other mechanisms, such as the kallikrein-bradykinin pathway. This is supported by observations that many DME patients have an incomplete response to intravitreal anti-VEGF therapies that are administered every four to eight weeks. Avoralstat targets the kallikrein-bradykinin system on the retinal vascular endothelial cells and may result in less vascular leakage and less edema. Avoralstat, delivered to the suprachoroidal space, is designed to provide long-lasting exposure to the retinal vessels, which could result in less frequent injections and a reduced burden on patients and the healthcare system.

On August 4, 2025, we announced that we were enrolling patients in the first clinical trial with suprachoroidal delivery of avoralstat in Australia. On November 3, 2025, we announced that we plan to seek a strategic partner for development beyond Phase 1.

STAR-0310

Pursuant to the Merger, on the Closing Date, we acquired STAR-0310, which is a monoclonal antibody OX40 antagonist that incorporates YTE half-life extension technology for the treatment of atopic dermatitis (“AD”) and potentially other indications. STAR-0310 was designed as a potentially best-in-class, long-acting OX40 inhibitor with the goal of addressing the need for a safe, effective, and infrequently administered AD treatment. AD is an immune disorder associated with loss of skin barrier function and itching and is caused by diverse mechanisms, spanning the spectrum of T cell-driven pathology. STAR-0310 is currently in a Phase 1a trial to assess the safety, tolerability, pharmacokinetics, and immunogenicity of STAR-0310 in healthy subjects. We plan to seek strategic alternatives for this asset.

Peramivir Injection (RAPIVAB, RAPIACTA, PERAMIFLU)

RAPIVAB (peramivir injection) was developed under a $234.8 million contract from the Biomedical Advanced Research and Development Authority within the U.S. Department of Health and Human Services. In January 2010, our partner, Shionogi, received the first approval for peramivir injection and launched it in Japan under the commercial name RAPIACTA. It is approved in Japan for the treatment of adults, children, and infants with uncomplicated seasonal

influenza and those patients at high-risk for complications associated with influenza. In August 2010, our partner, Green Cross, received marketing and manufacturing approval from the Korean Food & Drug Administration under the commercial name PERAMIFLU to treat patients with influenza A & B viruses, including pandemic H1N1 and avian influenza. See "*Collaborations, License and Other Relationships*" below for a discussion of these licensing arrangements.

Peramivir was also approved in the United States in 2014, Taiwan in 2016, Canada in 2017, and Australia in 2018. A Supplemental New Drug Application was approved in the United States in February 2021, extending RAPIVAB's availability for the treatment of acute uncomplicated influenza to pediatric patients six months and older. Prior to this approval, peramivir had been indicated in the United States for pediatric patients two years and older. In the United States, peramivir is indicated for the treatment of acute uncomplicated influenza in patients who have been symptomatic for no more than two days.

On September 30, 2024, we announced that the U.S. Department of Health and Human Services ("HHS") awarded us up to a $69 million contract for the procurement of up to 95,625 doses over a five-year period of RAPIVAB (peramivir injection) for the treatment of influenza (the "HHS Contract"). The HHS Contract, awarded by the HHS Office of the Administration for Strategic Preparedness and Response ("ASPR"), supplied the Center for the Strategic National Stockpile, the nation's largest supply of life-saving pharmaceuticals and medical supplies for use in a public health emergency. The HHS Contract was structured with a 12-month base ordering period and four optional 12-month ordering periods, which the U.S. Government could exercise on an annual basis. ASPR executed the first ordering period for $13.9 million to supply 19,125 doses of peramivir by September 29, 2025. We delivered 16,821 and 2,304 doses of peramivir during 2025 and 2024, respectively. On May 15, 2025, ASPR notified us of its intent to not exercise any additional optional ordering periods available under the agreement.

Collaborations, License and Other Relationships

ORLADEYO

Torii Pharmaceutical Co., Ltd. ("Torii")

On November 5, 2019, we entered into a Commercialization and License Agreement with Torii (the "Original Torii Agreement"), granting Torii the exclusive right to commercialize ORLADEYO for the prevention of HAE attacks in Japan. Under the Original Torii Agreement, we received an upfront, non-refundable payment of $22.0 million. We received an additional milestone payment of $15.0 million in the second quarter of 2021 upon receipt from the Japanese National Health Insurance System ("NHI") of a reimbursement price approval for ORLADEYO.

On November 30, 2023, we entered into an Amended and Restated Commercialization and License Agreement with Torii (as amended, the "Torii Agreement").

Under the Torii Agreement, we are entitled to receive tiered royalty payments, ranging from 20% to 80% of annual net sales of ORLADEYO in Japan during each calendar year. We are now responsible for all commercial promotion activities to support ORLADEYO sales in Japan, and Torii is responsible for HAE disease awareness activities in Japan. We will receive a 20% royalty on annual Japanese sales below a prespecified threshold and an 80% royalty on annual Japanese sales above the prespecified threshold.

Torii's updated royalty payment obligations commenced on November 30, 2023 and will expire upon the later of (i) the tenth anniversary of the date of first commercial sale of ORLADEYO in Japan, (ii) the expiration of our patents covering ORLADEYO, and (iii) the expiration of regulatory exclusivity for ORLADEYO in Japan.

Neopharmed Gentili S.p.A. ("Neopharmed")

On June 27, 2025, we entered into a stock purchase agreement (the "Stock Purchase Agreement") with BioCryst Ireland Limited ("BioCryst Ireland"), a private limited company incorporated under the laws of Ireland and a wholly owned subsidiary of BioCryst, and Neopharmed. On October 1, 2025, under the terms of the Stock Purchase Agreement, we sold to Neopharmed all of our equity interests in BioCryst Ireland, which, together with its subsidiaries, holds certain assets, rights, and employees related to our European ORLADEYO business. We received cash proceeds of $250.0 million, plus customary purchase price adjustments as set forth in the Stock Purchase Agreement. In addition, Neopharmed has agreed to pay us up to $14.0 million if certain revenue milestones are achieved prior to December 31, 2032.

Concurrent with the closing of the transactions contemplated by the Stock Purchase Agreement, on October 1, 2025, we and BioCryst Ireland amended and restated our existing intellectual property licence agreement pursuant to which we will continue to grant to BioCryst Ireland certain rights with respect to ORLADEYO in the territory (the "Amended and Restated IP Licence Agreement"). The terms of the Amended and Restated IP Licence Agreement may also extend to the pediatric line extension of ORLADEYO, subject to certain regulatory approvals.

On October 1, 2025, we also entered into a supply agreement with BioCryst Ireland, pursuant to which we will be the exclusive supplier of ORLADEYO products to BioCryst Ireland for commercialization in the territory. Additionally, we entered into a global brand and support agreement with BioCryst Ireland, which provides for coordination of brand and regulatory activities between us and BioCryst Ireland regarding ORLADEYO products. Lastly, on October 1, 2025, we entered into a trademark license agreement with BioCryst Ireland, pursuant to which we granted to BioCryst Ireland a non-exclusive transitionary license to use the "BioCryst" name, solely to develop, manufacture and commercialize ORLADEYO products in the territory for a limited period of time, and an exclusive license to use the ORLADEYO product name to commercialize ORLADEYO products for such uses for the term of the Amended and Restated IP Licence Agreement, in each case subject to the terms and conditions set forth therein.

Other Collaborations for ORLADEYO

We have entered into a number of collaborations with commercial partners to help support the global commercialization of ORLADEYO. In 2021, we entered into supply and distribution agreements with Neopharm Ltd. ("Neopharm") and NewBridge Pharmaceuticals ("NewBridge") to support commercialization efforts in Israel and the United Arab Emirates ("UAE"), respectively. Under the terms of these agreements, Neopharm has the exclusive rights to commercialize ORLADEYO in Israel and the Palestinian Authority, and NewBridge will support commercialization efforts in the UAE, as well as the Gulf Cooperation Council and Iraq. On June 9, 2022, we announced that we entered into an exclusive collaboration with Pint Pharma to register and promote ORLADEYO in the pan-Latin America region. Under the terms of the agreement, Pint Pharma is responsible for obtaining and maintaining all marketing authorizations and for commercializing ORLADEYO in the region. On January 23, 2023, we announced that we entered into a collaboration with Swixx BioPharma AG ("Swixx") to commercialize ORLADEYO in Central and Eastern Europe ("CEE"). Under the terms of the agreement, Swixx is responsible for commercializing ORLADEYO in 15 markets within CEE. Pursuant to the Stock Purchase Agreement with Neopharmed, we transferred the agreement with Swixx to Neopharmed. On July 19, 2023, we announced that we entered into a collaboration with Er-Kim Pharmaceuticals to commercialize ORLADEYO in Turkey.

Navenibart

Kaken Pharmaceutical Co., Ltd. ("Kaken")

On August 6, 2025, Astria entered into a license agreement (the "Kaken License Agreement"), pursuant to which it granted an exclusive license under certain patent rights and know-how controlled by Astria for Kaken to develop, package, and commercialize navenibart for the prevention of HAE attacks in humans in Japan. Under the Kaken License Agreement, Astria received an upfront payment of $16.0 million in the fourth quarter of 2025, with the potential for an additional $16.0 million in total commercialization and sales milestones. In addition to these payments, Astria is also eligible for tiered royalties with the royalty rate as a percentage of net sales from the mid-teens to 30%. Pursuant to the terms of the Kaken License Agreement, Kaken will also provide support for the ALPHA-ORBIT Phase 3 trial in Japan, be responsible for regulatory submissions in Japan, and reimburse Astria for a portion of the costs of the navenibart Phase 3 program.

Peramivir Injection (RAPIVAB, RAPIACTA, PERAMIFLU)

Shionogi & Co., Ltd. ("Shionogi")

In February 2007, we entered into a License, Development and Commercialization Agreement (as amended, supplemented or otherwise modified, the "Shionogi Agreement"), an exclusive license agreement with Shionogi to develop and commercialize peramivir in Japan for the treatment of seasonal and potentially life-threatening human influenza. In October 2008, we and Shionogi amended the Shionogi Agreement to expand the territory covered by the agreement to include Taiwan. The Shionogi Agreement provided for an upfront payment in exchange for the rights to injectable formulations of peramivir in Japan, development milestone payments (which have all been paid), commercial milestone payments, and royalty payments on product sales of peramivir, in accordance with the terms of the Shionogi Agreement.

Generally, all payments under the Shionogi Agreement are non-refundable and non-creditable, but they are subject to audit. Shionogi is responsible for all development, regulatory, and marketing costs in Japan. The term of the Shionogi Agreement is from February 28, 2007 until terminated. Either party may terminate the Shionogi Agreement in the event of an uncured breach. Shionogi has the right of termination without cause. In the event of termination, all license and rights granted to Shionogi shall terminate and shall revert back to us. We developed peramivir under a license from the University of Alabama Birmingham ("UAB") and have paid sublicense payments to UAB on the upfront payments and will owe sublicense payments on any future event payments and/or royalties received by us from Shionogi.

Shionogi Royalty Financing and Non-Recourse Notes Payable

On March 9, 2011, we completed a $30.0 million financing transaction to monetize certain future royalty and milestone payments under the Shionogi Agreement. Pursuant to the transaction, JPR Royalty Sub LLC, a wholly-owned subsidiary of the Company ("Royalty Sub"), issued $30.0 million in aggregate principal amount of its PhaRMA Senior Secured 14.0% Notes due 2020 (the "PhaRMA Notes") in a private placement to institutional investors. The PhaRMA Notes were issued under an indenture, dated as of March 9, 2011 (the "Indenture"), by and between Royalty Sub and U.S. Bank National Association, as Trustee. We received net proceeds of $22.7 million from this transaction.

Principal and interest on the PhaRMA Notes are payable from, and are secured by the rights to royalty and milestone payments under the Shionogi Agreement, which were transferred by us to Royalty Sub in 2011. Royalty Sub's obligations to pay principal and interest on the PhaRMA Notes are obligations solely of Royalty Sub and are without recourse to any other person, including the Company, except to the extent of our pledge of our equity interests in Royalty Sub in support of the PhaRMA Notes.

In September 2014, Royalty Sub was unable to pay the full amount of interest payable in September 2013 by the next succeeding payment date for the PhaRMA Notes, which was September 1, 2014. This inability constituted an event of default under the terms of the Indenture. As of December 31, 2025, the PhaRMA Notes remained in default. While Royalty Sub continues to pay the holders of the PhaRMA Notes any royalty payments received from Shionogi, which are immaterial, we wrote off the balance due under the PhaRMA Notes to other income as a debt extinguishment as of December 31, 2021.

Green Cross Corporation ("Green Cross")

In June 2006, we entered into an agreement with Green Cross to develop and commercialize peramivir in Korea. Under the terms of the agreement, Green Cross is responsible for all development, regulatory, and commercialization costs in Korea and we are entitled to share in profits resulting from the sale of peramivir in Korea, including the sale of peramivir to the Korean government for stockpiling purposes. Furthermore, Green Cross will pay us a premium over its cost to supply peramivir for development and any future marketing of peramivir products in Korea. Both parties have the right to terminate the agreement in the event of an uncured material breach. In the event of termination, all rights, data, materials, products, and other information would be transferred to us.

Additional Collaborations

We also have non-material license agreements with certain third parties, such as Albert Einstein College of Medicine of Yeshiva University ("AECOM"), Industrial Research, Ltd. ("IRL"), and the University of Alabama at Birmingham ("UAB"), which require that we make certain payments related to development of the product candidates covered by these agreements, net sales on any resulting product made by us, and annual license fees. We licensed a series of potent inhibitors of purine nucleoside phosphorylase ("PNP") from AECOM and IRL, as well as an exclusive worldwide license of galidesivir for any antiviral use, and we have agreements with UAB for influenza neuraminidase and complement inhibitors. There is currently no material activity between us and UAB on these agreements, but when we license this technology, such as in the case of the Shionogi and Green Cross agreements, or commercialize products related to these programs, we owe sublicense fees or royalties on amounts received.

As discussed in "*Note 16—Collaborative and Other Relationships*" in the Notes to Consolidated Financial Statements in Part II, Item 8 of this report, we entered into a license agreement with Clearside Biomedical, Inc. to develop our investigational plasma kallikrein inhibitor, avoralstat, with Clearside's SCS Microinjector® to deliver avoralstat to the back of the eye through the suprachoroidal space to treat patients with DME. In addition, on October 4, 2023, Astria entered into a license agreement (the "Ichnos License Agreement") with Ichnos Sciences SA and Ichnos Sciences Inc. (collectively, "Ichnos") pursuant to which Ichnos granted to Astria an exclusive (even as to Ichnos and its affiliates),

worldwide, and sublicensable right and license to certain patent rights and related know-how to develop, manufacture, and commercialize Ichnos' proprietary OX40 portfolio, which includes STAR-0310.

Patents and Proprietary Information

Our success will depend in part on our ability to obtain and enforce patent protection for our products, methods, processes, and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. We own or have rights to certain proprietary information, proprietary technology, issued and allowed patents and patent applications which relate to compounds we are developing. We actively seek, when appropriate, protection for our products, proprietary technology, and proprietary information by means of U.S. and foreign patents, trademarks, and contractual arrangements. In addition, we rely upon trade secrets and contractual arrangements to protect certain of our proprietary information, proprietary technology, and products and product candidates.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective patent claims and enforcing those claims once granted. We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated, rendered unenforceable or circumvented, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, the rights granted under any issued patents may not provide us with competitive advantages against competitors with similar compounds or technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us in a manner that does not infringe our patents or other intellectual property. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates or those developed by our partners can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

As of December 31, 2025, we have been issued approximately 39 U.S. patents that expire between 2027 and 2040 and that relate to our kallikrein inhibitor compounds, neuraminidase inhibitor compounds, broad-spectrum antiviral ("BSAV") compounds, PNP inhibitor compounds, and complement-mediated disease program compounds. We have licensed a number of compounds protected by certain composition of matter patents from AECOM and IRL, totaling one additional U.S. patent that expires in 2029. Additionally, we have approximately 30 Patent Cooperation Treaty or U.S. patent applications pending related to kallikrein inhibitor compounds, neuraminidase inhibitor compounds, BSAV compounds, PNP inhibitor compounds, KLK5 program compounds, and complement-mediated disease program compounds. In addition, as of December 31, 2025, Astria has approximately 12 Patent Cooperation Treaty or U.S. patent applications pending that relate to its anti-kallikrein monoclonal antibody program and anti-OX40 monoclonal antibody program. As of December 31, 2025, no U.S. patents have issued related to these programs. Astria has also licensed intellectual property from Ichnos that relates to its anti-OX40 monoclonal antibody program totaling 3 additional U.S. patents that expire in 2032 and 2 pending U.S. patent applications. Our pending applications may not result in issued patents, our patents may not cover the products of interest or may not be enforceable in all, or any, jurisdictions and our patents may not provide us with sufficient protection against competitive products or otherwise be commercially viable. After expiration of composition of matter patents for our products and product candidates, we may rely on data exclusivity, or in some cases, secondary pharmaceutical patents (such as patents covering solid pharmaceutical forms, salt forms, dosing regimens, and methods of use). The enforceability of these secondary patents varies from jurisdiction to jurisdiction and may not be allowed or enforceable in some jurisdictions where we may seek approval. We may not have the funds to continue patent prosecution or to defend all of our existing patents in our current patent estate and may selectively abandon patents or patent families worldwide or in certain territories.

Our success is also dependent upon the skills, knowledge and experience of our scientific and technical personnel, none of which is patentable. To help protect our rights, we require all employees, consultants, advisors and partners to enter into confidentiality agreements, which prohibit the disclosure of confidential information to anyone outside of BioCryst and, where possible, require disclosure and assignment to us of their ideas, developments, discoveries, and inventions. These agreements may not provide adequate protection for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information.

Competition

The pharmaceutical and biotechnology industries are intensely competitive. Many companies, including biotechnology, chemical and pharmaceutical companies, are actively engaged in activities similar to ours, including research, development, and commercialization of drugs for the treatment of rare medical conditions. Many of these companies have substantially greater financial and other resources, larger research and development staffs, and more extensive commercial and manufacturing organizations than we do. In addition, many have considerable experience in preclinical testing, clinical trials, and other regulatory approval procedures. In addition, there are also academic institutions, governmental agencies and other research organizations who conduct research in areas in which we are working.

We expect to encounter significant competition for any of the pharmaceutical products we plan to develop. Companies that successfully complete clinical trials, obtain required regulatory approvals, and commence commercial marketing and sales of their products may achieve a significant competitive advantage. Our commercial potential could also be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products that we may develop. Our product candidates, even if successfully tested and developed, may not be adopted by physicians over other products and may not offer economically feasible alternatives to other therapies. Any of these competitive factors may impact our decisions with respect to our products, product candidates and early-stage discovery programs. See "*Risk Factors—Risks Relating to Our Business—Risks Relating to Competing in our Industry*" in Part I, Item 1A of this report for further discussion of these risks. In addition, the approval of a generic drug or biosimilar of one of our products or a product with which we compete could have a material impact on our business because it may be significantly less costly to bring to market and may be priced significantly lower than our products or the other products with which we compete.

HAE

HAE is an autosomal dominant disease characterized by painful, unpredictable, recurrent attacks of inflammation affecting the hands, feet, face, abdomen, urogenital tract, and the larynx. The inflammation can be disfiguring, debilitating, or in the case of laryngeal attacks, life-threatening. Prevalence for HAE is uncertain but is estimated to be approximately 1 case per 33,000 to 67,000 persons without known differences among ethnic groups and is generally caused by deficient (Type I) or dysfunctional (Type II) levels of C1-inhibitor ("C1-INH"), a naturally occurring molecule that is known to inhibit kallikrein, bradykinin, and other serine proteases in the blood. If left untreated, HAE can result in a mortality rate as high as 50% primarily due to upper airway obstruction. There are several licensed therapies for HAE, including the following:

- C1-INH replacement therapy is available as an acute therapy (Berinert®) and as a prophylactic therapy (Haegarda® and Cinryze®). These therapies are dosed subcutaneously and intravenously. Recombinant C1-INH (Ruconest®) is also available as an acute therapy.

- Kallikrein Inhibitors — Kalbitor® (ecallantide) is a specific recombinant plasma kallikrein inhibitor that is dosed subcutaneously by healthcare providers to treat acute HAE attacks. Takhzyro® (lanadelumab-flyo) is a monoclonal antibody approved for prophylaxis of HAE attacks and can be self-administered as a subcutaneous injection. EKTERLY® (sebetralstat) is an oral small-molecule plasma kallikrein inhibitor self-administered to treat acute HAE attacks.

- Anti-factor XII mAb — Andembry® (garadacimab) is a monoclonal antibody approved for prophylaxis of HAE attacks and can be self-administered as a monthly subcutaneous injection following loading dose.

- Prekallikrein Antisense — DAWNZERA™ (donidalorsen) is a prekallikrein-directed antisense oligonucleotide approved for prophylaxis of HAE attacks and can be self-administered as a subcutaneous injection every 4 weeks or every 8 weeks.

- Bradykinin receptor antagonist — Firazyr® (icatibant) and generic icatibant are indicated for the treatment of acute attacks and are administered by subcutaneous injection.

- Other medications — Prophylactic administration of synthetic attenuated androgens (generically available as danazol or stanozolol) has been utilized to reduce the frequency or severity of attacks. However, long-term use of danazol or stanozolol may result in liver damage, virilization and arterial hypertension. Six-month liver

function tests, annual lipid profiles, and biennial hepatic ultrasound are recommended for patients on chronic androgen therapy.

We are aware of a number of HAE therapies in (or have recently completed) clinical development that, if approved, may compete with ORLADEYO or navenibart. These include:

Company	Asset	Mechanism of Action	Route of Administration	Trial Phase	Role in Therapy
Pharvaris	Deucrictibant (PHVS416/PHVS719)	B2 receptor antagonist	Oral	III	Acute and Prophylaxis
ADARx	Onvuzosiran (ADX-324)	siRNA	Subcutaneous	III	Prophylaxis
Intellia	Lonvo-z (NTLA-2002)	Gene Editing	Intravenous	III	One-time Prophylaxis
Argo Biopharma	BW-20805	SiRNA	Subcutaneous	II	Prophylaxis
Poseida Therapeutics	P-KLKB1-101	Gene Editing	Intravenous	Preclinical	One-time Prophylaxis

Netherton Syndrome

Netherton syndrome is a serious, rare, lifelong genetic disorder affecting the skin, hair, and immune system, caused by lack of normal function of a natural inhibitor of KLK5. While there are currently no approved treatments for Netherton syndrome, we are aware of a number of therapies in development for treatment that, if approved, may compete with BCX17725 (e.g., Quoin Pharmaceuticals Ltd.'s QRX-003 in Phase III, ResVita Bio's Pre-Investigational New Drug, RVB-003, and Azitra Inc.'s ATR-12 in Phase I).

Diabetic Macular Edema

Avoralstat, our investigational plasma kallikrein inhibitor, is designed to treat patients with DME through delivery of avoralstat to the back of the eye through the suprachoroidal space. There are several approved anti-VEGF therapies available for the treatment of DME, including F. Hoffmann-La Roche Ltd.'s ("Roche") VABYSMO® (faricimab-svoa) and Regeneron Pharmaceuticals, Inc.'s EYLEA® (aflibercept). In addition, we are aware of a number of products in development that would offer alternatives to anti-VEGF therapies, which could affect the competitive environment for our products, including Rezolute Inc.'s RZ402, Merck & Co. Inc.'s Restoret™ (MK-3000, formerly EYE103), Ocular Therapeutix™'s AXPAXLI ™ and EyePoint Pharmaceutical Inc.'s DURAVYU™ (formerly EYP-1901).

Antivirals

The pharmaceutical market for products that prevent or treat influenza is very competitive. Key competitive factors for RAPIVAB (peramivir injection) include, among others, efficacy, ease of use, safety, price and cost-effectiveness, storage and handling requirements, and reimbursement. A number of products are currently available in the United States and/or other countries, including Japan, for the prevention or treatment of influenza, including seasonal flu vaccines, Roche's TAMIFLU® (oseltamivir), generic oseltamivir, GlaxoSmithKline plc's RELENZA®, Genentech and Shionogi's XOFLUZA® and Daiichi's INAVIR®. In addition, FUJIFILM Corporation's favipiravir, a polymerase inhibitor, is approved in Japan.

Various government entities throughout the world are offering incentives, grants, and contracts to encourage additional investment into preventative and therapeutic agents against influenza, which may have the effect of further increasing the number of our competitors and/or providing advantages to certain competitors.

Atopic Dermatitis

AD is an immune disorder associated with loss of skin barrier function and itching, caused by diverse mechanisms, spanning the spectrum of T cell-driven pathology. There are a number of therapies approved for the treatment of AD, including RINVOQ® (upadacitinib), CIBINQO™ (abrocitinib), DUPIXENT® (dupilumab), ADBRY® (tralokinumab-ldrm), EBLGYSS (lebrikizumab) and NEMLUVIO (nemolizumab), and OLUMIANT (baricitinib) in the European Union.

In addition, there are a number of other product candidates in early-stage development for moderate-to-severe AD, including Nektar Therapeutics (rezpegaldesleukin), Pfizer (PF-07275315 and PF-07264660), LEO Pharma (temtokibart, LEO 152020), Akesobio (AK120), Connect Biopharma (rademikibart), Biosion (bosakitug), Apogee Therapeutics (APG777), InnoCare Pharma (ICP-332), Kymera Therapeutics (KTK-474), GSK (GSK1070806), UCB (UCB9741 and UCB1381), Union Therapeutics (orismilast), J&J (JNJ-7528 and JNJ-5939), Celldex Therapeutics (barzolvolimab), Evommune (EVO301 and EVO756), Eli Lilly (ucenprubart), Sanofi (SAR444656) and Opsidio (OpSCF).

Government Regulation

Our business is subject to extensive regulation by the FDA and foreign governments. These regulations include, among other things, regulations for the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical and biological products. The regulatory review and approval process is lengthy, expensive, and uncertain. Before obtaining regulatory approvals for the commercial sale of any products, we or our partners must demonstrate that our product candidates are safe and effective for use in humans. Before a new product can be marketed, considerable data demonstrating a biological product candidate's quality, safety, purity, and potency, or a small molecule drug candidate's quality, safety and efficacy, must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority. For biological product candidates (such as our protein therapeutic product candidates), potency is similar to efficacy and is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result. The approval process takes many years, substantial expenses may be incurred, and significant time may be devoted to clinical development. Further, the duration of the approval process may be exacerbated by global health concerns or other considerations that could prevent regulatory authorities from conducting their inspections, reviews, or other regulatory activities that could significantly impact the ability of such authorities to timely review and process our regulatory submissions.

Even if the FDA or foreign regulatory authorities approve a product candidate, the approval may limit the indicated uses for the product candidate, impose other restrictions on the product candidate, and/or may require post-approval studies that could impair the commercial viability of the product candidate. Even upon any approval to market our potential products, whether in the United States or internationally, we will continue to be subject to extensive regulatory requirements. These requirements are wide ranging and govern, among other things:

- adverse drug or biological product experience reporting regulations;
- product promotion;
- product manufacturing, including good manufacturing practice requirements; and
- product changes or modifications.

These government regulations are a significant factor in the production and marketing of any pharmaceutical or biological products that we develop or acquire. Failure to comply with applicable FDA and other regulatory requirements at any stage during the regulatory process may subject us to sanctions, including:

- delays;
- warning or untitled letters;
- fines;
- product recalls or seizures;
- injunctions;
- penalties;
- refusal of the FDA or any foreign regulatory authority to review pending market approval applications or supplements to approval applications;
- total or partial suspension of production;
- civil penalties;
- withdrawals of previously approved marketing applications; and
- criminal prosecutions.

The policies of the FDA and foreign regulatory authorities may change, and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or approval of new indications for our existing products. We cannot predict the likelihood, nature, or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

FDA Regulation

Before testing potential product candidates in humans, we carry out laboratory and animal studies to determine safety and biological activity. In general, after completing preclinical trials, we must file an investigational new drug application ("IND"), including a proposal to begin clinical trials, with the FDA. In April 2025, the FDA published a roadmap to reduce animal testing in preclinical safety studies, including those required in INDs, with scientifically validated new approach methodologies. Thirty days after filing an IND, a phase 1 human clinical trial can start, unless the FDA places a hold on the trial.

Clinical trials to support a new drug application ("NDA") for a pharmaceutical product or a biologics license application ("BLA") for a biological product, are typically conducted in three sequential phases, but the phases may overlap.

Phase 1 — During phase 1, which involves the initial introduction of the drug into healthy volunteers, the product candidate is tested to assess metabolism, pharmacokinetic, and pharmacological actions and safety, including side effects associated with increasing doses.

Phase 2 — Phase 2 usually involves trials in a limited patient population to: (1) assess the efficacy of the product candidate in specific, targeted indications; (2) assess dosage tolerance and optimal dosage; and (3) identify possible adverse effects and safety risks.

Phase 3 — If a product candidate is found to be potentially effective and to have an acceptable safety profile in phase 2 evaluations, phase 3 clinical trials, also sometimes called pivotal studies, major studies, or advanced clinical trials, are typically undertaken to further demonstrate clinical efficacy and to further test for safety within an expanded patient population at geographically dispersed clinical trial sites.

Initiation and completion of the clinical trial phases are dependent upon many factors, including things that are beyond our control. For example, the clinical trials cannot begin at a particular site until that site receives approval from its Institutional Review Board ("IRB"), which reviews the protocol and related documents. This approval process can take several weeks to several months to complete. In addition, clinical trials are dependent on patient enrollment, but the rate at which patients enroll in a study depends on:

- willingness of investigators to participate in a study;
- ability of clinical sites to obtain approval from their IRB;
- the availability of existing or other experimental drugs for the disease we intend to treat;
- the willingness of patients to participate; and
- the availability of patients meeting the eligibility criteria.

Delays in planned patient enrollment may result in increased expense and longer development timelines. A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA regulatory requirements in order to use the study as support for an IND or application for marketing approval or licensure. Good clinical practice standards are required for clinical studies regardless of the location of the study.

After successful completion of the required clinical testing, generally an NDA, for a pharmaceutical product candidate, or a BLA, for a biological product candidate, is submitted. Upon receipt of the NDA or BLA, the FDA will review the application for completeness. Within 60 days, the FDA will determine if the application is sufficiently complete to warrant full review and will consider the application "filed" at that time. Also upon receipt of the application, the FDA will assign a review priority to the application. Priority review applications are usually reviewed within 6 months; standard review applications are usually reviewed within 10 months. The FDA may refer NDAs or BLAs for new molecular entities or new biologics to an appropriate advisory committee for review and evaluation in regard to providing a recommendation as to whether the application should be approved. The FDA is not bound to follow the recommendation of an advisory committee.

Following the review of the application, which may include requests for additional information from the sponsor and results from inspections of manufacturing and clinical sites, the FDA will issue an "action letter" on the application. The action letter will either be an "approval letter," in which case the product may be lawfully marketed in the United States, or

a “complete response letter.” A complete response letter will state that the FDA cannot approve the NDA or BLA in its present form and, usually, will describe all of the specific deficiencies that the FDA has identified in the application. The complete response letter, when possible, will include the FDA’s recommended actions to place the application in a condition for approval. Deficiencies can be minor (e.g., labeling changes) or major (e.g., requiring additional clinical trials). A complete response letter may also be issued before the FDA conducts the required facility inspection and/or reviews labeling, leaving the possibility that additional deficiencies in the original NDA or BLA could be subsequently cited. An applicant receiving a complete response letter is permitted to resubmit the NDA or BLA addressing the identified deficiencies (in which case a new two- or six-month review cycle will begin), or withdraw the NDA or BLA. The FDA may consider a failure to take action within one year of a complete response letter to be a request to withdraw, unless the applicant has requested an extension of time in which to resubmit the NDA or BLA. If the FDA approves an NDA or BLA, the marketing of the product will be limited to the particular disease states and conditions of use that are described in the product label. The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and criminal liability under applicable state and federal laws.

Post-Approval

Approved drugs and biologics that are manufactured or distributed in the United States pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion, and reporting of adverse experiences with the product. For example, advertising and promotion are subject to stringent FDA rules and oversight, and as an NDA holder, we may be held responsible for any advertising and promotion that is not in compliance with the rules and regulations. In particular, the claims in all promotional materials and activities must be consistent with the FDA approvals for approved products and must be appropriately substantiated and fairly balanced with information on the safety risks and limitations of the products. We also may engage in appropriate truthful, non-misleading, and non-promotional scientific exchange concerning our products.

In addition, for biological products, as part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. After a BLA is approved for a biological product, the product also may be subject to official lot release. If the product is subject to official release by the FDA, the manufacturer submits a sample of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer’s tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, and potency or effectiveness of biologics.

After approval, most changes to the approved product, such as adding new indications or other labeling claims and some manufacturing and supplier changes, are subject to prior FDA review and approval. The FDA may impose a number of post-approval requirements as a condition of approval of an NDA or BLA. For example, the FDA may require post-marketing testing, including phase 4 clinical trials, and surveillance programs to further assess and monitor the product’s safety and effectiveness after commercialization.

We and all of our contract manufacturers are also required to comply with the applicable FDA current Good Manufacturing Practice (“cGMP”) regulations during clinical development and to ensure that the product can be consistently manufactured to meet the specifications submitted in an NDA or BLA. The cGMP regulations include requirements relating to product quality, investigation and remediation of issues through corrective and preventative actions, as well as the corresponding maintenance of records and documentation. Manufacturing facilities must be approved by the FDA before they can be used to manufacture our products. Based on an inspection, the FDA determines whether manufacturing facilities are in compliance with applicable regulations. Manufacturing facilities in non-United States countries that are utilized to manufacture drugs or biologics for distribution into the United States are also subject to inspection by the FDA. Additionally, failure to comply with local regulatory requirements could affect production and availability of product in relevant markets. A company that is found to have failed to comply with applicable cGMP regulations may be subject to significant liability, including civil and criminal liability under applicable state and federal laws.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation, if sought, must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA or BLA applicant with FDA orphan drug designation for a particular active ingredient to receive FDA approval of the designated drug for the disease indication for which it has such designation is entitled to a seven-year exclusive marketing period ("orphan drug exclusivity") in the United States for that product, for that indication. During the seven-year period, the FDA may not finally approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the license holder cannot supply sufficient quantities of the product. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition, provided that the sponsor has conducted appropriate clinical trials required for approval. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application user fee for the orphan indication.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan drug designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In *Catalyst Pharms., Inc. v. Becerra*, the United States Court of Appeals for the Eleventh Circuit disagreed with the FDA's longstanding position that orphan drug exclusivity only applies to the approved use or indication within an eligible disease. This decision created uncertainty in the application of orphan drug exclusivity. In January 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order - that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. In view of the overturn of the Chevron doctrine in *Loper Bright Enterprises v. Raimondo*, this U.S. Supreme Court decision may invite various stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies, including regulatory exclusivities, which could lead to uncertainties in the industry.

The FDA's interpretation of the scope of orphan drug exclusivity may change. In light of recent litigation and FDA announcements, the scope of orphan drug exclusivity and other issues relating to the FDA's implementation of the Orphan Drug Act with respect to both previously approved and future products continues to evolve and may be the subject of further litigation or legislative action.

Fast Track Designation

Under the Fast Track program, the sponsor of an IND may request the FDA to designate the product candidate as a Fast Track drug if it is intended to treat a serious or life-threatening condition and data demonstrate its potential to fulfill an unmet medical need. The FDA must determine if the product candidate qualifies for Fast Track designation within 60 days of receipt of the sponsor's request. Once the FDA designates a product candidate as a Fast Track candidate, it is required to facilitate the development and expedite the review of that drug by providing more frequent communication with, and guidance to, the sponsor. The key benefits of Fast Track designation are the eligibility for priority review, rolling review (submission of portions of an application before the complete marketing application is submitted), and accelerated approval, if relevant criteria are met.

In addition to other benefits, such as greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track product candidate's NDA or BLA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's review period as specified under the Prescription Drug User Fee Act for filing and reviewing an application does not begin until the last section of the NDA or BLA has been submitted. Additionally, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Breakthrough Therapy Designation

In addition, the Food and Drug Administration Safety and Innovation Act of 2012 ("FDASIA") established the Breakthrough Therapy designation. A sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the drug or biologic is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If a drug or biologic is designated as breakthrough therapy, the FDA will provide more intensive guidance on the drug development program and expedite its review.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the "Hatch-Waxman Amendments") amending the Federal Food, Drug, and Cosmetic Act ("FDCA"), Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application ("ANDA") to the agency. Upon approval of an ANDA, the FDA indicates that the generic product is "therapeutically equivalent" to the drug product previously approved under an NDA, known as the reference listed drug ("RLD"), and it assigns a therapeutic equivalence rating to the approved generic drug in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book". Physicians and pharmacists consider the therapeutic equivalence rating to mean that a generic drug is fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of a therapeutic equivalence rating often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of nonpatent exclusivity for the RLD has expired. The FDCA provides a period of five years of data exclusivity for NDAs containing a new chemical entity. In cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification (discussed further below), in which case the applicant may submit its application four years following the original product approval (referred to as the "NCE-1 date"). The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication.

Hatch-Waxman Patent Certification and the 30 Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or a method of using the product. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

505(b)(2) New Drug Applications

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA pursuant to an NDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant, and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on the FDA's previous findings of safety and effectiveness is scientifically and legally appropriate, it may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform additional bridging studies or measurements, including clinical trials, to support the change from the previously approved reference drug. The FDA may then approve the new drug candidate for all, or some, of the label indications for which the reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

To the extent that a Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. As a result, approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Biosimilars and Reference Product Exclusivity

The Affordable Care Act ("ACA") includes a subtitle called the Biologics Price Competition and Innovation Act ("BPCIA"), which created an abbreviated approval pathway for biological products that are highly similar, or "biosimilar," to or interchangeable with an FDA-approved reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, is generally shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

The FDA has issued guidance documents intended to inform prospective applicants and facilitate the development of proposed biosimilars and interchangeable biosimilars, as well as to describe the FDA's interpretation of certain statutory requirements added by the BPCIA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitted under the abbreviated approval pathway for the

lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. On December 20, 2020, Congress amended the Public Health Service Act as part of the COVID-19 relief bill to further simplify the biosimilar review process by making it optional to show that conditions of use proposed in labeling have been previously approved for the reference product, which used to be a requirement of the application. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact and implementation of the BPCIA is subject to significant uncertainty.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug or biological product 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. With the enactment of FDASIA, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA or BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot accept or approve another application.

Patent Term Restoration and Extension

A patent claiming a new drug or biological product may be eligible for a limited patent term extension under the Hatch-Waxman Amendments. Those Amendments permit a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA or BLA, plus the time between the submission date of an NDA or BLA and ultimate approval. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug or biological product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Foreign Regulation

In addition to regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials and marketing approval, commercial sales, and distribution of drugs. Foreign regulatory approval processes include all of the risks associated with FDA approval set forth above, as well as additional country-specific regulations. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. Some countries, such as certain countries in Latin America and in the Middle East, have review processes and data requirements similar to those of the European Union, and, in some cases, can rely on prior marketing approval from U.S. or EU regulatory authorities. The regulatory process in these countries may include manufacturing/ testing facility inspections, testing of drug product upon importation and other domestic requirements. Certain Asian countries may require local clinical-trial data for bridging purposes as part of the drug registration process in addition to global clinical trials, which can add to overall drug development and registration timelines. In most of the Asian markets, registration timelines depend on marketing approval in the United States or the European Union.

The requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary greatly from country to country, some of which are discussed below, and may also include post-approval commitments.

European Union

The various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Clinical trials in the European Union are governed by Clinical Trials Regulation (EU) No 536/2014 (the "Regulation"), which was adopted in April 2014 and replaced Clinical Trials Directive 2001/20/EC, as amended, as a system for the approval of clinical trials in the European Union which had been implemented through national legislation of the member states. The Regulation came into effect on January 31, 2022 with a three-year transition period in which clinical trial sponsors were able to choose among different submission pathways. The Regulation, which is directly applicable in all EU member states, aims to simplify and streamline the approval of clinical trials in the European Union. For instance, the Regulation provides for a streamlined application procedure via a single entry point, the EU clinical trials portal (Clinical Trials Information System, "CTIS"). Further, it features strictly defined deadlines for the assessment of clinical trial applications and introduces enhanced transparency requirements, including mandatory submission of a summary of clinical trial results to CTIS.

Manufacturing and import into the European Union of investigational medicinal products for use in clinical trials is subject to the holding of appropriate authorizations and must be carried out in accordance with cGMP.

Under EU regulatory systems, we may submit marketing authorizations either under a centralized or, for products not falling within the mandatory scope of the centralized procedure, decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all EU member states. It is compulsory for specific pharmaceutical products, including for medicines developed by means of certain biotechnological processes (including hybridoma and monoclonal antibody methods), products designated as orphan pharmaceutical products, advanced therapy pharmaceutical products and pharmaceutical products with a new active substance indicated for the treatment of certain diseases. Under the centralized procedure, a single marketing authorization application is submitted to the Committee for Medicinal Products for Human Use of the European Medicines Agency ("EMA"), which then makes a recommendation to the European Commission ("EC"). The EC makes the final determination on whether to approve the application. The decentralized procedure provides for mutual recognition of national approval decisions, and the holder of a national marketing authorization may submit an application to the remaining member states. The decentralized procedure is only available for pharmaceutical products not falling within the mandatory scope of the centralized procedure.

The EC has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years and updated from time to time. In Europe, a competitor may reference data supporting approval of an innovative biological product, but will not be able to get on the market until 10 years after the product's first marketing authorization in the European Economic Area ("EEA"). This 10-year marketing exclusivity period may be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilars in other countries that could compete with our products. Currently, an EU "pharma package" reform is under way and may change these timelines or their exact makeup if adopted. While the Council of the European Union and the European Parliament have reached a provisional deal on such reform, it has not yet been adopted and is still subject to change.

United Kingdom

The United Kingdom formally left the European Union on January 31, 2020 ("Brexit"). Under the Protocol on Ireland and Northern Ireland in the withdrawal agreement (as modified by the Windsor Framework), certain EU rules continue to apply in Northern Ireland in areas such as goods and customs. The European Union and the United Kingdom have agreed on a trade and cooperation agreement ("TCA") which includes provisions affecting the life sciences sector (including on customs and tariffs). There are some specific provisions concerning pharmaceuticals, including the mutual recognition of GMP and issued GMP documents. The TCA does not, however, contain wholesale mutual recognition of U.K. and EU pharmaceutical regulations and product standards.

The government of the United Kingdom has enacted the Medicines and Medical Devices Act 2021. The purpose of the act is to enable the existing regulatory frameworks in relation to human medicines and clinical trials of human medicines, among others, to be updated. The powers under the act may only be exercised in relation to specified matters and must safeguard public health. The Medicines and Medical Devices Act 2021 supplements the United Kingdom Medical Devices Regulations 2002, which are based on the EU Medical Devices Directive as amended to reflect the United Kingdom's post-Brexit regulatory regime. Notably, the Regulations do not include any of the revisions that have been made by the EU Medical Devices Regulation (EU) 2017/745, which has gained full application in all EU member states since May 26, 2021, but is not applicable in the United Kingdom as "retained law." Reform under the Medicines and Medical Devices Act 2021 is being implemented on a phased basis via secondary legislation, following a series of consultations with core aspects of the new regime coming into force on June 16, 2025.

Japan

Under the Japanese regulatory system administered by the Japanese Pharmaceuticals and Medical Devices Agency ("PMDA"), pre-marketing approval and clinical studies are required for all pharmaceutical products. To obtain manufacturing/marketing approval, we must submit an application for approval to the Ministry of Health, Labor and Welfare ("MHLW") with results of nonclinical and clinical studies to show the quality, efficacy, and safety of a new drug. A data compliance review, good Clinical Practices on-site inspection, cGMP audit, and detailed data review are undertaken by the PMDA. The application is then discussed by the committees of the Pharmaceutical Affairs and Food Sanitation Council ("PAFSC"). Based on the results of these reviews, the final decision on approval is made by the MHLW. In Japan, the National Health Insurance system maintains a Drug Price List specifying which pharmaceutical products are eligible for reimbursement, and the MHLW sets the prices of the products on this list. The price will be determined within 60 to 90 days following approval unless the applicant disagrees, which may result in extended pricing negotiations. The government generally introduces price cut rounds every other year and also mandates price decreases for specific products. New products judged innovative or useful, that are indicated for pediatric use, or that target orphan or small population diseases, however, may be eligible for a pricing premium. The Japanese government has also promoted the use of generics, where available.

Fraud and Abuse and Related Regulatory Laws

We are subject to various federal and state laws pertaining to healthcare "fraud and abuse," including both federal and state anti-kickback and false claims laws. Outside of the United States, we may be subject to analogous foreign laws and regulations in the various jurisdictions in which we operate. These laws and regulations apply to our or our partners' operations, sales and marketing practices, price reporting, and relationships with physicians and other customers and third-party payors. Anti-kickback laws generally prohibit a manufacturer from soliciting, offering, receiving, or paying any remuneration to generate business, including the purchase or prescription of a particular drug. Although the specific provisions of these laws vary, their scope is generally broad and there may be no regulations, guidance or court decisions that clarify how the laws apply to particular industry practices. False claims laws prohibit, among other things, anyone from knowingly presenting, or causing to be presented, for payment to third party payors (including Medicare and Medicaid) claims for reimbursement or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services.

In addition, we are subject to the federal Physician Sunshine Act and certain similar physician payment and drug pricing transparency legislation in various states. The transparency-focused provisions apply to manufacturers with products reimbursed under certain government programs and require those manufacturers to disclose annually to the federal government certain payments made to covered recipients (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors, as well as other healthcare personnel including physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians (as defined above) and their

immediate family members. State laws also may require disclosure of pharmaceutical pricing information and marketing expenditures.

Violations of the federal Physician Sunshine Act and similar legislation or the fraud and abuse laws may be punishable by civil or criminal sanctions, including fines and civil monetary penalties, and future exclusion from participation in government healthcare programs.

Reimbursement and Healthcare Reform

In both the United States and other countries, sales and reimbursement of any approved products will depend, in part, on the extent to which the costs of such products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly challenging the prices charged for medical products and services and imposing controls to manage costs. The containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our net revenue and results. In addition, there is significant uncertainty regarding the reimbursement status of newly approved healthcare products.

Adequate coverage and reimbursement in the United States and other countries is critical to the commercial success of approved products. Recently in the United States, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed, among other things, to reform government program reimbursement methodologies. In addition, individual states in the United States have been increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Third-party payors are increasingly challenging the prices charged for medical products and services and, in some cases, imposing restrictions on the coverage of particular drugs. Many third-party payors negotiate the price of medical services and products and develop formularies that establish pricing and reimbursement levels. Exclusion of a product from a formulary can lead to its sharply reduced usage in the third-party payor's patient population. The process for obtaining coverage can be lengthy and costly, and it could take several months before a particular payor initially reviews a product and makes a decision with respect to coverage. For example, third-party payors may require cost-benefit analysis data in order to demonstrate the cost-effectiveness of a particular product.

Outside the United States, ensuring adequate coverage and payment for drug products can have challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct an active comparator clinical trial to demonstrate the relative effectiveness of our therapeutic product candidates or products to other available therapies to support our pricing, which could be expensive and result in delays in our commercialization efforts. Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved healthcare products. Recent budgetary pressures in many EU countries are also causing governments to consider or implement various cost-containment measures, including reference price grouping, price freezes, increased price cuts, and rebates. If budget pressures continue, governments may implement additional cost-containment measures. Cost-control initiatives could decrease the price we might establish for products that we may develop or sell, which would result in lower product revenues or royalties payable to us. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products.

The Patient Protection and Affordable Care Act ("PPACA") made extensive changes to the delivery of healthcare in the United States. The PPACA included numerous provisions that affect pharmaceutical companies, some of which became effective immediately and others of which have taken effect over the past several years. For example, the PPACA expanded healthcare coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The PPACA also imposed substantial costs on pharmaceutical manufacturers, such as an increase in liability for rebates paid to Medicaid, new drug discounts that must be offered to certain enrollees in the Medicare prescription drug benefit, an

annual fee imposed on all manufacturers of brand prescription drugs in the United States, and an expansion of an existing program requiring pharmaceutical discounts to certain types of hospitals and federally subsidized clinics. The PPACA also contains cost containment measures that could reduce reimbursement levels for healthcare items and services generally, including pharmaceuticals. It also required reporting and public disclosure of payments and other transfers of value provided by pharmaceutical companies to physicians and teaching hospitals.

In August 2022, the Inflation Reduction Act ("IRA") was enacted and includes provisions requiring that (1) beginning in 2026, mandatory price setting be introduced in Medicare for certain drugs paid for under Parts B and D, whereby manufacturers must accept a price established by the government or face penalties on all U.S. sales (starting with 10 drugs in 2026, adding 15 in 2027 and 2028, and adding 20 in 2029 and subsequent years, such that by 2031 approximately 100 drugs could be subject to such set prices); (2) starting in 2024, Medicare Part D be redesigned to cap beneficiary out-of-pocket costs and, beginning January 1, 2025, federal reinsurance be reduced in the catastrophic phase (resulting in a shift and increase of such costs to Part D plans and manufacturers, including by requiring manufacturer discounts on certain drugs); and (3) beginning October 1, 2022, manufacturers owe rebates on drugs reimbursed under Medicare Part D if price increases outpace inflation, and beginning January 1, 2023, manufacturers owe rebates on drugs reimbursed under Medicare Part B if price increases outpace inflation. Although the IRA has passed, and the Centers for Medicare & Medicaid Services has finalized policies implementing many aspects of the IRA, the environment remains dynamic. Since early 2025, the presidential administration has taken various executive actions intended to decrease the price of prescription medications to so-called "most favored nation" levels (i.e., to prices commensurate with the lowest prices paid in certain economically developed countries outside the United States), to make certain medications available for sale on direct-to-patient sale platforms, and to repatriate the revenues companies earn if the U.S. Government compels other nations' governments to increase prices in those nations. Meanwhile, the presidential administration and Congress are continuing to consider drug pricing reforms. Further, certain U.S. states also have enacted legislation intended to limit the price of prescription medications. Other potential policies cover a wide range of areas, including allowing the importation of drugs from other countries; increasing transparency in drug pricing; and using third-party value assessments to determine drug prices.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare could result in decreased net revenues from our pharmaceutical products and decreased potential returns from our development efforts. In addition, pharmaceutical and device manufacturers are also required to report and disclose certain payments and transfers of value to, and investment interests held by, physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties for payments, transfers of value, or ownership or investment interests not reported in an annual submission. Compliance with the federal and state laws is difficult and time consuming, and companies that do not comply with these laws can face severe civil penalties.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. For example, legislation has been enacted in certain states and at a federal level that requires manufacturers and other entities in the drug supply chain to track and trace each prescription drug at the saleable unit level through the distribution system. The FDA has finalized and proposed regulations implementing such requirements at a federal level. Compliance with these or any other new requirements may increase our operational expenses and impose significant administrative burdens.

Data Privacy and Security Laws

Pharmaceutical companies may be subject to U.S. federal and state health information privacy, security, data breach notification, and consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) which may govern the collection, use, disclosure, and protection of health-related and other personal data. State laws may be more stringent, broader in scope, or offer greater individual rights with respect to protected health information ("PHI"), than the federal Health Insurance Portability and Accountability Act of 1996, as amended, and its implementing regulations, which are collectively referred to as HIPAA, and state laws may differ from each other, which may complicate compliance efforts. Entities that are found to be in violation of HIPAA or that enter into a resolution agreement with the HHS to settle actual or potential allegations of HIPAA noncompliance may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations.

Many state laws govern the privacy of personal data in specified circumstances. For example, in California the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (together, "CCPA") establishes a privacy framework for covered businesses by creating an expanded definition of personal data, establishing

data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. While certain clinical trial data and information governed by HIPAA are currently exempt from the CCPA, other personal data may be covered. Many other states, such as Virginia, Colorado and Utah, have also enacted comprehensive privacy laws, and it is possible that additional states will follow suit.

Outside the United States, an increasing number of laws and regulations around the world may govern data privacy and security. For example, EU member states, the United Kingdom, Switzerland, and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. In the EEA, the collection and use of personal data, including clinical trial data, generally is governed by the provisions of the General Data Protection Regulation ("GDPR"). The GDPR, together with other legislation, regulations, and guidelines of the states in the EEA, the United Kingdom, and Switzerland governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze, and transfer personal data, including health data from clinical trials and adverse event reporting. The GDPR also imposes additional special protections for "special category data," which includes health, biometric and genetic information of data subjects located in the EEA. Further, the GDPR provides a broad right for EU member states to create supplemental national laws, for example, relating to the processing of health, genetic and biometric data, which could further limit our ability to use and share such data or could cause our costs to increase and harm our business and financial condition. The GDPR and similar legislation grant individuals the opportunity to object to the processing of their personal data, allow them to request deletion of personal data in certain circumstances, and provide the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated.

Further, the GDPR and similar legislation, such as the United Kingdom GDPR and Switzerland's Federal Data Protection Act, impose strict rules on the transfer of personal data out of the EEA, the United Kingdom, Switzerland, and other countries to the United States or other regions that have not been deemed to offer "adequate" privacy protections. These obligations and regulations also concern security breach notifications, security and confidentiality of the personal data, and imposition of substantial potential fines for breaches of the data protection obligations. Local data protection authorities may interpret the GDPR and other data protection laws differently and impose additional requirements, which add to the complexity of processing personal data in or from the EEA, the United Kingdom, or Switzerland. Guidance on implementation and compliance practices are often updated or otherwise revised.

Similarly, the increasing use of artificial intelligence ("AI") and machine learning technology in the biopharmaceutical industry presents new risks and challenges, as the disclosure and use of personal data in AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating AI, including the EU Artificial Intelligence Act.

The EU Clinical Trials Regulation also imposes obligations to make publicly available certain information generated from clinical trials. Only very limited information is exempted from disclosure, i.e. commercially confidential information (which is construed increasingly narrowly) and protected personal data. It may be possible for others to use this data (for example, competitors who may use this data in their own research and development programs) once this data is in the public domain.

We are also subject to the supervision of local data protection authorities in those jurisdictions where we undertake clinical trials. We depend on a number of third parties in relation to the provision of our services, a number of which process personal data of EU individuals on our behalf. With each such provider we are required to enter into contractual arrangements under which they are contractually obligated to only process personal data according to our instructions, and conduct diligence to ensure that they have sufficient technical and organizational security measures in place.

We are also subject to evolving European privacy laws on electronic marketing and cookies. For example, the European Union was for many years in the process of replacing the e-Privacy Directive (2002/58/EC) with a new set of rules taking the form of a regulation that would be directly implemented in the laws of each EU member state. While this e-Privacy Regulation was originally intended to be adopted in 2018, the proposal was withdrawn in 2025, and the timing of the potential adoption of a replacement or supplemental regulation remains unclear.

Anti-Corruption Laws

We are also subject to the U.S. Foreign Corrupt Practices Act ("FCPA"), which prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. Similar laws exist in other countries, such as the United Kingdom or in EU member states, that restrict improper payments to public and private parties. Many countries have laws prohibiting these types of payments within the respective country. In addition to these anti-corruption laws, we are subject to import and export control laws, tariffs, trade measures and countermeasures, trade barriers, economic sanctions, and regulatory limitations on our ability to operate in certain foreign markets.

Corporate Compliance

In order to ensure compliance with applicable laws and regulations, our Chief Financial Officer, Chief Legal Officer, and Chief People Officer oversee compliance training, education, auditing, and monitoring; enforce disciplinary guidelines for any infractions of our corporate polices; implement new policies and procedures; respond to any detected issues; and undertake corrective action procedures. Our controls address compliance with laws and regulations that govern public pharmaceutical companies, including, but not limited to, the following: federal and state law, such as the Sarbanes-Oxley Act of 2002 and the FCPA; Nasdaq listing requirements; the regulations of the Financial Industry Regulatory Authority, the SEC, the FDA, and HHS; and applicable laws and regulations administered by foreign regulatory authorities, including those of the European Union, the United Kingdom, and Japan. Our standard operating procedures are designed to provide a framework for corporate governance in accordance with ethical standards and best legal practices.

Human Capital Resources

As of December 31, 2025, we had approximately 435 employees, of whom approximately 118 employees were engaged in the research and development function of our operations, which we define to include any employee included in research and development expenses for financial reporting purposes. Our research and development staff, many of whom hold Ph.D. or M.D. degrees, have diversified experience in biochemistry, pharmacology, X-ray crystallography, synthetic organic chemistry, computational chemistry, medicinal chemistry, chemical engineering, clinical development, quality assurance, and regulatory affairs.

We believe that our ability to successfully execute on our strategic initiatives is highly dependent upon our ability to recruit, retain, and reward our employees. We engage in targeted recruitment strategies to fill highly skilled positions. Our employees enjoy competitive salaries and benefits, as well as equity participation. Our compensation philosophy is designed to provide an appealing, competitive, and rewarding compensation program that encourages retention, high personal and company performance, strong cultural and ethical behavior, and incentives aligned with stockholder interests.

We are committed to providing a workplace that protects the health and well-being of our employees. All employees are required to abide by our Code of Conduct and Ethics ("Code of Conduct") and health and safety parameters and to contribute to a positive, inclusive, and friendly company culture. Where we believe such arrangements can be effective, we have implemented flexible working arrangements, including work from home arrangements, for our employees. We consider our relations with our employees to be satisfactory.

Corporate Information

We are a Delaware corporation originally founded in 1986. Our corporate headquarters is located at 4505 Emperor Blvd., Suite 200, Durham, North Carolina 27703, and our corporate telephone number is (919) 859-1302. For more information about us, please visit our website at *www.biocryst.com*. The information on our website is not incorporated into this report.

Financial Information

For information related to our revenues, profits, net income (loss) and total assets, in addition to other financial information, please refer to the Consolidated Financial Statements and Notes to Consolidated Financial Statements contained in Part II, Item 8 of this report. Financial information about revenues derived from countries outside the United States is included in Note 3 to the Consolidated Financial Statements contained in this report.

Available Information

Our website address is *www.biocryst.com*. We make available, free of charge, on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. We also make available at our website copies of our audit committee charter, compensation committee charter, corporate governance and nominating committee charter and our Code of Conduct, which applies to all our employees as well as the members of our Board of Directors. Any amendment to, or waiver from, our Code of Conduct will be posted on our website.

ITEM 1A. RISK FACTORS

An investment in our stock involves risks. You should carefully read this entire report and consider the following uncertainties and risks, which may adversely affect our business, financial condition or results of operations, along with all of the other information included in our other filings with the SEC, before making an investment decision regarding our common stock. Additionally, while some of the factors, events and contingencies described herein may have occurred in the past, the disclosures herein are not representations as to whether or not they have occurred and are instead provided because future occurrences thereof could adversely affect the Company.

Risks Relating to Our Business

Financial and Liquidity Risks

We may not achieve sustained profitability.

Although we achieved net income on a U.S. GAAP basis for the year ended December 31, 2025 for the first time on an annual basis, we have not yet achieved sustained profitability. Our expectations as to the sustainability of our profitability may change based upon our ability to execute our commercialization goals and operational initiatives and whether or not the assumptions underlying our projected revenues and expenses are correct. Our beliefs and projections regarding the attainment of our financial goals may differ from actual results based on market factors like competition, patient and physician acceptance of our products, reimbursement levels, or on our ability to execute our operational and budget plans, including management's ability to properly forecast our capital allocation needs. To achieve sustained profitability, we, or our collaborative partners, must successfully manufacture and develop or acquire products and product candidates, receive regulatory approvals, and successfully commercialize our products and/or enter into profitable commercialization arrangements with other parties. Even if we are able to successfully commercialize our existing products, or to develop or otherwise acquire new commercially viable products, certain obligations we have to third parties, including, without limitation, our obligation to pay RPI and OMERS, as applicable, royalties on certain revenues from ORLADEYO under the Royalty Purchase Agreements (as defined in "*Note 9—Royalty Financing Obligations*" in the Notes to Consolidated Financial Statements in Part II, Item 8 of this report), may reduce the profitability of such products.

Because of the numerous risks and uncertainties associated with developing or acquiring product candidates, launching new products, and their potential for commercialization, we are unable to predict the extent of any potential future losses. Even though we have achieved profitability in a given reporting period, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve sustained profitability on our anticipated timeline, or at all, the market value of our common stock will likely decline.

We may need to raise additional capital or obtain additional financing in the future. If we are unable to raise capital or obtain additional financing if and when needed, we may need to adjust our operations.

We have sustained operating losses for the majority of our corporate history. Even if we achieve sustained profitability, in order to continue future operations, progress our drug discovery and development programs, engage in strategic business development activities and commercialize our products and product candidates, we may be required to raise additional capital or obtain additional financing in the future. In addition to seeking strategic partnerships and transactions, we may access the equity or debt markets, incur additional borrowings, or seek other sources of funding to meet liquidity needs at any time, including to take advantage of attractive opportunities in the capital markets. Additional funding, whether through additional sales or issuances of securities, additional borrowings, collaborative arrangements with partners, or from other sources, may not be available if or when needed or in a form or on terms acceptable to us. The issuance of preferred or common stock or convertible securities, with terms and prices significantly more favorable than those of our currently outstanding common stock, could have the effect of diluting or adversely affecting the holdings or rights of our existing stockholders. Additional borrowings may subject us to more restrictive covenants than are currently applicable to us under the Blackstone Loan Agreement (defined below). In addition, collaborative arrangements may require us to transfer certain material rights to our corporate partners. Insufficient funds or lack of an acceptable partnership have in the past, and may again in the future, require us to delay, scale-back or eliminate certain of our research and development programs.

As our programs advance, our costs could increase. Our expenses, revenues and cash utilization rate could vary significantly depending on many factors, including: our ability to effectively manage our product candidate pipeline; our ability to obtain regulatory approvals for our product candidates; our ability to maintain regulatory approvals for,

successfully commercialize, and achieve sustained market acceptance of our products; our future business development activities; our ability to secure partnerships with third parties for our product candidates when deemed advisable; the amount of funding we receive from partnerships with third parties for the development and commercialization of our products and product candidates; the commercial success of our products achieved by our partners; the progress and results of our current and proposed clinical trials for our product candidates; and the progress made in the manufacture of our lead products and the progression of our other programs.

Our liquidity needs will largely be determined by the success of operations in regard to the commercialization of our products, particularly ORLADEYO, the progression of our product candidates, including the progress, timeline and ultimate outcome of our development programs (including, but not limited to, formulation progress, long-term human safety studies, clinical trial investigations, and carcinogenicity, drug-drug interaction, toxicity, or other required studies), as well as any post-approval studies for our products, and our ability to execute our budget plans. Constriction and volatility in the equity and debt markets, including as a result of the impacts of inflation, increased interest rates, disruption or instability in the banking industry, geopolitical instability, or public health emergencies such as the COVID-19 pandemic, may restrict our future flexibility to raise capital if and when such needs arise. Our current plans for managing our liquidity needs primarily include controlling the timing and spending on our research and development programs and commercializing our approved products. See "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources*" in Part II, Item 7 of this report for additional information about our liquidity needs, capital requirements, potential funding alternatives, and adequacy of available funds.

Furthermore, we have exposure to many different industries, financing partners and counterparties, including commercial banks, investment banks and partners (which include investors, licensing partners, distribution partners, and others), which may be unstable or may become unstable in the current economic and political environment, including as a result of the impacts of inflation, increased interest rates, disruption or instability in the banking industry, U.S. Government shutdowns, changes in presidential administration in the United States, geopolitical instability, actual or threatened public health emergencies, outbreaks of disease, epidemics or pandemics (such as the COVID-19 pandemic). Any such instability may impact these parties' ability to fulfill contractual obligations to us, or it might limit or place burdensome conditions upon future transactions with us. Also, it is possible that suppliers may be negatively impacted as a result of economic and political instability. Any such unfavorable outcomes in our current programs or unfavorable economic conditions have in the past and could again place severe downward pressure on the price of our common stock and may decrease opportunities to raise capital in the capital or credit markets, and further could reduce the return available on invested corporate cash, which, if severe and sustained, could have a material and adverse impact on our results of operations and cash flows and limit our ability to continue development and commercialization of our products and product candidates.

There can be no assurance that any of our plans will be successful or that additional capital will be available to us on reasonable terms, or at all, if needed. If we are unable to obtain sufficient additional capital if and when needed, we may be forced to adjust or curtail our operations; delay, reduce, or stop ongoing clinical trials or commercialization efforts; cease operations altogether; or file for bankruptcy.

Risks Relating to the Merger

If the benefits of the Merger do not meet the expectations of investors or securities analysts, the market price of our common stock may decline.

The market price of our common stock may decline as a result of the Merger if we do not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial analysts or the effect of the Merger on our financial results is not consistent with the expectations of financial analysts. Accordingly, holders of our common stock following the consummation of the Merger may experience a loss as a result of a decline in the market price of such common stock. In addition, a decline in the market price of our common stock following the consummation of the Merger could adversely affect our ability to issue additional securities if needed and to obtain additional financing in the future.

Combining Astria with our business may be more difficult, costly or time consuming than expected and the combined company may fail to realize the anticipated benefits and synergies of the Merger.

The success of the Merger will depend, in part, on the ability to realize the anticipated benefits and cost savings from combining our business and Astria's business. To realize the anticipated benefits and synergies from the Merger, we must successfully integrate and combine our businesses in a manner that permits those benefits and synergies to be realized. If we are not able to successfully achieve these objectives, the anticipated benefits of the Merger may not be realized fully or

at all or may take longer to realize than expected. In addition, the actual cost savings and anticipated benefits of the Merger could be less than anticipated, and integration may result in additional unforeseen expenses.

An inability to realize the full extent of the anticipated benefits of the Merger, as well as any delays encountered in the integration process, could have an adverse effect on the revenues, levels of expenses and operating results of the combined company, which may adversely affect the value of our common stock.

Prior to completion of the Merger, we and Astria have operated independently. It is possible that the integration process could result in the loss of key employees, the disruption of our business or inconsistencies in standards, controls, procedures and policies that adversely affect our ability to maintain relationships with employees and counterparties or to achieve the anticipated benefits and cost savings of the Merger. Integration efforts may also divert management attention during this transition period, which may have an adverse effect on our Company.

We are in the early stages of integrating Astria into our business, and unknown or unanticipated risks associated with Astria's business or product candidates could adversely affect us.

Although we conducted due diligence on Astria prior to consummation of the Merger, we are still relatively new to Astria's business and its operations, including its product candidates. As a result, we may not yet be aware of all material risks, liabilities, or challenges associated with Astria's business or product candidates (in particular, navenibart), including risks that were not identified or fully appreciated during our due diligence process. There can be no assurance that our due diligence identified all risks, liabilities, or other material matters, that all material issues that could be uncovered through a customary level of due diligence were identified, or that factors outside of our control will not later arise. Even where due diligence successfully identifies certain risks, unexpected risks may arise, and previously known risks may materialize in a manner that is inconsistent with our preliminary risk assessments or assumptions.

We will likely incur substantial expenses related to the Merger.

We expect that we will incur substantial expenses in connection with completion of the Merger and combining the business, operations, networks, systems, technologies, policies and procedures of the two companies. Although we have assumed that a certain level of transaction and combination expenses will be incurred, there are a number of factors beyond our control that could affect the total amount or the timing of our combination expenses. There can be no assurance that the anticipated benefits related to the integration of Astria with our business will be realized to offset these transaction and integration expenses over time.

Issuance of shares of our common stock in connection with the Merger may adversely affect the market price of our common stock.

In connection with the payment of the merger consideration, we issued 17.5% of the shares of our common stock issued and outstanding immediately prior to the effective time of the Merger. The issuance of these new shares of our common stock may result in fluctuations in the market price of our common stock, including a stock price decrease. In addition, former Astria stockholders or holders of other Astria securities may decide not to hold the shares of our common stock that they have received in connection with the Merger, and our stockholders may decide to reduce their investment in us as a result of the changes to our investment profile as a result of the Merger, which may result in further fluctuations in the market price of our common stock, including a stock price decrease.

Risks Relating to Product Development and Commercialization

Our success depends in part upon our ability to manage our product candidate pipeline, advance our product candidates through the various stages of development, especially through the clinical trial process, and to receive regulatory approvals for the commercial sale of our product candidates.

The success of our business depends in part upon our ability to manage our product candidate pipeline, including through expanding the pipeline, as appropriate, through our internal identification and discovery of product candidates or otherwise in-licensing or acquiring products or product candidates and integrating them into our business effectively and efficiently; advancing our product candidates through the various stages of development; and receiving regulatory approvals for the commercial sale of our product candidates. Identifying, selecting, and in-licensing or acquiring products or product candidates requires substantial expense and technical and financial expertise, and if we are unable to effectively

manage our pipeline or integrate viable products or product candidates into our business on acceptable terms, or at all, our business and product development efforts could suffer.

To receive the regulatory approvals necessary for the commercial sale of our product candidates, we or our partners must demonstrate through preclinical studies and clinical trials that each product candidate is safe and effective. The development process and related regulatory process are complex and uncertain. The preclinical and clinical development of our product candidates is susceptible to the risk of failure inherent at any stage of drug or biologic development, including failure to demonstrate efficacy, or for biologics, purity and potency, and safety, failure to demonstrate adequate benefit-risk balance, failure to achieve a commercially attractive and competitive product label, failure to achieve approval in commercially attractive indications, the occurrence of adverse events that are severe or medically or commercially unacceptable, our or our partners' failure to comply with trial protocols, applicable regulatory requirements, or industry standards, or a determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or be approved in accordance with our development plans or at all. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. For example, any successful results of preclinical and early clinical work for avoralstat, BCX17725, navenibart and our early-stage discovery programs do not guarantee the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and for some product candidates, there may not be an ideal model for preclinical testing. We also cannot guarantee that any preclinical studies and clinical trials will be conducted as planned or completed on schedule, if at all, or that the results of such trials will be sufficient to support regulatory approval for our product candidates.

Progression of our product candidates through the clinical development process is dependent upon our trials indicating that our product candidates have adequate safety and efficacy or purity and potency in the patients being treated by achieving predetermined endpoints according to the clinical trial protocols, as well as an adequate benefit-risk profile. Failure to achieve any of these endpoints or to show adequate benefit-risk profile in any of our programs has in the past, and could again in the future, result in delays in, modifications to, or discontinuations of our trials or require the performance of additional unplanned trials. If any of our product candidates is associated with adverse events or undesirable side effects or has properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a benefit-risk perspective. Product candidates that initially show promise in clinical or preclinical testing have in the past, and could again in the future, later be found to be associated with or to cause undesirable or unexpected side effects that could result in substantial modifications or delays in the development plans for our product candidates, significant unexpected costs, or the termination of programs.

In addition, the development plans for our product candidates, including our clinical trials, may not be adequately designed or executed, which could negatively affect the outcome and analysis of study results. Because of the cost and duration of clinical trials, we have decided in the past, and may in the future decide, to discontinue development of product candidates for various reasons, including, but not limited to, that such product candidates are unlikely to show favorable results in clinical trials, unlikely to help advance a product to the point of a meaningful collaboration, or unlikely to have reasonable commercial potential.

Undesirable or inconclusive data in our preclinical studies and clinical trials or side effects in humans could result in the FDA or foreign regulatory authorities refusing to approve a product candidate for any targeted indications or imposing restrictions or warnings that could impact development or the ultimate commercial viability of a product candidate. In addition, the FDA or foreign regulatory authorities may determine that study data from our product candidates necessitates additional studies or study designs which differ from our planned development strategy, and such regulatory authorities may also require patient monitoring and testing or may implement restrictions or other conditions on our development activities, any of which could materially impact the cost and timing of our planned development strategy. We, our partners, the FDA, or foreign regulatory authorities have previously, and may again in the future, pause enrollment in, suspend, or terminate clinical trials at any time if we or they believe the trial participants face unacceptable health risks.

Our ability to complete the clinical development process successfully is dependent upon many factors, including, but not limited to:

- our or our partners' ability to secure suitable clinical sites and investigators and to enroll and maintain an adequate number of patients on a timely basis or at all;
- patients that enroll in a clinical trial may not comply with the clinical trial protocols or maintain contact with investigators to provide complete data during and after treatment;

- our product candidates may not prove to be either safe or effective for our targeted indications, or at all, or may produce unfavorable or inconclusive results;
- we or our partners may decide, or be required by regulatory authorities, to pause enrollment in, suspend, or terminate clinical research for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate, noncompliance with regulatory requirements or their standards of conduct or evolving guidance, or findings of undesirable effects caused by a chemically or mechanistically similar product or product candidate;
- regulatory authorities may disagree with our or our partners' clinical trial protocols or our or their interpretation of data from preclinical studies and clinical trials;
- clinical protocols or study procedures may not be adequately designed or followed by the investigators, including ensuring that all data is accurately recorded and reported;
- formulation improvements may not work as expected, which could negatively impact commercial demand for our product candidates;
- regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we or our partners enter into agreements for clinical and commercial supplies;
- the supply or quantity of raw materials or manufactured product candidates or other materials necessary to conduct development activities may be insufficient, inadequate, or unavailable at an acceptable cost, and we or our partners may experience interruptions in supply;
- our or our partners' development plans may be delayed or changed as a result of changes in development strategy, the impact of new or different regulations, requirements, and guidelines, or other unexpected events or conditions;
- the cost of preclinical studies and clinical trials may be greater than we anticipate;
- we or our third-party contractors, including those manufacturing our product candidates or components or ingredients thereof, or conducting clinical trials or laboratory testing on our or our partners' behalf, may fail to comply with regulatory requirements and industry standards or meet contractual obligations in a timely manner or at all; and
- the impact of any global health epidemic or pandemic, such as COVID-19, on one or more of the foregoing factors.

Clinical trials are lengthy and expensive. Many of the factors listed above could result in increased clinical development costs or longer clinical development times for any of our programs. We and our partners incur substantial expense for, and devote significant time to, preclinical testing and clinical trials, yet we cannot be certain that the tests and trials will ever result in the commercial sale of a product. Even if we or our partners successfully complete clinical trials for our product candidates, we or our partners might not file the required regulatory submissions in a timely manner or may not receive regulatory approval for the product candidates, which in either case would adversely impact or preclude our ability to generate any revenues from product sales or licensing arrangements. In addition, any product candidate, if approved, may be subject to restrictions on labeling, marketing, distribution, prescribing, and use, which could adversely impact the sales of such product.

If our development collaborations with third parties, such as our development partners, contractors and contract research organizations, fail, the development of our product candidates will be delayed or stopped.

We rely heavily upon third parties for many important stages of our product candidate development, including, but not limited to:

- discovery of natural proteins that cause or enable biological reactions necessary for the progression of the disease or disorder;
- execution of certain pharmacology preclinical studies and late-stage development for our compounds and product candidates;
- management of our phase 1, 2 and 3 clinical trials, including medical monitoring, laboratory testing, and data management;
- execution of toxicology studies that may be required to obtain approval for our product candidates;
- formulation improvement strategies and methods;
- manufacturing the starting materials and drug substance required to formulate our products and the product candidates to be used in our clinical trials, toxicology studies and any potential commercial product;
- provision of cell banks or cell line technologies; and

- management of certain regulatory interactions outside of the United States.

Our failure to engage in successful collaborations at any one of these stages would greatly impact our business. If we do not license protein targets or inhibitors from academic institutions or from other biotechnology companies on acceptable terms, or at all, our drug development efforts could suffer. Similarly, if the contract research organizations or third-party contractors that conduct our initial or late-stage clinical trials, conduct our toxicology or other studies, manufacture our starting materials, drug substance and product candidates, provide laboratory testing or other services (including clinical operation services) in connection with our clinical trials, provide medical writing services, or assist with our regulatory function breach their obligations to us, perform their services inconsistent with industry standards, or fail to comply with regulatory requirements, this would delay or prevent both the development of our product candidates and the availability of any potential commercial product.

If we lose our relationship with any one or more of these parties, we could experience a significant delay in both identifying another comparable provider and then contracting for its services. We may be unable to retain an alternative provider on reasonable terms, if at all. Even if we locate an alternative provider, it is likely that this provider may need additional time to respond to our needs and may not provide the same type or level of service as the original provider. In addition, any provider that we retain will be subject to applicable FDA current Good Laboratory Practices, current Good Manufacturing Practices ("cGMP"), and current Good Clinical Practices, and comparable foreign standards. We do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of our product candidates could be delayed. If any of the foregoing risks is realized, our business, financial condition and results of operations could be materially adversely affected.

If we or our partners do not obtain regulatory approvals for our product candidates or maintain regulatory approvals for our products, we or our partners will not be able to commercialize and sell these products and potential products, which would significantly harm our business because we will receive no revenue.

We or our partners must obtain regulatory approvals before marketing or selling our products. If the FDA or a comparable foreign regulatory authority delays or denies regulatory approval of one of our product candidates, or revokes approval of a previously approved product, we would be unable to market or sell the product in the applicable jurisdiction and would not receive revenue from sales or licensing arrangements related thereto, which could have a material and adverse impact on our business.

The process of preparing for and obtaining regulatory approval in any jurisdiction may be lengthy and expensive, and approval is never certain. Because of the risks and uncertainties inherent to the development process, our product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain approval. As discussed under "*Risk Factors—Risks Relating to Our Business—Risks Relating to Product Development and Commercialization—Our success depends in part upon our ability to manage our product candidate pipeline, advance our product candidates through the various stages of development, especially through the clinical trial process, and to receive regulatory approvals for the commercial sale of our product candidates*," we and our partners have experienced, and may again in the future experience, any number of unfavorable outcomes during or as a result of preclinical studies and clinical trials that could delay or prevent regulatory approval of our product candidates, or negatively impact our management's credibility, our value and our operating results.

Even if the FDA or foreign regulatory authorities approve a product candidate, the approval may limit the indicated uses for a product candidate, impose other restrictions on the product candidate, and/or may require post-approval studies that could impair the commercial viability of a product candidate. Even upon any approval to market our potential products, whether in the United States or internationally, we will continue to be subject to extensive regulatory requirements, as discussed under "*Risk Factors—Risks Relating to Our Business—Legal and Regulatory Risks—We are subject to various laws and regulations related to our products and product candidates, and if we or our partners do not comply with these laws and regulations, we could face substantial penalties*."

Our failure to comply with existing or future regulatory requirements for regulatory approval, or our loss of, or changes to, previously obtained approvals, could impair our ability to generate any revenues from product sales or licensing arrangements, which could have a material adverse effect on our business, financial condition, and results of operations.

We focus primarily on rare diseases, which may create additional risks and challenges, including that the target patient populations of our products and product candidates may be small.

Because we focus primarily on developing drugs as treatments for rare diseases, we may seek orphan drug, breakthrough therapy or fast track designations for our product candidates in the United States or the equivalent designations elsewhere in the world. Often, regulatory authorities have broad discretion in determining whether or not to grant such designations. We cannot guarantee that our product candidates will receive orphan drug status from the FDA or equivalent designations from other regulatory authorities. Even with an orphan drug designation for our current and potential future product candidates, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for an existing or future product candidate, that exclusivity may not effectively protect the product from competition.

In addition, we do not know if, when, or how the FDA, Congress, or future judicial challenges may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. See "*Business—Government Regulation—FDA Regulation—Orphan Drugs*" in Part 1, Item 1 of this report.

We also cannot guarantee that we will receive breakthrough therapy, fast track, or equivalent designations, which provide certain potential benefits such as more frequent meetings with the applicable regulatory authorities to discuss development plans, intensive guidance on efficient drug development programs, and potential eligibility for rolling review or priority review. Even if we are successful in obtaining any such designations for our product candidates, such designations may not lead to faster development or regulatory review or approval and do not increase the likelihood that our product candidates will receive marketing approval. We may not be able to obtain or maintain these designations for our product candidates that receive them, and our competitors may obtain these designations for their product candidates, which could impact our ability to develop and commercialize our products and product candidates or compete with such competitors, which may adversely impact our business, financial condition or results of operations.

Given the small number of patients who have the diseases that we are targeting, it is important to our ability to grow and sustain profitability that we continue to successfully identify patients with these rare diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our products and product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for each of our products and product candidates may be limited or may not be amenable to treatment with our products and product candidates, and new patients may become increasingly difficult to identify or access. Further, even if we obtain significant market share for our products and product candidates, because the potential target populations are small, we may not maintain profitability or generate sufficient long-term revenue growth to sustain our business.

If the FDA or comparable foreign regulatory authorities approve generic versions of any of our drug products that receive marketing approval, or such authorities do not grant our products appropriate periods of data or market exclusivity before approving generic versions of our products, the sales of our products could be adversely affected.

Once an NDA is approved, the drug covered thereby becomes a "reference-listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations." Manufacturers may seek marketing approval of generic versions of reference-listed drugs through submission of abbreviated new drug applications, or ANDAs, in the United States, as described in "*Business—Government Regulation—FDA Regulation—Abbreviated New Drug Applications for Generic Drugs*" in Part I, Item 1 of this report. Generic drugs may be significantly less costly to bring to market than the reference-listed drug and companies that produce generic drugs are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference-listed drug is typically lost to the generic drug.

The FDA may not approve an ANDA for a generic drug until any applicable period of non-patent exclusivity for the reference-listed drug has expired, as described in "*Business—Government Regulation—FDA Regulation—Abbreviated New Drug Applications for Generic Drugs*" in Part I, Item 1 of this report, but such exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of

reference to all of the nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. Manufacturers may seek to launch generic drugs following the expiration of the marketing exclusivity period, even if we still have patent protection for such drugs.

Competition that our drug products or product candidates may face from generic drugs could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates. Our future revenues, profitability and cash flows could also be materially and adversely affected and our ability to obtain a return on the investments we have made in those product candidates may be substantially limited if our products or, if and when approved, product candidates, are not afforded the appropriate periods of non-patent exclusivity.

We may face competition from biosimilars, which may have a material adverse impact on the future commercial prospects of our biological products and product candidates.

Even if we are successful in achieving regulatory approval to commercialize a biological product candidate faster than our competitors, we may face competition from biosimilars with respect to our biological product candidates. In the United States, the BPCIA was included in the ACA and created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar," or biosimilar, to or "interchangeable" with an FDA-approved biological product. The BPCIA prohibits the FDA from approving a biosimilar or interchangeable product that references a brand biological product until 12 years after the licensure of the reference product, but permits submission of an application for a biosimilar or interchangeable product to the FDA four years after the reference product was first licensed. The BPCIA does not prevent another company from developing a product that is highly similar to the innovative product, generating its own data, and seeking approval. The law is complex and continues to evolve through ongoing FDA implementation and judicial interpretation. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. Modification of the BPCIA, or changes to the interpretation or implementation of the BPCIA, could have a material adverse effect on the future commercial prospects for our biological products and product candidates.

If competitors are able to obtain marketing approval for biosimilars referencing our biological products, our biological products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences which could adversely affect our business and financial results.

The commercial viability of any approved product could be compromised if the product is less effective than expected, causes undesirable side effects that either were not previously identified or were worse than expected, or fails to achieve market acceptance within the medical community.

If, after obtaining regulatory approval of a product, we or others discover that the product is less effective than previously believed or causes undesirable side effects that either were not previously identified or were worse than expected, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of, or impose marketing or manufacturing restrictions on, the product, or require us or our partners to create a medication guide outlining the risks of unidentified side effects for distribution to patients;
- we or our partners may be required to recall the product, change the way the product is administered, conduct additional clinical trials, or be subject to civil or criminal penalties; and
- the product may become less competitive and our reputation may suffer.

Even after receiving regulatory approval, any product could fail to gain sufficient, or any, market acceptance by physicians, patients, third-party payors, health authorities and others in the medical community. For example, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies. If an approved product does not achieve an adequate level of market acceptance, it may not generate significant revenues. The occurrence of any of the foregoing could have a material and adverse impact on our business.

If we fail to successfully commercialize or establish collaborative relationships to commercialize or develop certain of our products and product candidates, or if any partner terminates or fails to perform its obligations under agreements

with us, potential revenues from commercialization of our products and product candidates could be reduced, delayed or eliminated.

Our business strategy includes successfully commercializing our product and product candidate portfolio. We believe this is best achieved by retaining full product rights or through collaborative arrangements with third parties as appropriate. As needed, potential third-party relationships could relate to preclinical development, clinical development, regulatory approval, marketing, sales, and distribution of our products and product candidates.

Currently, we have established collaborative relationships, including with, among others, third-party distributors for ORLADEYO in certain markets, with Torii for ORLADEYO in Japan, with Neopharmed for the commercialization of ORLADEYO in Europe, with each of Shionogi and Green Cross for the development and commercialization of peramivir, and with Clearside for the development of avoralstat with Clearside's SCS Microinjector®. In addition, in August 2025, Astria announced that it exclusively licensed development and commercialization rights in Japan to Kaken for navenibart. The process of establishing and implementing collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- we or our partners may seek to renegotiate or terminate our relationships due to unsatisfactory commercial, regulatory or clinical results, including post-approval clinical commitments, a change in business strategy, a change of control or other reasons;
- our contracts for collaborative arrangements may expire;
- the possibility that expiration or termination of collaborative relationships, such as those with certain of our distribution partners, may trigger repurchase obligations of the Company for unsold product held by our partners;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we have had in the past, and in the future may have, disputes with a partner that could lead to litigation or arbitration, which could result in substantial costs and divert the attention of our management;
- we do not have day-to-day control over the activities of our partners and have limited control over their decisions;
- our ability to generate future event payments and royalties from our partners depends upon their abilities to establish the safety and efficacy of our product candidates, obtain regulatory approvals and achieve market acceptance of products developed from our product candidates;
- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;
- we or our partners may not devote sufficient capital or resources toward our products and product candidates;
- our partners may declare bankruptcy or face other financial distress that could put our partnership or collaborative arrangements at risk, such as Clearside's recent filing for Chapter 11 bankruptcy; and
- we or our partners may not comply with applicable government regulatory requirements.

If we or our partners fail to fulfill our responsibilities in a timely manner, or at all, our development and commercialization efforts related to that collaboration could be reduced, delayed or terminated, or it may be necessary for us to assume responsibility for activities that would otherwise have been the responsibility of our partner. If we are unable to establish and maintain collaborative relationships on acceptable terms, when or where needed, we may have to delay or discontinue further development or commercialization of one or more of our products or product candidates, undertake commercialization activities at our own expense or find alternative sources of funding. Any delay in the development or commercialization of our products and product candidates would severely affect our business, because if our product candidates do not progress through the development process or reach the market in a timely manner, or at all, or if our products do not achieve market success, we may not receive any revenues from product sales or licensing arrangements.

The results of our partnership with Torii may not meet our current expectations.

We have a partnership agreement with Torii for ORLADEYO in Japan. Under our agreement with Torii, we are responsible for all field promotional activities with respect to ORLADEYO in Japan, which we conduct through our Japanese subsidiary, BioCryst Japan K.K. Furthermore, we remain responsible for regulatory activities with respect to ORLADEYO in Japan, and we use third parties to satisfy those regulatory responsibilities and certain other obligations in Japan. If any party fails to meet its obligations, the commercial success of ORLADEYO in Japan and the economic benefit expected could be negatively impacted.

There can be no assurance that our or our partners' commercialization efforts, methods, and strategies for our products or technologies will succeed, and our future revenue generation is uncertain.

There can be no assurance that our or our partners' commercialization efforts, methods and strategies will succeed or maintain success. We may be unable to establish or sufficiently increase our sales, marketing and distribution capabilities for products we currently, or plan to, commercialize. Our ability to receive revenue from products we or our partners commercialize is subject to several risks, including:

- we or our partners may fail to complete clinical trials successfully, or satisfy post-marketing commitments, sufficient to obtain and maintain regulatory agency marketing approval;
- many competitors are more experienced and have significantly more resources, and their products could reach the market faster, be more cost effective or have a better efficacy or tolerability profile than our products and product candidates;
- we may fail to employ a comprehensive and effective intellectual property strategy, which could result in decreased commercial value of our Company, our products and product candidates, or royalties associated with such products (e.g., the loss of the peramivir patent in Korea, which may result in a reduced royalty from Green Cross);
- we may fail to employ a comprehensive and effective regulatory strategy, which could result in a delay or failure in commercialization of our products;
- our and our partners' ability to successfully commercialize our products is affected by the competitive landscape;
- revenue from product sales depends on our ability to obtain and maintain favorable pricing;
- reimbursement is constantly changing, which could greatly affect usage of our products;
- future revenue from product sales will depend on our ability to successfully complete clinical studies, obtain regulatory approvals, and manufacture, market, distribute and commercialize our future approved products; and
- the impact of public health emergencies or the outbreak of disease, such as the COVID-19 pandemic, on us or our partners.

In addition, future revenue from sales of ORLADEYO is subject to uncertainties and will depend on several factors, including, but not limited to, the success of our and our partners' commercialization efforts in the United States and elsewhere, the number of new patients switching to ORLADEYO, patient retention and demand, the number of physicians prescribing ORLADEYO, the rate of monthly prescriptions, reimbursement from third-party and government payors, the number of patients receiving free product, our pricing strategy, and market trends.

Even if we are able to successfully commercialize our existing products, or to develop new commercially viable products, certain obligations we have to third parties, including, without limitation, our obligations to pay royalties on certain revenues from ORLADEYO under the Royalty Purchase Agreements, may reduce the profitability of such products.

We have expanded our development and regulatory capabilities and implemented sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We have experienced significant growth in the number of our employees and the scope of our operations. To manage our growth, we must continue to implement and improve our managerial, operational and financial systems and processes, and continue to recruit and train qualified personnel as needed. Due to our limited financial resources and the limited experience of our management team in managing a company with such growth, we may not be able to effectively manage such expansion of our operations, implement appropriate systems and processes in a timely manner or at all, or recruit, train, and retain qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. In addition, if a commercial launch for any product or product candidate for which we recruit a commercial team and establish marketing capabilities in any region is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We depend on third-party vendors in the manufacture and distribution of our products, product candidates and the materials for our products and product candidates. If we cannot rely on existing third-party vendors, we will be required

to incur significant costs and potential delays in finding new third-party vendors, which could adversely impact the development and commercialization timeframes for our products and product candidates.

We depend on third-party vendors, including third-party manufacturers, distributors, and specialty pharmacies, in the manufacture and distribution of our products, product candidates, and the materials for our products and product candidates. Often, especially in the early development and commercialization process, we have only one or limited sources for a particular product or service, such as manufacturing and/or distribution. We depend on these third-party vendors to perform their obligations in a timely manner and in accordance with applicable governmental regulations. Our third-party vendors, particularly our third-party manufacturers and distributors, each of which may be the only vendor we have engaged for a particular product, product candidate, or service or in a particular region, may encounter difficulties with meeting our requirements, including, but not limited to, problems involving, as applicable:

- insufficient resources being devoted in the manner necessary to satisfy our requirements within expected timeframes;
- inconsistent production yields;
- product liability claims or recalls of commercial product;
- difficulties in scaling production to commercial and validation sizes;
- interruption of the delivery of materials required for the manufacturing process;
- failure to distribute commercial supplies of our products to commercial vendors or end users in a timely manner;
- scheduling of plant time with other vendors or unexpected equipment failure;
- potential catastrophes that could strike their facilities or have an effect on infrastructure;
- potential impurities in our drug substance or products that could affect availability of product for our clinical trials or future commercialization;
- poor quality control and assurance or inadequate process controls;
- failure to provide us with accurate or timely information regarding inventory, the number of patients who are using our products, or serious adverse events and/or product complaints regarding our products;
- inability of third parties to satisfy their financial obligations to us or to others;
- potential breach of the manufacturing or distribution agreement by the third party;
- possible termination or non-renewal of an agreement by the third party at a time that is costly or inconvenient to us; and
- lack of compliance or cooperation with regulations and specifications or requests set forth by the FDA or other foreign regulatory agencies or local customs.

The process of manufacturing pharmaceutical products, devices and, in particular, biologics, is complex, highly regulated, and subject to multiple risks. Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics, difficulties in scaling the production process and use of excipients which may, among other things, impact shelf life and present concerns with process controls. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, other supply disruptions and higher costs. If microbial, viral or other contaminations are discovered at the facilities of our third-party contract manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of drug product and adversely affect our business.

Many additional factors could cause production or distribution interruptions with the manufacture and distribution of any of our products and product candidates, including human error, natural disasters, pandemics, labor disputes or shortages, acts of terrorism or war, equipment malfunctions, raw material shortages or supply chain issues. If our commercial distribution partners are not able to satisfy our requirements within the expected timeframe, or are unable to provide us with accurate or timely information and data, including with respect to inventory and sales, serious adverse events, and/or product complaints, our business, including our commercialization efforts for and sales of ORLADEYO, may be at risk. In addition, if specialty pharmacy services, including our third-party call center services, which provide patient support and financial services, prescription intake and distribution, reimbursement adjudication, and ongoing compliance support, are not effectively managed, the continuance of our commercialization efforts for and sales of ORLADEYO may be delayed or compromised.

In addition, our contract manufacturers may not be able to manufacture the materials required for our products or product candidates at a cost or in quantities necessary to make them commercially viable. Our raw materials, drug substances, products, and product candidates are manufactured by a limited group of suppliers, including some at a single

facility. If any of these suppliers were unable to produce these items, this could significantly impact our supply of products and product candidate material for further preclinical testing and clinical trials. Additionally, if we are unable to timely establish an alternate supply from one or more third-party contract manufacturers, we could experience delays in our development efforts as we seek to locate and qualify new or additional manufacturers. For particular products, product candidates, services or particular regions where we rely on a single vendor, these and other related risks are exacerbated for us.

Our third-party manufacturers also may not meet our manufacturing requirements. Furthermore, changes in the manufacturing process or procedures, including a change in the location where the drug is manufactured or a change of a third-party manufacturer, may require prior review and approval in accordance with the FDA's cGMP and comparable foreign requirements. This review may be costly and time-consuming and could delay or prevent the launch of a product. The FDA or foreign regulatory authorities may at any time implement new standards, or change their interpretation and enforcement of existing standards, for manufacture, packaging or testing of products. If we or our contract manufacturers are unable to comply, we or they may be subject to regulatory action, civil actions or penalties, any of which could be costly to us and could result in a delay or shortage of product.

We currently contract with a foreign contract manufacturing organization ("CMO") in China for the manufacturing of one of our product candidates. Foreign CMOs may be subject to U.S. legislation, including the BIOSECURE Act, sanctions, trade restrictions and other foreign regulatory requirements, which could increase the cost or reduce the supply of material available to us or delay the procurement or supply of such material.

If we are unable to maintain current third-party relationships, or enter into new agreements with additional third parties on commercially reasonable terms, or at all, or if there is poor manufacturing or distribution performance or failure to comply with any regulatory agency on the part of any of our third-party vendors, we may not be able to complete development of, obtain timely approval of, or commercialize our products and product candidates.

Commercialization of our products by us and our partners is subject to the potential commercialization risks described herein and numerous additional risks. Any potential revenue benefits to us, including in the form of milestone payments, royalties or other consideration, are highly speculative.

Commercial success of our products is uncertain and is subject to all the risks and uncertainties disclosed in our other risk factors relating to drug development and commercialization. In addition, commercialization of our products is subject to further risks and may be negatively impacted by a number of factors, including, but not limited to, the following:

- our products may not prove to be adequately safe and effective for market approval in markets other than the markets in which they are currently approved;
- necessary funding for post-marketing commitments and further development of our products may not be available timely, at all, or in sufficient amounts;
- advances in competing products could substantially replace potential demand for our products;
- government and third-party payors may not provide sufficient coverage or reimbursement, which would negatively impact the demand for our products;
- we may not be able to supply commercial material, including supplying sufficient product to meet commercial demand, and our partners may not be able to maintain or establish sufficient and acceptable commercial manufacturing, either directly or through third-party manufacturers;
- the commercial demand for and acceptance of our products by healthcare providers and by patients may not be sufficient to result in substantial product revenues to us or to our partners and may result in little to no revenue, milestone payments, or royalties to us;
- effectiveness of marketing and commercialization efforts for our products by us or our partners;
- market satisfaction with existing alternative therapies;
- perceived efficacy relative to other available therapies;
- disease prevalence;
- cost of treatment;
- our pricing and reimbursement strategy may not be effective;
- new legislative or regulatory proposals may influence our pricing and reimbursement strategy, which could impact product revenues;
- pricing and availability of imports or alternative products;
- marketing and sales activities of competitors;
- shifts in the medical community to new treatment paradigms or standards of care; and

- relative convenience and ease of administration.

Risks Relating to Competing in Our Industry

We face intense competition, and if we are unable to compete effectively, the demand for our products may be reduced.

The biotechnology and pharmaceutical industries are highly competitive and subject to rapid and substantial technological change. There are many companies seeking to develop products for the same indications that we currently target. Our competitors in the United States and elsewhere are numerous and include, among others, major multinational pharmaceutical and chemical companies and specialized biotechnology firms. Most of these competitors have greater resources than we do, including greater financial resources, larger research and development staffs and more experienced manufacturing, marketing, and sales organizations. In addition, most of our competitors have greater experience than we do in conducting clinical trials and obtaining FDA and other regulatory approvals. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals of product candidates more rapidly than we do for products that compete with our products. Companies that complete clinical trials, obtain required regulatory approvals, and commence commercial sale of their drugs before we do may achieve a significant competitive advantage, including patent and FDA exclusivity rights that would delay our ability to market products. We face, and will continue to face, competition in the commercialization of our products, licensing of potential product candidates for desirable disease targets, and development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. Competition may also arise from, among other things:

- other drug development technologies;
- methods of preventing or reducing the incidence of disease, including vaccines; and
- new small molecule or other classes of therapeutic agents.

Developments by others may render our products, product candidates, or technologies obsolete or noncompetitive.

We received FDA approval of ORLADEYO, an oral, once-daily therapy for the prevention of HAE attacks in adults and pediatric patients aged 12 years and older, in December 2020, and subsequently received regulatory approvals for ORLADEYO in other global markets. In December 2025, the FDA approved the use of an oral pellet formulation of once-daily ORLADEYO for prophylactic therapy in pediatric patients with HAE aged 2 to <12 years. We are also performing research on or developing products for the treatment of several other rare diseases, and we expect to encounter significant competition for our pharmaceutical products and product candidates. Companies that complete clinical trials, obtain required funding or government support, obtain required regulatory approvals and commence commercial sales or stockpiling orders of their products before their competitors may achieve a significant competitive advantage. Various government entities throughout the world may also offer incentives, grants and contracts to encourage additional investment into certain preventative and therapeutic agents, which may have the effect of further increasing the number of our competitors and/or providing advantages to certain competitors. In addition, the approval of a generic drug or biosimilar of one of our products or a product with which we compete could have a material impact on our business because it may be significantly less costly to bring to market and may be priced significantly lower than our products or the other products with which we compete. See "*Business—Competition*" in Part I, Item 1 of this report for further discussion of our competitors, competitive products or programs, and the competitive conditions in these and other therapeutic areas.

If one or more of our competitors' products or programs, including potential competitors not currently identified, are successful, the market for our products may be reduced or eliminated.

Compared to us, many of our competitors and potential competitors have substantially greater:

- capital resources;
- research and development resources, including personnel and technology;
- regulatory experience;
- preclinical study and clinical testing experience;
- manufacturing, marketing, and sales experience; and
- production facilities.

Any of these competitive factors could impede our funding efforts, render our products, product candidates, or technologies noncompetitive or eliminate or reduce demand for our products and product candidates.

Legal and Regulatory Risks

We are subject to various laws and regulations related to our products and product candidates, and if we or our partners do not comply with these laws and regulations, we could face substantial penalties.

Our and our partners' activities related to approved products or, following their regulatory approval (if applicable), any of our product candidates under development, are subject to regulatory and law enforcement authorities in the United States (including the FDA, the Federal Trade Commission, the Department of Justice ("DOJ"), the HHS, Office of Inspector General, and state and local governments) and their foreign equivalents.

We are responsible for reporting adverse drug or biological product experiences, have responsibility for certain post-approval studies, and may have responsibilities and costs related to a recall or withdrawal of our products from sale in the jurisdictions in which they are approved. We may also incur liability associated with product manufacturing contracted by us or in support of any of our partners. We are required to maintain records and provide data and reports to regulatory agencies related to our products (e.g., risk evaluation and mitigation strategies, track and trace requirements, and adverse events), and we may incur certain promotional regulatory and government pricing risks, all of which could have a material adverse impact on our operations and financial condition. Similar responsibilities would apply upon regulatory approval of any of our other product candidates currently under development.

In addition, we are subject to the federal Physician Payment Sunshine Act and certain similar physician payment and drug pricing transparency legislation in various states. We are also subject to various federal and state laws pertaining to healthcare "fraud and abuse," including both federal and state anti-kickback and false claims laws. Outside of the United States, we may be subject to analogous foreign laws and regulations in the various jurisdictions in which we operate. These laws and regulations apply to our and our partners' operations, sales and marketing practices, price reporting, and relationships with physicians and other customers and third-party payors. Although we seek to comply with these statutes, it is possible that our practices, or those of our partners, might be challenged under healthcare fraud and abuse, anti-kickback, false claims or similar laws. Violations of the federal Physician Payment Sunshine Act and similar legislation or the fraud and abuse laws may be punishable by civil or criminal sanctions, including fines and civil monetary penalties, and future exclusion from participation in government healthcare programs.

The principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to certain regulatory authorities, including the FDA and comparable foreign regulatory authorities. Consequently, the FDA or other regulatory authority may conclude that a financial relationship between us and a principal investigator creates a conflict of interest or otherwise affects interpretation of the study. In the event of a conflict of interest with respect to a study, the integrity of the data generated at the applicable clinical trial site may be questioned or the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

The FDA and foreign regulatory authorities may also impose post-approval commitments on us for approved products, which we may not complete successfully or on time for any number of reasons, including, but not limited to, lack of funds to complete the studies and insufficient interest by appropriate sites, investigators or study subjects. We are currently subject to certain post-approval commitments and evolving FDA guidance. If we fail to comply with any post-approval legal and regulatory requirements, we could be subject to penalties, and our products could be subject to continual recordkeeping and reporting requirements, review and periodic inspections by the FDA and other regulatory bodies. Regulatory approval of a product may be subject to limitations on the indicated uses for which the product may be marketed or to other restrictive conditions of approval that limit our ability to promote, sell or distribute a product. Furthermore, the approval of our products and any other future product candidates may be subject to requirements for costly post-approval testing and surveillance to monitor their safety or efficacy or certain post-approval labeling, packaging and storage requirements.

Advertising and promotion are subject to stringent oversight from the FDA and foreign regulators, and as a holder of an approved marketing application, we may be held responsible for any advertising and promotion that is not in compliance with applicable rules and regulations. Applicable regulatory authorities, competitors, and other third parties may take the position that we are not in compliance with such regulations. In addition to medical education efforts, we may offer patient support services to assist patients receiving treatment with our commercially approved products, and these support services have increasingly become the focus of government investigation.

Adverse event information concerning approved products must be reviewed, and as a holder of an approved marketing application, we are required to make expedited and periodic adverse event reports to the FDA and other regulatory authorities. In addition, the research, manufacturing, distribution, sale and promotion of products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services ("CMS"), other divisions of HHS, the DOJ and individual U.S. Attorney offices within the DOJ, state and local governments, and foreign equivalents of the foregoing. All of these activities are also potentially subject to healthcare false claims and fraud and abuse laws, as well as consumer protection and unfair competition laws.

If our operations with respect to our products that are subject to healthcare laws and regulations are found to be in violation of any of the healthcare fraud and abuse laws described above or in "*Business—Government Regulation*" in Part I, Item 1 of this report or any other governmental regulations that apply to us, we may be subject to liability and penalties, including civil and criminal penalties, damages, fines, debarment or exclusion from participating in government-funded healthcare programs such as Medicare or Medicaid, and the curtailment or restructuring of our operations. Any penalties, damages, fines, debarment, exclusion, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with all applicable fraud and abuse laws may be costly.

We cannot predict the likelihood, nature or extent of government regulation or other measures that may arise from future legislation or administrative or executive action, either in the United States or abroad.

The policies of the FDA and other regulatory authorities may change, including as a result of changes in presidential administration of the United States, and additional government regulations or executive orders may be enacted that could prevent, limit or delay regulatory approval of our product candidates, change our continuing compliance obligations, impact our product pricing and/or revenues, affect our supply chain or otherwise adversely affect our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, we may not be able to obtain new marketing approvals, and we may not achieve sustained profitability. In addition, significant tariffs, trade measures or other restrictions imposed and related countermeasures taken by impacted foreign countries could adversely affect our operations and financial results. We cannot predict the likelihood, nature or extent of government regulation or other measures that may arise from future legislation or administrative or executive action, either in the United States or abroad.

In June 2024, the Supreme Court overruled the *Chevron* doctrine, which had given deference to regulatory agencies' statutory interpretations of ambiguous regulations in litigation against federal government agencies, such as the FDA. The overruling of the *Chevron* doctrine may significantly increase the number of challenges brought by companies and other stakeholders against federal agencies such as the FDA and its longstanding decisions and policies, including the FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of regulatory submissions. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action.

Further, under the new leadership at HHS under the current administration, agency reorganization, mass layoffs due to the reduction in force initiative and other measures may impact the normal operations of the FDA as well as other federal agencies. FDA may lack adequate staff and resources to meet current review, approval, and inspection schedules, which could delay our anticipated timelines. Recent developments at the FDA include announcement of a plan to phase out animal testing for monoclonal antibodies and certain other drugs, the proposed rare disease evidence principles (RDEP) program to facilitate approval of drugs to treat rare diseases with very small patient populations with significant unmet medical need and with a known genetic defect that is the major driver of the pathophysiology, and the announcement of a new Commissioner's National Priority Voucher program for companies supporting certain U.S. national health priorities and interests. To the extent our competitors are selected for this new voucher pilot program, or are otherwise able to participate in any of these initiatives intended to accelerate drug development and application review, and obtain faster approval than us, our competitive position may be harmed. The FDA has also increased its scrutiny of foreign drug manufacturing facilities and other contractors based in China, especially with respect to the transfer of biological materials, genetic data, and other sensitive data of U.S. patients to parties located in China. It is unclear how our industry and our clinical programs will be impacted by policies and regulations implemented under the current administration and FDA

leadership, or other executive orders. There is significant uncertainty in the industry and how federal agencies like the FDA will change in the coming years under the current administration. To the extent the agency reorganization and other agency changes lead to disruptions in the FDA's operations, our correspondence and regulatory review processes with the FDA may be materially delayed.

Our employees, consultants and partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are subject to the risk of fraud or other misconduct by our employees, consultants and partners, including intentional or unintentional failures to comply with FDA regulations or similar regulations of comparable other regulatory authorities, provide accurate information to the FDA or comparable other regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable other regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee and consultant misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee and consultant misconduct, whether intentional, reckless, negligent, or unintentional, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We and our partners may be subject to new legislation, regulatory proposals and healthcare payor initiatives that may increase our costs of compliance and adversely affect our or our partners' ability to commercialize our products or develop our product candidates.

We are subject to new legislation, regulatory, and healthcare payor initiatives, including the Patient Protection and Affordable Care Act ("PPACA"), which made extensive changes to the delivery of healthcare in the United States, as discussed in "*Business—Government Regulation*" in Part I, Item 1 of this report. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare could result in decreased net revenues from our pharmaceutical products and decrease potential returns from our development efforts. In addition, pharmaceutical and device manufacturers are also required to report and disclose certain payments and transfers of value to, and investment interests held by, physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties for payments, transfers of value, or ownership or investment interests not reported in an annual submission. Compliance with the PPACA and state laws with similar provisions is difficult and time-consuming, and companies that do not comply with these state laws face civil penalties. Because of the breadth of these laws and the narrowness of the applicable safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. For example, legislation has been enacted in certain states and at a federal level that requires manufacturers and other entities in the drug supply chain to track and trace each prescription drug at the saleable unit level through the distribution system. The FDA has finalized and proposed regulations implementing such requirements at a federal level. Our compliance with these requirements may be deemed insufficient and we could face a material adverse effect on our business, financial condition, results of operations and growth prospects. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition and results of operations.

Adequate coverage and reimbursement in the United States and other markets is essential to the commercial success of our approved products. Recently in the United States, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. For example, the Inflation Reduction Act of 2022 ("IRA") implements a number of drug pricing measures intended to lower the cost of prescription drugs and related healthcare reforms, including limits on price increases and subjecting an escalating number of drugs to annual price negotiations with

CMS. The IRA includes several provisions that will impact our business to varying degrees, including provisions that reduced the out-of-pocket spending cap for Medicare Part D beneficiaries to $2,100 in 2026; impose new manufacturer financial liability on all drugs in Medicare Part D; allow the U.S. Government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for drug prices that increase faster than inflation; and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication or indications are for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications for more than one disease or condition, it may not qualify for the orphan drug exemption.

In 2025, the U.S. Government took various steps, both legislative and executive, intended to lower the cost of prescription drugs. The President issued multiple executive orders and took other steps to secure pharmaceutical manufacturers' agreements to lower certain U.S. prescription drug prices to most favored nation levels, to facilitate direct-to-patient sales of certain U.S. prescription drugs, and to secure agreements to repatriate increased ex-U.S. revenues generated as a result of U.S. Government action that increases drug prices outside the United States. On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law in the United States. The OBBBA contains a variety of provisions that could impact our business and results of operations. On January 15, 2026, the White House proposed that Congress enact the Great Healthcare Plan Act, which seeks to lower prescription drug and insurance prices. Multiple U.S. states have also enacted legislation intended to decrease the price of prescription drugs.

We cannot be sure whether additional legislation or rule-making related to the IRA or drug pricing more generally will be issued or enacted, how insurance pharmacy benefit managers and other insurance providers that manage benefits for Medicare recipients will react to the IRA, or what impact, if any, such additional changes will have on the insurance coverage and profitability of our products or any of our product candidates, if approved for commercial use, in the future. The full effect of the IRA on our business and the healthcare industry in general is not yet known. The IRA or other government efforts to reduce the price of prescription drugs or to limit the amount that governments pay for healthcare products and services could result in additional pricing pressure and have a significant impact on our business.

In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Third-party payors are increasingly challenging the prices charged for medical products and services and, in some cases, imposing restrictions on the coverage of particular drugs. Many third-party payors negotiate the price of medical services and products and develop formularies which establish pricing and reimbursement levels. Exclusion of a product from a formulary can lead to its sharply reduced usage in the third-party payor's patient population. The process for obtaining coverage can be lengthy and costly, and we expect that it could take several months before a particular payor initially reviews a product and makes a decision with respect to coverage. For example, third-party payors may require cost-benefit analysis data from us in order to demonstrate the cost-effectiveness of our products or any other product we might bring to market. For any individual third-party payor, we may not be able to provide data sufficient to gain reimbursement on a similar or preferred basis to competitive products, or at all, which may have a material adverse effect on our business, financial condition and results of operations.

We may be subject to data privacy and security risks, and our actual or perceived failure to comply with regulations and other legal obligations related to privacy and data protection could harm our business.

We may be subject to legal obligations at the international, federal, state, and local level related to privacy and data protection, as described in "*Business—Government Regulation—Data Privacy and Security Laws*" in Part I, Item 1 of this report. Compliance with stringent and evolving international and U.S. data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use, and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. For example, we may be subject to the California Consumer Privacy Act ("CCPA"), which gives California residents expanded rights to access and require deletion of their personal data, opt out of certain personal data sharing, and receive detailed information about how their personal data is used. The CCPA provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we may maintain about California residents.

We also may be subject to international privacy and data protection laws, such as the General Data Protection Regulation ("GDPR") in the European Economic Area ("EEA") and similar legislation in the United Kingdom and

Switzerland. See "*Business—Government Regulation—Data Privacy and Security Laws*" in Part I, Item 1 of this report and "*Risks Relating to Our Business—Risks Relating to International Operations—Our actual or perceived failure to comply with European or other international governmental laws and regulations and other legal obligations related to privacy, data protection and information security could harm our business*" in this section for additional discussion of privacy laws and regulations. Failure to comply with these laws and regulations could result in government enforcement actions, private litigation, or harm to our reputation and our business.

Despite our efforts, our personnel or third parties on whom we rely may fail to comply with such data privacy and security obligations, which could negatively impact our business operations. If we or the third parties on which we rely 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, 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.

If, because of our use of hazardous materials, we violate any environmental controls or regulations that apply to such materials, we may incur substantial costs and expenses in our remediation efforts.

Our research and development involves the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and some waste products. Accidental contamination or injury from these materials could occur. In the event of an accident, we could be liable for any damages that result, and any liabilities could exceed our resources. Compliance with environmental laws and regulations or a violation of such environmental laws and regulations could require us to incur substantial unexpected costs, which would materially and adversely affect our results of operations.

Intellectual Property Risks

If we fail to adequately protect or enforce our intellectual property rights, the value of those rights would diminish, and if we fail to secure the rights to patents of others, it could adversely affect our business.

Our success will depend in part on our ability and the abilities of our partners to obtain, protect and enforce viable intellectual property rights including, but not limited to, trade name, trademark and patent protection for our Company and subsidiaries and the products, methods, processes and other technologies we may license or develop, to preserve our trade secrets, and to operate without infringing the proprietary rights of third parties both domestically and abroad. The patent position of biotechnology and pharmaceutical companies is generally highly uncertain, involves complex legal and factual questions and has recently been the subject of much litigation. Neither the United States Patent and Trademark Office ("USPTO"), the Patent Cooperation Treaty offices, nor the courts of the United States and other jurisdictions have consistent policies nor predictable rulings regarding the breadth of claims allowed or the degree of protection afforded under many biotechnology and pharmaceutical patents. Further, we may not have worldwide patent protection for all of our product candidates and our intellectual property rights may not be legally protected or enforceable in all countries throughout the world. In some jurisdictions, some of our product candidates in certain programs, including our HAE program, may have short or no composition of matter patent life and we may therefore rely on orphan drug exclusivity or data exclusivity. There can be no assurance that we will obtain orphan drug exclusivity or data exclusivity in every jurisdiction. Further, in some jurisdictions, we may rely on formulation patents or method of use patents. Both the ability to achieve issuance and the enforcement of formulation and method of use patents can be highly uncertain and can vary from jurisdiction to jurisdiction, and such patents may therefore not adequately prevent competitors and potential infringers in some jurisdictions. The validity, scope, enforceability, and commercial value of the rights protected by such patents, therefore, is highly uncertain.

We also rely on trade secrets to protect technology in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. In addition, increasing restrictions on non-compete agreements could increase the difficulty of protecting certain proprietary information. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborators and advisors, our ability to receive patent protection or protect our proprietary information may be imperiled.

We may be involved in legal proceedings to protect or enforce our patents, the patents of our partners or our other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights, or may design around our patent claims to produce competitive products that fall outside the scope of our patents. For example, a third party may develop a competitive drug that is similar to one or more of our products or product candidates but that has a different composition that falls outside the scope of our patent protection. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive, time-consuming, and unsuccessful. An adverse result in any legal proceeding could put one or more of our patents at risk. Our success depends in part on avoiding the infringement of other parties' patents and other intellectual property rights as well as avoiding the breach of any licenses relating to our technologies and products. In the United States, patent applications filed in recent years are confidential for 18 months after the earliest effective filing date, while older applications are not published until the patent issues. As a result, avoiding patent infringement may be difficult and we may inadvertently infringe third-party patents or proprietary rights. These third parties could bring claims against us, our partners or our licensors that even if resolved in our favor, could cause us to incur substantial expenses and, if resolved against us, could additionally cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, our partners or our licensors, we or they could be forced to stop or delay research, development, manufacturing or sales of any infringing product in the country or countries covered by the patent we infringe, unless we can obtain a license from the patent holder. Such a license may not be available on acceptable terms, or at all, particularly if the third party is developing or marketing a product competitive with the infringing product. Even if we, our partners or our licensors were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property.

In addition, as described under "*Business—Government Regulation—FDA Regulation—Abbreviated New Drug Applications for Generic Drugs*" in Part I, Item 1 of this report, third parties may not file an ANDA for a generic drug with the FDA until the expiration of five years following the original product approval unless the submission is accompanied by a Paragraph IV certification, in which case third parties may submit an ANDA four years following the original product approval (referred to as the "NCE-1 date"). The NCE-1 date for ORLADEYO was in December 2024. In January 2025 and January 2026, we received a Paragraph IV notice of certification from Annora advising that Annora has submitted an ANDA to the FDA seeking approval to manufacture, use or sell a generic version of ORLADEYO in the United States prior to the expiration of four patents listed in the FDA's Orange Book, which expire in 2039. On March 10, 2025, as supplemented by the First Amended Complaint filed in December 2025, we filed a patent infringement lawsuit in the United States District Court for the District of Delaware against the Defendants (as defined in "*Legal Proceedings*" included in Part I, Item 3 of this report) asserting infringement of the challenged patents arising from Annora's ANDA filing with the FDA. For further information, see the section titled "*Legal Proceedings*" included in Part I, Item 3 of this report and "*Note 19— Commitments and Contingencies*" in the Notes to Consolidated Financial Statements in Part II, Item 8 of this report. We intend to vigorously defend our intellectual property rights protecting ORLADEYO. Additional third parties could challenge our applicable patents, which may result in our initiation of patent infringement litigation in response to such challenge. We cannot predict how any additional third party would address our listed patents, whether we would sue on any such patents, or the outcome of any such suit. However, litigation to enforce or defend intellectual property rights is complex, costly, and involves significant commitments of management's time.

If we or our partners are unable or fail to adequately initiate, protect, defend or enforce our intellectual property rights in any area of commercial interest or in any part of the world where we wish to seek regulatory approval for our products, methods, processes and other technologies, the value of our products and product candidates to produce revenue would diminish. Additionally, if our products, methods, processes, and other technologies or our commercial use of such products, processes, and other technologies, including, but not limited to, any trade name, trademark or commercial strategy infringe the proprietary rights of other parties, we could incur substantial costs. The USPTO and the patent offices of other jurisdictions have issued to us a number of patents for our various inventions, and we have in-licensed several patents from various institutions. We have filed additional patent applications and provisional patent applications with the USPTO. We have filed a number of corresponding foreign patent applications and intend to file additional foreign and U.S. patent applications, as appropriate. We have also filed certain trademark and trade name applications worldwide. We cannot assure you as to:

- the degree and range of protection any patents will afford against competitors with similar products;
- if and when patents will issue;
- if patents do issue, we cannot be sure that we will be able to adequately defend such patents and whether or not we will be able to adequately enforce such patents; or
- whether or not others will obtain patents claiming aspects similar to those covered by our patent applications.

If the USPTO or other foreign patent office upholds patents issued to others or if the USPTO grants patent applications filed by others, we may have to:

- obtain licenses or redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in those patents; or
- pay damages.

We may initiate, or others may bring against us, litigation or administrative proceedings related to intellectual property rights, including proceedings before the USPTO or other foreign patent office. Any judgment adverse to us in any litigation or other proceeding arising in connection with a patent or patent application could materially and adversely affect our business, financial condition and results of operations. In addition, the costs of any litigation or administrative proceeding may be substantial whether or not we are successful.

Our success is also dependent in part upon the skills, knowledge and experience, none of which is patentable, of our scientific and technical personnel. To help protect our rights, we require all employees, consultants, advisors and partners to enter into confidentiality agreements that prohibit the disclosure of confidential information to anyone outside of our Company and require disclosure and assignment to us of their ideas, developments, discoveries and inventions. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information, and if any of our proprietary information is disclosed, our business will suffer because our revenues depend upon our ability to license or commercialize our products and product candidates and any such events would significantly impair the value of such products and product candidates.

We have diversified our pipeline to include the development of protein therapeutics, which may create additional risks and challenges.

We have diversified our pipeline beyond small-molecule medicines to develop protein therapeutics. The development of protein therapeutics may create additional risks and challenges, including, among others:

- patent protection for protein therapeutics may be narrower in scope than for our small-molecule medicines, and our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our protein therapeutic candidates or prevent others from designing around our claims;
- formulation issues with our protein therapeutic candidates may require redevelopment of the formulation, which may be time-consuming or unsuccessful;
- the patent applications that we own or in-license may fail to result in issued patents with claims that cover our protein therapeutic candidates in the United States or in other countries;
- our competitors may be able to more easily develop and seek patent protection on similar protein therapeutic candidates; and
- orally-administered drugs are often less expensive and present a reduced treatment burden as compared to protein therapeutics and therefore would have competitive advantages if they were developed and shown to be safe and effective for the indication that our protein therapeutic product candidates are targeting.

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

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology and pharmaceutical industries involves both technological and legal complexity. Therefore, obtaining and enforcing such patents is costly, time-consuming, and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

We employ certain individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Our efforts to vet our employees, consultants, and independent contractors and prevent their use of the proprietary information or know-how of others in their work for us may not be successful, and we may in the future be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distract management and other employees.

Product Liability Risks

We face an inherent risk of liability in the event that the use or misuse of our products or product candidates results in personal injury or death, and our product liability insurance coverage may be insufficient.

If the use or misuse of any products we sell, or a partner sells, harms people, we may be subject to costly and damaging product liability claims brought against us by consumers, healthcare providers, pharmaceutical companies, third-party payors or others. The use of our product candidates in clinical trials, including post-marketing clinical studies, could also expose us to product liability claims. We cannot predict all of the possible harms or side effects that may result from the use of our products or the testing of product candidates, and therefore, the amount of insurance coverage we currently have may not be adequate to cover all liabilities or defense costs we might incur. A product liability claim or series of claims brought against us could give rise to a substantial liability that could exceed our resources. Even if claims are not successful, the costs of defending such claims and potential adverse publicity could be harmful to our business.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and face even greater risks upon commercialization by us of our products or product candidates. We have product liability insurance covering our clinical trials. Clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance or increase our existing coverage at a reasonable cost to protect us against losses that could have a material adverse effect on our business. An individual may bring a product liability claim against us if one of our products or product candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any product liability claim brought against us, with or without merit, could result in:

- liabilities that substantially exceed our product liability insurance, which we would then be required to pay from other sources, if available;
- an increase of our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, or at all;
- the withdrawal of clinical trial volunteers or patients;
- damage to our reputation and the reputation of our products, resulting in lower sales;
- regulatory investigations that could require costly recalls or product modifications;
- litigation costs; and
- the diversion of management's attention from managing our business.

Risks Relating to Contractual Arrangements

We may face risks related to our former U.S. Government contracts.

We had contracts with the Biomedical Advanced Research and Development Authority within HHS and the National Institute of Allergy and Infectious Diseases within HHS for the development of galidesivir as a treatment for diseases caused by RNA pathogens, including Marburg virus disease, Yellow Fever and Ebola virus disease. In contracting with U.S. Government agencies, we became subject to various U.S. Government contract requirements, including general clauses for a cost-reimbursement research and development contract, which may limit our reimbursement. While all U.S. Government funding for galidesivir expired in 2022, we may still face risks related to these U.S. Government contracts pending final close out of these contracts.

If we fail to reach milestones or to make annual minimum payments or otherwise breach our obligations under our license agreements, our licensors may terminate our agreements with them and/or seek additional remedies.

If we are unable or fail to meet payment obligations, performance milestones relating to the timing of regulatory filings, product supply obligations, post-approval commitments, or development and commercial diligence obligations; are unable or fail to make milestone payments or material data use payments in accordance with applicable provisions; or fail to pay the minimum annual payments under any of our in-licenses relating to our products or product candidates, our licensors may terminate the applicable license and/or seek other available remedies. As a result, our development of the respective product candidate or commercialization of the product would cease.

Because continuing events of default exist under the PhaRMA Notes, the holders of the PhaRMA Notes may be able to foreclose on the collateral securing the PhaRMA Notes and our equity interest in Royalty Sub. As a result, we may not realize the benefit of future royalty payments, if any, that might otherwise accrue to us following repayment of the PhaRMA Notes and we could otherwise be adversely affected.

In March 2011, JPR Royalty Sub LLC, our wholly-owned subsidiary ("Royalty Sub"), issued $30.0 million in aggregate principal amount of PhaRMA Senior Secured 14.0% Notes due on December 1, 2020 (the "PhaRMA Notes"). The PhaRMA Notes are secured principally by (i) certain royalty and milestone payments under our agreement with Shionogi, pursuant to which Shionogi licensed from us the rights to market peramivir in Japan and Taiwan and (ii) the pledge by us of our equity interest in Royalty Sub. Since September 1, 2014, payments from Shionogi have been insufficient for Royalty Sub to service its obligations under the PhaRMA Notes, resulting in a continuing event of default with respect to the PhaRMA Notes since that time. In addition, the PhaRMA Notes had a final legal maturity date of December 1, 2020, at which time the outstanding principal amount of the PhaRMA Notes of $30.0 million, together with accrued and unpaid interest of $20.6 million, was due in full. The failure by Royalty Sub to repay these amounts at the maturity date constituted an additional event of default under the PhaRMA Notes. As Royalty Sub has been unable to service its obligations under the PhaRMA Notes and continuing events of default exist under the PhaRMA Notes, the holders of the PhaRMA Notes may be able to foreclose on the collateral securing the PhaRMA Notes and our equity interest in Royalty Sub and may exercise other remedies available to them under the indenture or other documents related to the PhaRMA Notes. In such event, we may not realize the benefit of future royalty payments, if any, that might otherwise accrue to us following repayment of the PhaRMA Notes, we may incur legal costs, and we might otherwise be adversely affected.

We cannot predict whether holders of PhaRMA Notes will seek to pursue any remedies as a result of the continuing events of default with respect to the PhaRMA Notes. The PhaRMA Notes are the obligation of Royalty Sub. Due to the non-recourse nature of the PhaRMA Notes, in the event of any potential foreclosure, we believe the primary impact to us would be the loss of future royalty payments, if any, from Shionogi and the legal costs associated with retiring the PhaRMA Notes. As a result, we do not currently expect the continuing events of default on the PhaRMA Notes to have a significant impact on our future results of operations or cash flows. However, we cannot assure you that this will be the case or that we will not otherwise be adversely affected as a result of the continuing events of default under the PhaRMA Notes or the failure by Royalty Sub to repay the PhaRMA Notes at maturity. While Royalty Sub continues to pay the holders of the PhaRMA Notes any royalty payments received from Shionogi, which are immaterial, we wrote off the balance due under the PhaRMA Notes to other income as a debt extinguishment as of December 31, 2021.

We have incurred significant indebtedness, which could adversely affect our business. Additionally, the Blackstone Loan Agreement (as defined below) contains conditions and restrictions that limit our flexibility in operating our business. We may be required to make a prepayment or repay our outstanding indebtedness earlier than we expect if a prepayment event or an event of default occurs, including a material adverse change with respect to us, which could have a material adverse effect on our business.

On January 23, 2026, we entered into a Loan Agreement (the "Blackstone Loan Agreement") with Blackstone Alternative Credit Advisors LP and Blackstone Life Science Advisors L.L.C., (together, "Blackstone"), as the Blackstone representatives thereunder, the guarantors from time to time party thereto, the lenders from time to time party thereto, and Wilmington Trust, National Association, as agent, pursuant to which the lenders funded initial term loans in the aggregate principal amount of $400.0 million. Subject to the mutual agreement between the Company, Blackstone and the lenders, we may request additional term loans up to an aggregate amount not exceeding $150.0 million. Under the Blackstone Loan Agreement, we will be required to pay to the lenders a prepayment premium or a make-whole premium, as applicable in the event that, prior to the fourth anniversary of the closing date of the Blackstone Loan Agreement, we prepay or repay, or are required to prepay or repay, voluntarily or pursuant to a mandatory prepayment obligation under the Blackstone Loan

Agreement (e.g., upon certain asset sales, a change of control of the Company and specified other events, subject to certain exceptions), all or part of the then-outstanding term loans under the Blackstone Loan Agreement, in each case, subject to certain exceptions as set forth in the Blackstone Loan Agreement.

Our indebtedness could have important consequences to our stockholders. For example, it:

- increases our vulnerability to adverse general economic or industry conditions;
- limits our flexibility in planning for, or reacting to, changes in our business or the industry in which we operate;
- makes us more vulnerable to increases in interest rates, as borrowings under the Blackstone Loan Agreement will accrue interest at variable rates, such that increases in interest rates will increase the associated interest payments that we are required to make on outstanding borrowings;
- requires us to dedicate a portion of our cash flow from operations to interest payments, limiting the availability of cash for other purposes;
- limits our ability to obtain additional financing or refinancing in the future for working capital or other purposes; and
- places us at a competitive disadvantage compared to our competitors that have less indebtedness.

Furthermore, the Blackstone Loan Agreement contains covenants that limit our ability to engage in specified types of transactions. Subject to certain exceptions, these covenants limit our ability to, among other things, dispose of assets; engage in certain mergers, acquisitions, and similar transactions; incur additional indebtedness; grant liens; make investments; pay dividends or make distributions or certain other restricted payments in respect of equity; prepay other indebtedness; enter into restrictive agreements; undertake fundamental changes; or amend certain material contracts.

The covenants contained in the Blackstone Loan Agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial without the lenders' permission or without repaying all outstanding obligations under the Blackstone Loan Agreement.

A breach of any of these covenants could result in an event of default under the Blackstone Loan Agreement. An event of default will also occur if, among other things, we fail to pay amounts due under the Blackstone Loan Agreement, we fail to repay certain other indebtedness having an aggregate principal amount in excess of a threshold amount, an insolvency event occurs with respect to us, judgments for the payment of money in excess of a threshold amount are entered into against us, or a material impairment of our ability to perform our obligations under the Blackstone Loan Agreement occurs or certain negative regulatory events occur. In the case of a continuing event of default under the Blackstone Loan Agreement, the lenders under the Blackstone Loan Agreement could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted to the lenders a security interest, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the Blackstone Loan Agreement are secured by a security interest in, subject to certain exceptions, substantially all of our assets. Because substantially all of our assets are pledged to secure the Blackstone Loan Agreement obligations, our ability to incur additional secured indebtedness or to sell or dispose of assets to raise capital may be impaired, which could have an adverse effect on our financial flexibility.

Risks Relating to International Operations

International expansion of our business exposes us to business, legal, regulatory, political, operational, financial, and economic risks.

We currently conduct clinical studies and regulatory activities and have hired employees outside of the United States. Doing business internationally involves a number of risks, including, but not limited to:

- multiple, conflicting, and changing laws and regulations such as privacy and data regulations, transparency regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits, and licenses;
- introduction of new health authority requirements and/or changes in health authority expectations;
- failure by us or our partners to obtain and maintain regulatory approvals for the use of our products in various countries;
- complexities and difficulties in obtaining and maintaining protection for, and enforcing, our intellectual property;

- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- limits on our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products, and exposure to foreign currency exchange rate fluctuations, which have been increasingly prevalent alongside a fluctuating U.S. dollar;
- natural disasters and political and economic instability, including wars, terrorism, political unrest, results of certain elections and votes, actual or threatened public health emergencies and outbreak of disease, epidemics or pandemics (e.g., the COVID-19 pandemic), boycotts, adoption or expansion of government trade restrictions, and other business restrictions;
- certain expenses including, among others, expenses for travel, translation, and insurance;
- regulatory and compliance risks that relate to maintaining accurate information and control over commercial operations and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, including its books and records provisions or anti-bribery provisions, and foreign laws and regulations; and
- regulatory and compliance risks relating to doing business with any entity that is subject to sanctions administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury.

Any of these factors could significantly harm our international expansion of operations and adversely affect our business and results of operations.

Additionally, in some countries, such as Japan, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our partners may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

Foreign currency exchange rate fluctuations could have an adverse impact on our results of operations, financial position, and cash flows.

We conduct operations in countries outside of the United States involving transactions in a variety of currencies other than the U.S. dollar. These transactions include, without limitation, commercial sales, contract manufacturing, and clinical trial activities. Although most of our revenues and expenses are denominated in U.S. dollars, we have foreign currency exposure to fluctuations in other foreign currencies, such as the Euro, British Pound, Japanese Yen and Canadian Dollar. Changes in the value of these currencies relative to the U.S. dollar may impact our consolidated operating results, including our revenues and expenses, causing fluctuations in our operating results from period to period and/or resulting in foreign currency transaction losses that adversely impact our results of operations, financial position, and cash flows. See "*Quantitative and Qualitative Disclosures about Market Risk—Foreign Currency Risk*" in Part II, Item 7A of this report for additional information about our foreign currency risk.

Our actual or perceived failure to comply with European or other international governmental laws and regulations and other legal obligations related to privacy, data protection and information security could harm our business.

Outside the United States, an increasing number of laws and regulations may govern data privacy and security. EU member states, the United Kingdom, Switzerland and other countries have adopted data protection laws and regulations, which impose significant compliance obligations. These laws include the GDPR and similar national legislation within the EEA, the United Kingdom GDPR, Switzerland's Federal Data Protection Act, the EU Clinical Trials Regulation, and the e-Privacy Directive (2002/58/EC), as well as laws and regulations outside Europe, and are discussed in more detail in "*Business—Government Regulation—Data Privacy and Security Laws*" in Part I, Item 1 of this report. Failure to comply with the requirements of these laws may result in significant fines. For example, noncompliance with the GDPR or related national data protection laws, which may deviate from the GDPR, may result in significant fines of up to 4.0% of global revenues, or €20.0 million, whichever is greater.

In addition to such fines, failure to comply with the requirements of the GDPR or similar national legislation may result in temporary or definitive bans on data processing and other corrective actions and subject us to litigation and/or adverse publicity, which could have material adverse effects on our reputation and business. As a result of the implementation of the GDPR, and other laws and regulations, we are required to put in place additional mechanisms to

ensure compliance with the data protection rules. For example, the GDPR requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for processing, requires the appointment of a data protection officer where sensitive personal data (i.e., health data) is processed on a large scale, introduces mandatory data breach notification throughout the European Union, imposes additional obligations on us when we are contracting with service providers and requires us to adopt appropriate privacy governance including policies, procedures, training and data audits. We depend on a number of third parties in relation to the provision of our services, a number of which process personal data of EU individuals on our behalf. With each such provider, we are required to enter into contractual arrangements under which they are contractually obligated to only process personal data according to our instructions, and conduct diligence to ensure that they have sufficient technical and organizational security measures in place. Other laws and regulations have requirements that are similar, and in some instances more far-reaching.

Compliance with evolving laws regarding the transfer of personal data to the United States and other countries also requires increased resources and may result in increased exposure to regulatory actions, 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. We are also subject to evolving European and other privacy laws on electronic marketing and cookies.

Compliance with the requirements imposed by the GDPR and other such laws can be time-consuming, expensive and difficult, and may increase our cost of doing business or require us to change our business practices, and despite our efforts we may not be successful in achieving compliance if our personnel, collaborators, partners or vendors do not comply with applicable data protection obligations. Despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely 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: 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.

Risks Relating to Technology

If our facilities, or the facilities of our third-party vendors, incur damage or power is lost for a significant length of time, our business will suffer.

We and our third-party vendors store commercial product, clinical and stability samples, and manufacturing data at our facilities that could be damaged if the facilities incur physical damage or in the event of an extended power failure. We have backup power systems in addition to backup generators to maintain power to all critical functions, but any loss of these products or samples could result in significant delays in our commercialization or drug development process.

In addition, we store most of our preclinical and clinical data at our facilities. While duplicate copies of most clinical data are secured off-site, and a significant portion of our data is included in regular backups of our systems, we could lose important data if our facilities incur damage, or if our vendor data systems fail, suffer damage or are destroyed. Any significant degradation or failure of our computer systems could cause us to inaccurately calculate or lose our data. Loss of data could result in significant delays in our drug development process, and any system failure could harm our business and operations.

Cyber incidents and related disruptions in our or our third-party vendors' information technology systems could adversely affect our business.

We are increasingly dependent on information technology systems to operate our business. In addition, the FDA and other U.S. and foreign regulatory authorities regulate, among other things, the record keeping and storage of data pertaining to potential pharmaceutical products. Like other companies in our industry, our information technology systems and infrastructure (as well as those of our third-party providers) and our lab equipment and operations technology may be vulnerable to cyber incidents, intrusions, and other similar activities that threaten the confidentiality, integrity, and availability of our information. These threats come from a variety of sources, including by computer hackers, foreign governments, foreign companies, or competitors, or may be breached by employee error, malfeasance or other disruption. These threats are prevalent, continue to rise, and are becoming increasingly difficult to detect. Recently, there have been reports of disruptions in billing and data systems in healthcare. Such cybersecurity events which materially disrupt the

healthcare system upon which our business relies could adversely affect our business if such disruption is widespread and continues for an extended period of time.

Cyber incidents could also include the use of artificial intelligence ("AI") and machine learning to launch more automated, targeted and coordinated attacks on targets. Cyber incidents may lead to operational outages, loss of intellectual property due to industrial espionage, malware, and financial or data attacks via social engineering. These risks have increased as we have experienced significant growth in the number of our employees and the scope of our operations and as virtual and remote working have become more widely used, and sensitive data is accessed by employees working in less secure, home-based environments. A breakdown, invasion, corruption, destruction, or interruption of information technology systems could negatively impact operations. If our systems are damaged, fail to function properly or otherwise become unavailable, we may incur substantial costs to repair or replace them, and we may experience loss of critical data and interruptions or delays in our ability to perform critical functions, which could adversely affect our business, financial condition or results of operations.

In addition, we rely on third-party service providers and technologies to operate significant information technology systems and business infrastructure, and we currently use these providers to perform business critical information technology and business services. 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 or will not be compromised.

We have experienced cybersecurity threats and incidents, which to date have not had a material impact on our reputation, business, financial condition, or operations; however; there is no assurance that such impacts will not be material in the future.

Any compromise of our data security could also result in a violation of applicable privacy and other laws, significant legal, regulatory, and financial exposure, damage to our reputation, loss or misuse of the information and a loss of confidence in our data security measures, which could harm our business. Loss or misuse of our intellectual property, clinical trial data, or commercially sensitive data could adversely impact our business. While we have implemented security measures designed to protect against security incidents and a significant portion of our data is included in regular backups of our systems, there can be no assurance that our efforts to protect our data and information technology systems will prevent breakdowns or breaches in our systems, or those of third parties with which we do business, and any such events could adversely affect our business.

From time to time, we use artificial intelligence in our business, and challenges with properly managing its use could adversely affect our business.

The increasing use of AI and machine learning technology in the biopharmaceutical industry, combined with an uncertain regulatory environment, presents new risks and challenges. From time to time, we adopt and integrate AI solutions into our systems for specific use cases reviewed by legal and information security, and applications of AI may become more important in our operations over time. Our vendors may incorporate AI tools into their offerings without disclosing this use to us, and the providers of these tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection. Moreover, the use of AI-based tools may lead to the inadvertent release of confidential or proprietary information, which may adversely impact our ability to realize the benefit of our intellectual property, cause us to incur liabilities as the result of any breaches of confidentiality, impact our ability to comply with data security and privacy laws, and introduce additional cybersecurity risks. Further, as the regulatory framework for these technologies evolves, it is possible that new laws and regulations will be adopted, or that existing laws and regulations may be interpreted in ways that would affect our business, including as a result of the cost to comply with such laws or regulations. Our competitors or other third parties may also incorporate AI into their businesses more efficiently than us, which could impair our ability to compete effectively and adversely affect our results of operations. The rapid innovation and developments surrounding AI, including potential government regulation of AI, may require significant resources to develop, test and maintain our implementations of AI.

Other Operational Risks

Our ability to maintain global brand uniformity for ORLADEYO may be impacted by the sale of our European ORLADEYO business.

In connection with the sale of our European ORLADEYO business, we entered into the Global Brand and Support Agreement, which provides for coordination of brand and regulatory activities regarding ORLADEYO products. While this agreement is intended to promote alignment on brand and related activities with Neopharmed, we do not have sole control over how ORLADEYO is positioned, supported or communicated in Europe, and we may not be able to maintain global brand uniformity with respect to ORLADEYO. This risk may be heightened given that ORLADEYO is indicated for a rare disease with a limited number of key opinion leaders and relatively few scientific publications or forums that reach a broad global audience. If we are unable to maintain a consistent and effective global brand presence for ORLADEYO, our ability to maximize the anticipated benefits of the sale, support future growth and realize the expected long-term value of ORLADEYO could be adversely affected.

Health epidemics or pandemics could materially adversely affect our business, operations, clinical development or commercialization plans and timelines, or that of third parties with whom we conduct business, including, without limitation, our development partners, manufacturers, CROs, and others, as well as the regulatory and government agencies with whom we work.

A health epidemic or pandemic, such as the COVID-19 pandemic, and related government orders or responsive business policies and procedures, could cause disruptions to our business, operations, and clinical development or commercialization plans and timelines, as well as the business and operations of third parties with whom we conduct business.

If our operations or those of third parties with whom we conduct business, such as development partners, manufacturers, CROs and others, are impaired or curtailed as a result of such events, the development and commercialization of our products and product candidates could be stopped or delayed, or the costs of such development and commercialization activities could increase, any of which could have a material adverse impact on our business. For example, our suppliers or other vendors may be unable to meet their obligations to us or perform their services as expected. In such circumstances, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Such delays could adversely impact our ability to meet our desired clinical development and any commercialization timelines.

In addition, our clinical trials were affected by the COVID-19 pandemic, and we may experience similar delays or interruptions due to health epidemics or pandemics in the future, which could adversely impact our clinical trial operations. Health epidemics or pandemics could also affect the operations of regulators and other health and governmental authorities, which could result in delays of reviews and approvals, inspections, or other regulatory activities.

The global impact of a health epidemic or pandemic, such as the COVID-19 pandemic, could also materially affect global economies and financial markets, which could reduce our ability to access the equity or debt capital markets or obtain other sources of capital if needed, which could negatively affect our liquidity. In addition, a recession or market correction could materially affect our business and the value of our common stock. Health epidemics or pandemics could also have the effect of heightening many of the other risks described in this report.

Our business, operations, clinical development or commercialization plans and timelines, and access to capital could be adversely affected by unpredictable and unstable market and economic conditions.

Our business, operations, clinical development or commercialization plans and timelines, and access to capital could be adversely affected by unpredictable and unstable market and economic conditions, including as a result of inflation, increased interest rates, disruption or instability in the banking industry, foreign exchange rate fluctuations, U.S. Government shutdowns, instability in connection with changes in the presidential administration in the United States, geopolitical instability, actual or threatened public health emergencies, or outbreaks of disease, epidemics or pandemics (such as the COVID-19 pandemic). The magnitude, duration and long-term effect of each of these factors, as well as the effects of actions taken by governments to address them, are unknown at this time, but they could result in further significant disruption of the global economy and financial markets. Our business may be adversely affected by any related economic downturn, volatile geopolitical and business environment, or continued market instability.

Unstable market and economic conditions could materially affect our ability to access the equity or debt capital markets or obtain other sources of capital if needed in the future, which could negatively affect our liquidity. In addition, a recession or market correction could materially affect our business and the value of our common stock.

Market and economic conditions continue to evolve, with the ultimate impacts being uncertain and subject to change. These effects could be material, and we will continue to monitor the economic climate closely. We do not know the full extent and magnitude of the impacts that any future developments will have on our business, on the healthcare system, or on the global economy. In addition, unstable market conditions could have the effect of heightening many of the other risks described in this report.

Insurance coverage is increasingly more costly and difficult to obtain or maintain.

While we currently have insurance for our business, property, directors and officers, and our products, insurance is increasingly more costly and narrower in scope, and we may be required to assume more risk in the future. If we are subject to claims or suffer a loss or damage in excess of our insurance coverage, we will be required to bear any loss in excess of our insurance limits. If we are subject to claims or suffer a loss or damage that is outside of our insurance coverage, we may incur significant uninsured costs associated with loss or damage that could have an adverse effect on our operations and financial position. Furthermore, any claims made on our insurance policies may impact our ability to obtain or maintain insurance coverage at reasonable costs or at all.

If we fail to retain our existing key personnel or fail to attract and retain additional key personnel, the development of our product candidates, the commercialization of our products, and the related growth of our business may be delayed or stopped.

The unexpected loss of service of our senior management and scientific team might impede the achievement of our development and commercial objectives. Competition for key personnel with the experience that we require is intense and is expected to continue to increase. Our inability to attract and retain the required number of skilled and experienced management, commercial, operational and scientific personnel may harm our business because we rely upon these personnel for many important functions of our business.

If our risk management committee and other compliance methods are not effective, our business, financial condition and operating results may be adversely affected.

Our ability to identify, manage and respond to the various risks related to our business is largely dependent on our established and maintained compliance, risk, audit and reporting systems and procedures. The Board of Directors has ultimate responsibility for risk oversight of the Company and carries out this duty through its committees. The Board of Directors may delegate oversight authority with respect to certain issues in a committee's applicable areas of expertise. At the Company level, our senior management team similarly monitors risk through the risk management committee and other sub-committees focused on specific areas of risk (e.g., cybersecurity, quality assurance). Membership of the risk management committee consists primarily of key department heads who are asked to bring to such committee relevant items for discussion that they or their teams have identified at the numerous sub-committees these individuals chair or attend. The risk management committee, along with the other sub-committees in the Company, identifies key risks and mitigation strategies which are reported directly to our senior management, the Audit Committee and to the full Board of Directors on a regular basis.

If our policies, procedures, and compliance systems, including our risk management committee, are not effective, or if we are not successful in monitoring or evaluating the risks to which we are or may be exposed, our business, reputation, financial condition and operating results could be materially adversely affected. We cannot provide assurance that our policies and procedures will always be effective, or that our management or the risk management committee would be able to identify any such ineffectiveness. If our compliance and risk management strategies are not effective, our business, financial condition and operating results may be adversely affected.

Future acquisitions, strategic investments, partnerships, alliances, or divestitures could be difficult to identify and integrate, divert the attention of management, disrupt our business, dilute stockholder value, materially change the risk profile of the Company and could fail to meet our expectations, any of which could adversely affect our operating results and financial condition.

We anticipate that we will seek to acquire or invest in businesses, products or technologies that we believe could complement or expand our portfolio or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various expenses in identifying, investigating and pursuing businesses or products. In addition, we may not be able to find and identify desirable acquisition targets or be successful in entering into an agreement with any particular target or consummating any such agreement. Even if we do consummate an

acquisition, in connection therewith we may be required to issue equity (thereby diluting our current stockholders) or debt, we may not be able to integrate successfully the acquired personnel, operations and technologies, or effectively manage the combined business following the acquisition, or the acquired business could otherwise fail to meet our expectations, which, in each case, could have a material adverse effect on our business projections, financial condition, results of operations and prospects.

In addition, we may divest or license all or a portion of certain business or product categories, which could cause a decline in revenue or profitability and may make our financial results more volatile. We may be unable to complete any such divestiture or license on terms favorable to us, within the expected timeframes, or at all. For example, we have announced plans to seek a strategic partner for the development of avoralstat beyond Phase 1 and to pursue strategic alternatives for STAR-0310; however, there can be no assurance that we will be able to successfully identify a suitable counterparty, negotiate acceptable terms, or complete any such transaction on a timely basis or at all. Our ability to consummate a transaction may also be adversely affected by events impacting third parties involved in or associated with these programs. For instance, Clearside's recent filing for Chapter 11 bankruptcy may limit our ability to find a strategic partner for avoralstat, complicate negotiations with potential partners, or reduce the likelihood or value of any strategic transaction. We may have continued financial exposure to divested or licensed businesses following the completion of any such transactions, including increased costs due to potential litigation, contingent liabilities and indemnification of the buyer or licensee related to, among other things, lawsuits, regulatory matters or tax liabilities. Such divestitures or licenses may also divert management's attention from our core businesses and lead to potential issues with employees, customers or suppliers.

Our business and operations could be negatively affected if we become subject to stockholder activism or hostile bids, which could cause us to incur significant expense, hinder execution of our business strategy and impact our stock price.

Stockholder activism, which takes many forms and arises in a variety of situations, has been increasingly prevalent. Stock price declines may also increase our vulnerability to unsolicited approaches. If we become the subject of certain forms of stockholder activism, such as proxy contests or hostile bids, the attention of our management and our Board of Directors may be diverted from execution of our strategy. Such stockholder activism could give rise to perceived uncertainties as to our future strategy, adversely affect our relationships with business partners and make it more difficult to attract and retain qualified personnel. Also, we may incur substantial costs, including significant legal fees and other expenses, related to activist stockholder matters. Our stock price could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any stockholder activism.

Risks Relating to Investing in Our Common Stock

Our existing principal stockholders hold a substantial amount of our common stock and may be able to influence significant corporate decisions, which may conflict with the interest of other stockholders.

Some of our stockholders own greater than 5% of our outstanding common stock. Our top ten stockholders own approximately 47% of our common stock and can individually, and as a group, influence our operations based upon their concentrated ownership and may also be able to influence the outcome of matters requiring approval of the stockholders, including the election of our directors and other corporate actions.

Our stock price has been, and is likely to continue to be, highly volatile, which could cause the value of an investment in our common stock to decline significantly.

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. Moreover, our stock price has fluctuated frequently, and these fluctuations are often not related to our financial results. For the twelve months ended December 31, 2025, the 52-week range of the market price of our stock was from $6.00 to $11.31 per share. The following factors, in addition to other risk factors described in this section, may have, and in some cases have had, a significant impact on the market price of our common stock:

- announcements of technological innovations or new products by us or our competitors;
- developments or disputes concerning patents or proprietary rights;
- additional dilution through sales or issuances of our common stock or other derivative securities;
- status of new or existing licensing or collaborative agreements and government contracts;
- announcements relating to the status of our programs;
- us or our partners achieving or failing to achieve development milestones;

- publicity regarding actual or potential medical results relating to products under development by us or our competitors;
- publicity regarding certain public health concerns for which we are or may be developing treatments;
- regulatory developments in both the United States and foreign countries;
- public concern as to the safety of pharmaceutical products;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts and the comparison of such estimates to our actual results;
- online automated financial platforms' treatment or classification of our financial information;
- changes in our public guidance;
- changes in the structure of healthcare payment systems, including developments in price control legislation;
- announcements by us or our competitors of significant acquisitions (such as the Merger), strategic partnerships, divestitures (such as the transaction with Neopharmed), joint ventures, capital commitments or other monetization transactions;
- additions or departures of key personnel or members of our Board of Directors;
- purchases or sales of substantial amounts of our stock by existing stockholders, including officers or directors;
- economic and other external factors or other disasters or crises; and
- period-to-period fluctuations in our financial results.

This volatility could cause the value of an investment in our common stock to decline significantly. In addition, companies that have experienced volatility in the market price of their stock in the past have been subject to securities class action litigation. Securities litigation, and any other type of litigation, brought against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business and adversely affect our results of operations.

If we fail to maintain effective internal control over financial reporting, we may not be able to produce accurate and timely financial statements, which may adversely affect investor confidence in us and our financial reporting, adversely affect our business and operating results and negatively impact the trading price of our common stock.

As a public company, we are required to maintain effective internal control over financial reporting (as described in "*Controls and Procedures*" in Part II, Item 9A of this report), and effective disclosure controls and procedures. If we identify one or more material weaknesses in our internal control over financial reporting, we will not be able to assert that our internal controls and procedures are effective. A material weakness, as defined in Rule 12b-2 under the Exchange Act, is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. In 2023, we identified and timely reported two material weaknesses in our internal control over financial reporting, which management determined to be subsequently remediated as of December 31, 2023 and September 30, 2024, respectively.

Although we believe the financial statements included in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented in conformity with U.S. GAAP, any failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If our internal control over financial reporting is not effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Future sales and issuances of securities may dilute the ownership interests of our current stockholders and cause our stock price to decline.

Future sales of our common stock by us or our current stockholders into the public market could cause the market price of our stock to fall. As of December 31, 2025, there were 213,059,576 shares of our common stock outstanding. We may from time to time issue securities in relation to a license arrangement, collaboration, merger or acquisition. See, for example, *"Risk Factors — Risks Relating to Our Business — Risks Relating to the Merger — Issuance of shares of our common stock in connection with the Merger may adversely affect the market price of our common stock."* We may also sell, for our own account, shares of common stock or other equity securities, from time to time at prices and on terms to be determined at the time of sale.

As of December 31, 2025, there were 49,805,077 stock options and restricted stock units outstanding and 6,852,136 shares available for issuance under our Amended and Restated Stock Incentive Plan, 5,705,339 stock options and restricted stock units outstanding and 1,459,895 shares available for issuance under our Amended and Restated Inducement Equity Incentive Plan, and 4,674,237 shares available for issuance under our Amended and Restated Employee Stock Purchase Plan. In addition, we could also make equity grants outside of our Amended and Restated Stock Incentive Plan or Amended and Restated Inducement Equity Incentive Plan. The shares underlying existing stock options, restricted stock units and possible future stock options, stock appreciation rights, restricted stock units and stock awards have been, or will be, registered pursuant to registration statements on Form S-8.

If some or all of such shares are sold or otherwise issued into the public market over a short period of time, our current stockholders' ownership interests may be diluted and the value of all publicly traded shares is likely to decline, as the market may not be able to absorb those shares at then-current market prices. Additionally, such sales and issuances may make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable, or at all.

We have anti-takeover provisions in our corporate charter documents that may result in outcomes with which you do not agree.

Our Board of Directors has the authority to issue up to 5,000,000 shares of undesignated preferred stock and to determine the rights, preferences, privileges and restrictions of those shares without further vote or action by our stockholders. The rights of the holders of any preferred stock that may be issued in the future may adversely affect the rights of the holders of common stock. The issuance of preferred stock could make it more difficult for third parties to acquire a majority of our outstanding voting stock.

In addition, our Certificate of Incorporation provides for staggered terms for the members of the Board of Directors and supermajority approval of the removal of any member of the Board of Directors and prevents our stockholders from acting by written consent. Our Certificate of Incorporation also requires supermajority approval of any amendment of these provisions. These provisions and other provisions of our Amended and Restated By-Laws and of Delaware law applicable to us could delay or make more difficult a merger, tender offer or proxy contest involving us.

We have never paid dividends on our common stock and do not anticipate doing so in the foreseeable future.

We have never paid cash dividends on our stock. We currently intend to retain all future earnings, if any, for use in the operation of our business. Accordingly, we do not anticipate paying cash dividends on our common stock in the foreseeable future.

Our Amended and Restated By-Laws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain litigation that may be initiated by our stockholders, which may limit a stockholder's ability to obtain a favorable judicial forum for such disputes with us or our directors, officers or employees.

Our Amended and Restated By-Laws provide that, unless we consent in writing to the selection of an alternative forum, 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, stockholders, employees or agents to us or our stockholders, (iii) any action asserting a claim against us or any of our directors, officers, stockholders, employees or agents arising out of or relating to any provision of the General Corporation Law of Delaware or our Certificate of Incorporation or Amended and Restated By-Laws, or (iv) any action against us or any of our directors, officers, stockholders, employees or agents governed by the internal affairs doctrine of the State of Delaware. This exclusive forum provision does not apply to establish the Delaware Court of Chancery as the forum for actions or proceedings brought to enforce a duty or liability created by the Securities Act of 1933, as amended, or the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction.

This exclusive forum provision may limit a stockholder's ability to choose its preferred judicial forum for disputes with us or our directors, officers, employees or agents, which may discourage the filing of lawsuits with respect to such claims. If a court were to find this exclusive forum provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in another jurisdiction, which could adversely affect our business and financial condition.

General Risk Factors

Natural disasters, epidemic or pandemic disease outbreaks, trade wars, armed conflicts, political unrest or other events could disrupt our business or operations or those of our development partners, manufacturers, regulators or other third parties with whom we conduct business now or in the future.

A wide variety of events beyond our control, such as natural disasters (including as a result of climate change), epidemic or pandemic disease outbreaks (such as the COVID-19 pandemic), trade wars, armed conflict, political unrest, government shutdowns, instability in connection with changes in the presidential administration in the United States, or other events could disrupt our business or operations or those of our development partners, manufacturers, regulatory authorities, or other third parties with whom we conduct business. These events may cause businesses and government agencies to be shut down, supply chains or trade to be interrupted, slowed, or rendered inoperable, and individuals to become ill, quarantined, or otherwise unable to work and/or travel due to health reasons or governmental restrictions. If our operations or those of third parties with whom we conduct business are impaired or curtailed as a result of these events, the development and commercialization of our products and product candidates could be impaired or halted, which could have a material adverse impact on our business. See, for example, "*Risk Factors—Risks Relating to Our Business—Other Operational Risks—Our business, operations, clinical development or commercialization plans and timelines, and access to capital could be adversely affected by unpredictable and unstable market and economic conditions*." In addition, other events, such as the Ukraine-Russia and Middle East conflicts, or rising tensions between China and Taiwan, could adversely impact our business. For example, the conflicts could lead to sanctions, embargoes, supply shortages, regional instability, geopolitical shifts, cyber-attacks, other retaliatory actions, and adverse effects on macroeconomic conditions, currency exchange rates, and financial markets, which could adversely impact our operations and financial results, as well as those of third parties with whom we conduct business.

We are subject to legal proceedings, which could harm our reputation or result in other losses or unexpected expenditure of time and resources.

From time to time, we may be involved in disputes, including, without limitation, disputes with our employees, collaborative partners, and third-party vendors. We may be called upon to initiate legal proceedings or to defend ourselves in such legal proceedings relating to our relationships with these parties, our decisions and actions or omissions with respect thereto, and our business. In addition, if our stock price is volatile, we may become involved in securities class action lawsuits in the future. Due to the inherent uncertainties in legal proceedings, we cannot accurately predict the ultimate outcome of any such proceeding. An unfavorable outcome in any such proceeding could have an adverse impact on our business, financial condition and results of operations. Any current or future dispute resolution or legal proceeding, regardless of the merits of any such proceeding, could harm our reputation and result in substantial costs and a diversion of management's attention and resources that are needed to successfully run our business.

ITEM 1B. *UNRESOLVED STAFF COMMENTS*

None.

ITEM 1C. *CYBERSECURITY*

We maintain a cybersecurity program that is reasonably designed to assess, identify, and manage risks from cybersecurity threats that may result in material adverse effects on the confidentiality, integrity, and availability of our information systems.

Governance

Board of Directors

Our Board of Directors, directly and through its committees, oversees the Company's risk management function. The Board of Directors has delegated the primary responsibility to oversee cybersecurity matters to the Audit Committee. The Audit Committee reviews the measures implemented by the Company to identify and mitigate data protection and cybersecurity risks. As part of such reviews, the Audit Committee regularly receives reports and presentations from members of our Cybersecurity Steering Committee as appropriate, with a minimum frequency of once per year. These reports and presentations address a wide range of topics including recent developments, status of ongoing and planned cybersecurity initiatives and strategies, evolving standards, vulnerability assessments, third-party and independent reviews,

the threat environment, security spend, technological trends and information security considerations arising with respect to the Company's peers and third parties. The Audit Committee reports to the Board of Directors on data protection and cybersecurity matters. We have protocols by which certain cybersecurity incidents are escalated within the Company and, where appropriate, reported to the Audit Committee, as well as ongoing updates regarding any such incident until it has been addressed.

Management

At the management level, the Chief Financial Officer, Chief Legal Officer and the Chief Data Innovation Officer attend meetings of the Company's Cybersecurity Steering Committee (discussed further below) to receive reports on ongoing cybersecurity matters. This ensures that management is involved in an ongoing dialogue regarding the Company's material risks from cybersecurity threats. In addition, members of the Cybersecurity Steering Committee provide updates on the Company's cybersecurity control and risk posture and the status of ongoing and planned cybersecurity initiatives and strategies to the Company's senior management team on an annual basis.

Cybersecurity Steering Committee

The Company has implemented a broad spectrum cross-functional approach to assessing, identifying, and managing risks from cybersecurity threats. Our Cybersecurity Steering Committee has broad oversight of the Company's cybersecurity risk management processes. The Cybersecurity Steering Committee is composed of the Company's Chief Financial Officer, Chief Legal Officer, Chief Data Innovation Officer, Senior Vice President, Information Technology, senior cybersecurity professionals, members of the finance and legal departments, and other individuals invited as appropriate on an ad hoc basis. On at least a quarterly basis, the Cybersecurity Steering Committee meets to discuss recent cybersecurity events or threats, status of ongoing and planned cybersecurity initiatives and strategies, external cybersecurity trends, and risk management measures implemented by the Company to identify and mitigate data protection and cybersecurity risks, among other topics. In addition to the scheduled meetings, the Cybersecurity Steering Committee is informed of potentially material cybersecurity events as they arise.

Within the Cybersecurity Steering Committee, our Executive Director, IT Risk Management and Strategy and our Senior Manager, Security Engineering are primarily responsible for assessing, monitoring, and managing our cybersecurity risks. Our Executive Director, IT Risk Management and Strategy has over a decade of relevant cybersecurity experience and reports to the Senior Vice President, Information Technology, who is managed by the Chief Data Innovation Officer. He served as a Senior Manager cybersecurity consultant for one of the Big Four accounting firms for several years and as the Information Security Officer of a financial services company. He holds an M.S. degree in cybersecurity, is a graduate instructional assistant in information security, and a Certified Information Systems Security Professional ("CISSP"). He leads the Company's information security program and sets the strategic direction for, and establishes and governs the structure of, the program.

Our Senior Manager, Security Engineering is managed by the Company's Executive Director, IT Risk Management and Strategy. He is the former Cloud Security Officer for IBM and has over 40 years of experience in information security and data privacy and has CISSP and Cisco Certified Network Associate (CCNA) certifications. He implements and oversees processes for the regular monitoring of our information systems and detection of cybersecurity vulnerabilities.

The Cybersecurity Steering Committee also works closely with members of the legal department to oversee compliance with legal and regulatory security requirements. In addition, the Cybersecurity Steering Committee has implemented controls and procedures that provide for the prompt escalation of certain cybersecurity incidents so that decisions regarding the public disclosure and reporting of such incidents can be made by management in a timely manner.

Risk Management and Strategy

Cybersecurity Program

The Company's cybersecurity program leverages the National Institute of Standards and Technology (NIST) Cybersecurity Framework (CSF) for governance and program management and refers to the Center for Internet Security (CIS) guidelines when reviewing the Company's security controls posture. The Company uses certain advanced security measures, regular system audits, third party monitoring tools, and ongoing intelligence gathering on the latest developments in cybersecurity to identify, assess, and manage potential vulnerabilities and risks. In addition, the Company engages third parties to assist with assessing, identifying and managing material risks from cybersecurity threats. Once the

relevant material risks have been identified, the Company implements controls and processes to help manage these risks, including conducting tabletop exercises to simulate response to a cybersecurity incident, regular testing (e.g., penetration tests, vulnerability scanning) and control gap analyses and assessments designed to confirm appropriate security controls are in place and are maintaining functionality in accordance with the established policies.

We also employ systems and processes designed to oversee, identify, and reduce the potential impact of cybersecurity threats associated with any third-party vendor, service provider or customer or otherwise implicating the third-party technology and systems we use.

Our cybersecurity program is integrated into the Company's overall risk management framework to help identify, assess, educate, and manage the Company's cybersecurity risk. Our Board of Directors and the Audit Committee, in its role assisting the Board of Directors in its oversight of the Company's risk management function, consider cybersecurity threat risks alongside other Company risks as part of our overall risk assessment.

Incident Response

The Company has adopted a technology incident response plan (IRP) applicable to all Company employees and contractors, which sets forth the process for responding to and documenting data and information technology-related incidents such as security breaches, system failures, data loss, and service interruption. The IRP provides a standardized framework for investigating, containing, documenting and mitigating cybersecurity incidents, including reporting findings and keeping senior management and other key stakeholders informed and involved as appropriate. The Company's employees are required to review the IRP and undergo additional cybersecurity training on a regular basis.

Material Cybersecurity Risk, Threats & Incidents

As detailed elsewhere in this report, we rely on information technology systems and third-party providers to operate our business. Despite ongoing efforts to continually improve our and our third-party providers' ability to protect against cyber incidents, our networks and infrastructure may be vulnerable to cyberattacks or intrusions, which could result in a violation of applicable privacy and other laws, significant legal and financial exposure, damage to our reputation, loss or misuse of the information or a loss of confidence in our data security measures, among other consequences. While we have not experienced any material cybersecurity threats or incidents, there can be no guarantee that we will not be the subject of future successful attacks, threats, or incidents. See "*Risk Factors—Risks Relating to Our Business—Risks Relating to Technology—Cyber incidents and related disruptions in our or our third-party vendors' information technology systems could adversely affect our business*" in Part I, Item IA of this report for additional information on cybersecurity risks we face, which should be read together with the foregoing information.

ITEM 2. *PROPERTIES*

We lease property in Durham, North Carolina, Birmingham, Alabama, and Boston, Massachusetts, as well as certain immaterial locations outside of the United States. Our headquarters, including our clinical and regulatory operations are based in Durham, while our principal research facility is located in Birmingham. We currently lease approximately 23,100 square feet in Durham through leases expiring June 30, 2029 and May 31, 2033, and we lease approximately 49,000 square feet in Birmingham through July 31, 2030, with options for additional extensions. In addition, we lease approximately 30,110 square feet in Boston, Massachusetts in connection with our acquisition of Astria under a lease that is scheduled to end on November 30, 2028.

ITEM 3. *LEGAL PROCEEDINGS*

In January 2025, the Company received a Paragraph IV notice of certification (the "First Notice Letter") from Annora Pharma Private Limited ("Annora") regarding U.S. Patent Nos. 10,662,160; 11,117,867; and 11,618,733. In January 2026, the Company received an additional Paragraph IV notice of certification (the "Second Notice Letter" and, together with the First Notice Letter, the "Notice Letters") from Annora regarding U.S. Patent No. 12,344,585. The Notice Letters advise that Annora has submitted an ANDA to the FDA seeking approval to manufacture, use or sell a generic version of ORLADEYO in the United States prior to the expiration of four patents listed in the FDA's Orange Book: U.S. Patent Nos. 10,662,160; 11,117,867; 11,618,733; and 12,344,585 (the "Challenged Patents"). The Notice Letters allege that the Challenged Patents, which expire in 2039, are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the generic product described in Annora's ANDA. The Notice Letters do not challenge the

following six ORLADEYO Orange Book patents that expire in 2035: U.S. Patent Nos. 10,125,102; 10,329,260; 10,689,346; 11,230,530; 11,708,333; and 12,116,346.

On March 10, 2025 (as supplemented by the First Amended Complaint filed in December 2025), the Company filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Annora, Hetero Labs Limited, Hetero USA, Inc., and Camber Pharmaceuticals, Inc. (collectively, the "Defendants"), asserting infringement of the Challenged Patents arising from Annora's ANDA filing with the FDA. The Company is seeking, among other remedies, equitable relief enjoining the Defendants from infringing the Challenged Patents, as well as an order that the effective date of any FDA approval of the ANDA would be a date no earlier than the expiration of the Challenged Patents (including any regulatory extensions). While the Company intends to vigorously defend its intellectual property rights protecting ORLADEYO, this matter is in the early stages of litigation and no assessment can be made as to the likely outcome of this matter or whether it will be material to the Company. Accordingly, an estimate of the potential loss, or range of loss, if any, to the Company relating to this matter is not possible at this time.

ITEM 4. ***MINE SAFETY DISCLOSURES***

Not applicable.

PART II

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

Market Information

Our common stock trades on the Nasdaq Global Select Market under the symbol BCRX.

Holders

As of February 20, 2026, there were approximately 162 holders of record of our common stock.

Dividends

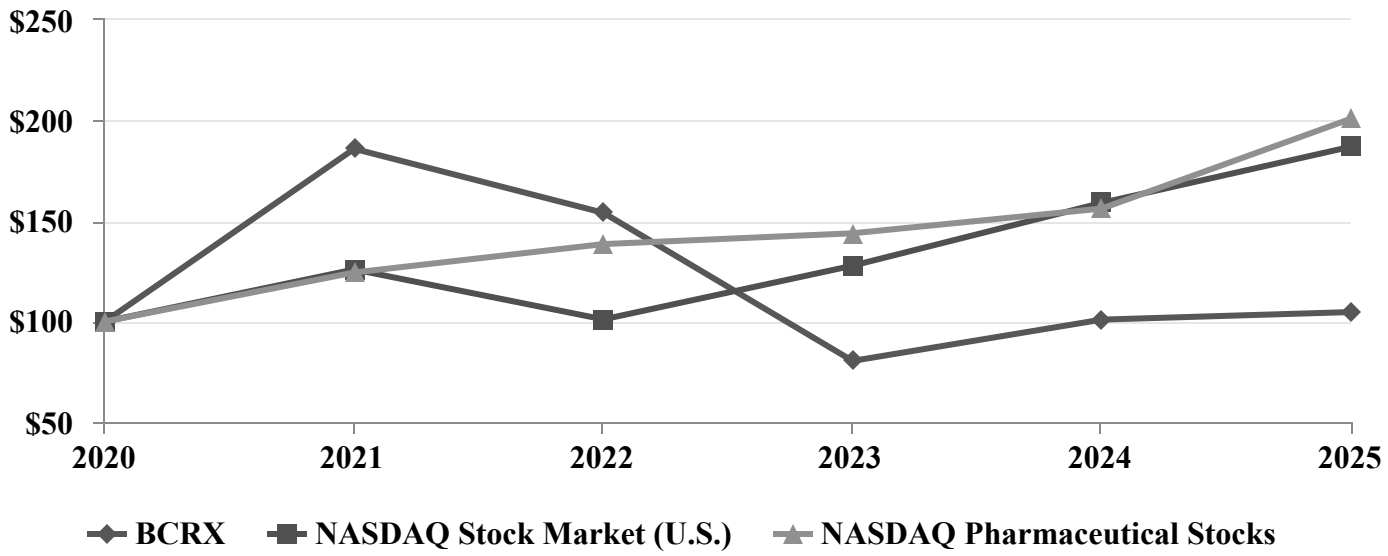
We have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future.

Stock Performance Graph

This performance graph is not "soliciting material," is not deemed filed with the SEC and is not to be incorporated by reference in any filing by us under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing. The stock price performance shown on the graph is not necessarily indicative of future price performance.

PERFORMANCE GRAPH FOR BIOCRYST

Indexed Comparison Since 2020



	Investment at 12/31/20	Investment at 12/31/21	Investment at 12/31/22	Investment at 12/31/23	Investment at 12/31/24	Investment at 12/31/25
BioCryst Pharmaceuticals, Inc.	$ 100.00	$ 185.91	$ 154.09	$ 80.40	$ 100.94	$ 104.70
Nasdaq Stock Market (United States)	100.00	125.89	101.05	127.76	159.03	186.96
Nasdaq Pharmaceutical Stocks	100.00	124.39	138.51	143.88	156.19	200.89

The above graph measures the change in a $100 investment in our common stock based on its closing price of $7.45 on December 31, 2020 and its year-end closing price thereafter. Our relative performance is then compared with the CRSP Total Return Indexes for the Nasdaq Stock Market (United States) and Nasdaq Pharmaceutical Stocks.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

There were no repurchases of our common stock during the fourth quarter of 2025.

ITEM 6. *RESERVED*

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

The following Management's Discussion and Analysis ("MD&A") is intended to help the reader understand our results of operations and financial condition. This MD&A is provided as a supplement to, and should be read in conjunction with, our audited financial statements and the accompanying notes to the financial statements and other disclosures included in this report (including the "Cautionary Note Regarding Forward-Looking Statements" at the beginning of this report and the "Risk Factors" section in Part I, Item 1A of this report).

Overview

We are a global biotechnology company focused on developing and commercializing medicines for hereditary angioedema ("HAE") and other rare diseases, driven by our deep commitment to improving the lives of people living with these conditions. We have built a robust commercial infrastructure to support the successful commercialization of ORLADEYO, an oral, once-daily therapy discovered and developed internally for the prevention of HAE attacks. Our business strategy includes leveraging this established commercial platform to successfully commercialize a pipeline of potential first-in-class or best-in-class oral small molecule and injectable protein therapeutics targeting a range of rare diseases. These programs are being pursued through both internal discovery efforts and strategic business development. By utilizing our existing commercial capabilities and focusing on rare disease markets, we believe that we can more effectively optimize our costs and strategically allocate resources to support long-term, sustainable growth.

Products and Product Candidates

ORLADEYO® (berotralstat)

ORLADEYO is an oral, once-daily therapy discovered and developed by us for the prevention of HAE attacks. A capsule formulation of ORLADEYO is approved in the United States and other global markets for the prevention of HAE attacks in adults and pediatric patients 12 years and older. In addition, in December 2025, the FDA approved an oral pellet formulation of once-daily ORLADEYO for prophylactic therapy in pediatric patients with HAE aged 2 to <12 years.

Based on proprietary analyses of HAE prevalence and market research studies with HAE patients, physicians, and payors in the United States and Europe, and five full years of commercialization experience with ORLADEYO, we anticipate that the global commercial market for ORLADEYO has the potential to reach a global peak of $1 billion in annual net ORLADEYO revenues. Based on our commercialization experience with ORLADEYO, we believe there is a seasonal impact to our business in the first quarter of each year due to typical first quarter requirements from payors for prescription reauthorization of specialty products, like ORLADEYO, that can temporarily move patients from paid drug to free product. These expectations are subject to numerous risks and uncertainties that may cause our actual results, performance, or achievements to be materially different. There can be no assurance that our commercialization methods and strategies will succeed, or that the market for ORLADEYO will develop in line with our current expectations. See "*Risk Factors—Risks Relating to Our Business—Risks Relating to Product Development and Commercialization—There can be no assurance that our or our partners' commercialization efforts, methods, and strategies for our products or technologies will succeed, and our future revenue generation is uncertain*" in Part I, Item 1A of this report for further discussion of these risks.

Revenue from sales of ORLADEYO in 2025, which was our fifth full year of ORLADEYO sales, is discussed under "*Results of Operations*" in this MD&A. Revenue from sales of ORLADEYO in future periods is subject to uncertainties and will depend on several factors, including, but not limited to the success of our and our partners' commercialization efforts in the United States and elsewhere, the number of new patients switching to ORLADEYO, patient retention and demand, the number of physicians prescribing ORLADEYO, the rate of monthly prescriptions, reimbursement from third-party and government payors, the number of patients receiving free product, our pricing strategy, and market trends. We monitor and analyze this data on an ongoing basis as we continue to commercialize ORLADEYO and adjust our forecasts accordingly.

Navenibart (STAR-0215)

On January 23, 2026 (the "Closing Date"), we completed the previously announced Merger (as defined below) with Astria (as defined below). Pursuant to the Merger, on the Closing Date, we acquired Astria's lead product candidate navenibart, an injectable monoclonal antibody designed to inhibit plasma kallikrein for the treatment of HAE. Navenibart is currently in Phase 3 clinical development, and the FDA has granted Fast Track and Orphan Drug designations to navenibart for the treatment of HAE. In addition, the European Commission has granted Orphan Medicinal Product Designation to navenibart for the treatment of HAE. The goal for navenibart is to develop a potentially best-in-class injectable prophylactic therapy with a differentiated every 3- and 6-month administration schedule, which could offer significant improvements over existing injectable options and address key unmet needs in the HAE patient community.

BCX17725 (Netherton syndrome)

BCX17725 is a potent and selective investigational protein therapeutic KLK5 inhibitor designed to provide best-in-class, potentially disease-modifying, treatment for people with Netherton syndrome. Netherton syndrome is a serious, rare, lifelong genetic disorder causing disruption of the skin barrier with premature separation of the skin layers, chronic inflammation and vulnerability to serious infections, caused by lack of normal function of a natural inhibitor of KLK5. People with Netherton syndrome often have itchy, red, scaly, inflamed skin, fragile hair, and are more likely to develop severe food allergies, asthma and eczema. Netherton syndrome can be life-threatening, especially during infancy when patients are vulnerable to dehydration and recurrent infections. Currently, there are no approved treatments that target the underlying cause of Netherton syndrome. BCX17725 is designed to replace missing functions of the natural KLK5 inhibitor, which could restore the normal skin barrier and result in improved skin function, including protection from severe inflammatory and infectious complications of the disease.

Avoralstat

Avoralstat, an investigational plasma kallikrein inhibitor, is designed to treat patients with diabetic macular edema ("DME") through the delivery of avoralstat to the back of the eye through the suprachoroidal space. DME is an important cause of vision loss in diabetes and is due to leakage of fluid from the blood vessels in the retina. While current treatments focus on vascular endothelial growth factor ("VEGF") inhibition, DME can develop from other mechanisms, such as the kallikrein-bradykinin pathway. This is supported by observations that many DME patients have an incomplete response to intravitreal anti-VEGF therapies that are administered every four to eight weeks. Avoralstat targets the kallikrein-bradykinin system on the retinal vascular endothelial cells and may result in less vascular leakage and less edema. Avoralstat, delivered to the suprachoroidal space, is designed to provide long-lasting exposure to the retinal vessels, which

could result in less frequent injections and a reduced burden on patients and the healthcare system. We plan to seek a strategic partner for development of avoralstat beyond phase 1.

STAR-0310

Pursuant to the Merger, on the Closing Date, we acquired STAR-0310, which is a monoclonal antibody OX40 antagonist that incorporates YTE half-life extension technology for the treatment of atopic dermatitis ("AD") and potentially other indications. STAR-0310 was designed as a potentially best-in-class, long-acting OX40 inhibitor with the goal of addressing the need for a safe, effective, and infrequently administered AD treatment. AD is an immune disorder associated with loss of skin barrier function and itching and is caused by diverse mechanisms, spanning the spectrum of T cell-driven pathology. STAR-0310 is currently in a Phase 1a trial to assess the safety, tolerability, pharmacokinetics, and immunogenicity of STAR-0310 in healthy subjects. We plan to seek strategic alternatives for this asset.

RAPIVAB®/RAPIACTA®/PERAMIFLU® (peramivir injection)

RAPIVAB (peramivir injection) is approved in the United States for the treatment of acute uncomplicated influenza for patients six months and older. Peramivir injection is also approved in Canada (RAPIVAB), Australia (RAPIVAB), Japan (RAPIACTA), Taiwan (RAPIACTA), and Korea (PERAMIFLU).

Revenues and Expenses

Our revenues are difficult to predict and depend on several factors, including those discussed in the "*Risk Factors*" section in Part I, Item 1A of this report. For example, our revenues depend, in part, on regulatory approval decisions for our products and product candidates, the effectiveness of our and our collaborative partners' commercialization efforts, market acceptance of our products, particularly ORLADEYO, and the resources dedicated to our products and product candidates by us and our collaborative partners, as well as entering into or modifying licensing agreements for our product candidates. Furthermore, revenues related to our collaborative development activities are dependent upon the progress toward, and the achievement of, developmental milestones by us or our collaborative partners.

Our operating expenses are also difficult to predict and depend primarily on research and development activities, including clinical research activities and the ongoing requirements of our development programs, as well as the costs of commercialization, drug manufacturing, direction from regulatory agencies, and the factors discussed in the "*Risk Factors*" section in Part I, Item 1A of this report. Management may be able to control the timing and level of research and development and selling, general and administrative expenses, but many of these expenditures will occur irrespective of our actions due to contractually committed activities and/or payments.

As a result of these factors, we believe that period-to-period comparisons are not necessarily meaningful, and you should not rely on them as an indication of future performance. Due to the foregoing factors, it is possible that our operating results will be below the expectations of market analysts and investors. In such event, the prevailing market price of our common stock could be materially adversely affected.

Recent Developments

ORLADEYO (berotralstat)

On November 6, 2025, we announced new data demonstrating the early and negative psychosocial impact of HAE and resulting emergency department and hospital visits on pediatric patients and their caregivers, as well as new one-year data from the ongoing APeX-P clinical trial showing early and sustained reductions in monthly attack rates over one year in pediatric patients with HAE aged 2 to <12 years treated with once-daily ORLADEYO.

On December 12, 2025, we announced that the FDA approved our new drug application ("NDA") for the use of an oral pellet formulation of once-daily ORLADEYO for prophylactic therapy in pediatric patients with HAE aged 2 to <12 years. ORLADEYO is the first and only targeted oral prophylactic therapy for children with HAE aged 2 to <12 years. We also filed an application for the use of ORLADEYO oral pellets in patients with HAE aged 2 to <12 years with the European Medicines Agency and the Japan Pharmaceutical and Medical Devices Agency, and additional regulatory filings are planned in other global territories.

Navenibart (STAR-0215)

On February 26, 2026, we announced that new positive, interim results from the long-term, open-label ALPHA-SOLAR trial show sustained, robust HAE attack suppression with navenibart administered every three and six months.

BCX17725 (Netherton syndrome)

On February 26, 2026, we announced that we expect to report data from the clinical trial of BCX17725 for the treatment of Netherton syndrome in up to 12 patients by the end of 2026.

Avoralstat

On November 3, 2025, we announced that we plan to seek a strategic partner for development of avoralstat beyond phase 1.

Neopharmed Gentili S.p.A. Transaction

As previously disclosed, on June 27, 2025, we entered into a stock purchase agreement (the "Stock Purchase Agreement") with BioCryst Ireland Limited ("BioCryst Ireland"), a private limited company incorporated under the laws of Ireland and a wholly owned subsidiary of the Company, and Neopharmed Gentili S.p.A., a corporation organized under the laws of Italy ("Neopharmed"). On October 1, 2025 (the "Closing"), under the terms of the Stock Purchase Agreement, we sold to Neopharmed all of our equity interests in BioCryst Ireland, which, together with its subsidiaries, holds certain assets, rights, and employees related to our European ORLADEYO business. At the Closing, we received total cash proceeds of $254.5 million, comprised of the purchase price of $250.0 million and customary purchase price adjustments of $4.5 million as set forth in the Stock Purchase Agreement. In addition, Neopharmed has agreed to pay us up to $14.0 million if certain revenue milestones are achieved prior to December 31, 2032. In connection with the Closing, Neopharmed also paid a $15.0 million royalty release fee to RPI 2019 Intermediate Finance Trust. See "*Note 2—Divestiture of BioCryst Ireland Limited*" in the Notes to Consolidated Financial Statements in Part II, Item 8 of this report for additional information about the sale of the European ORLADEYO business.

Pharmakon Loan Agreement

On October 8, 2025, we used a portion of the proceeds from the sale of the European ORLADEYO business to pay off in full the outstanding principal balance of $198.7 million and terminate the Pharmakon Loan Agreement (as defined below).

Astria Therapeutics, Inc. Merger

On October 14, 2025, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Axel Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company ("Merger Sub"), and Astria Therapeutics, Inc., a Delaware corporation ("Astria"). Pursuant to the Merger Agreement, on the Closing Date, Merger Sub merged with and into Astria, with Astria surviving as a wholly owned subsidiary of the Company (the "Merger").

Under the terms of the Merger Agreement, at the effective time of the Merger (the "Effective Time"), each share of Astria common stock, par value $0.001 per share, issued and outstanding immediately prior to the Effective Time (excluding shares held by BioCryst, Astria or their wholly owned subsidiaries or dissenting stockholders) was converted into the right to receive (i) 0.59 of a share of the Company's common stock (and, if applicable, cash in lieu of fractional shares), and (ii) $8.55 in cash, without interest, subject to certain adjustments and applicable withholding taxes. Holders of Astria's Series X Convertible Preferred Stock, warrants, and certain options were treated as set forth in the Merger Agreement.

Blackstone Loan Agreement

On the Closing Date, we also entered into a Loan Agreement (the "Blackstone Loan Agreement") with Blackstone Alternative Credit Advisors LP and Blackstone Life Sciences Advisors L.L.C., (together, "Blackstone"), as the Blackstone representatives thereunder, the guarantors from time to time party thereto, the lenders from time to time party thereto, and Wilmington Trust, National Association, as agent, pursuant to which the lenders funded initial term loans in the aggregate principal amount of $400.0 million (the "Term Loans"). Subject to the mutual agreement between the Company,

Blackstone and the lenders, we may request additional term loans up to an aggregate principal amount not exceeding $150.0 million. Our obligations under the Blackstone Loan Agreement are secured by a security interest in, subject to certain exceptions, substantially all of our and our subsidiaries' assets. We used the proceeds from the Term Loans (i) to pay the cash portion of the consideration required to consummate the Merger and pay other expenses related to the Merger and (ii) to pay the fees, premiums, expenses and other transaction costs incurred in connection with the transactions related to the Merger and the Loan Agreement. The maturity date of the Term Loans under the Loan Agreement is January 23, 2031, the fifth anniversary of the Closing Date. See "*Note 21—Subsequent Events*" in the Notes to Consolidated Financial Statements in Part II, Item 8 of this report for additional information about the Blackstone Loan Agreement.

Results of Operations

The discussion below presents a summary of our results of operations for fiscal years 2025 and 2024. See Part II, Item 7, "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations*" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on February 25, 2025, for a summary of our results of operations for the fiscal year ended December 31, 2023.

Year Ended December 31, 2025 Compared to 2024

Revenues

The following table summarizes our revenues for the periods indicated (in thousands):

	Years Ended December 31,	
	2025	**2024**
ORLADEYO:		
U.S.	$ 548,779	$ 385,961
Rest of world	14,402	8,569
European ORLADEYO business	38,658	43,130
Total ORLADEYO	601,839	437,660
License revenue	243,980	—
Other revenues	29,018	13,052
Total revenues	$ 874,837	$ 450,712

Total revenues increased to $874.8 million for the year ended December 31, 2025 compared to $450.7 million for the year ended December 31, 2024. The $424.1 million increase in total revenues was primarily driven by the following:

- $244.0 million increase in license revenue primarily comprised of $243.3 million related to the license of intellectual property to Neopharmed;
- $168.7 million increase in ORLADEYO revenue, excluding revenues associated with our European ORLADEYO business, primarily due to an increase in volume of direct sales of ORLADEYO, which was driven by strong patient demand, an increase in price, and an increase in the rate of paid shipments; and
- $16.0 million increase in other revenue primarily attributed to an increase in direct sales of peramivir.

These increases were partially offset by a $4.5 million decrease in revenues associated with our European ORLADEYO business due to the sale of our European ORLADEYO business to Neopharmed on October 1, 2025.

Cost of product sales

The following table summarizes our cost of product sales for the periods indicated (in thousands):

	Years Ended December 31,	
	2025	2024
Cost of product sales	$ 16,610	$ 9,390
European ORLADEYO business	2,465	2,879
Total cost of product sales	$ 19,075	$ 12,269

Cost of product sales increased to $19.1 million for the year ended December 31, 2025 compared to $12.3 million for the year ended December 31, 2024. The increase in cost of product sales was primarily due to the increase in peramivir direct sales.

Research and development expenses

Research and development expenses include all direct and indirect expenses relating to research and development activities. Direct expenses consist of compensation for research and development personnel and costs of outside parties to conduct laboratory studies, develop manufacturing processes and manufacture the product candidates, and conduct and manage clinical trials, as well as other costs related to our clinical and preclinical studies. Additionally, direct expenses consist of those costs necessary to discontinue and close out a development program, including termination fees and other commitments. Indirect expenses consist of lab supplies and services, facility expenses, depreciation of development equipment and other overhead of our research and development efforts. Research and development expenses vary according to the number of programs in clinical development and the stage of development of our clinical programs. Later stage clinical programs tend to cost more than earlier stage programs due to the longer length of time of the clinical trials and the higher number of patients enrolled in these clinical trials.

We do not maintain or evaluate internal research and development costs on a program-by-program basis. As a result, a significant portion of our research and development expenses are not tracked on a program-by-program basis as the costs may benefit multiple programs. Beginning in the year ended December 31, 2025, we no longer allocate non-program specific external costs or internal costs to programs. These costs are separately presented on the respective line items listed below. Research and development expenses have been reclassified for the year ended December 31, 2024 for comparability. There is no impact on total research and development expenses.

The following table summarizes our research and development expenses, including program specific costs and shared or indirect operating costs recognized as research and development expenses for the periods indicated (in thousands):

	Years Ended December 31,	
	2025	2024
Berotralstat	$ 11,171	$ 10,301
BCX17725	17,304	12,388
Avoralstat	9,497	7,547
Factor D Program	456	8,534
Research, discovery and preclinical programs	17,677	12,733
Compensation and related personnel costs	51,015	57,094
Stock-based compensation	29,510	31,285
Other non-program specific and indirect costs	27,957	32,033
European ORLADEYO business (excluding stock-based compensation)	1,539	2,723
Total research and development expenses	$ 166,126	$ 174,638

Research and development expenses decreased to $166.1 million for the year ended December 31, 2025 from $174.6 million for the year ended December 31, 2024. The decrease was primarily driven by the following:

- $8.1 million decrease in Factor D Program due to the discontinuation and close-out of the program in 2024;
- $6.1 million decrease in compensation and related personnel costs primarily attributed to a decrease in research and development related headcount net of $2.0 million of expense associated with our December 2025 workforce reduction;
- $4.1 million decrease in other non-program specific and indirect costs primarily attributed to a decrease in the general and administrative expense allocation due to our commercial progression;
- $1.8 million decrease in stock-based compensation expense primarily due to the acceleration of stock-based compensation expense upon adoption of the Retirement Policy (as defined in "*Note 13—Stock-Based Compensation*" in the Notes to Consolidated Financial Statements in Part II, Item 8 of this report) in July 2024 and a decrease in research and development related headcount, partially offset by an increase in restricted stock unit awards granted; and
- $1.2 million decrease in research and development expenses associated with our European ORLADEYO business (excluding stock-based compensation) due to the sale of our European ORLADEYO business to Neopharmed on October 1, 2025.

These decreases were partially offset by the following:

- $4.9 million increase in BCX17725 primarily due to an increase in manufacturing and clinical operations as we enroll our phase 1 trial in healthy volunteers and patients;
- $4.9 million increase in research, discovery and preclinical programs due to investigational new drug application-enabling activities related to our early-phase pipeline programs;
- $2.0 million increase in avoralstat due to an increase in manufacturing and clinical startup activities; and
- $0.9 million increase in berotralstat primarily attributed to an increase in manufacturing and other costs to support FDA approval in pediatric patients.

Selling, general, and administrative expenses

Sales and marketing expenses include compensation, benefits, and related costs associated with sales and marketing personnel, safety, regulatory, manufacturing, and distribution activities related to marketed products, market research, marketing, medical affairs, market access, and advertising costs. General and administrative expenses include compensation, benefits, and related costs associated with general and administrative personnel, quality activities related to marketed products, finance, human resources, information technology, legal expenses, licenses and other administrative costs, including transaction-related costs.

The following table summarizes our selling, general, and administrative expenses for the periods indicated (in thousands):

	Years Ended December 31,	
	2025	2024
Sales and marketing (excluding stock-based compensation)	$ 146,590	$ 116,914
General and administrative (excluding stock-based compensation)	107,917	70,055
European ORLADEYO business (excluding stock-based compensation)	38,584	45,251
Stock-based compensation	55,556	34,128
Total selling, general, and administrative expenses	$ 348,647	$ 266,348

Sales and marketing expenses (excluding stock-based compensation) increased to $146.6 million for the year ended December 31, 2025 from $116.9 million for the year ended December 31, 2024. The increase was primarily driven by the following:

- $4.9 million increase in manufacturing related costs, including $3.9 million of process development costs;
- $4.9 million increase in compensation and related personnel costs due to the transition of certain regulatory, safety, and manufacturing support roles from research and development to sales and marketing in connection with ORLADEYO's continued commercial progression;
- $4.7 million increase in compensation and related personnel costs primarily due to compensation increases as a result of strong performance and annual merit increases;
- $2.8 million increase in distribution related costs primarily attributed to increased ORLADEYO sales;
- $1.8 million of expense associated with our December 2025 workforce reduction;
- $0.7 million of transaction-related costs; and
- $11.1 million increase in other sales and marketing expenses, primarily related to costs to support the launch of ORLADEYO in pediatric patients and ORLADEYO commercial growth.

General and administrative expenses (excluding stock-based compensation) increased to $107.9 million for the year ended December 31, 2025 from $70.1 million for the year ended December 31, 2024. The increase was primarily driven by the following:

- $20.4 million of transaction-related costs associated with the sale of our European ORLADEYO business to Neopharmed and the Merger with Astria;
- $11.2 million increase in compensation and related personnel costs primarily due to an increase in compensation and average general and administrative headcount, including $4.4 million due to the transition of certain quality support roles from research and development to general and administrative in connection with ORLADEYO's continued commercial progression;
- $3.8 million increase due to a change in the allocation of general and administrative expenses to research and development expenses; and
- $2.5 million of expense associated with our December 2025 workforce reduction.

Expenses associated with our European ORLADEYO business (excluding stock-based compensation) decreased to $38.6 million for the year ended December 31, 2025 from $45.3 million for the year ended December 31, 2024 due to the sale of our European ORLADEYO business to Neopharmed on October 1, 2025.

Stock-based compensation expense increased to $55.6 million for the year ended December 31, 2025 from $34.1 million for the year ended December 31, 2024. The increase was primarily due to a modification to extended the post-termination exercise period of certain vested stock option awards at the time of retirement for certain individuals to the original expiration date, resulting in $11.3 million of incremental expense, and an increase in restricted stock unit awards granted.

Other income (expense)

For the year ended December 31, 2025, interest income was $10.7 million compared to $14.7 million for the year ended December 31, 2024. The decrease in interest income was primarily the result of an overall decrease in our average investment portfolio and a decrease in interest rates. Net foreign currency losses were $0.2 million for the year ended December 31, 2025 compared to $0.6 million for the year ended December 31, 2024.

Interest expense for the year ended December 31, 2025 was $78.9 million compared to $98.5 million for the year ended December 31, 2024. Interest expense is primarily comprised of non-cash interest expense due to the amortization of interest associated with the royalty financing obligations and interest expense associated with the borrowings under the Pharmakon Loan Agreement (as defined below), including the amortization of the deferred financing costs, associated with the borrowings under the Pharmakon Loan. The decrease in interest expense was primarily the result of the payoff of the Pharmakon Term Loan in three separate prepayments in 2025 totaling $323.7 million and a decrease in the effective

interest rate during the period in which the debt was outstanding in 2025. In addition, there was a decrease in interest expense associated with our OMERS Royalty Purchase Agreement (as defined in "*Note 9—Royalty Financing Obligations*" in the Notes to Consolidated Financial Statements in Part II, Item 8 of this report) as result of a lower outstanding principal balance.

For the year ended December 31, 2025, we recognized a one-time loss on extinguishment of debt of $17.3 million as a result of the payoff of the Pharmakon Term Loan.

For the year ended December 31, 2025, other income was $12.1 million, which was primarily comprised of the $4.3 million mark-to-market adjustment on liability classified awards, $3.6 million gain recognized on the sale of BioCryst Ireland to Neopharmed, $2.1 million of pre-close transaction services BioCryst performed on behalf of Neopharmed, and $1.6 million of post-close transition services BioCryst provided to Neopharmed.

Income tax expense

For the year ended December 31, 2025, income tax expense was $3.5 million compared to $1.9 million for the year ended December 31, 2024. The increase in income tax expense was primarily driven by the increase in domestic and foreign taxable income for the year ended December 31, 2025 compared to the year ended December 31, 2024.

Liquidity and Capital Resources

Sources of Liquidity

Our operations have principally been funded through our credit facilities; revenues from ORLADEYO; royalty financing transactions; public offerings and private placements of equity securities; and cash from collaborative and other research and development agreements, including U.S. Government contracts. In addition to the above, we have received funding from other sources, including government grants, research grants, and interest income on our investments.

On the Closing Date, we entered into the Blackstone Loan Agreement, pursuant to which the lenders funded the initial Term Loans in the aggregate principal amount of $400.0 million. We used the proceeds from the Term Loans to pay the cash portion of the consideration required to consummate the Merger. The maturity date of the Term Loans under the Blackstone Loan Agreement is January 23, 2031, the fifth anniversary of the Closing Date. Our obligations under the Blackstone Loan Agreement are secured by a security interest in, subject to certain exceptions, substantially all of our and our subsidiaries' assets.

The Blackstone Loan Agreement also contains representations and warranties and affirmative and negative covenants customary for financings of this type, as well as customary events of default. Certain of the customary negative covenants limit our ability and certain of our subsidiaries to, among other things, dispose of assets, engage in mergers, acquisitions and similar transactions, incur additional indebtedness, grant liens, make investments, pay dividends or make distributions or certain other restricted payments in respect of equity, prepay certain other indebtedness, enter into restrictive agreements, undertake fundamental changes or amend certain material contracts, among other customary covenants, in each case subject to certain exceptions. A failure to comply with the covenants in the Blackstone Loan Agreement, or an occurrence of any other event of default, could permit the lenders under the Blackstone Loan Agreement to declare the borrowings thereunder, together with accrued interest and fees, and any applicable yield protection premium, to be immediately due and payable. See *"Note 21—Subsequent Events"* in the Notes to Consolidated Financial Statements in Part II, Item 8 of this report for additional information about the Blackstone Loan Agreement.

On April 17, 2023, we entered into a $450.0 million Loan Agreement (the "Pharmakon Loan Agreement") with BioPharma Credit Investments V (Master) LP and BPCR Limited Partnership, as lenders, and BioPharma Credit PLC, as collateral agent for the lenders. The Pharmakon Loan Agreement provided for an initial term loan in the principal amount of $300.0 million (the "Tranche A Loan"), which was funded on April 17, 2023. We utilized a portion of the proceeds from the Tranche A Loan to repay the approximate $241.8 million of outstanding indebtedness under the then-existing credit facility with Athyrium Opportunities III Co-Invest 1 LP and to pay transaction costs and fees, and we used the remaining net proceeds of approximately $25.8 million for other general corporate purposes.

The Pharmakon Loan Agreement also provided for three additional term loan tranches in principal amounts of $50.0 million each, which we could have requested, at our option, on or prior to September 30, 2024. We chose not to request any of the additional term loan tranches. The maturity date of the Pharmakon Loan Agreement was April 17, 2028. On April 18, 2025, we made a partial prepayment of $75.0 million of the outstanding principal amount under the Pharmakon Loan

Agreement, and on July 24, 2025, we made an additional partial prepayment of $50.0 million of the outstanding principal amount under the Pharmakon Loan Agreement. On October 8, 2025, we used a portion of the proceeds from the sale of the European ORLADEYO business to pay off in full the outstanding principal balance of $198.7 million and terminate the Pharmakon Loan Agreement.

In 2020 and 2021, we entered into the Royalty Purchase Agreements (as defined in "*Note 9—Royalty Financing Obligations*" in the Notes to Consolidated Financial Statements in Part II, Item 8 of this report) with RPI 2019 Intermediate Finance Trust ("RPI") and OCM IP Healthcare Holdings Limited, an affiliate of OMERS Capital Markets ("OMERS"). Under the Royalty Purchase Agreements, RPI and OMERS are entitled to receive tiered, sales-based royalties on net product sales of ORLADEYO in the United States and certain key European markets (collectively, the "Key Territories"), and other markets where we sell ORLADEYO directly or through distributors. In addition, RPI and OMERS are entitled to receive a tiered revenue share on amounts generally received by us on account of ORLADEYO sublicense revenue or net sales by licensees outside of the Key Territories. Our required payments to OMERS commenced with the calendar quarter beginning October 1, 2023. No royalty payments are due on direct sales over $550.0 million. See "*Note 9—Royalty Financing Obligations*" in the Notes to Consolidated Financial Statements in Part II, Item 8 of this report for additional information about these financing transactions.

Our principal sources of liquidity at December 31, 2025 were approximately $335.9 million in cash and cash equivalents and available-for-sale investments.

Cash Flows

The following table summarizes our cash flows for each period presented (in thousands):

	Years Ended December 31,	
	2025	**2024**
Net cash provided by (used in):		
Operating activities	$ 347,369	$ (52,020)
Investing activities	(13,694)	52,593
Financing activities	(349,931)	(5,761)
Effect of exchange rates on cash, cash equivalents and restricted cash	1,270	(936)
Decrease in cash, cash equivalents and restricted cash	$ (14,986)	$ (6,124)

Operating Activities

During the year ended December 31, 2025, net cash provided by operating activities of $347.4 million consisted primarily of net income of $263.9 million and $140.4 million of non-cash items. Non-cash items were primarily comprised of $85.1 million of stock-based compensation expense, $53.2 million of non-cash interest expense on royalty financing obligations, a $17.5 million contra-revenue adjustment related to the modification of equity awards in connection with the sale of BioCryst Ireland, and a $17.3 million loss on extinguishment of debt. Net income and non-cash items were partially offset by $56.9 million of changes in operating assets and liabilities, primarily due to a decrease in royalty financing obligations and increases in receivables and accounts payable and accrued expenses, and $23.7 million in payments of Pharmakon PIK interest.

During the year ended December 31, 2024, net cash used in operating activities of $52.0 million consisted primarily of a net loss of $88.9 million and $87.3 million of changes in operating assets and liabilities, primarily due to a decrease in royalty financing obligations and increases in receivables and accounts payable and accrued expenses, partially offset by $124.1 million of non-cash items. Non-cash items primarily consisted of $65.4 million of stock-based compensation expense, $56.0 million of non-cash interest expense on royalty financing obligations, and $11.6 million of non-cash interest expense on secured term loan and amortization of debt issuance costs, partially offset by $11.5 million of amortization of premiums and discounts on investments.

Investing Activities

During the year ended December 31, 2025, net cash used in investing activities of $13.7 million primarily related to purchases of investment securities and proceeds from the sale of BioCryst Ireland, net of cash divested, partially offset by sales and maturities of investment securities.

During the year ended December 31, 2024, net cash provided by investing activities of $52.6 million primarily related to maturities of investment securities, partially offset by purchases of investment securities.

Financing Activities

During the year ended December 31, 2025, net cash used in financing activities of $349.9 million primarily consisted of the repayment of Pharmakon term loan principal and related prepayment premium and fees totaling $309.9 million, $22.9 million in principal payments on royalty financing obligations, $15.5 million in payments of royalty release fees to RPI and OMERS in connection with the sale of the Company's European ORLADEYO business to Neopharmed, and $8.8 million of withholding taxes paid on stock-based awards, partially offset by $9.1 million of net proceeds from common stock issued under stock-based compensation plans.

During the year ended December 31, 2024, net cash used in financing activities of $5.8 million primarily consisted of withholding taxes paid on stock-based awards and principal payments on finance lease liabilities, partially offset by net proceeds from common stock issued under stock-based compensation plans.

Plan of Operation and Future Funding Requirements

We intend to contain costs and cash flow requirements by closely managing our third-party costs and headcount, leasing scientific equipment and facilities, and contracting with other parties to conduct certain research and development projects. We may incur additional expenses, potentially resulting in significant losses, as we continue to pursue our research and development activities, commercialize ORLADEYO, and engage in strategic business development. We may incur additional expenses related to the filing, prosecution, maintenance, defense, and enforcement of patent and other intellectual property claims and additional regulatory costs as our clinical programs advance through later stages of development or as regulatory exclusivity for our products expires. The objective of our investment policy is to ensure the safety and preservation of invested funds, as well as to maintain liquidity sufficient to meet cash flow requirements. We place our excess cash with high credit quality financial institutions. We invest in marketable debt securities that may consist of U.S. Treasury obligations, U.S government agency securities, money market funds, certificates of deposit, and corporate notes and bonds in order to limit the amount of our credit exposure. We have not realized any significant losses on our investments.

In the future, we may finance our needs principally from the following:

- our existing capital resources and interest earned on that capital;
- revenues from product sales;
- payments under current or future collaborative and licensing agreements with corporate partners;
- lease, royalty, or loan financing; and
- public or private equity and/or debt financing.

Our current and planned clinical trials, plus the related development, manufacturing, regulatory approval process requirements, and additional resources required for the continuing development of our product candidates and the commercialization of our products will consume significant capital resources and could increase our expenses.

Our expenses, revenues and cash utilization rate could vary significantly depending on many factors, including the progress and results of our current and proposed clinical trials for our product candidates; the progress made in the manufacturing of our lead product candidates; the success of our commercialization efforts for, and market acceptance of, our products; the overall progression of our other programs; our business development activities; the amount of funding or assistance, if any, we receive from new partnerships with third parties for the development and/or commercialization of our products and product candidates; the development progress of any collaborative agreements for our product candidates; and the amount and timing of funding we receive, if any, from U.S. Government contracts.

Based on our expectations for revenue and operating expenses, we believe our financial resources will be sufficient to fund our operations for at least the next 12 months. Our liquidity needs will be largely determined by the success of operations in regard to the successful commercialization of our products and the future progression of our product candidates. From time to time, we evaluate other opportunities to fund future operations, including: (1) out-licensing rights to certain of our products or product candidates, pursuant to which we would receive cash milestone payments; (2) obtaining additional product candidate regulatory approvals, which would generate revenue, milestone payments and cash flow; (3) reducing spending on one or more research and development programs, including by discontinuing development; (4) restructuring operations to change our overhead structure; and/or (5) securing U.S. Government funding of our programs, including obtaining procurement contracts. We may, in the future, issue securities, including common stock, preferred stock, depositary shares, purchase contracts, warrants, debt securities, and units, through private placement transactions or registered public offerings. Our future liquidity needs, and our ability to address those needs, will largely be determined by the success of our products and product candidates; the success of our business development efforts; the timing, scope, and magnitude of our research and development and commercial expenses; and key developments and regulatory events and our decisions in the future.

Our long-term capital requirements and the adequacy of our available funds will depend upon many factors, including:

- sustained market acceptance of approved products and successful commercialization of such products by either us or our partners;
- the progress and magnitude of our research, drug discovery and development programs;
- changes in existing collaborative relationships;
- our ability to establish additional collaborative relationships if and when needed;
- the extent to which our partners will share in the costs associated with the development of our programs or run the development programs themselves;
- our ability to negotiate favorable development and marketing strategic alliances for certain products and product candidates;
- any decision to build or expand internal development and commercial capabilities;
- the scope and results of preclinical studies and clinical trials to identify and develop product candidates;
- our ability to engage sites and enroll subjects in our clinical trials;
- the scope of manufacturing of our products to support our commercial operations and of our product candidates to support our preclinical research and clinical trials;
- increases in personnel and related costs to support the development and commercialization of our products and product candidates;
- the scope of manufacturing of our drug substance and product candidates required for future NDA filings;
- competitive and technological advances;
- the time and costs involved in obtaining regulatory approvals;
- post-approval commitments for any products that receive regulatory approval;
- our business development activities; and
- the costs involved in all aspects of intellectual property strategy and protection, including the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims.

We may, in the future, be required to raise additional capital to complete the development and commercialization of our products and product candidates, and we may seek to raise capital in the future, including to take advantage of favorable opportunities in the capital markets. Additional funding may not be available when needed or in the form or on terms acceptable to us. Our future working capital requirements, including the need for additional working capital, will largely be determined by the advancement of our portfolio of product candidates and the commercialization of ORLADEYO. More specifically, our working capital requirements will be dependent on the number, magnitude, scope and timing of our development programs; regulatory approval of our product candidates; the cost, timing and outcome of regulatory reviews, regulatory investigations, and changes in regulatory requirements; the costs of obtaining patent protection for our product candidates; the timing and terms of business development activities; the rate of technological advances relevant to our operations; the efficiency of manufacturing processes developed on our behalf by third parties; the timing, scope and magnitude of commercial spending; and the level of required administrative support for our daily operations. See "*Risk Factors—Risks Relating to Our Business—Financial and Liquidity Risks*" in Part I, Item 1A of this report for further discussion of the risks related to obtaining additional capital.

Critical Accounting Estimates

The preparation of these consolidated financial statements in accordance with U.S. GAAP requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures for the periods presented. Some of these estimates can be subjective and complex with a significant level of estimation uncertainty, and, consequently, actual results may differ from these estimates. The judgments and assumptions used by management are based on historical experience and information available to us at the time that we make these estimates and judgments. To the extent there are material differences between these estimates and actual results, our consolidated financial statements will be affected. Although we believe that our judgments and estimates are appropriate, actual results may differ from these estimates.

While our significant accounting policies are more fully described in "*Note 1—Significant Accounting Policies and Concentrations of Risk*" in the Notes to Consolidated Financial Statements in Part II, Item 8 of this report, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

The application of Accounting Standards Codification ("ASC") Topic 606 substantially impacts our reported results, particularly product sales, net, which requires certain estimates in determining the transaction price.

Net revenue from sales of ORLADEYO is recorded at net selling price (transaction price), which includes reserves for variable consideration such as (i) estimated government rebates, such as Medicaid and Medicare Part D reimbursements, and estimated managed care rebates, (ii) estimated chargebacks, (iii) estimated costs of co-payment assistance programs, and (iv) product returns. These reserves, representing our best estimates of the amount of consideration to which we are entitled based on the terms of the applicable contracts and statutory requirements, are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable if no payments are required of us or a current liability if a payment is required of us. Actual amounts of consideration may differ from our estimates. If actual results vary from estimates, these estimates are adjusted, which would affect net product revenue and earnings in the period such variances become known.

The most subjective of these estimates are government and managed care rebates. We contract with group purchasing organizations associated with managed care organizations and participate in certain government programs or, collectively, third-party payors, so that ORLADEYO will be eligible for purchase by, or partial or full reimbursement from, such third-party payors. We estimate the rebates we will provide to third-party payors and deduct these estimated amounts from total gross product revenues at the time the revenues are recognized, resulting in a reduction of product revenue and the establishment of a current liability. We estimate the rebates that we will provide to third-party payors based upon (i) our contracts with these third-party payors, (ii) the contractually mandated discounts applicable to the programs, and (iii) product distribution information obtained from our specialty pharmacy regarding payor mix.

Research and Development Expenses and Related Accruals

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with applicable Company personnel to identify services that have been performed on our behalf and estimating the actual work completed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. When evaluating the adequacy of accrued expenses, we consider facts and circumstances known to us at the time, which can include assumptions such as expected patient enrollment, site activation and estimated project duration. Examples of estimated accrued research and development expenses include (i) fees paid to CROs in connection with preclinical and toxicology studies and clinical trials, (ii) fees paid to investigative sites in connection with clinical trials, (iii) fees paid to contract manufacturers in connection with the production of our raw materials, drug substance, drug products, and product candidates, and (iv) professional fees.

The financial terms of our agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of milestones. We record liabilities under these contractual commitments when we determine

an obligation has been incurred, regardless of the timing of the invoice. In expensing service fees, we estimate the time period over which services will be performed and the level of effort expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of these costs, our actual expenses could differ from our estimates.

Royalty Financing Obligations

Under the royalty financing obligations, RPI and OMERS are entitled to receive sales-based royalties on net product sales of ORLADEYO. Interest expense is accrued using the effective interest rate method over the estimated period each of the related liabilities will be paid. This requires us to estimate the total amount of future royalty payments to be generated from product sales over the life of the agreements. We impute interest on the carrying values of each of the royalty financing obligations and record interest expense using an imputed effective interest rate. We reassess the expected royalty payments each reporting period and account for any changes through adjustments to the effective interest rates on a prospective basis. The assumptions used in determining the expected repayment terms of the debt and amortization periods of the issuance costs requires that we make estimates that could impact the carrying value of each of the liabilities, as well as the periods over which associated issuance costs will be amortized. A significant increase or decrease in forecasted net sales could materially impact each of the liability balances, interest expense and the time periods for repayment.

Income Taxes

The liability method is used in our accounting for income taxes. Significant management judgment is required in determining our provision for income taxes, deferred tax assets and liabilities and any valuation allowance recorded against net deferred tax assets. We have recorded a valuation allowance against substantially all potential tax assets, due to uncertainties in our ability to utilize deferred tax assets, primarily consisting of certain net operating losses carried forward, before they expire. The valuation allowance is based on estimates of future earnings in each of the jurisdictions in which we operate and the period over which our deferred tax assets will be recoverable.

We account for uncertain tax positions in accordance with U.S. GAAP. Uncertain tax positions are recorded based upon certain recognition and measurement criteria. We re-evaluate uncertain tax positions and consider various factors, including, but not limited to, changes in tax law and the measurement of tax positions taken or expected to be taken in tax returns. We adjust the amount of the liability to reflect any subsequent changes in the relevant facts and circumstances surrounding the uncertain tax positions.

Recent Accounting Pronouncements

"*Note 1—Significant Accounting Policies and Concentrations of Risk*" in the Notes to the Consolidated Financial Statements included in Part II, Item 8 of this report discusses accounting pronouncements recently issued or proposed but not yet required to be adopted.

ITEM 7A. *QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.*

Interest Rate Risk

We are subject to interest rate risk on our investment portfolio as of December 31, 2025. We invest in marketable securities in accordance with our investment policy. The primary objectives of our investment policy are to preserve capital, maintain proper liquidity to meet operating needs and earn a competitive level of return. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. We place our excess cash with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of credit exposure. Some of the securities we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate.

Our investment exposure to market risk for changes in interest rates relates to the increase or decrease in the amount of interest income we can earn on our portfolio, changes in the market value due to changes in interest rates and other market factors, as well as the increase or decrease in any realized gains and losses. Our investment portfolio includes only marketable securities and instruments with active secondary or resale markets to help ensure portfolio liquidity. A hypothetical 100 basis point increase or decrease in interest rates along the entire interest rate yield curve would not significantly affect the fair value of our interest sensitive financial instruments, but may affect our future earnings and cash

flows. We generally have the ability to hold our fixed-income investments to maturity and, therefore, do not expect that our operating results, financial position or cash flows will be materially impacted due to a sudden change in interest rates. However, our future investment income may fall short of expectations due to changes in interest rates, or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates or other factors, such as changes in credit risk related to the securities' issuers. To minimize this risk, we schedule our investments to have maturities that coincide with our expected cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, we do not believe that we have material exposure to interest rate risk arising from our investments. Generally, our investments are not collateralized. We have not realized any significant losses from our investments.

We do not use interest rate derivative instruments to manage exposure to interest rate changes. We ensure the safety and preservation of invested principal funds by limiting default risk, market risk and reinvestment risk. We reduce default risk by investing exclusively in investment grade securities.

Foreign Currency Risk

Most of our revenues and expenses are denominated in U.S. dollars. Our royalties from Torii are in Japanese Yen. We also had other transactions denominated in foreign currencies during the year ended December 31, 2025, including contract manufacturing and ex-U.S. clinical trial activities, and we expect to continue to do so. In addition, during the nine months ended September 30, 2025, we had transactions denominated in foreign currencies related to our operations in Europe. Our limited foreign currency exposure relative to our operations is to fluctuations in the Euro, British Pound, and Canadian Dollar.

We do not anticipate that foreign currency transaction gains or losses will be significant at our current level of operations. We have not engaged in foreign currency hedging during 2025; however, we may do so in the future.

Inflation Risk

Inflation generally impacts us by potentially increasing our operating expenses, including cost of product sales, clinical trial costs and selling activities. We do not believe that inflation has had a material impact on our business or results of operations during the periods for which the consolidated financial statements are presented in this report. Significant adverse changes in inflation could negatively impact our future results of operations.

ITEM 8. ***FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA***

BIOCRYST PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except par value amounts)

	December 31,	
	2025	**2024**
Assets		
Current assets:		
Cash and cash equivalents	$ 89,736	$ 104,713
Restricted cash	201	210
Short-term investments	185,011	216,137
Trade receivables	106,818	79,069
Inventory, net	5,398	8,087
Prepaid expenses and other current assets	17,182	13,752
Total current assets	404,346	421,968
Long-term inventory, net	23,990	23,187
Property and equipment, net	8,783	7,777
Long-term investments	61,164	20,323
Right of use assets	10,203	12,008
Other assets	5,672	5,157
Total assets	$ 514,158	$ 490,420
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 15,826	$ 11,644
Accrued expenses	126,413	113,292
Share-based liability	13,743	—
Operating lease liabilities	317	937
Finance lease liabilities	1,312	1,835
Royalty financing obligations	38,455	32,676
Total current liabilities	196,066	160,384
Operating lease liabilities	8,571	7,924
Finance lease liabilities	1,441	2,124
Royalty financing obligations	427,233	481,053
Secured term loan	—	314,869
Total liabilities	633,311	966,354
Stockholders' deficit:		
Preferred stock, $0.01 par value; shares authorized - 5,000; no shares issued and outstanding at December 31, 2025 and 2024	—	—
Common stock, $0.01 par value; shares authorized - 450,000; shares issued and outstanding – 213,060 and 208,543 at December 31, 2025 and 2024, respectively	2,131	2,085
Additional paid-in capital	1,384,857	1,291,100
Accumulated other comprehensive income	38	921
Accumulated deficit	(1,506,179)	(1,770,040)
Total stockholders' deficit	(119,153)	(475,934)
Total liabilities and stockholders' deficit	$ 514,158	$ 490,420

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(In thousands, except per share amounts)

	Years Ended December 31,		
	2025	**2024**	**2023**
Revenues:			
Product sales, net	$ 623,151	$ 442,668	$ 324,696
License and other revenues	251,686	8,044	6,716
Total revenues	874,837	450,712	331,412
Expenses:			
Cost of product sales	19,075	12,269	4,481
Research and development	166,126	174,638	216,566
Selling, general and administrative	348,647	266,348	214,074
Total operating expenses	533,848	453,255	435,121
Income (loss) from operations	340,989	(2,543)	(103,709)
Other income (expense):			
Interest income	10,668	14,746	15,777
Interest expense	(78,872)	(98,516)	(108,239)
Foreign currency losses, net	(152)	(641)	(1,039)
Loss on extinguishment of debt	(17,332)	—	(29,019)
Other income	12,090	—	—
Total other expense, net	(73,598)	(84,411)	(122,520)
Income (loss) before income taxes	267,391	(86,954)	(226,229)
Income tax expense	3,530	1,927	310
Net income (loss)	$ 263,861	$ (88,881)	$ (226,539)
Other comprehensive income (loss):			
Foreign currency translation adjustment	(674)	(776)	180
Unrealized (loss) gain on available for sale investments	(209)	360	1,131
Total other comprehensive (loss) income	(883)	(416)	1,311
Net comprehensive income (loss)	$ 262,978	$ (89,297)	$ (225,228)
Net income (loss) per common share: basic	$ 1.26	$ (0.43)	$ (1.18)
Weighted average shares of common stock outstanding: basic	209,893	206,696	192,198
Net income (loss) per common share: diluted	$ 1.21	$ (0.43)	$ (1.18)
Weighted average shares of common stock outstanding: diluted	218,581	206,696	192,198

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended December 31,		
	2025	**2024**	**2023**
Cash flows from operating activities:			
Net income (loss)	$ 263,861	$ (88,881)	$ (226,539)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	1,389	1,246	1,655
Inventory obsolescence	985	1,350	422
Stock-based compensation expense	85,066	65,413	55,615
Equity modification associated with sale of BioCryst Ireland	17,548	—	—
Mark-to-market adjustment on share-based liability	(4,313)	—	—
Payment of Pharmakon PIK Interest	(23,704)	—	—
Non-cash interest expense on royalty financing obligations	53,163	55,969	70,356
Non-cash interest expense on secured term loan and amortization of debt issuance costs	1,387	11,638	15,447
Amortization of discount on investments, net	(4,331)	(11,473)	(10,263)
Loss on extinguishment of debt	17,332	—	29,019
Loss on impairment	—	—	1,548
Gain on sale of non-financial asset	(550)	—	—
Gain on sale of BioCryst Ireland	(3,566)	—	—
Changes in operating assets and liabilities:			
Increase in receivables	(36,806)	(22,698)	(6,095)
Increase in inventory	(1,639)	(4,164)	(1,450)
(Increase) decrease in prepaid expenses and other assets	(7,827)	1,959	(6,820)
Decrease in royalty financing obligations	(68,428)	(77,155)	(29,337)
Increase in accounts payable and accrued expenses	57,802	14,776	12,531
Decrease in deferred revenue	—	—	(1,230)
Net cash provided by (used in) operating activities	347,369	(52,020)	(95,141)
Cash flows from investing activities:			
Acquisitions of property and equipment	(2,468)	(1,124)	(2,168)
Purchases of investments	(262,240)	(266,763)	(514,407)
Sales and maturities of investments	256,647	320,480	385,077
Sale of non-financial asset	550	—	—
Proceeds from sale of BioCryst Ireland, net of cash divested	(6,183)	—	—
Net cash (used in) provided by investing activities	(13,694)	52,593	(131,498)
Cash flows from financing activities:			
Net proceeds from common stock issued under stock-based compensation plans	9,115	3,444	8,340
Withholding taxes paid on stock-based awards	(8,847)	(7,535)	(2,172)
Common stock issued to directors in lieu of cash retainer	59	34	342
Net proceeds from term loans	—	—	300,000
Repayment of principal on term loans	(300,000)	—	(240,452)
Prepayment premium and fees on term loans	(9,886)	—	(21,261)
Payment of debt issuance costs on Pharmakon Tranche A term loan	—	—	(11,147)
Principal payments on royalty financing obligations	(22,883)	—	—
Payment of royalty release fees	(15,500)	—	—
Principal payments on finance lease liabilities	(1,989)	(1,704)	(1,165)
Net cash (used in) provided by financing activities	(349,931)	(5,761)	32,485
Effect of exchange rates on cash, cash equivalents and restricted cash	1,270	(936)	362
Decrease in cash, cash equivalents and restricted cash	(14,986)	(6,124)	(193,792)

Cash, cash equivalents and restricted cash:			
Beginning of year	106,323	112,447	306,239
End of year	$ 91,337	$ 106,323	$ 112,447
Reconciliation of cash, cash equivalents and restricted cash:			
Cash and cash equivalents	$ 89,736	$ 104,713	$ 110,643
Restricted cash	201	210	1,804
Restricted cash in other assets	1,400	1,400	—
Total cash, cash equivalents and restricted cash	$ 91,337	$ 106,323	$ 112,447
Supplemental cash flow disclosure:			
Cash paid for interest	$ 23,735	$ 30,383	$ 22,139
Taxes withheld on stock-based awards included in accrued expenses	$ 132	$ 758	$ 4,199
Capitalized software costs included in accrued expenses	$ 608	$ —	$ —

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount				
Balance at December 31, 2022	187,906	$ 1,879	$ 1,158,118	$ 26	$ (1,454,620)	$ (294,597)
Net loss	—	—	—	—	(226,539)	(226,539)
Other comprehensive income	—	—	—	1,311	—	1,311
Exercise of stock options, net	1,276	13	6,101	—	—	6,114
Vesting of restricted stock units	1,276	13	(13)	—	—	—
Shares withheld for taxes for vesting of restricted stock units	(59)	(1)	(369)	—	—	(370)
Employee stock purchase plan sales	338	4	2,592	—	—	2,596
Exercise of warrants	14,997	150	(150)	—	—	—
Issuance of shares to directors in lieu of cash retainer	37	—	342	—	—	342
Stock-based compensation expense	—	—	55,615	—	—	55,615
Balance at December 31, 2023	205,771	$ 2,058	$ 1,222,236	$ 1,337	$ (1,681,159)	$ (455,528)
Net loss	—	—	—	—	(88,881)	(88,881)
Other comprehensive loss	—	—	—	(416)	—	(416)
Exercise of stock options	548	5	2,275	—	—	2,280
Vesting of restricted stock units	1,902	19	(19)	—	—	—
Shares withheld for taxes for vesting of restricted stock units	(94)	(1)	(688)	—	—	(689)
Employee stock purchase plan sales	412	4	1,849	—	—	1,853
Issuance of shares to directors in lieu of cash retainer	4	—	34	—	—	34
Stock-based compensation expense	—	—	65,413	—	—	65,413
Balance at December 31, 2024	208,543	$ 2,085	$ 1,291,100	$ 921	$ (1,770,040)	$ (475,934)
Net income	—	—	—	—	263,861	263,861
Other comprehensive loss	—	—	—	(883)	—	(883)
Exercise of stock options, net	1,487	15	7,864	—	—	7,879
Vesting of restricted stock units	2,796	28	(28)	—	—	—
Shares withheld for taxes for vesting of restricted stock units	(142)	(1)	(1,061)	—	—	(1,062)
Employee stock purchase plan sales	369	4	2,294	—	—	2,298
Issuance of shares to directors in lieu of cash retainer	7	—	59	—	—	59
Stock-based compensation expense	—	—	85,137	—	—	85,137
Reclassification of equity awards to share-based liability	—	—	(2,558)	—	—	(2,558)
Remeasurement of share-based liability	—	—	2,050	—	—	2,050
Balance at December 31, 2025	213,060	$ 2,131	$ 1,384,857	$ 38	$ (1,506,179)	$ (119,153)

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(In thousands)

Note 1— Significant Accounting Policies and Concentrations of Risk

The Company

BioCryst Pharmaceuticals, Inc. (the "Company") is a global biotechnology company focused on developing and commercializing medicines for hereditary angioedema ("HAE") and other rare diseases, driven by the Company's deep commitment to improving the lives of people living with these conditions. The Company has built a robust commercial infrastructure to support the successful commercialization of ORLADEYO®, an oral, once-daily therapy discovered and developed internally for the prevention of HAE attacks. The Company's business strategy includes leveraging this established commercial platform to successfully commercialize a pipeline of potential first-in-class or best-in-class oral small-molecule and injectable protein therapeutics targeting a range of rare diseases. These programs are being pursued through both internal discovery efforts and strategic business development. By utilizing its existing commercial capabilities and focusing on rare disease markets, the Company believes that it can more effectively optimize its costs and strategically allocate resources to support long-term, sustainable growth. The Company was founded in 1986 and incorporated in Delaware in 1991, and its headquarters is located in Durham, North Carolina.

The Company's marketed products include oral, once-daily ORLADEYO® for the prevention of HAE attacks and RAPIVAB® (peramivir injection) for the treatment of acute uncomplicated influenza in the United States. ORLADEYO has received regulatory approval in the United States and other global markets. The Company is commercializing ORLADEYO in each of these territories directly or through other parties. In addition to its approval in the United States, peramivir injection has received regulatory approvals in Canada (RAPIVAB), Australia (RAPIVAB), Japan (RAPIACTA), Taiwan (RAPIACTA) and Korea (PERAMIFLU).

Based on the Company's expectations for revenue and operating expenses, the Company believes its financial resources available at December 31, 2025 will be sufficient to fund its operations for at least the next 12 months. The Company's liquidity needs will be largely determined by the success of operations in regard to the successful commercialization of its products and the future progression of its product candidates. From time to time, the Company evaluates other opportunities to fund future operations, including: (1) out-licensing rights to certain of its products or product candidates, pursuant to which the Company would receive cash milestone payments; (2) obtaining additional product candidate regulatory approvals, which would generate revenue, milestone payments and cash flow; (3) reducing spending on one or more research and development programs, including by discontinuing development; (4) restructuring operations to change its overhead structure; and/or (5) securing U.S. Government funding of its programs, including obtaining procurement contracts. The Company may, in the future, issue securities, including common stock, preferred stock, depositary shares, purchase contracts, warrants, debt securities and units, through private placement transactions or registered public offerings. The Company's future liquidity needs, and ability to address those needs, will largely be determined by the success of its products and product candidates; the success of its business development efforts; the timing, scope and magnitude of its research and development and commercial expenses; and key developments and regulatory events and its decisions in the future.

Basis of Presentation

The consolidated financial statements include the accounts of the Company and its subsidiaries. All intercompany transactions and balances among the consolidated entities have been eliminated from the consolidated financial statements. The Company operates and manages its business as one reportable and operating segment (see "*Note 18—Segment Information*").

The Company's consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). Such consolidated financial statements reflect all adjustments that are, in management's opinion, necessary to present fairly, in all material respects, the Company's consolidated financial position, results of operations, and cash flows. There were no adjustments other than normal recurring adjustments. Certain prior year amounts have been reclassified to conform to the current year presentation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. Actual results could differ from those estimates.

Revenue Recognition

The Company recorded the following revenues for the years ended December 31, 2025, 2024, and 2023 (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Product sales, net	$ 623,151	$ 442,668	$ 324,696
License revenue	243,980	—	—
Collaborative and other revenues	7,706	8,044	6,716
Total revenues	$ 874,837	$ 450,712	$ 331,412

Pursuant to Accounting Standards Codification ("ASC") Topic 606, the Company recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this core principle, Topic 606 includes provisions within a five-step model that includes (i) identifying the contract with a customer, (ii) identifying the performance obligations in the contract, (iii) determining the transaction price, (iv) allocating the transaction price to the performance obligations, and (v) recognizing revenue when, or as, an entity satisfies a performance obligation.

At contract inception, the Company identifies the goods or services promised within each contract, assesses whether each promised good or service is distinct and determines those that are performance obligations. The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied.

Product Sales, Net

The Company's principal sources of product sales are sales of ORLADEYO and sales of peramivir (RAPIVAB/ RAPIACTA/PERAMIFLU) to the Company's licensing partners and to the U.S. Department of Health and Human Services ("HHS"). In the United States, the Company generally ships ORLADEYO directly to patients through a single specialty pharmacy, which is considered its customer. Outside the United States, the Company generally sells ORLADEYO to specialty distributors which are considered its customers.

The Company recognizes revenue when the customer obtains control of the product, which generally occurs upon delivery.

Net revenue from sales of ORLADEYO is recorded at net selling price (transaction price), which includes reserves for variable consideration such as (i) estimated government rebates, such as Medicaid and Medicare Part D reimbursements, and estimated managed care rebates, (ii) estimated chargebacks, (iii) estimated costs of co-payment assistance programs and (iv) product returns. These reserves, representing the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the applicable contracts and statutory requirements, are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable if no payments are required of the Company or a current liability if a payment is required of the Company. Actual amounts of consideration may differ from the Company's estimates. If actual results vary from estimates, these estimates are adjusted, which would affect net product revenue and earnings in the period such variances become known.

Government and Managed Care Rebates. The Company contracts with group purchasing organizations associated with managed care organizations and participates in certain government programs, collectively, third-party payors, so that ORLADEYO will be eligible for purchase by, or partial or full reimbursement from, such third-party payors. The Company estimates the rebates it will provide to third-party payors and deducts these estimated amounts from total gross product revenues at the time the revenues are recognized, resulting in a reduction of product revenue and the establishment of a current liability. The Company estimates the rebates that it will provide to third-party payors based upon (i) the Company's

contracts with these third-party payors, (ii) the contractually mandated discounts applicable to the programs, and (iii) product distribution information obtained from the Company's specialty pharmacy regarding payor mix.

Chargebacks. Chargebacks are discounts that occur when certain contracted customers, pharmacy benefit managers, insurance companies, and government programs purchase directly from the Company's specialty pharmacy. These customers purchase the Company's product under contracts negotiated between them and the Company's specialty pharmacy. The specialty pharmacy, in turn, charges back to the Company the difference between the price that the specialty pharmacy paid and the negotiated price paid by the contracted customers, which may be higher or lower than the specialty pharmacy's purchase price with the Company. The Company estimates chargebacks and adjusts gross product revenues and establishes a current liability at the time revenues are recognized.

Co-payment assistance programs. Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. Based upon the terms of the program and co-payment assistance utilization reports received from the specialty pharmacy, the Company estimates the co-payment assistance amounts, which are recorded in the same period in which the related revenue is recognized, resulting in a reduction of product revenue and establishment of a current liability.

Patient assistance programs. The Company offers a patient assistance program that provides free drug product, for a limited period of time, to allow a patient's insurance coverage to be established. Based on patient assistance program utilization reports provided by the specialty pharmacy, the Company records gross revenue of the product provided and a full reduction of the revenue amount for the free drug discount.

Product returns. The Company does not provide contractual return rights to its customers, except in instances where the product is damaged or defective. Non-acceptance by the patient of shipped drug product by the specialty pharmacy is reflected as a reversal of sales in the period in which the sales were originally recorded. Reserves for estimated non-acceptances by patients are recorded as a reduction of revenue in the period that the related revenue is recognized, as well as a reduction to accounts receivable. Estimates of non-acceptance are based on quantitative information provided by the specialty pharmacy.

License and Collaborative and Other Revenues

The Company has collaboration and license agreements with a number of third parties. The terms of the agreements typically include one or more of the following: upfront license fees; development, regulatory and sales-based milestone payments; and royalties on net sales of licensed products. For agreements with multiple performance obligations, revenue is allocated to each performance obligation based on its relative standalone selling price. The Company uses judgment to identify performance obligations and determine whether variable consideration should be included in the transaction price.

Upfront license fees. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from upfront license fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company determines whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue.

Development, regulatory or commercial milestone payments. At the inception of each arrangement that includes payments based on the achievement of certain development, regulatory and commercial events, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or the customer's control are not considered probable until the milestone is achieved. At the end of each subsequent reporting period, the Company re-evaluates the probability of achieving such development and regulatory milestones and any related constraint, and if necessary, adjusts the Company's estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis and recognized as revenue during the period of adjustment.

Sales-based milestone payments and royalties. For arrangements that include sales-based royalties, including milestone payments based on the volume of sales, the Company determines whether the license is deemed to be the predominant item to which the royalties or sales-based milestones relate and if such is the case, the Company recognizes

revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Cash and Cash Equivalents

The Company considers cash equivalents to be highly liquid investments with maturities of three months or less from the date of purchase.

Restricted Cash

Total restricted cash was $1,601 and $1,610 as of December 31, 2025 and 2024, respectively, and primarily consisted of $1,400 as of December 31, 2025 and 2024, for a letter of credit the Company is required to maintain associated with its Birmingham lease. The letter of credit associated with the Birmingham lease of $1,400 is reflected within other assets in the Consolidated Balance Sheets as of December 31, 2025 and 2024.

Investments

The Company invests in high credit quality investments in accordance with its investment policy. The objectives of the Company's investment policy are to eliminate or greatly minimize the probability of a loss of principal value, maintain sufficient liquidity to meet cash flow requirements, and earn a competitive level of return. The Company places its excess cash with high credit quality financial institutions to limit the amount of its credit exposure. In accordance with its policy, the Company is able to invest in marketable debt securities that may consist of U.S. Treasury obligations, U.S government agency securities, money market funds, certificates of deposits, and corporate notes and bonds. The Company's investment policy requires it to purchase high-quality marketable securities with a maximum individual maturity of two years and requires an average portfolio maturity of no more than 12 months. Some of the securities in which the Company invests may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, the Company schedules its investments with maturities that coincide with expected cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, the Company does not believe it has a material exposure to interest rate risk arising from its investments. The Company has not realized any significant losses from its investments.

The Company classifies all of its investments as available-for-sale. Available-for-sale investments are reported at fair value at each balance sheet date, and include any unrealized holding gains and losses in accumulated other comprehensive income, unless an unrealized loss is considered to be other than temporary, in which case the unrealized loss is charged to operations. The Company reviews its investments for other than temporary declines in fair value below cost basis at the end of each reporting period and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Factors considered to determine whether an unrealized loss is temporary include whether a decline in fair value below the amortized cost basis is due to credit-related factors or non-credit-related factors, the financial condition and near-term prospects of the Company, and the Company's intent and ability to hold the investment to allow for an anticipated recovery in fair value. A credit-related impairment is recognized as an allowance in the balance sheet with a corresponding adjustment to earnings. Any impairment that is not credit-related is recognized in other comprehensive income, net of applicable taxes unless deemed other than temporary. Realized gains and losses are reflected in interest and other income in the Consolidated Statements of Comprehensive Income (Loss) and are determined using the specific identification method with transactions recorded on a settlement date basis. Investments with original maturities at date of purchase beyond three months and which mature at or less than 12 months from the balance sheet date are classified as current. Investments with a maturity beyond 12 months from the balance sheet date are classified as long-term.

Fair Value Measurements

Assets and liabilities recorded at fair value on a recurring basis in the Consolidated Balance Sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement

date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

Assets measured at fair value on a recurring basis include cash equivalents and investments (See "*Note 4—Investments*"). The carrying amounts reflected in the Consolidated Balance Sheets for cash and cash equivalents, trade receivables, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Trade Receivables

The Company's trade receivables represent amounts due from its customers and partners for product sales and royalties. Trade receivables are generally stated at the invoiced amount with standard payment terms that require payment within 30 to 90 days and do not bear interest.

The Company provides reserves against trade receivables for estimated losses that may result from a customer's inability to pay. Receivables are evaluated to determine if any reserve or allowance should be recorded based on consideration of the current economic environment, expectations of future economic conditions, specific circumstances and the Company's own historical collection experience. Amounts determined to be uncollectible are charged or written-off against the reserve.

Inventory

The Company values its inventory at the lower of cost or estimated net realizable value and classifies inventory based on when consumption or sale of the inventory is expected to occur, either within 12 months from the balance sheet date (short-term) or beyond (long-term). The Company uses an actual cost method and determines the cost of its inventory on a first-in, first-out basis. Raw materials and work-in-process include all inventory costs prior to packaging and labeling, including raw material, active product ingredient, and the drug product. Finished goods include packaged and labeled products.

The Company's inventory is subject to expiration dating. At each reporting date, the Company evaluates the carrying value of its inventory and provides valuation reserves for any estimated excess, obsolete, short-dated or unmarketable inventory. In addition, the Company may experience spoilage of its raw materials and supplies. The Company's determination that a valuation reserve might be required, in addition to the quantification of such reserve, requires it to utilize significant judgment. Additionally, the Company's inventory is subject to strict quality control and monitoring that is performed throughout the manufacturing process, including release of work-in-process to finished goods. In the event that certain batches or units of product do not meet quality specifications, the Company will record a write-down of any potential unmarketable inventory to its estimated net realizable value and record the expense as cost of product in the Consolidated Statements of Comprehensive Income (Loss).

Prior to obtaining initial regulatory approval for an investigational product candidate, the Company expenses costs relating to production of pre-launch inventory as research and development expense in its Consolidated Statements of Comprehensive Income (Loss) in the period incurred. After regulatory approval has been received, the Company capitalizes inventory costs.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Computer equipment and office equipment are depreciated over a life of three years. Laboratory equipment, software, and furniture and fixtures are depreciated over a life of five years. Leasehold improvements are amortized over their estimated useful lives or the expected lease term, whichever is less. Construction in progress reflects amounts incurred for construction or improvements of property and equipment that have not been placed in service.

The Company periodically reviews its property and equipment for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are

written down to their estimated fair values. Property and equipment to be disposed of are reported at the lower of carrying amount or fair value less cost to sell.

Accrued Expenses

The Company enters into contractual agreements with third-party vendors who provide research and development, manufacturing, distribution, and other services in the ordinary course of business. Some of these contracts are subject to milestone-based invoicing, and services are completed over an extended period of time. The Company records liabilities under these contractual commitments when it determines an obligation has been incurred, regardless of the timing of the invoice. This process involves reviewing open contracts and purchase orders, communicating with applicable Company personnel to identify services that have been performed on its behalf and estimating the actual work completed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of actual cost. The majority of service providers invoice the Company monthly in arrears for services performed. The Company estimates accrued expenses as of each balance sheet date based on the facts and circumstances known at that time, which can include assumptions such as expected patient enrollment, site activation and estimated project duration. The Company accrues expenses for clinical trial activities based on the estimates of services received pursuant to contracts with multiple research institutions and clinical research organizations ("CROs") that conduct and manage clinical trials on the Company's behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones.

The Company periodically confirms the accuracy of its estimates with the service providers and makes adjustments if necessary. Examples of estimated accrued expenses include (i) fees paid to CROs in connection with preclinical and toxicology studies and clinical trials; (ii) fees paid to investigative sites in connection with clinical trials; (iii) fees paid to contract manufacturers in connection with the production of the Company's raw materials, drug substance, drug products, and product candidates; and (iv) professional fees. If the Company underestimates or overestimates the level of these costs, actual expenses could differ from such estimates.

Cost of Product Sales

Cost of product sales includes the cost of producing inventory that is related to product revenue during the respective period. Cost of product sales also includes costs related to excess or obsolete inventory adjustment charges.

Research and Development Expenses

Research and development expenses include all direct and indirect expenses relating to research and development activities, including costs associated with product development efforts, preclinical trials, clinical trials and manufacturing activities. Research and development expenses are expensed as incurred. Most of the Company's clinical and preclinical studies are performed by third-party CROs. Costs for studies performed by CROs are accrued based upon estimates of the actual work completed in accordance with the third-party agreements. Advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are expensed when the related goods are delivered or the related services are performed.

Direct expenses consist of compensation for research and development personnel and costs of outside parties to conduct laboratory studies, develop manufacturing processes and manufacture the product candidate, conduct and manage clinical trials, as well as other costs related to the Company's clinical and preclinical studies. Additionally, direct expenses consist of those costs necessary to discontinue and close out a development program, including termination fees and other commitments. Indirect expenses consist of lab supplies and services, facility expenses, depreciation of development equipment and an allocation of general and administrative overhead costs that support the Company's research and development efforts.

Selling, General and Administrative Expenses

Selling, general and administrative expenses are comprised of sales and marketing expenses and general and administrative expenses. Sales and marketing expenses include compensation, benefits, and related costs associated with sales and marketing personnel, safety, regulatory, manufacturing, and distribution activities related to marketed products, market research, marketing, medical affairs, market access, and advertising costs. Advertising costs related to

ORLADEYO of $13,824, $13,566 and $14,404 were expensed as incurred for the years ended December 31, 2025, 2024 and 2023, respectively.

General and administrative expenses include compensation, benefits, and related costs associated with general and administrative personnel, quality activities related to marketed products, finance, human resources, information technology, and legal expenses, licenses and other administrative costs, including transaction-related costs. All patent related costs are expensed to general and administrative expenses when incurred as recoverability of such expenditures is uncertain.

Leases

The Company leases certain assets under operating and finance leases, which consist of real estate leases, laboratory equipment leases and office equipment leases as of December 31, 2025. The Company determines whether a contract is, or contains, a lease at inception. The Company accounts for lease obligations in accordance with ASU 2016-02: *Leases (Topic 842)*, which requires a lessee to recognize a right-of-use asset and a lease liability in its balance sheet for most leases. The Company elected the practical expedient that exempts leases with an initial lease term of twelve months or less, as well as the practical expedient that allows companies to select, by class of underlying asset, not to separate lease and non-lease components.

Certain of the Company's operating leases provide for renewal options, which can vary by lease. The right-of-use asset and lease liabilities in the Company's Consolidated Balance Sheets represent payments over the lease term, which include renewal options for certain real estate leases that the Company is reasonably certain to exercise. Certain operating leases include rent escalation provisions, which the Company recognizes as expense on a straight-line basis. Lease expense for leases with an initial term of twelve months or less was not material.

The discount rate used to determine the Company's right-of-use asset and lease liability is the Company's incremental borrowing rate on a collateralized basis over a similar term and amount in a similar economic environment, as generally an implicit rate in the lease is not readily determinable.

The Company has not made any residual value guarantees related to its leases; therefore, the Company has no corresponding liability recorded in its Consolidated Balance Sheets.

Stock-Based Compensation

All share-based payments, including grants of stock option awards and restricted stock unit awards, are recognized in the Company's Consolidated Statements of Comprehensive Income (Loss) based on their fair values. Stock-based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period of the award. Determining the appropriate fair value model and the related assumptions for the model requires judgment, including estimating the stock price volatility and the expected term. The Company utilizes the Black-Scholes option-pricing model or binomial lattice model to value its stock option awards. The Company reduces stock-based compensation expense for estimated forfeitures. The estimation of share-based payment awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from the Company's current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised. Actual results, and future changes in estimates, may differ substantially from the Company's current estimates.

Debt

Costs directly associated with term loan borrowings were capitalized and netted against the corresponding debt liabilities in the Consolidated Balance Sheets. These costs were amortized to interest expense over the terms of the corresponding borrowings using the effective interest rate method. When utilizing the effective interest method, in periods in which payment-in-kind ("PIK") interest was designated and added to the outstanding principal balance of the borrowing, the amortization of the deferred debt fees and issuance costs was accretive.

Royalty Financing Obligations

The royalty financing obligations are eligible to be repaid based on royalties from net sales of ORLADEYO. Interest expense is accrued using the effective interest rate method over the estimated period each of the related liabilities will be paid. This requires the Company to estimate the total amount of future royalty payments to be generated from product sales over the life of the agreements. The Company imputes interest on the carrying value of each of the royalty financing

obligations and records interest expense using an imputed effective interest rate. The Company reassesses the expected royalty payments each reporting period and accounts for any changes through adjustments to the effective interest rates on a prospective basis. The assumptions used in determining the expected repayment terms of the debt and amortization periods of the issuance costs require that the Company make estimates that could impact the carrying values of each of the liabilities, as well as the periods over which associated issuance costs will be amortized. A significant increase or decrease in forecasted net sales could materially impact each of the liability balances, interest expense and the time periods for repayment.

Income Taxes

The liability method is used in the Company's accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse.

Significant management judgment is required in determining the Company's provision for income taxes, deferred tax assets and liabilities and any valuation allowance recorded against net deferred tax assets. The Company has recorded a valuation allowance against substantially all potential tax assets, due to uncertainties in its ability to utilize deferred tax assets, primarily consisting of certain net operating losses carried forward, before they expire. The valuation allowance is based on estimates of future earnings in each of the jurisdictions in which the Company operates and the period over which its deferred tax assets will be recoverable.

The Company accounts for uncertain tax positions in accordance with U.S. GAAP. Uncertain tax positions are recorded based upon certain recognition and measurement criteria. The Company re-evaluates uncertain tax positions and considers various factors, including, but not limited to, changes in tax law and the measurement of tax positions taken or expected to be taken in tax returns. The Company adjusts the amount of the liability to reflect any subsequent changes in the relevant facts and circumstances surrounding the uncertain tax positions. The Company recognizes interest and penalties related to income tax matters in income tax expense.

The Company accrues for U.S. state taxes and foreign income taxes for jurisdictions where the Company has presence and nexus has been established.

Research and development costs are capitalized and amortized over a 15-year period in accordance with Section 174 of the Internal Revenue Code of 1986, as amended ("IRC"). The amortization period begins with the midpoint of any taxable year that IRC Section 174 costs are first incurred, regardless of whether the expenditures were made prior to or after July 1, and runs until the midpoint of year sixteen.

Certain countries in which the Company has operations have adopted legislation influenced by the Organization for Economic Cooperation and Development ("OECD") Pillar Two rules, including a minimum tax rate of 15%. It is uncertain whether the U.S. will enact legislation to adopt the Pillar Two framework. While the Company is currently not within the scope of the rules, it is continuing to review and evaluate additional guidance released by the OECD, along with the pending legislative adoption by additional individual countries where the Company operates.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law, making permanent certain provisions of the Tax Cuts and Jobs Act, including permanent 100% bonus depreciation, expensing of domestic research costs, and amendments to the business interest expense limitation. In accordance with ASC Topic 740, Income Taxes, the Company recognized the effects of the new tax law in the period of enactment. As the Company maintains a full valuation allowance on its U.S. federal deferred tax assets, the legislation did not have a material impact on its consolidated financial statements for the year ended December 31, 2025.

Foreign Currency

The functional currency of each of the Company's foreign subsidiaries is primarily the local currency of the country in which the subsidiary operates. The Company's asset and liability accounts are translated at the current exchange rate as of the balance sheet date. Revenue and expense accounts are translated at the average exchange rate over the period. Adjustments resulting from the translation of the financial statements of the Company's foreign subsidiaries into U.S. dollars are accumulated as a separate component of stockholders' equity within accumulated other comprehensive income. Gains or losses resulting from transactions denominated in foreign currencies are included in foreign currency losses, net, within the Consolidated Statement of Comprehensive Income (Loss).

Net Income (Loss) Per Share

Basic net income (loss) per share is based upon the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is based upon the weighted average number of common shares outstanding and potentially dilutive common shares during the period as determined by using the treasury stock method. Potential common equivalent shares are excluded if their effect is anti-dilutive.

Accumulated Other Comprehensive Income

Accumulated other comprehensive income is comprised of cumulative foreign currency translation adjustments and unrealized gains and losses on available-for-sale investments and is disclosed as a separate component of stockholders' equity. Realized gain and loss amounts on available-for-sale investments are reclassified from accumulated other comprehensive income and recorded as interest and other income in the Consolidated Statements of Comprehensive Income (Loss). There were no realized gains or losses reclassified out of accumulated other comprehensive income for the years ended December 31, 2025, 2024 and 2023.

Significant Customers and Other Risks

Significant Customers

The Company's primary sources of revenue and cash flow are the sales of ORLADEYO in the United States and license revenue related to the sale of the Company's European ORLADEYO business to Neopharmed Gentili S.p.A. (see "*Note 2—Divestiture of BioCryst Ireland Limited* ") for the year ended December 31, 2025.

ORLADEYO is generally distributed through an arrangement with a single specialty pharmacy in the United States. The specialty pharmacy subsequently sells ORLADEYO to its customers (pharmacy benefit managers, insurance companies, government programs and group purchasing organizations) and dispenses product to patients. Peramivir is also generally distributed through the same specialty pharmacy in the United States. The specialty pharmacy's inability or unwillingness to continue these distribution activities could adversely impact the Company's business, results of operations and financial condition. Product revenue where the specialty pharmacy is considered the customer was approximately 88%, 87%, and 89% of total product sales for the years ended December 31, 2025, 2024, and 2023, respectively. The Company is distributing ORLADEYO in other global markets directly or through other parties.

Risks from Third-Party Manufacturing and Distribution Concentration

The Company relies on a single source manufacturer for active pharmaceutical ingredient and finished drug product manufacturing of product candidates in development and on a single specialty pharmacy for distribution of approved drug product in the United States. Delays or disruption in the manufacture or distribution of any product could adversely impact the future procurement stockpiling of the Company's commercial product, commercial revenue and product candidates.

Further, the Company's drug development activities are performed by a limited group of third-party vendors. If any of these vendors were unable to perform its services, this could significantly impact the Company's ability to complete its drug development activities.

Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash and cash equivalents, investments, and accounts receivable. The Company maintains its cash and cash equivalents with high-credit quality financial institutions in the United States. Such amounts may exceed federally-insured limits. The Company believes it has established guidelines for investment of its excess cash relative to diversification and maturities that maintain safety and liquidity. To minimize the exposure due to adverse shifts in interest rates, the Company maintains a portfolio of investments with an average maturity of approximately 12 months or less.

The Company's receivables from sales of ORLADEYO are primarily due from one customer, resulting in a concentration of credit risk.

Recently Adopted Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board ("FASB") issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires public entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company adopted ASU 2023-09 as of January 1, 2025. The adoption of this standard resulted in additional disclosures but did not have a material effect on the Company's consolidated balance sheet, statement of comprehensive income (loss), or statement of cash flows (see "*Note 14—Income Taxes*").

New Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires public entities, on an annual and interim basis, to provide disaggregated disclosure of certain income statement expenses into specified categories within the footnotes to the financial statements. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2024-03 will have on its disclosures. The Company does not expect the adoption of this ASU to have a material effect on its consolidated balance sheet, statement of comprehensive income (loss), or statement of cash flows.

In September 2025, the FASB issued ASU 2025-06, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software, which clarifies and modernizes the accounting for costs related to internal-use software, eliminating references to project stages and clarifying the threshold entities apply to begin capitalizing costs. ASU 2025-06 is effective for fiscal years beginning after December 15, 2027, and interim periods within those annual reporting periods, with early adoption permitted. The Company plans to early adopt ASU 2025-06 as of January 1, 2026. The Company does not expect the adoption of this ASU to have a material effect on its consolidated balance sheet, statement of comprehensive income (loss), or statement of cash flows.

The Company does not expect any other recently issued accounting standards to have a material impact to its financial statements or disclosures.

Note 2— Divestiture of BioCryst Ireland Limited

On June 27, 2025, the Company entered into a definitive agreement (the "Stock Purchase Agreement") with BioCryst Ireland Limited ("BioCryst Ireland"), a wholly owned subsidiary that operates the European ORLADEYO business, and Neopharmed Gentili S.p.A. ("Neopharmed"). On October 1, 2025 (the "Closing"), under the terms of the Stock Purchase Agreement, the Company sold to Neopharmed all of its equity interests in BioCryst Ireland, which, together with its subsidiaries, held certain assets, rights, and employees related to the Company's European ORLADEYO business.

Concurrent with the Closing of the transactions contemplated by the Stock Purchase Agreement, on October 1, 2025, the Company and BioCryst Ireland amended and restated their existing intellectual property licence agreement pursuant to which the Company will continue to grant to BioCryst Ireland certain commercialization, manufacturing, and development rights with respect to ORLADEYO in the Territory, as defined in the Stock Purchase Agreement (the "Amended and Restated IP Licence Agreement"). The Company retains ownership and control of the underlying intellectual property. The terms of the Amended and Restated IP Licence Agreement also extend to the pediatric line extension of ORLADEYO, subject to certain regulatory approvals.

At the Closing, the Company received total cash proceeds of $254,477, comprised of the purchase price of $250,000 and customary purchase price adjustments of $4,477 as set forth in the Stock Purchase Agreement. In addition, Neopharmed will pay the Company up to $14,000 if certain revenue milestones are achieved prior to December 31, 2032. Concurrent with the Closing, Neopharmed also paid a $15,000 royalty release fee to RPI 2019 Intermediate Finance Trust on the Company's behalf. Pursuant to the Amended and Restated IP Licence Agreement, the Company is entitled to receive quarterly royalty payments from BioCryst Ireland equal to amounts owed under its Royalty Purchase Agreements with RPI and OMERS for the sale of ORLADEYO products in the Territory (See "*Note 9— Royalty Financing Obligations").*

In connection with the Closing, on October 1, 2025, the Company entered into the following additional agreements with BioCryst Ireland:

- a supply agreement, pursuant to which the Company will be the exclusive supplier of ORLADEYO products to BioCryst Ireland for commercialization in the Territory (the "Supply Agreement");

- a global brand and support agreement, which provides for coordination of brand and regulatory activities between the Company and BioCryst Ireland regarding ORLADEYO products (the "Global Brand and Support Agreement");

- a mutual transition services agreement, pursuant to which the Company and BioCryst Ireland will provide each other with certain transition services for the periods of time and for the compensation set forth under the agreement, on customary commercial terms (the "Transition Services Agreement"); and

- a trademark license agreement, pursuant to which the Company granted to BioCryst Ireland a non-exclusive transitionary license to use the "BioCryst" name, solely to develop, manufacture and commercialize ORLADEYO products in the Territory for a limited period of time, and an exclusive license to use the ORLADEYO product name to commercialize ORLADEYO products for such uses for the term of the Amended and Restated IP Licence Agreement, in each case subject to the terms and conditions set forth therein (the "Trademark License Agreement").

The following table summarizes the carrying value of the major classes of assets and liabilities sold (in thousands):

	October 1, 2025
Cash and cash equivalents	$ 14,840
Trade receivables	10,285
Inventory, net	1,965
Prepaid expenses and other current assets	1,902
Non-current assets	4,058
Accounts payable	(1,714)
Accrued expenses	(24,371)
Other current liabilities	(338)
Non-current liabilities	(436)
Net assets sold	$ 6,191

The Company accounted for the transaction as (i) a license of intellectual property and (ii) the sale of BioCryst Ireland. The Company recognized $243,271 as "License and other revenues" in the Consolidated Statements of Comprehensive Income (Loss) at Closing related to the license which represents functional intellectual property. The Company will recognize quarterly royalty payments and milestone revenue from the license as the ORLADEYO product sales in the Territory occur. During the three months ended December 31, 2025, the Company recognized $708 related to the first quarterly royalty payment in "License and other revenues" in the Consolidated Statements of Comprehensive Income (Loss).

The Company recognized a gain on sale of $3,566, which is recorded in "Other income" in the Consolidated Statements of Comprehensive Income (Loss). The gain reflects the excess of consideration allocated to BioCryst Ireland over the carrying value of its net assets, together with the release of $1,100 of cumulative translation adjustments upon deconsolidation.

In connection with the transaction, the Company modified certain stock option awards and restricted stock unit awards held by employees who transferred to Neopharmed. The modifications allowed previously unvested awards to continue to vest and extended the post-termination exercise periods for certain vested stock option awards, subject to the employees' continued service to Neopharmed. These post-close services benefit Neopharmed and the incremental fair value conveyed through the modified awards represents consideration payable to Neopharmed and was recognized as contra-revenue when the revenue related to the license of intellectual property was recognized at Closing (see "*Note 13—Stock-Based Compensation*").

The European ORLADEYO business was not considered a discontinued operation under ASC 205-20, as it did not represent a strategic shift that would have a major effect on the Company's operations or financial results. Therefore, the results of operations for the European ORLADEYO business are included in income from continuing operations for all periods presented. BioCryst Ireland and its subsidiaries were classified as held for sale beginning in the second quarter of 2025. The Company no longer maintains any foreign operations or foreign presence in the territories formerly served by BioCryst Ireland following completion of the transaction.

Note 3— Revenue

The Company recorded the following revenues for the years ended December 31, 2025, 2024, and 2023 (in thousands):

	Years Ended December 31,		
	2025	2024	2023
ORLADEYO:			
U.S.	$ 548,779	$ 385,961	$ 288,361
Outside of U.S.	53,060	51,699	37,629
Total ORLADEYO	601,839	437,660	325,990
License revenue	243,980	—	—
Other revenues	29,018	13,052	5,422
Total revenues	$ 874,837	$ 450,712	$ 331,412

ORLADEYO revenues represent total revenues from product sales and royalties. License revenue represents revenue related to the license of intellectual property to Neopharmed (see "*Note 2— Divestiture of BioCryst Ireland Limited"*) and quarterly royalty payments from BioCryst Ireland (see "*Note 9— Royalty Financing Obligations"*). Other revenues primarily relate to the Company's product sales and royalties for peramivir.

No individual country outside of the U.S. exceeded 10% of total revenues for the years ended December 31, 2025, 2024, and 2023.

Note 4— Fair Value Measurements and Investments

Fair Value Measurements

Fair value is an exit price, representing the amount that would be received from the sale of an asset or paid to transfer a liability in an orderly transaction between market participants. Fair value is determined based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect certain market assumptions. As a basis for considering such assumptions, U.S. GAAP establishes a three-tier value hierarchy, which prioritizes the inputs used to develop the assumptions and for measuring fair value as follows: (Level 1) observable inputs such as quoted prices in active markets for identical assets; (Level 2) inputs other than the quoted prices in active markets that are observable either directly or indirectly; and (Level 3) unobservable inputs for which there is little or no market data, which requires the Company to develop its own assumptions. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

Assets measured at fair value on a recurring basis were as follows (in thousands):

	December 31, 2025			
	Quoted Price in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets				
Money market funds	$ 35,800	$ —	$ —	$ 35,800
Obligations of U.S. Government and its agencies	—	246,175	—	246,175
Total assets measured at fair value	$ 35,800	$ 246,175	$ —	$ 281,975

	December 31, 2024			
	Quoted Price in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets				
Money market funds	$ 40,893	$ —	$ —	$ 40,893
Obligations of U.S. Government and its agencies	—	236,460	—	236,460
Total assets measured at fair value	$ 40,893	$ 236,460	$ —	$ 277,353

The Company's investments consist of fixed income securities whose valuations are based on observable direct and indirect inputs, primarily quoted prices of similar, but not identical, instruments in active markets or quoted prices for identical or similar instruments in markets that are not active. These fair values are obtained from independent pricing services.

Investments

The following tables summarize the fair value of the Company's investments by type (in thousands):

	December 31, 2025				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Obligations of U.S. Government and its agencies	$ 244,455	$ 1,491	$ 234	$ (5)	$ 246,175
Total investments	$ 244,455	$ 1,491	$ 234	$ (5)	$ 246,175

	December 31, 2024				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Obligations of U.S. Government and its agencies	$ 234,902	$ 1,121	$ 451	$ (14)	$ 236,460
Total investments	$ 234,902	$ 1,121	$ 451	$ (14)	$ 236,460

As of December 31, 2025, the Company had one security with a total estimated fair value of $20,303 in an unrealized loss position. The Company believes the unrealized loss represents a temporary decline primarily resulting from

interest rate changes. The Company does not have an intent to sell this investment, and it is more likely than not that the investment will be held until recovery of its amortized cost basis. As such, no allowance was recognized.

The following table summarizes the scheduled maturity for the Company's investments at December 31, 2025 and 2024 (in thousands):

	December 31,	
	2025	2024
Maturing in one year or less	$ 185,011	$ 216,137
Maturing after one year through two years	61,164	20,323
Total investments	$ 246,175	$ 236,460

Note 5— Trade Receivables

Product sales

Receivables from product sales are recorded for amounts due to the Company related to sales of ORLADEYO and peramivir. At December 31, 2025 and 2024, receivables, net of reserves, related to sales of ORLADEYO were $92,351 and $76,282, respectively. At December 31, 2025 and 2024, receivables related to sales of peramivir were $10,491 and $564, respectively.

License and other revenue

At December 31, 2025 and 2024, receivables related to license and other revenue were $3,976 and $2,223, respectively.

Note 6— Inventory

At December 31, 2025 and 2024, the Company's inventory related to ORLADEYO and peramivir.

The Company's inventories consisted of the following (in thousands):

	December 31,	
	2025	2024
Raw materials	$ 9,997	$ 10,006
Work-in-process	12,891	16,152
Finished goods	7,275	7,765
Total inventory	30,163	33,923
Reserves	(775)	(2,649)
Total inventory, net	$ 29,388	$ 31,274

Note 7— Property and Equipment

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

	December 31,	
	2025	2024
Furniture and fixtures	$ 1,201	$ 1,463
Office equipment	620	729
Software	326	1,252
Laboratory equipment	5,593	6,222
Leasehold improvements	10,437	10,363
Construction in progress	—	97
Total property and equipment	18,177	20,126
Less accumulated depreciation and amortization	(9,394)	(12,349)
Property and equipment, net	$ 8,783	$ 7,777

Depreciation expense for the years ended December 31, 2025, 2024, and 2023 was $1,389, $1,246, and $1,655, respectively.

During the year ended December 31, 2023, the Company recorded an impairment loss of $1,548 and contract termination fees of $440 related to the discontinuation of the Birmingham research facilities expansion, which was recognized in research and development expenses during the year ended December 31, 2023. The Company did not record any impairment losses during the years ended December 31, 2025 and 2024.

Note 8— Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2025	2024
Compensation and benefits	$ 50,857	$ 48,631
Revenue-related reserves for discounts and allowances	26,632	32,116
Professional fees	11,899	6,637
Research and development costs	10,163	9,198
Inventory	10,002	836
Royalties payable	8,960	14,590
Transaction-related costs	5,480	—
Other	2,420	1,284
Total accrued expenses	$ 126,413	$ 113,292

Note 9— Royalty Financing Obligations

On December 7, 2020, the Company and RPI 2019 Intermediate Finance Trust ("RPI") entered into a Purchase and Sale Agreement (the "2020 RPI Royalty Purchase Agreement"), pursuant to which the Company sold to RPI the right to receive certain royalty payments from the Company for a purchase price of $125,000 in cash. Under the 2020 RPI Royalty Purchase Agreement, RPI is entitled to receive tiered, sales-based royalties on net product sales of ORLADEYO in the United States and certain key European markets (collectively, the "Key Territories"), and other markets where the Company sells ORLADEYO directly or through distributors (collectively, the "Direct Sales") in an amount equal to: (i) 8.75% of aggregate annual net sales of ORLADEYO for annual net sales up to $350,000 and (ii) 2.75% of annual net sales for annual net sales between $350,000 and $550,000. No royalty payments are payable on annual Direct Sales over $550,000.

Under the 2020 RPI Royalty Purchase Agreement, RPI is also entitled to receive a tiered revenue share on ORLADEYO sublicense revenue or net sales by licensees outside of the Key Territories (the "Other Markets") equal to: (i) 20% of the proceeds received by the Company for upfront license fees and development milestones for ORLADEYO in the Other Markets, (ii) 20% of proceeds received on annual net sales of up to $150,000 in the Other Markets, and (iii) 10% of proceeds received by the Company on annual net sales between $150,000 and $230,000 in the Other Markets. No royalty payments are payable on annual net sales above $230,000 in the Other Markets.

On November 19, 2021, the Company and RPI entered into (i) a Purchase and Sale Agreement (the "2021 RPI Royalty Purchase Agreement" and together with the 2020 RPI Royalty Purchase Agreement, the "RPI Royalty Purchase Agreements"), pursuant to which the Company sold to RPI the right to receive certain royalty payments from the Company for a purchase price of $150,000 in cash, and (ii) a Purchase and Sale Agreement with OCM IP Healthcare Holdings Limited, an affiliate of OMERS Capital Markets ("OMERS") (the "OMERS Royalty Purchase Agreement" and collectively with the RPI Royalty Purchase Agreements, the "Royalty Purchase Agreements"), pursuant to which the Company sold to OMERS the right to receive certain royalty payments from the Company for a purchase price of an additional $150,000 in cash.

Under the 2021 RPI Royalty Purchase Agreement, RPI is entitled to receive tiered, sales-based royalties on Direct Sales in an amount equal to: (i) 0.75% of aggregate annual net sales of ORLADEYO for annual net sales up to $350,000 and (ii) 1.75% of annual net sales of ORLADEYO for annual net sales between $350,000 and $550,000. No royalty payments are payable on Direct Sales over $550,000. RPI is also entitled to receive a tiered revenue share on ORLADEYO sublicense revenue or net sales by licensees in the Other Markets in an amount equal to (i) 3.0% of proceeds received by the Company on annual net sales of up to $150,000 in the Other Markets and (ii) 2.0% of proceeds received by the Company on annual net sales between $150,000 and $230,000 in the Other Markets. No royalty payments are payable on annual net sales above $230,000 in the Other Markets.

The royalties payable under the 2021 RPI Royalty Purchase Agreement are in addition to the royalties payable to RPI under the 2020 RPI Royalty Purchase Agreement.

Concurrent with entering into the 2021 RPI Royalty Purchase Agreement, the Company and RPI entered into a Common Stock Purchase Agreement pursuant to which the Company sold common stock to RPI for a premium of $4,269. The premium was deferred and is being amortized through interest expense using the effective interest method over the term of the applicable arrangement.

Under the OMERS Royalty Purchase Agreement, for the calendar quarter beginning October 1, 2023, OMERS was entitled to receive tiered, sales-based royalties on Direct Sales in an amount equal to: (i) 7.5% of aggregate annual net sales of ORLADEYO for annual net sales up to $350,000 and (ii) 6.0% of annual net sales of ORLADEYO for annual net sales between $350,000 and $550,000 (with no royalty payments payable on annual Direct Sales over $550,000). Commencing with the calendar quarter beginning January 1, 2024, OMERS is entitled to receive tiered, sales-based royalties on Direct Sales in an amount equal to: (i) 10.0% of aggregate annual net sales of ORLADEYO for annual net sales up to $350,000 and (ii) 3.0% of annual net sales of ORLADEYO for annual net sales between $350,000 and $550,000 (with no royalty payments payable on annual Direct Sales over $550,000).

Under the OMERS Royalty Purchase Agreement, OMERS is also entitled to receive a tiered revenue share on ORLADEYO sublicense revenue or net sales by licensees in the Other Markets in an amount equal to: (i) 20.0% of the proceeds received by the Company for upfront license fees and development milestones for ORLADEYO in the Other Markets, (ii) 20.0% of proceeds received by the Company on annual net sales of up to $150,000 in the Other Markets, and (iii) 10.0% of proceeds received by the Company on annual net sales between $150,000 and $230,000 in the Other Markets. No royalty payments are payable on annual net sales above $230,000 in the Other Markets. OMERS is also entitled to receive profit share amounts of up to 10% from certain other permitted sales in certain other markets.

Under the 2020 RPI Royalty Purchase Agreement, the Company is required to make royalty payments of amounts owed to RPI each calendar quarter following the first commercial sale of ORLADEYO in any country. Under the 2021 RPI Royalty Purchase Agreement, the Company is required to make payments to RPI in respect of net sales or sublicense revenue in each calendar quarter from and after October 1, 2021. Under the OMERS Royalty Purchase Agreement, the Company is required to make payments to OMERS in respect of net sales or sublicense revenue in each calendar quarter from and after October 1, 2023. OMERS will no longer be entitled to receive any payments on the date in which aggregate payments actually received by OMERS equals 155.0% of the $150,000 purchase price.

The transactions contemplated by each of the Royalty Purchase Agreements are referred to herein as the "Royalty Sales".

Under the Royalty Purchase Agreements, the Company has agreed to specified affirmative and negative covenants, including covenants regarding periodic reporting of information by the Company to RPI and OMERS, third-party audits of royalties paid under the Royalty Purchase Agreements, and restrictions on the ability of the Company or any of its subsidiaries to incur indebtedness other than certain royalty sales and as was permitted to be incurred under the terms of the Athyrium Credit Agreement (as defined in Note 10 herein) through its payoff and termination on April 17, 2023 or, subsequent to that date, the Pharmakon Loan Agreement (as defined in Note 10 herein), as applicable. See "*Note 10—Debt*" for further details on the Athyrium Credit Agreement and the Pharmakon Loan Agreement. The restrictions under the Royalty Purchase Agreements on the ability of the Company or any of its subsidiaries to incur indebtedness are eliminated after the achievement of certain specified milestones in the Royalty Purchase Agreements.

In connection with the Stock Purchase Agreement, RPI and OMERS provided their written consent of the consummation of the sale of the Company's European ORLADEYO business. Concurrent with the Closing, Neopharmed paid a $15,000 royalty release fee to RPI on behalf of the Company, which is included in "License and other revenues" in the Consolidated Statements of Comprehensive Income (Loss), and the Company paid a $500 royalty release fee to OMERS. The payments were accounted for as a debt modification and the royalty release fees, totaling $15,500, were capitalized as a reduction to "Royalty financing obligations" in the Consolidated Balance Sheets and are being amortized as interest expense using the effective interest rate method. In accordance with the Stock Purchase Agreement, the Company will receive quarterly royalty payments from BioCryst Ireland equal to amounts owed under its Royalty Purchase Agreements with RPI and OMERS for the sale of ORLADEYO products in the Territory, which are recognized as "License and other revenues" in the Consolidated Statements of Comprehensive Income (Loss). See "*Note 2—Divestiture of BioCryst Ireland Limited*" for additional information on the sale of the Company's European ORLADEYO business.

The cash consideration obtained pursuant to the Royalty Purchase Agreements is recorded in "Royalty financing obligations" in the Company's Consolidated Balance Sheets. Deferred financing costs, which consisted primarily of advisory and legal fees, were capitalized as a reduction to "Royalty financing obligations" and are being amortized using the effective interest method over the terms of the arrangements. The fair values of the royalty financing obligations at the time of the transactions were based on the Company's estimates of future royalties expected to be paid to the counterparties over the terms of the arrangements. The Company subsequently records the obligations at their carrying values using the effective interest method. As of December 31, 2025 and 2024, the carrying values of the royalty financing obligations under the Royalty Purchase Agreements approximated their fair values and were measured based on the Company's current estimates of future payments to RPI and OMERS over the lives of the agreements, which are considered Level 3 inputs. The Company utilizes the prospective method to account for subsequent changes in the estimated future royalties to be paid by the Company to the counterparties over the lives of the arrangements. Under the prospective method, new effective interest rates are determined based on the revised estimates of future cash flows. The new effective interest rates are the discount rates that equate the present value of the revised estimates of remaining cash flows with the carrying amounts of the royalty financing obligations and will be used to recognize interest expense for the remaining periods. The Company periodically assesses the amount and timing of expected royalty payments using internal projections of future net product sales, which are based on key assumptions, including paid patients and price. To the extent such payments are greater or less than the Company's initial estimates or the timing of such payments is materially different than its original estimates, the Company will prospectively adjust the amortization of the royalty financing obligations and the effective interest rates. On a quarterly basis, the Company assesses the projected royalty payments relative to the projected interest accretion for the next twelve months to determine if the royalty liability balances are reduced relative to the current outstanding liabilities. In such case of excess payments relative to interest accretion for the next twelve months, the excess payments are considered to be a short-term liability and classified within current liabilities in the Company's Consolidated Balance Sheets.

During the year ended December 31, 2025, there were no significant changes to the amount and timing of expected royalties under the Royalty Purchase Agreements based on the Company's latest forecasts related to ORLADEYO sales.

The following table shows the royalty financing obligations activity for the years ended December 31, 2025, 2024, and 2023 (in thousands) as well as the effective interest rate as of December 31, 2025:

	2020 RPI Royalty Agreement	2021 RPI Royalty Agreement	OMERS Royalty Agreement	Total
Balance as of December 31, 2022	$ 164,981	$ 173,651	$ 163,023	$ 501,655
Non-cash interest expense on royalty financing obligations	38,267	14,188	17,901	70,356
Royalty revenues paid and payable	(28,768)	(2,494)	(9,150)	(40,412)
Balance as of December 31, 2023	$ 174,480	$ 185,345	$ 171,774	$ 531,599
Non-cash interest expense on royalty financing obligations	39,585	—	16,384	55,969
Royalty revenues paid and payable	(33,652)	(4,205)	(35,982)	(73,839)
Balance as of December 31, 2024	$ 180,413	$ 181,140	$ 152,176	$ 513,729
Non-cash interest expense on royalty financing obligations	39,240	—	13,923	53,163
Royalty revenues paid and payable	(37,267)	(6,296)	(42,141)	(85,704)
Payment of royalty release fees	(12,827)	(2,173)	(500)	(15,500)
Balance as of December 31, 2025	$ 169,559	$ 172,671	$ 123,458	$ 465,688
Effective interest rate	23.4%	—%	10.3%	

Cash paid for interest on the royalty financing obligations was $68,428, $77,155, and $29,337 for the years ended December 31, 2025, 2024, and 2023, respectively.

Note 10—Debt

Pharmakon Loan Agreement

On April 17, 2023, the Company entered into a $450,000 Loan Agreement (the "Pharmakon Loan Agreement") with BioPharma Credit Investments V (Master) LP and BPCR Limited Partnership, as lenders, and BioPharma Credit PLC, as collateral agent for the lenders. Certain of the Company's wholly-owned subsidiaries were guarantors to the Pharmakon Loan Agreement. The Pharmakon Loan Agreement provided for an initial term loan in the principal amount of $300,000 (the "Tranche A Loan") funded on April 17, 2023 (the "Tranche A Closing Date"). The Company used a portion of the proceeds from the Tranche A Loan to repay the $241,787 of outstanding indebtedness (principal and interest due as of April 17, 2023) under the then-existing Athyrium Credit Agreement (defined below) and to pay associated transaction costs and fees, and used the remaining net proceeds of $25,805 for other general corporate purposes.

The Pharmakon Loan Agreement also provided for three additional term loan tranches, at the Company's option, in principal amounts of $50,000 each (each a "Subsequent Tranche Loan" and, collectively with the Tranche A Loan, the "Pharmakon Term Loans" and each, a "Pharmakon Term Loan"). The Company chose not to request any Subsequent Tranche Loans and the options have since expired. The maturity date of the Pharmakon Loan Agreement was April 17, 2028 (the "Maturity Date"), the fifth anniversary of the Tranche A Closing Date.

The Pharmakon Loan Agreement provided for quarterly interest-only payments until the Maturity Date, with the unpaid principal amount of the outstanding Pharmakon Term Loans due and payable on the Maturity Date. During the first 18 months following the Tranche A Closing Date, the Company had the option to make a portion of the applicable interest payment on the Tranche A Loan in-kind (a "Pharmakon PIK Interest Payment") by capitalizing as principal up to 50% of the amount of interest accrued on the Tranche A Loan during the applicable interest period. The Pharmakon Term Loans bore interest at a rate equal to the three-month Secured Overnight Financing Rate ("SOFR"), which could be no less than 1.75%, plus 7.00%, per annum or, for each interest period in which a Pharmakon PIK Interest Payment was made, with respect to the Tranche A Loan, SOFR plus 7.25%, per annum.

The Tranche A Loan accrued interest at an effective interest rate of 12.27% during the period in which the debt was outstanding for the year ended December 31, 2025, compared to 13.14% and 13.30% for the years ended December 31, 2024 and 2023, respectively.

The Pharmakon Loan Agreement also contained representations and warranties and affirmative and negative covenants customary for financings of this type, as well as customary events of default.

In 2025, the Company paid off in full the outstanding principal balance on the Pharmakon Term Loan in three separate prepayments totaling $323,704. In accordance with the Pharmakon Loan Agreement, the voluntary prepayments were subject to a prepayment premium equal to 3.00% of the principal amount of the Pharmakon Term Loan being prepaid. As a result, the Company incurred $9,711 and $173 in prepayment premiums and fees, respectively. Additionally, unamortized deferred financing costs of $7,448 associated with the Pharmakon Term Loan were written-off at the time of the repayments. Collectively, the prepayment premiums, fees, and unamortized deferred financing costs totaled $17,332 and are reflected as a one-time loss on extinguishment of debt in the Consolidated Statements of Comprehensive Income (Loss) for the year ended December 31, 2025.

Interest expense and on the Tranche A Loan for the year ended December 31, 2025 was $23,274 and quarterly interest payments were paid at the end of each quarterly period.

As of December 31, 2024, the Company had total borrowings of $300,000 under the Pharmakon Loan Agreement. Interest expense on the Tranche A Loan for the year ended December 31, 2024 was $39,874. As allowable under the Pharmakon Loan Agreement, the Company designated and accounted for 50% of the quarterly interest payments for each of the three months ended March 31, 2024 and June 30, 2024 as a Pharmakon PIK Interest Payment and the total amount of $10,041 was added to the outstanding principal balance of the borrowing. The remaining 50% of the total quarterly interest payments for the three months ended March 31, 2024 and June 30, 2024 and the full quarterly interest payments for the three months ended September 30, 2024 and December 31, 2024 totaling $29,833 in aggregate was paid at the end of each quarterly period. As of December 31, 2024, borrowings, including the Pharmakon PIK Interest Payments, totaled $323,704.

As of December 31, 2023, the Company had total borrowings of $300,000 under the Pharmakon Loan Agreement. Interest expense on the Tranche A Loan for the year ended December 31, 2023 was $27,326. As allowable under the Pharmakon Loan Agreement, the Company designated and accounted for 50% of the quarterly interest payments for the year ended December 31, 2023 as a Pharmakon PIK Interest Payment and the total amount of $13,663 was added to the outstanding principal balance of the borrowing. The remaining 50% of the total quarterly interest payments of $13,663 was paid at the end of each quarterly period. As of December 31, 2023, borrowings, including the Pharmakon PIK Interest Payments, totaled $313,663.

The fair value of the debt approximated its carrying value based on prevailing interest rates as of the balance sheet date and was considered as Level 2 in the fair value hierarchy.

Debt fees and issuance costs incurred with the Tranche A Loan under the Pharmakon Loan Agreement totaled $11,147 and were deferred and amortized as interest expense on an effective interest rate method over the term of the Tranche A Loan. Deferred financing amortization of $1,387, $1,597, and $715 was recognized for the years ended December 31, 2025, 2024, and 2023, respectively.

Athyrium Credit Agreement

On December 7, 2020, the Company entered into a $200,000 Credit Agreement (the "Athyrium Credit Agreement") with Athyrium Opportunities III Co-Invest 1 LP ("Athyrium"), as lender and as administrative agent for the lenders. Certain of the Company's direct and indirect subsidiaries were guarantors to the Athyrium Credit Agreement. The Athyrium Credit Agreement provided for an initial term loan in the principal amount of $125,000 (the "Term A Loan"), which was received by the Company on December 7, 2020.

The Athyrium Credit Agreement also provided for two additional term loans, at the Company's option, in the respective principal amounts of $25,000 (the "Term B Loan") and $50,000 (the "Term C Loan" and, collectively with the Term A Loan and the Term B Loan, the "Athyrium Term Loans"). Having achieved all required revenue-based milestones, the Company exercised its option to draw upon the additional funding available under the Athyrium Credit Agreement, borrowing the principal amounts of $25,000 under the Term B Loan and $50,000 under the Term C Loan. Both the Term B Loan and the Term C Loan were funded on July 29, 2022 in the aggregate principal amount of $75,000. The Company

incurred deferred debt fees and issuance costs associated with the Term B and Term C Loans of $3,428. The Term B Loan and the Term C Loan were subject to all the provisions under the Athyrium Credit Agreement.

The Athyrium Term Loans accrued interest at an effective interest rate of 13.71% during the period in which the debt was outstanding for the year ended December 31, 2023.

Quarterly interest payments under the Athyrium Credit Agreement for the year ended December 31, 2023 totaled $8,476. Deferred financing amortization of $1,069 was recognized for the year ended December 31, 2023.

On April 17, 2023, the outstanding principal of the Athyrium Term Loans, including the Athyrium PIK Interest Payments of $240,452 along with interest accrued of $1,335 for the first 17 days of the quarterly interest period ended June 30, 2023, was repaid with the funding received through the Pharmakon Loan Agreement.

In accordance with the Athyrium Credit Agreement, upon the prepayment or repayment of all or any of the Athyrium Term Loans, the Company was obligated to pay an exit fee in an amount equal to 2.00% of the principal amount of the Athyrium Term Loans prepaid or repaid. In addition, each Athyrium Term Loan was subject to a 1.00% commitment fee at its respective borrowing date. As a result, the Company incurred prepayment and final payment fees of $17,261 upon repayment of the Athyrium Term Loans. Additionally, unamortized deferred financing costs of $11,758 associated with the Athyrium Term Loans were written off at the time of repayment. Collectively, the prepayment and final payment fees and unamortized deferred financing costs totaled $29,019 and are reflected as a one-time loss on extinguishment of debt in the Consolidated Statements of Comprehensive Income (Loss) for the year ended December 31, 2023.

Note 11— Lease Obligations

The Company leases certain assets under operating leases, which primarily consist of real estate leases, and finance leases, which generally consist of laboratory equipment leases and office equipment leases. The Company's real estate agreements expire at various times between 2026 through 2033 and include renewal options that range from three to five years in length.

Lease expense under operating and finance leases was as follows (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Operating lease expense	$ 2,007	$ 2,301	$ 2,018
Finance lease expense:			
Amortization of right-of-use assets	2,099	1,766	1,212
Interest on lease liabilities	340	316	201
Total finance lease expense	$ 2,439	$ 2,082	$ 1,413

Other supplemental information related to leases was as follows:

	As of December 31,	
	2025	2024
Weighted average remaining lease term:		
Operating leases	9.4 years	9.0 years
Finance leases	2.3 years	2.6 years
Weighted average discount rate:		
Operating leases	10.70 %	10.91 %
Finance leases	9.77 %	8.66 %

The following table summarizes the presentation in the Consolidated Balance Sheets of the Company's operating leases (in thousands):

	Balance Sheet Location	As of December 31, 2025	As of December 31, 2024
Operating lease assets:			
Operating lease assets, net	Right of use assets	$ 7,548	$ 8,061
Operating lease liabilities:			
Current operating lease liabilities	Operating lease liabilities – current liabilities	$ 317	$ 937
Non-current operating lease liabilities	Operating lease liabilities – long-term liabilities	8,571	7,924
Total operating lease liabilities		$ 8,888	$ 8,861

The following table summarizes the presentation in the Consolidated Balance Sheets of the Company's finance leases (in thousands):

	Balance Sheet Location	As of December 31, 2025	As of December 31, 2024
Finance lease assets:			
Finance lease assets, net	Right of use assets	$ 2,655	$ 3,947
Finance lease liabilities:			
Current finance lease liabilities	Finance lease liabilities – current liabilities	$ 1,312	$ 1,835
Non-current finance lease liabilities	Finance lease liabilities – long-term liabilities	1,441	2,124
Total finance lease liabilities		$ 2,753	$ 3,959

Operating lease assets are recorded net of accumulated amortization of $2,305 and $6,065 as of December 31, 2025 and 2024, respectively. Finance lease assets are recorded net of accumulated amortization of $3,798 and $4,059 as of December 31, 2025 and 2024, respectively.

Maturities of lease liabilities as of December 31, 2025 are as follows (in thousands):

	Operating Leases	Finance Leases
2026	$ 1,153	$ 1,520
2027	1,462	1,050
2028	1,506	486
2029	1,538	26
2030	1,590	—
Thereafter	7,433	—
Total lease payments	14,682	3,082
Less imputed interest	(5,794)	(329)
Total	$ 8,888	$ 2,753

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

	Years Ended December 31,		
	2025	2024	2023
Cash paid for amounts included in the measurement of lease liabilities			
Operating cash flows for finance leases	$ 340	$ 316	$ 201
Operating cash flows for operating leases	$ 1,466	$ 2,156	$ 1,920
Operating lease assets obtained in exchange for operating lease liabilities	$ 366	$ 438	$ 4,695
Finance lease assets obtained in exchange for finance lease liabilities	$ 870	$ 1,391	$ 2,971
Non-cash increase to operating lease assets due to remeasurement of operating lease liabilities	$ 786	$ 254	$ 924

Note 12— Stockholders' Equity

Sales of Common Stock

On November 20, 2025, the Company filed with the Securities and Exchange Commission (the "SEC"), and amended on December 15, 2025, a registration statement on Form S-4. This registration statement was declared effective by the SEC on December 18, 2025 and registered the Company's offer of up to 45,000 shares of the Company's common stock in connection with the Merger (as defined in "*Note 21— Subsequent Events"* herein).

On February 27, 2024, the Company filed an automatic shelf registration statement on Form S-3 with the SEC. This shelf registration statement became effective automatically upon filing and allows the Company to sell an indeterminate number of securities, including common stock, preferred stock, depositary shares, purchase contracts, warrants, debt securities, and units, from time to time at prices and on terms to be determined at the time of sale.

On October 23, 2023, certain entities affiliated with Baker Bros. Advisors LP (the "Baker Entities") net exercised the remaining balance of the pre-funded warrants held by such Baker Entities that were issued on November 21, 2019. Additionally, certain of the Baker Entities net exercised all of the pre-funded warrants that were issued on June 1, 2020. The exercises resulted in the issuance of 14,997 common shares.

Shares Reserved for Future Issuance of Common Stock

The Company had reserved shares of common stock for issuance as follows (in thousands):

	December 31,	
	2025	2024
Shares reserved for exercises of outstanding stock options	43,344	44,240
Shares reserved for vesting of restricted stock units	12,166	10,112
Shares reserved for future issuance under the Stock Incentive Plan	6,852	1,065
Shares reserved for future issuance under the Inducement Equity Incentive Plan	1,460	1,699
Shares reserved for future issuance under the Employee Stock Purchase Plan	4,674	5,042
Total shares reserved for future issuance	68,496	62,158

Note 13— Stock-Based Compensation

As of December 31, 2025, the Company had three stock-based employee compensation plans: the Amended and Restated Stock Incentive Plan ("Incentive Plan"), the Amended and Restated Inducement Equity Incentive Plan ("Inducement Plan") and the Amended and Restated Employee Stock Purchase Plan ("ESPP"). The Incentive Plan was most recently amended and restated on April 21, 2025 and approved by the Company's stockholders on June 12, 2025. The Inducement Plan was most recently amended and restated by the Company's Board of Directors on October 26, 2023. The ESPP was most recently amended and restated by the Company's Board of Directors on July 7, 2023.

The Company recorded the following stock-based compensation expense (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Incentive Plan	$ 77,203	$ 56,207	$ 44,581
Inducement Plan	7,113	8,414	9,958
ESPP	821	792	1,076
Total stock-based compensation costs	85,137	65,413	55,615
Capitalized stock-based compensation costs	(71)	—	—
Total stock-based compensation costs included in operating expenses	$ 85,066	$ 65,413	$ 55,615

The following table summarizes the presentation of stock-based compensation expense in the Consolidated Statement of Comprehensive Income (Loss):

	Years Ended December 31,		
	2025	2024	2023
Research and development	$ 29,510	$ 31,285	$ 29,377
Selling, general and administrative	55,556	34,128	26,238
Total stock-based compensation costs included in operating expenses	$ 85,066	$ 65,413	$ 55,615

Retirement Policy

In July 2024, the Company adopted the BioCryst Pharmaceuticals, Inc. Equity Award Retirement Policy (the "Retirement Policy"). The Retirement Policy provides for the continued vesting of certain unvested awards granted more than one year prior to the date of retirement according to the original vesting schedule of the award. Employees are eligible for the Retirement Policy upon meeting age, service, and notice period requirements and receipt of notice of their eligibility from the Company. The Company considered the adoption of the Retirement Policy to be a modification of existing awards under ASC Topic 718, *Compensation - Stock Compensation* ("ASC 718"). The modification did not result in any incremental compensation cost. However, the adoption of the Retirement Policy resulted in a new estimate of the requisite service period for certain awards. In connection with the modification as a result of the adoption of the Retirement Policy, the Company accelerated the recognition of stock-based compensation expense of $7,569 during the year ended December 31, 2024.

Extension of Exercise Period

In December 2025, the Company extended the post-termination exercise period of certain vested stock option awards at the time of retirement for certain individuals to the original expiration date of the option awards. The Company considered this to be a modification of existing awards under ASC 718 and determined the incremental fair value associated with the modification using a binomial lattice model. In connection with the modification, the Company recognized incremental stock-based compensation expense of $11,267 during the year ended December 31, 2025.

Sale of the European ORLADEYO Business

In connection with the sale of the European ORLADEYO business, the Company modified certain outstanding stock option awards and restricted stock unit awards held by employees who transferred to Neopharmed. Under the original terms of the Company's Incentive Plan and Inducement Plan, unvested awards would have been forfeited upon the employees' termination with the Company at Closing. As part of the negotiated transaction, the Company approved modifications that (i) allowed previously unvested awards to continue to vest based on continued service to Neopharmed after Closing and (ii) extended the post-termination exercise period for certain vested stock option awards.

The modified terms provide for continued vesting and extended exercisability only if the employees remain employed by Neopharmed for specified periods following the Closing. As the vesting of the modified awards depends on service to Neopharmed, the awards are considered to contain an "other" condition under ASC 718 and are therefore classified as liability awards until the service to Neopharmed is provided.

The Company considered the continued vesting of unvested awards to be a Type III modification under ASC 718 and measured the awards at their modification-date fair value. The Company considered the extension of the post-termination exercise period for certain vested stock option awards to be a Type I modification under ASC 718 and calculated the incremental fair value provided in the modification on the modification date. As the post-close services benefit Neopharmed and the fair value conveyed through the modified awards represents consideration payable to Neopharmed, the total fair value of $17,548 resulting from the modifications was recognized as contra-revenue when the revenue related to the license of intellectual property was recognized at Closing pursuant to ASC 606 (see "*Note 2—Divestiture of BioCryst Ireland Limited*"). The liability for the modified awards is remeasured to fair value each reporting period. The options are valued using a Black-Scholes option pricing model which incorporates significant unobservable inputs. This remeasurement resulted in the recognition of a $4,313 gain in Other income in the Consolidated Statement of Comprehensive Income (Loss) and a $2,050 increase to additional paid-in capital for the year ended December 31, 2025.

Stock Incentive Plan

The Company grants stock option awards and restricted stock unit awards to its employees, directors, and consultants under the Incentive Plan. Under the Incentive Plan, stock option awards are granted with an exercise price equal to the market price of the Company's common stock at the date of grant. Stock option awards and restricted stock unit awards granted to employees generally vest 25% each year until fully vested after four years.

Stock option awards and restricted stock unit awards granted to non-employee directors of the Company generally vest over one year. Stock option awards granted to new non-employee directors when they first join the Company's Board of Directors generally vest, subject to the terms of the Incentive Plan, in 36 equal monthly installments over a three-year period measured from the grant date. All stock option awards have contractual terms of 10 years. Restricted stock unit awards granted to new non-employee directors when they first join the Company's Board of Directors generally vest, subject to the terms of the Incentive Plan, in three equal annual installments beginning on the first anniversary of the grant date.

The vesting and exercise provisions of all awards granted under the Incentive Plan are subject to acceleration in the event of certain stockholder-approved transactions, or upon the occurrence of a change in control as defined in the Incentive Plan.

The following table summarizes stock option activity under the Incentive Plan:

	Shares (in thousands)	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	39,082	$ 7.96		
Granted	4,714	7.38		
Exercised	(1,224)	5.23		$ 4,139
Cancelled or Forfeited	(3,908)	9.34		
Outstanding at December 31, 2025	38,664	$ 7.83	5.67	$ 34,248
Exercisable at December 31, 2025	26,503	$ 7.98	4.39	$ 26,715
Vested and expected to vest at December 31, 2025	37,372	$ 7.84	5.57	$ 33,360

The total intrinsic value of stock option awards exercised under the Incentive Plan was $863 and $3,601 during the years ended December 31, 2024 and 2023, respectively. The aggregate intrinsic value represents the total proceeds (calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the

Company's common stock on the date of exercise for those stock options) received by all individuals who exercised stock option awards during the period.

The following table summarizes restricted stock unit activity under the Incentive Plan:

	Shares (in thousands)	Weighted Average Grant Date Fair Value
Unvested at December 31, 2024	9,289	$ 7.73
Granted	5,804	7.26
Vested	(2,548)	8.34
Forfeited	(1,404)	6.13
Unvested at December 31, 2025	11,141	$ 7.40

For restricted stock unit awards granted under the Incentive Plan, the fair value of the awards is determined based on the market value of the Company's shares on the grant date. The weighted average grant date fair value of these awards granted during 2025, 2024, and 2023 was $7.26, $7.32, and $6.71, respectively. The fair value of the restricted stock unit awards is amortized to expense over the vesting periods using a straight-line expense attribution method.

As of December 31, 2025, total unrecognized compensation cost related to unvested restricted stock unit awards granted under the Incentive Plan was $63,984, which is expected to be recognized over a weighted average period of 3.1 years.

Inducement Equity Incentive Plan

The Company has the ability to grant stock option and restricted stock unit awards to newly-hired employees as inducements material to each employee entering employment with the Company. Awards granted to newly-hired employees generally vest 25% each year until fully vested after four years and are subject to the terms and conditions of the Inducement Plan. All stock option awards have contractual terms of 10 years. The vesting and exercise provisions of all awards granted under the Inducement Plan are subject to acceleration in the event of certain stockholder-approved transactions, or upon the occurrence of a change in control as defined in the Inducement Plan.

The following table summarizes stock option activity under the Inducement Plan:

	Shares (in thousands)	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	5,158	$ 8.44		
Granted	268	7.57		
Exercised	(266)	5.66		$ 1,018
Cancelled or Forfeited	(480)	10.54		
Outstanding at December 31, 2025	4,680	$ 8.33	4.41	$ 7,454
Exercisable at December 31, 2025	3,607	$ 8.24	3.70	$ 6,758
Vested and expected to vest at December 31, 2025	4,432	$ 8.33	4.46	$ 7,247

The total intrinsic value of stock option awards exercised under the Inducement Plan was $495 and $1,803 during the years ended December 31, 2024 and 2023, respectively. The aggregate intrinsic value represents the total proceeds (calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the

Company's common stock on the date of exercise for those stock options) received by all individuals who exercised stock option awards during the period.

The following table summarizes restricted stock unit activity under the Inducement Plan:

	Shares (in thousands)	Weighted Average Grant Date Fair Value
Unvested at December 31, 2024	823	$ 8.53
Granted	641	8.14
Vested	(248)	9.25
Forfeited	(191)	8.16
Unvested at December 31, 2025	1,025	$ 8.17

For restricted stock unit awards granted under the Inducement Plan, the fair value of the awards is determined based on the market value of the Company's shares on the grant date. The weighted average grant date fair value of these awards granted during 2025, 2024, and 2023 was $8.14, $6.51, and $7.81, respectively. The fair value of the restricted stock unit awards is amortized to expense over the vesting periods using a straight-line expense attribution method.

As of December 31, 2025, total unrecognized compensation cost related to unvested restricted stock unit awards granted under the Inducement Plan was $5,972, which is expected to be recognized over a weighted average period of 3.0 years.

Weighted Average Assumptions for Stock Option Awards Granted to Employees and Directors under the Incentive and Inducement Plans

For stock option awards granted under the Incentive Plan and the Inducement Plan, the fair value is estimated on the date of grant using a Black-Scholes option pricing model and the assumptions noted below. The fair value of the stock option awards is amortized to expense over the vesting periods using a straight-line expense attribution method.

Historically, the expected term was based on the average of the assumption that all outstanding stock option awards will be exercised at full vesting and the assumption that all outstanding stock option awards will be exercised at the midpoint of the current date (if already vested) or at full vesting (if not yet vested) and the full contractual term. Effective July 1, 2023, the expected term is based on the historical settlement of options by taking into account exercises and post-vesting terminations and weighing them based on the number of options settled. This change in approach did not have a significant impact on the value of the stock option awards granted. The expected volatility represents the historical volatility on the Company's publicly-traded common stock. The Company has assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future. The weighted average risk-free interest rate is the implied yield currently available on zero-coupon government issues with a remaining term equal to the expected term.

Stock Incentive Plan

The following table summarizes the key assumptions used by the Company to value the stock option awards granted under the Incentive Plan during the years ended December 31, 2025, 2024, and 2023:

	Years Ended December 31,		
	2025	2024	2023
Expected Term in Years	6.4	5.7	5.7
Expected Volatility	74.8 %	83.5 %	82.5 %
Expected Dividend Yield	0.0 %	0.0 %	0.0 %
Risk-Free Interest Rate	3.9 %	4.5 %	3.9 %
Weighted average grant date fair value per share	$ 5.14	$ 5.28	$ 4.75

The total fair value of the stock option awards vested under the Incentive Plan was $31,005, $35,151, and $33,731 during the years ended December 31, 2025, 2024, and 2023, respectively. As of December 31, 2025, total unrecognized compensation cost related to unvested stock option awards granted under the Incentive Plan was $47,444, which is expected to be recognized over a weighted average period of 2.6 years.

Inducement Equity Incentive Plan

The following table summarizes the key assumptions used by the Company to value the stock option awards granted under the Inducement Plan during the years ended December 31, 2025, 2024, and 2023:

	Years Ended December 31,		
	2025	**2024**	**2023**
Expected Term in Years	6.4	5.8	5.6
Expected Volatility	79.3 %	83.3 %	83.5 %
Expected Dividend Yield	0.0 %	0.0 %	0.0 %
Risk-Free Interest Rate	3.9 %	4.2 %	4.0 %
Weighted average grant date fair value per share	$ 5.47	$ 4.61	$ 5.79

The total fair value of the stock option awards vested under the Inducement Plan was $5,354, $7,225, and $7,698 during the years ended December 31, 2025, 2024, and 2023, respectively. As of December 31, 2025, total unrecognized compensation cost related to unvested stock option awards granted under the Inducement Plan was $3,953, which is expected to be recognized over a weighted average period of 2.3 years.

Employee Stock Purchase Plan

The Company has reserved a total of 7,975 shares of common stock to be purchased under the ESPP, of which 4,674 shares remain available for purchase at December 31, 2025. Eligible employees may authorize up to 15% of their salary to purchase common stock at the lower of 85% of the beginning or 85% of the ending price during six-month purchase intervals. No more than three thousand shares may be purchased by any one employee at each purchase date, and no employee may purchase stock having a fair market value at the commencement date of $25 or more in any one calendar year.

During the years ended December 31, 2025, 2024, and 2023, the Company issued 369, 412, and 338 shares of common stock under the ESPP, respectively, at a weighted average price per share of $6.24, $4.50, and $7.68, respectively. Compensation expense for shares purchased under the ESPP related to the purchase discount and the “look-back” option were determined using a Black-Scholes option pricing model. The weighted average grant date fair values of shares granted under the ESPP during the years ended December 31, 2025, 2024, and 2023, were $2.35, $1.99, and $3.82, respectively.

Note 14— Income Taxes

The components of income (loss) before provision for income taxes were as follows (in thousands):

	Years Ended December 31,		
	2025	**2024**	**2023**
Domestic	$ 172,638	$ (62,515)	$ (206,674)
Foreign	94,753	(24,439)	(19,555)
Income (loss) before provision for income taxes	$ 267,391	$ (86,954)	$ (226,229)

The components of the expense (benefit) for income taxes were as follows (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Current expense (benefit) provision:			
U.S. Federal	$ —	$ —	$ —
State	3,502	1,118	(45)
Foreign	1,240	1,163	1,037
Total current expense provision	4,742	2,281	992
Deferred expense (benefit) provision:			
U.S. Federal	—	—	—
State	(184)	79	(120)
Foreign	(1,028)	(433)	(562)
Total deferred expense provision	(1,212)	(354)	(682)
Total expense provision	$ 3,530	$ 1,927	$ 310

Income taxes paid, net of refunds received, were as follows (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Federal	$ —	$ —	$ —
State			
California	901	(239)	—
Other	38	623	1,176
Foreign			
Germany	329	105	114
United Kingdom	855	646	81
Other	680	468	63
Total income taxes paid, net of refunds received	$ 2,803	$ 1,603	$ 1,434

The differences between the Company's effective tax rate and the statutory tax rate in 2025, 2024, and 2023 were as follows (in thousands):

	Years Ended December 31,					
	2025		2024		2023	
	Amount	Percent	Amount	Percent	Amount	Percent
Income tax expense (benefit) at federal statutory rate	$ 56,152	21 %	$ (18,260)	21 %	$ (47,508)	21 %
State and local income taxes, net of federal income tax effect [(a)]	2,569	1 %	955	(1)%	(351)	— %
Foreign tax effects						
Ireland						
Statutory tax rate difference between Ireland and the United States	(8,262)	(3)%	2,457	(3)%	1,648	(1)%
Sale of European ORLADEYO business	(12,960)	(5)%	—	— %	—	— %
Changes in valuation allowances	1,711	1 %	3,603	(4)%	2,423	(1)%
Other	(880)	— %	30	— %	46	— %
Other foreign jurisdictions	704	— %	(228)	— %	464	— %
Tax credits						
Research and development tax credits	(1,323)	— %	(1,764)	2 %	(3,725)	1 %
Expiration of research and development tax credits	3,574	1 %	2,514	(3)%	831	— %
Changes in valuation allowances	(52,454)	(20)%	8,695	(10)%	42,139	(19)%
Nontaxable or nondeductible items						
Share-based payment awards	4,837	2 %	2,780	(3)%	2,625	(1)%
Sale of European ORLADEYO business	3,867	1 %	—	— %	—	— %
Other	1,285	— %	899	(1)%	388	— %
Changes in unrecognized tax benefits	(217)	— %	353	— %	825	— %
Other adjustments	4,927	2 %	(107)	— %	505	— %
Income tax expense at effective income tax rate	$ 3,530	1 %	$ 1,927	(2)%	$ 310	— %

[(a)] For the year ended December 31, 2025, state taxes in California, Michigan, Minnesota, Kentucky, and New Jersey made up the majority (greater than 50 percent) of the tax effect in this category. For the year ended December 31, 2024, state taxes in Colorado, Illinois, Maine, Massachusetts, New Jersey, and Texas made up the majority of the tax effect in this category. For the year ended December 31, 2023, state taxes in Colorado, Illinois, Michigan, New Jersey, and Texas made up the majority of the tax effect in this category.

The Company recognizes the impact of a tax position in its financial statements if it is more likely than not that the position will be sustained on audit based on the technical merits of the position. The Company has concluded that it has an uncertain tax position pertaining to its research and development and orphan drug credit carryforwards. The Company has established these credits based on information and calculations it believes are appropriate and the best estimate of the underlying credit. Any changes to the Company's unrecognized tax benefits are offset by an adjustment to the valuation allowance and there would be no impact on the Company's financial statements. The Company does not expect its unrecognized tax benefits to change significantly over the next 12 months. If recognized, none of these tax benefits would affect the effective tax rate due to the valuation allowance.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	2025	2024
Balance at January 1,	$ 14,715	$ 14,362
Additions to current period tax positions	386	353
Reductions to prior period tax positions	(603)	—
Balance at December 31,	$ 14,498	$ 14,715

The Company's ability to utilize the net operating loss and tax credit carryforwards in the future may be subject to substantial restrictions in the event of past or future ownership changes as defined in Section 382 of the IRC and similar state tax law.

Significant components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
Net federal and state operating losses	$ 82,049	$ 105,865
Research and development credits	85,254	87,287
Royalty income	106,695	117,570
Stock-based compensation	40,070	34,486
Capitalized R&D	40,875	82,476
Leasing obligations	2,666	2,806
Other	26,744	22,693
Total deferred tax assets	384,353	453,183
Deferred tax liabilities:		
Fixed assets	(1,245)	(797)
Right of use asset	(2,337)	(2,620)
Total deferred tax liabilities	(3,582)	(3,417)
Valuation allowance	(380,519)	(448,740)
Net deferred tax assets	$ 252	$ 1,026

The majority of the Company's deferred tax assets relate to net operating loss and research and development carryforwards that can only be realized if the Company is profitable in future periods. It is uncertain whether the Company will realize any tax benefit related to these carryforwards. Accordingly, the Company has provided a valuation allowance against substantially all the net deferred tax assets due to uncertainties as to their ultimate realization. The valuation allowance will remain at the full amount of the deferred tax assets until it is more likely than not that the related tax benefits will be realized. The Company's valuation allowance decreased by $68,221 in 2025, and increased by $11,642, and $47,490 in 2024 and 2023, respectively.

As of December 31, 2025, the Company had U.S. federal operating loss carryforwards of $351,348, state operating loss carryforwards of $154,550, and U.S. research and development and orphan drug credit carryforwards of $99,751, which will expire at various dates from 2026 through 2045. Federal losses, state losses, and research and development credit carryforwards began expiring in 2021. As of December 31, 2025 the Company had no foreign net operating loss carryforwards.

Tax years 2022-2025 remain open to examination by the major taxing jurisdictions to which the Company is subject. Additionally, years prior to 2022 are also open to examination for loss and credit carryforwards from those years. The Company recognizes interest and penalties accrued related to unrecognized tax benefits as components of its income tax provision. However, there were no provisions or accruals for interest and penalties in 2025, 2024, and 2023.

As of December 31, 2025, the Company has minimal accumulated undistributed earnings generated by its foreign subsidiaries which have already been subject to local and U.S. tax as part of the global intangible low-taxed income provisions. The Company intends to indefinitely reinvest these earnings, as well as future earnings from its foreign subsidiaries, to fund its international operations. In addition, the Company expects future U.S. cash generation will be sufficient to meet future U.S. cash needs.

Note 15— Employee 401(k) Plan

In January 1991, the Company adopted an employee retirement plan ("401(k) Plan") under Section 401(k) of the IRC covering all employees. Employee contributions may be made to the 401(k) Plan up to limits established by the Internal Revenue Service. Company matching contributions may be made at the discretion of the Board of Directors. The Company made matching contributions of $5,761, $6,030, and $5,716 in 2025, 2024, and 2023, respectively.

Note 16— Collaborative and Other Relationships

ORLADEYO

Torii Pharmaceutical Co., Ltd. ("Torii")

On November 5, 2019, the Company entered into a Commercialization and License Agreement with Torii (the "Original Torii Agreement"), granting Torii the exclusive right to commercialize ORLADEYO for the prevention of HAE attacks in Japan. Under the Original Torii Agreement, the Company received an upfront, non-refundable payment of $22,000. The Company received an additional milestone payment of $15,000 in the second quarter of 2021 upon receipt from the Japanese National Health Insurance System of a reimbursement price approval for ORLADEYO. In addition, the Company was entitled to receive tiered royalty payments, ranging from 20% to 40% of annual net sales of ORLADEYO in Japan during each calendar year. Torii's royalty payment obligations were subject to customary reductions in certain circumstances, but could not be reduced by more than 50% of the amount that otherwise would have been payable to the Company in the applicable calendar quarter.

The Company identified performance obligations under the Original Torii Agreement related to (i) the license to develop and commercialize ORLADEYO, (ii) regulatory approval support, and (iii) reimbursement pricing approval support. These were each determined to be distinct from the other performance obligations. The Company allocated the $22,000 upfront consideration to the identified performance obligations using estimation approaches to determine the standalone selling prices under ASC Topic 606. Specifically, in determining the value related to the license, a valuation approach utilizing risk adjusted discounted cash flow projections was used, and an expected cost plus margin approach was utilized for the other performance obligations.

On November 30, 2023, the Company entered into an Amended and Restated Commercialization and License Agreement with Torii (as amended, the "Torii Agreement"). Under the Torii Agreement, the Company is entitled to receive tiered royalty payments, ranging from 20% to 80% of annual net sales of ORLADEYO in Japan during each calendar year. The Company is now responsible for all commercial promotion activities to support ORLADEYO sales in Japan, and Torii is responsible for HAE disease awareness activities in Japan. The Company will receive a 20% royalty on annual Japanese sales below a prespecified threshold and an 80% royalty on annual Japanese sales above the prespecified threshold.

Torii's updated royalty payment obligations commenced on November 30, 2023 and expire upon the later of (i) the tenth anniversary of the date of first commercial sale of ORLADEYO in Japan, (ii) the expiration of the Company's patents covering ORLADEYO, and (iii) the expiration of regulatory exclusivity for ORLADEYO in Japan.

The Company determined that the Torii Agreement represented a contract modification to be accounted for as if it were part of the Original Torii Agreement under ASC Topic 606. As the performance obligations under the Original Torii Agreement had been fully satisfied, the Company was not required to adjust revenue previously recognized.

Neopharmed

On October 1, 2025, the Company sold its European ORLADEYO business to Neopharmed. Under the terms of the Stock Purchase Agreement, the Company is entitled to receive certain royalty and milestone payments from the license based on ORLADEYO product sales in the Territory. See "*Note 2— Divestiture of BioCryst Ireland Limited"* for further information.

Peramivir Injection (RAPIVAB, RAPIACTA, PERAMIFLU)

U.S. Department of Health and Human Services ("HHS")

In September 2024, the HHS awarded the Company up to a $69,388 contract for the procurement of up to 95.6 thousand doses over a five-year period of RAPIVAB (peramivir injection) for the treatment of influenza. The contract, awarded by the HHS Office of the Administration for Strategic Preparedness and Response ("ASPR"), supplied the Center for the Strategic National Stockpile, the nation's largest supply of life-saving pharmaceuticals and medical supplies for use in a public health emergency. The contract was structured with a 12-month base ordering period and four optional 12-month ordering periods, which the government could exercise on an annual basis. ASPR executed the first ordering period for $13,878. The Company delivered 16.8 thousand doses of peramivir under this contract and recorded revenue of $12,206 for the year ended December 31, 2025. The Company delivered 2.3 thousand doses of peramivir under this contract and recorded revenue of $1,672 for the year ended December 31, 2024. On May 15, 2025, ASPR notified the Company of its intent to not exercise any additional optional ordering periods available under the agreement.

Shionogi & Co., Ltd. ("Shionogi")

In February 2007, the Company entered into an exclusive license agreement with Shionogi to develop and commercialize peramivir in Japan for the treatment of seasonal and potentially life-threatening human influenza. Under the terms of the agreement, Shionogi obtained rights to injectable formulations of peramivir in Japan. In October 2008, the Company and Shionogi amended the license agreement to expand the territory covered by the agreement to include Taiwan. Shionogi has commercially launched peramivir under the commercial name RAPIACTA in Japan and Taiwan. The Company developed peramivir under a license from University of Alabama Birmingham "UAB" and owes sublicense payments to UAB on any future milestone payments and/or royalties received by the Company from Shionogi.

Green Cross Corporation ("Green Cross")

In June 2006, the Company entered into an agreement with Green Cross to develop and commercialize peramivir in Korea. Under the terms of the agreement, Green Cross is responsible for all development, regulatory, and commercialization costs in Korea and the Company is entitled to share in profits resulting from the sale of peramivir in Korea, including the sale of peramivir to the Korean government for stockpiling purposes. Furthermore, Green Cross will pay the Company a premium over its cost to supply peramivir for development and any future marketing of peramivir products in Korea.

Other Collaborations and Relationships

Clearside Biomedical, Inc. ("Clearside")

On November 3, 2023, the Company announced that it entered into a license agreement (the "Clearside Agreement") with Clearside, enabling the Company to develop its investigational plasma kallikrein inhibitor, avoralstat, with Clearside's SCS Microinjector® to deliver avoralstat to the back of the eye through the suprachoroidal space to treat patients with diabetic macular edema.

Under the Clearside Agreement, Clearside received a $5,000 upfront license fee from the Company, which was recognized in research and development expenses during the year ended December 31, 2023. Clearside is eligible to receive up to an additional $30,000 in clinical and regulatory milestone payments, and up to a total of $47,500 in three post-approval sales-based milestone payments as annual global net sales progress to $2,000,000. The Company will pay Clearside tiered mid-single digit royalties on annual global net product sales, at three tiers, including a top tier of >$1,500,000.

Note 17— Workforce Reduction

2025 Workforce Reduction

In December 2025, the Company had a workforce reduction. The majority of the impacted employees had termination dates in December 2025, with certain employees exiting in the first quarter of 2026. The Company notified all impacted employees in December 2025.

In accordance with ASC Topic 712, *Nonretirement Postemployment Benefits* ("ASC 712"), and ASC Topic 420, *Exit or Disposal Costs* ("ASC 420"), the Company recognized $6,314 of costs related to the workforce reduction during the year ended December 31, 2025, of which $2,040 was recognized in research and development expenses and $4,274 was recognized in selling, general and administrative expenses in the Consolidated Statement of Comprehensive Income (Loss). The following table summarizes the accrued liability activity recorded in connection with the workforce reduction for the year ended December 31, 2025 (in thousands):

Workforce reduction expense recorded during the year ended December 31, 2025	$	6,314
Amounts paid during the year ended December 31, 2025		(836)
Balance at December 31, 2025	$	5,478

The Company does not expect to incur any additional significant costs related to this workforce reduction. The remaining unpaid costs are expected to be disbursed during the period of January 1, 2026 through December 31, 2026.

2024 Workforce Reduction

In January 2024, the Company announced a reduction of workforce. The majority of the impacted employees had a termination date in January 2024, with certain employees exiting later in 2024. The Company notified the impacted employees in January 2024.

The Company incurred costs related to employee severance, benefits, and related costs which were accounted for as ongoing terminations benefits under ASC 712. As of December 31, 2023, it was considered probable that payment would be owed and the amount of payment was considered to be reasonably estimable, which resulted in the recognition of $3,380 of costs related to the workforce reduction during the year ended December 31, 2023, of which $3,026 was recognized in research and development expenses and $354 was recognized in selling, general and administrative expenses in the Consolidated Statement of Comprehensive Income (Loss). All of these costs were paid during the year ended December 31, 2024.

In addition, the employees impacted by the workforce reduction received an amount equal to the bonus amount the employee would have received through continued employment with the Company, which was considered a one-time termination benefit pursuant to ASC 420. As a result, $1,264 was recognized during the three months ended March 31, 2024, the period in which the communication occurred, of which $1,201 was recognized in research and development expenses, and $63 was recognized in selling, general and administrative expenses in the Consolidated Statement of Comprehensive Income (Loss). All of these costs were paid during the three months ended March 31, 2024.

The following table summarizes the accrued liability activity recorded in connection with the workforce reduction for the year ended December 31, 2024 (in thousands):

Balance at December 31, 2023	$	3,380
Workforce reduction expense recorded during the year ended December 31, 2024		1,264
Amounts paid during the year ended December 31, 2024		(4,644)
Balance at December 31, 2024	$	—

Note 18— Segment Information

The Company operates as one reportable and operating segment, centered around its commercialized product, ORLADEYO, and its pipeline with the goal of developing first-in-class or best-in-class oral small-molecule and injectable protein therapeutics to target a range of rare diseases. The determination of a single segment is consistent with the

consolidated financial information regularly provided to the Company's chief operating decision maker ("CODM"). The Chief Executive Officer, as the CODM, uses consolidated, single-segment financial information for purposes of evaluating performance, making operating decisions, allocating resources, and planning and forecasting for future periods.

The CODM assesses performance and decides how to allocate resources based on consolidated net income (loss). This measure is used to monitor budget versus actual results to evaluate the performance of the segment. The CODM uses consolidated cash, cash equivalents and investments as the measure of segment assets. As of December 31, 2025 and 2024, the Company's cash, cash equivalents, and investments were $335,911 and $341,173, respectively.

The following table illustrates information about segment revenues, significant segment expenses, and segment net income (loss) for the years ended December 31, 2025, 2024, and 2023 (in thousands):

	Years Ended December 31,		
	2025	**2024**	**2023**
Revenues	$ 874,837	$ 450,712	$ 331,412
Less[1]:			
Cost of product sales	19,075	12,269	4,481
Research and development (excluding stock-based compensation)			
Berotralstat	12,148	10,950	13,780
BCX17725	17,304	12,389	10,218
Avoralstat	9,497	7,547	6,314
Factor D Program	456	8,534	40,111
Research, discovery and preclinical programs	17,677	12,733	12,286
Compensation and related personnel costs	51,576	59,010	64,377
Other non-program specific and indirect costs	27,958	32,190	40,103
Sales and marketing (excluding stock-based compensation)	177,085	152,166	134,262
General and administrative (excluding stock-based compensation)	116,006	80,054	53,574
Stock-based compensation	85,066	65,413	55,615
Interest income	(10,668)	(14,746)	(15,777)
Interest expense	78,872	98,516	108,239
Foreign currency losses, net	152	641	1,039
Loss on extinguishment of debt	17,332	—	29,019
Other income	(12,090)	—	—
Income tax expense	3,530	1,927	310
Segment net income (loss)	263,861	(88,881)	(226,539)
Reconciliation of segment profit or loss:			
Adjustments and reconciling items	—	—	—
Consolidated net income (loss)	$ 263,861	$ (88,881)	$ (226,539)

[1] The significant segment expenses align with the segment-level information that is regularly provided to the CODM.

All material long-lived assets of the Company reside in the U.S. For geographic information about the Company's product revenues, see "*Note 3—Revenue*".

Note 19— Commitments and Contingencies

Abbreviated New Drug Application

In January 2025, the Company received a Paragraph IV notice of certification (the "First Notice Letter") from Annora Pharma Private Limited ("Annora") regarding U.S. Patent Nos. 10,662,160; 11,117,867; and 11,618,733. In January 2026, the Company received an additional Paragraph IV notice of certification (the "Second Notice Letter" and, together with the First Notice Letter, the "Notice Letters") from Annora regarding U.S. Patent No. 12,344,585. The Notice Letters advise that Annora has submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking approval to manufacture, use or sell a generic version of ORLADEYO in the United States prior to the expiration of four patents listed in the FDA's Orange Book: U.S. Patent Nos. 10,662,160; 11,117,867; 11,618,733; and 12,344,585 (the "Challenged Patents"). The Notice Letters allege that the Challenged Patents, which expire in 2039, are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the generic product described in Annora's ANDA. The Notice Letters do not challenge the following six ORLADEYO Orange Book patents that expire in 2035: U.S. Patent Nos. 10,125,102; 10,329,260; 10,689,346; 11,230,530; 11,708,333; and 12,116,346.

On March 10, 2025 (as supplemented by the First Amended Complaint filed in December 2025), the Company filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Annora, Hetero Labs Limited, Hetero USA, Inc., and Camber Pharmaceuticals, Inc. (collectively, the "Defendants"), asserting infringement of the Challenged Patents arising from Annora's ANDA filing with the FDA. The Company is seeking, among other remedies, equitable relief enjoining the Defendants from infringing the Challenged Patents, as well as an order that the effective date of any FDA approval of the ANDA would be a date no earlier than the expiration of the Challenged Patents (including any regulatory extensions). While the Company intends to vigorously defend its intellectual property rights protecting ORLADEYO, this matter is in the early stages of litigation and no assessment can be made as to the likely outcome of this matter or whether it will be material to the Company. Accordingly, an estimate of the potential loss, or range of loss, if any, to the Company relating to this matter is not possible at this time.

Note 20— Net Income (Loss) Per Share

Basic and diluted net income (loss) per share for the years ended December 31, 2025, 2024, and 2023 were calculated as follows (in thousands, except per share amounts):

	Years Ended December 31,		
	2025	2024	2023
Numerator:			
Net income (loss)	$ 263,861	$ (88,881)	$ (226,539)
Denominator:			
Weighted average shares of common stock outstanding: basic	209,893	206,696	192,198
Net income (loss) per common share: basic	$ 1.26	$ (0.43)	$ (1.18)
Effect of dilutive securities:			
Stock options to purchase common stock	4,854	—	—
Unvested restricted stock unit awards	3,815	—	—
Shares issuable under the employee stock purchase plan	19	—	—
Dilutive potential common shares	8,688	—	—
Weighted average shares of common stock outstanding: diluted	218,581	206,696	192,198
Net income (loss) per common share: diluted	$ 1.21	$ (0.43)	$ (1.18)

For the year ended December 31, 2025, the dilutive effect of outstanding stock options, restricted stock unit awards, and shares issuable under the employee stock purchase plan was calculated using the treasury method, whereby all such awards are assumed to be exercised at the beginning of the period. The hypothetical proceeds from such exercises, including the average unrecognized stock compensation expense for outstanding stock options, restricted stock units and shares issuable under the employee stock purchase plan, were assumed to be used to purchase outstanding common stock at

the average price during the period. The net share impact of dilutive securities was added to the weighted average basic common shares outstanding to calculate weighted average diluted shares outstanding.

For the years ended December 31, 2024 and 2023, during which the Company recorded a net loss, all potentially dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share, and thus they are considered "anti-dilutive." For these periods, the weighted average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share of common stock is the same.

The following table summarizes potential shares of common stock that were excluded from the computation of diluted net income (loss) per share attributable to common stockholders as they were anti-dilutive:

	As of December 31,		
	2025	**2024**	**2023**
Outstanding stock options	29,204	44,240	41,032
Unvested restricted stock unit awards	2,870	10,112	6,507
Total	32,074	54,352	47,539

Note 21— Subsequent Events

Astria Therapeutics, Inc. Merger

On October 14, 2025, the Company, Axel Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company ("Merger Sub"), and Astria Therapeutics, Inc., a Delaware corporation ("Astria"), entered into an Agreement and Plan of Merger (the "Merger Agreement"). Pursuant to the Merger Agreement, on January 23, 2026 (the "Closing Date"), Merger Sub merged with and into Astria, with Astria surviving as a wholly owned subsidiary of the Company (the "Merger").

Under the terms of the Merger Agreement, at the effective time of the Merger (the "Effective Time"), each share of Astria common stock, par value $0.001 per share, issued and outstanding immediately prior to the Effective Time (excluding shares held by BioCryst, Astria or their wholly owned subsidiaries or dissenting stockholders) was converted into the right to receive (i) 0.59 of a share of the Company's common stock (and, if applicable, cash in lieu of fractional shares), and (ii) $8.55 in cash, without interest, subject to certain adjustments and applicable withholding taxes. Holders of Astria's Series X Convertible Preferred Stock, warrants, and certain options were treated as set forth in the Merger Agreement.

On the Closing Date, the Company completed the Merger for cash consideration of $636,809 and issued 37,282 shares of common stock to Astria's equity holders for total equity consideration of $251,656. The Merger will be accounted for using the acquisition method of accounting in accordance with ASC Topic 805, *Business Combinations.* Accordingly, the acquired assets (including separately identifiable intangible assets) and assumed liabilities of Astria will be recorded at their respective fair values and added to those of BioCryst. The excess of the total consideration paid in connection with the Merger over the net fair values will be recorded as goodwill. Due to the limited amount of time between the acquisition date and the date that these financial statements are issued, the purchase price allocation is not yet complete, and the Company is unable to quantify the impact of the Merger on the financial statements.

Blackstone Loan Agreement

On the Closing Date, the Company entered into a Loan Agreement (the "Blackstone Loan Agreement") with Blackstone Alternative Credit Advisors LP and Blackstone Life Sciences Advisors L.L.C., (together, "Blackstone"), as the Blackstone representatives thereunder, the guarantors from time to time party thereto, the lenders from time to time party thereto, and Wilmington Trust, National Association, as agent, pursuant to which the lenders funded initial term loans in the aggregate principal amount of $400.0 million (the "Term Loans"). Subject to the mutual agreement between the Company, Blackstone and the lenders, the Company may request additional term loans up to an aggregate principal amount not exceeding $150.0 million. The maturity date of the Term Loans under the Blackstone Loan Agreement is January 23, 2031 (the "Maturity Date"), the fifth anniversary of the Closing Date.

The Blackstone Loan Agreement provides for quarterly interest-only payments until the Maturity Date, with the unpaid principal amount of the outstanding Term Loans due and payable on the Maturity Date. Until the second

anniversary of the Closing Date, the Company has the option to make a portion of the applicable interest payment on the Term Loans in kind (a "PIK Interest Payment") by capitalizing as principal on the Term Loans up to 200 basis points of interest that is payable for such interest period. The Term Loans will bear interest at a rate equal to the three-month SOFR rate, which shall be no less than 1.75%, plus 4.50%, per annum and, for any interest period in which a PIK Interest Payment is made, the interest margin for such borrowing will be increased by 0.50% per annum on all Term Loans for which the Company has made a PIK Interest Payment for the applicable interest period. The Company's obligations under the Blackstone Loan Agreement are secured by a security interest in, subject to certain exceptions, substantially all of the assets of BioCryst and its subsidiaries. The Blackstone Loan Agreement also contains representations and warranties and affirmative and negative covenants customary for financings of this type, as well as customary events of default.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of BioCryst Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of BioCryst Pharmaceuticals, Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of comprehensive income (loss), stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2025, and the related notes (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 26, 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.

Divestiture of BioCryst Ireland Limited

Description of the Matter

As described in Note 2 to the consolidated financial statements, the Company sold to Neopharmed Gentili S.p.A ("Neopharmed") all of its equity interests in BioCryst Ireland, and amended and restated their existing intellectual property license agreement. In connection with the transaction, the Company modified certain stock option awards and restricted stock unit awards held by employees who transferred to Neopharmed. The Company received cash proceeds of $254.5 million and will receive up to $14 million if certain revenue milestones are achieved. Concurrent with the closing, Neopharmed also paid a $15 million royalty release fee to Royalty Pharma Investments 2019 Intermediate Finance Trust on the Company's behalf. The Company will receive quarterly royalty payments from BioCryst Ireland equal to amounts owed under its Royalty Purchase Agreements with RPI and OMERS for the sale of ORLADEYO products in the Territory, as defined in the Stock Purchase Agreement.

The Company accounted for the transaction as (i) the license of intellectual property, recognizing $243.3 million as "License and other revenues" and (ii) the sale of BioCryst Ireland, recognizing $3.6 million as "Other income" on the Consolidated Statements of Comprehensive Income (Loss).

Auditing the accounting for the sale of BioCryst Ireland and license of intellectual property was complex and judgmental due to the interpretation of technical accounting requirements to (i) determine the proper unit of account as it relates to the sale of BioCryst Ireland and the license of intellectual property and (ii) account for the modification of certain stock option awards and restricted stock unit awards as consideration payable to Neopharmed which was recognized as contra-revenue when the revenue related to the license of intellectual property was recognized at closing.

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 processes to account for the sale of BioCryst Ireland and the license of intellectual property.

To test the Company's accounting for the transaction, we performed audit procedures that included, among others, reading the executed contracts associated with the sale of BioCryst Ireland and license of intellectual property and assessing the completeness and accuracy of the significant terms identified by management for purposes of determining the appropriate accounting treatment. With the assistance of those with specialized knowledge, we evaluated management's accounting assessment that documented the factors that the Company considered in determining the application of the accounting framework, including the determination of the unit of account as it relates to the sale of BioCryst Ireland and the license of intellectual property and the assessment of the modification of certain stock option awards and restricted stock unit awards held by employees who transferred to Neopharmed and related calculations (including testing the underlying data).

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1993.

Raleigh, North Carolina
February 26, 2026

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of BioCryst Pharmaceuticals, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited BioCryst 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, BioCryst 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 comprehensive income (loss), stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2025, and the related notes and our report dated February 26, 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 Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit 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
Raleigh, North Carolina
February 26, 2026

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

None.

ITEM 9A. *CONTROLS AND PROCEDURES*

Evaluation of Disclosure Controls and Procedures

We maintain a set of disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. We carried out an evaluation as required by paragraph (b) of Rule 13a-15 or Rule 15d-15 under the Exchange Act, under the supervision and with the participation of 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 Rule 13a-15(e) or Rule 15d-15(e) under the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2025, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. As defined in Rule 13a-15(f) or Rule 15d-15(f) under the Exchange Act, internal control over financial reporting is a process designed by, or under the supervision of, our principal executive and principal financial officers 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 the financial statements in accordance with U.S. GAAP. Internal control over financial reporting includes policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and the dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our 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.

In connection with the preparation of our annual financial statements, management has undertaken an assessment of the effectiveness of our 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 Framework). Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls.

Based on this assessment, management has concluded that, as of December 31, 2025, our internal control over financial reporting was effective. Management believes our internal control over financial reporting will provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

Ernst & Young LLP, the independent registered public accounting firm that audited our financial statements included in this report, has issued an attestation report on the effectiveness of the Company's internal control over financial reporting as of December 31, 2025, a copy of which is included in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. *OTHER INFORMATION*

Director and Officer Trading Arrangements

During the three months ended December 31, 2025, none of the Company's directors or officers adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" (as each of those terms is defined in Item 408(a) of Regulation S-K).

ITEM 9C. *DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS*

Not applicable.

PART III

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

We have adopted an Insider Trading Policy which governs the purchase, sale, and other dispositions of the Company's securities by us and our directors, officers, employees, and other covered persons. We believe this policy is reasonably designed to promote compliance with insider trading laws, rules and regulations and listing standards applicable to the Company. A copy of our Insider Trading Policy is filed as Exhibit 19 to this Annual Report on Form 10-K.

The other information required by this item is set forth under the captions "*Items to be Voted upon — 1. Election of Directors,*" "*Executive Officers,*" and "*Corporate Governance*" in our definitive Proxy Statement for the 2026 Annual Meeting of Stockholders and incorporated herein by reference.

ITEM 11. *EXECUTIVE COMPENSATION*

The information required by this item is set forth under the captions "*Compensation Discussion and Analysis,*" *"Executive Compensation,"* "*2025 Director Compensation,*" "*Compensation Committee Interlocks and Insider Participation,*" *and* "*Compensation Committee Report*" in our definitive Proxy Statement for the 2026 Annual Meeting of Stockholders and incorporated herein by reference.

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

The information required by this item is set forth under the captions "*Equity Compensation Plan Information*" and "*Security Ownership of Certain Beneficial Owners and Management*" in our definitive Proxy Statement for the 2026 Annual Meeting of Stockholders and incorporated herein by reference.

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

The information required by this item is set forth under the caption "*Corporate Governance*" in our definitive Proxy Statement for the 2026 Annual Meeting of Stockholders and incorporated herein by reference.

ITEM 14. *PRINCIPAL ACCOUNTING FEES AND SERVICES*

Our independent registered public accounting firm is Ernst & Young LLP, Raleigh, NC, Auditor Firm ID: 42.

The information required by this item is set forth under the caption "*Items to be Voted upon — 2. Ratification of Appointment of Independent Registered Public Accountants for 2026*" in our definitive Proxy Statement for the 2026 Annual Meeting of Stockholders and incorporated herein by reference.

PART IV

ITEM 15. *EXHIBITS, FINANCIAL STATEMENT SCHEDULES*

(a) Financial Statements

The following financial statements appear in Item 8 of this report:

No financial statement schedules are included because the information is either provided in the consolidated financial statements or is not required under the related instructions or is inapplicable and such schedules therefore have been omitted.

(b) Exhibits

Number	Description
3.1	Third Restated Certificate of Incorporation of BioCryst Pharmaceuticals, Inc. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed December 22, 2006.
3.2	Certificate of Amendment to the Third Restated Certificate of Incorporation of BioCryst Pharmaceuticals, Inc. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed July 24, 2007.
3.3	Certificate of Amendment to the Third Restated Certificate of Incorporation of BioCryst Pharmaceuticals, Inc. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed May 7, 2014.
3.4	Certificate of Elimination of the Series B Junior Participating Preferred Stock. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed May 13, 2020.
3.5	Certificate of Amendment to the Third Restated Certificate of Incorporation of BioCryst Pharmaceuticals, Inc. Incorporated by reference to Exhibit 3.2 to the Company's Form 8-K filed May 13, 2020.
3.6	Amended and Restated By-Laws of BioCryst Pharmaceuticals, Inc., effective January 16, 2024. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed January 18, 2024.
4.1	Description of Securities. Incorporated by reference to Exhibit 4.1 to the Company's Form 10-K filed March 1, 2021.
4.2	Indenture, dated as of March 9, 2011 by and between JPR Royalty Sub LLC and U.S. Bank National Association, as trustee. Incorporated by reference to Exhibit 4.3 to the Company's Form 10-Q filed May 6, 2011.

10.1&	BioCryst Pharmaceuticals, Inc. Stock Incentive Plan (as amended and restated March 8, 2014). Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed May 5, 2014.
10.2&	BioCryst Pharmaceuticals, Inc. Stock Incentive Plan (as amended and restated May 23, 2016). Incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-8, filed May 23, 2016.
10.3&	BioCryst Pharmaceuticals, Inc. Stock Incentive Plan (as amended and restated April 3, 2017). Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed May 30, 2017.
10.4&	BioCryst Pharmaceuticals, Inc. Stock Incentive Plan (as amended and restated September 17, 2018). Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed October 31, 2018.
10.5&	BioCryst Pharmaceuticals, Inc. Stock Incentive Plan (as amended and restated April 12, 2019). Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed June 4, 2019.
10.6&	BioCryst Pharmaceuticals, Inc. Stock Incentive Plan (as amended and restated March 19, 2020). Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed May 13, 2020.
10.7&	BioCryst Pharmaceuticals, Inc. Stock Incentive Plan (as amended and restated April 1, 2021). Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed May 26, 2021.
10.8&	BioCryst Pharmaceuticals, Inc. Stock Incentive Plan (as amended and restated as of April 18, 2022). Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed June 7, 2022.
10.9&	BioCryst Pharmaceuticals, Inc. Stock Incentive Plan (as amended and restated as of April 24, 2023). Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed June 14, 2023.
10.10&	BioCryst Pharmaceuticals, Inc. Stock Incentive Plan (as amended and restated as of April 22, 2024). Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed June 13, 2024.
10.11&	BioCryst Pharmaceuticals, Inc. Stock Incentive Plan (as amended and restated as of April 21, 2025). Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed June 16, 2025.
10.12&	Form of Notice of Grant of Non-Employee Director Automatic Stock Option and Stock Option Agreement under the BioCryst Pharmaceuticals, Inc. Stock Incentive Plan. Incorporated by reference to Exhibit 10.4 to the Company's Form 10-K filed March 4, 2008.
10.13&	Form of Notice of Grant of Stock Option and Stock Option Agreement under the BioCryst Pharmaceuticals, Inc. Stock Incentive Plan. Incorporated by reference to Exhibit 10.5 to the Company's Form 10-K filed March 4, 2008.
10.14&	Standard Stock Option Agreement under the BioCryst Pharmaceuticals, Inc. Stock Incentive Plan. Incorporated by reference to Exhibit 10.7 to the Company's Form 10-K filed March 2, 2015.
10.15&	Form of Notice of Grant of Stock Option and Standard Stock Option Agreement under the BioCryst Pharmaceuticals, Inc. Stock Incentive Plan. Incorporated by reference to Exhibit 10.2 to the Company's Form 10-Q filed on May 6, 2025.
10.16&	Form of Notice of Grant of Non-Employee Director Stock Option and Stock Option Agreement under the BioCryst Pharmaceuticals, Inc. Stock Incentive Plan. Incorporated by reference to Exhibit 10.3 to the Company's 10-Q filed August 5, 2022.

10.17&	Form of Notice of Grant of Restricted Stock Unit Award and Restricted Stock Unit Agreement under the BioCryst Pharmaceuticals, Inc. Stock Incentive Plan. Incorporated by reference to Exhibit 10.14 to the Company's Form 10-K filed February 28, 2022.
10.18&	Form of Notice of Grant of Non-Employee Director Restricted Stock Unit Award and Restricted Stock Unit Agreement under the BioCryst Pharmaceuticals, Inc. Stock Incentive Plan. Incorporated by reference to Exhibit 10.4 to the Company's Form 10-Q filed August 5, 2022.
10.19&	Form of Notice of Performance-Based Restricted Stock Unit Award and Performance-Based Restricted Stock Unit Agreement under the BioCryst Pharmaceuticals, Inc. Stock Incentive Plan. Incorporated by reference to Exhibit 10.4 to the Company's Form 10-Q filed August 6, 2024.
10.20&	BioCryst Pharmaceuticals, Inc. Employee Stock Purchase Plan (as amended and restated as of July 7, 2023). Incorporated by reference to Exhibit 10.3 to the Company's Form 10-Q filed August 7, 2023.
10.21&	BioCryst Pharmaceuticals, Inc. Inducement Equity Incentive Plan (effective as of April 24, 2019). Incorporated by reference to Exhibit 99.1 to the Company's Form S-8 (File No. 333-231108) filed April 29, 2019.
10.22&	BioCryst Pharmaceuticals, Inc. Inducement Equity Incentive Plan (as amended and restated February 7, 2020). Incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q filed May 11, 2020.
10.23&	BioCryst Pharmaceuticals, Inc. Inducement Equity Incentive Plan (as amended and restated July 17, 2020). Incorporated by reference to Exhibit 99.1 to the Company's Form S-8 (File No. 333-245024) filed August 12, 2020.
10.24&	BioCryst Pharmaceuticals, Inc. Inducement Equity Incentive Plan (as amended and restated July 23, 2021). Incorporated by reference to Exhibit 99.1 to the Company's Form S-8 (File No. 333-259919) filed September 30, 2021.
10.25&	BioCryst Pharmaceuticals, Inc. Inducement Equity Incentive Plan (as amended and restated August 31, 2022). Incorporated by reference to Exhibit 99.1 to the Company's Form S-8 (File No. 333-267193) filed August 31, 2022.
10.26&	BioCryst Pharmaceuticals, Inc. Inducement Equity Incentive Plan (as amended and restated as of October 26, 2023). Incorporated by reference to Exhibit 10.2 to the Company's Form 10-Q filed November 8, 2023.
10.27&	Form of Notice of Grant of Stock Option and Standard Stock Option Agreement under the BioCryst Pharmaceuticals, Inc. Inducement Equity Incentive Plan. Incorporated by reference to Exhibit 10.16 to the Company's Form 10-K filed March 1, 2021.
10.28&	Form of Notice of Grant of Restricted Stock Unit Award and Restricted Stock Unit Agreement under the BioCryst Pharmaceuticals, Inc. Inducement Equity Incentive Plan. Incorporated by reference to Exhibit 10.25 to the Company's Form 10-K filed February 27, 2023.
10.29&	BioCryst Pharmaceuticals, Inc. Amended and Restated Non-Employee Director Compensation Policy, effective April 21, 2025. Incorporated by reference to Exhibit 10.3 to the Company's Form 10-Q filed on May 6, 2025.
10.30&	BioCryst Pharmaceuticals, Inc. Annual Incentive Plan (effective as of December 16, 2020). Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed December 17, 2020.
10.31&	Executive Relocation Policy. Incorporated by reference to Exhibit 10.2 to the Company's Form 10-K filed March 4, 2008.

(10.32)&	Retirement Letter between BioCryst Pharmaceuticals, Inc. and Jon Stonehouse, dated December 28, 2025.
10.33&	Amended and Restated Employment Letter Agreement between BioCryst Pharmaceuticals, Inc. and Alane P. Barnes, dated August 4, 2021. Incorporated by reference to Exhibit 10.6 to the Company's Form 10-Q filed August 9, 2021.
(10.34)&	Employment Letter Agreement, effective January 1, 2026, by and between BioCryst Pharmaceuticals, Inc. and Charles Gayer.
10.35&	Employment Letter Agreement between BioCryst Pharmaceuticals, Inc. and Dr. Helen M. Thackray, dated February 18, 2021. Incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q filed May 7, 2021.
10.36&	Amendment No. 1 to the Employment Letter Agreement between BioCryst Pharmaceuticals, Inc. and Dr. Helen M. Thackray, dated September 24, 2021. Incorporated by reference to Exhibit 10.9 to the Company's Form 10-Q filed November 4, 2021.
10.37&	Separation Agreement, effective September 1, 2025, by and between BioCryst Pharmaceuticals, Inc. and Helen Thackray. Incorporated by reference to Exhibit 10.3 to the Company's Form 10-Q filed on November 4, 2025.
(10.38)&	Amended and Restated Employment Agreement, effective July 23, 2025, by and between BioCryst Pharmaceuticals, Inc. and Babar Ghias.
(10.39)&	Employment Letter Agreement, effective January 1, 2026, by and between BioCryst Pharmaceuticals, Inc. and Ron Dullinger.
10.40†	License, Development and Commercialization Agreement dated as of February 28, 2007, by and between the Company and Shionogi & Co., Ltd. Incorporated by reference to Exhibit 10.28 to the Company's Form 10-K filed March 1, 2021.
10.41†	First Amendment to License, Development and Commercialization Agreement, effective as of September 30, 2008, between the Company and Shionogi & Co., Ltd. Incorporated by reference to Exhibit 10.29 to the Company's Form 10-K filed March 1, 2021.
10.42	Purchase and Sale Agreement, dated as of March 9, 2011 between BioCryst Pharmaceuticals, Inc. and JPR Royalty Sub LLC. Incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q filed May 6, 2011.
10.43	Pledge and Security Agreement, dated as of March 9, 2011 between BioCryst Pharmaceuticals, Inc. and U.S. Bank National Association, as trustee. Incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q filed May 6, 2011.
10.44†	Purchase and Sale Agreement, dated as of December 7, 2020, between BioCryst Pharmaceuticals, Inc. and RPI 2019 Intermediate Finance Trust. Incorporated by reference to Exhibit 10.91 to the Company's Form 10-K filed March 1, 2021.
10.45†	Purchase and Sale Agreement, dated as of November 19, 2021, between BioCryst Pharmaceuticals, Inc. and RPI 2019 Intermediate Finance Trust. Incorporated by reference to Exhibit 10.102 to the Company's Form 10-K filed on February 28, 2022.

10.46†	Purchase and Sale Agreement, dated as of November 19, 2021, between BioCryst Pharmaceuticals, Inc. and OCM IP Healthcare Holdings Limited. Incorporated by reference to Exhibit 10.103 to the Company's Form 10-K filed on February 28, 2022.
10.47†	Common Stock Purchase Agreement, dated as of November 19, 2021, between BioCryst Pharmaceuticals, Inc. and RPI Intermediate Finance Trust. Incorporated by reference to Exhibit 10.104 to the Company's Form 10-K filed on February 28, 2022.
(10.48)&	BioCryst Pharmaceuticals, Inc. Equity Award Retirement Policy, effective July 1, 2024, as updated December 18, 2024.
10.49	Amended and Restated IP Licence Agreement, effective October 1, 2025, by and between BioCryst Pharmaceuticals, Inc. and BioCryst Ireland Limited. Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed October 1, 2025.
10.50	Supply Agreement, effective October 1, 2025, by and between BioCryst Pharmaceuticals, Inc. and BioCryst Ireland Limited. Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed October 1, 2025.
10.51	Global Brand and Support Agreement, effective October 1, 2025, by and between BioCryst Pharmaceuticals, Inc. and BioCryst Ireland Limited. Incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed October 1, 2025.
10.52	Transition Services Agreement, effective October 1, 2025, by and between BioCryst Pharmaceuticals, Inc. and BioCryst Ireland Limited. Incorporated by reference to Exhibit 10.4 to the Company's Form 8-K filed October 1, 2025.
10.53	Trademark License Agreement, effective October 1, 2025, by and between BioCryst Pharmaceuticals, Inc. and BioCryst Ireland Limited. Incorporated by reference to Exhibit 10.5 to the Company's Form 8-K filed October 1, 2025.
10.54	Agreement and Plan of Merger by and among BioCryst Pharmaceuticals, Inc., Axel Merger Sub, Inc. and Astria Therapeutics, Inc., dated October 14, 2025. Incorporated herein by reference to Exhibit 2.1 to the Company's Form 8-K filed on October 14, 2025.
(10.55)†	Loan Agreement, dated as of January 23, 2026, by and among BioCryst Pharmaceuticals, Inc., as borrower, the guarantors from time to time party thereto, Blackstone Alternative Credit Advisors LP and Blackstone Life Sciences Advisors L.L.C., as the Blackstone representatives thereunder, the lenders from time to time party thereto and Wilmington Trust, National Association, as agent.
(10.56)	Joinder Agreement, dated as of January 23, 2026, by and between Astria Therapeutics, Inc. and Wilmington Trust, National Association.
(10.57)	Joinder Agreement, dated as of January 23, 2026, by and between Astria Securities Corporation and Wilmington Trust, National Association.
10.58	Stock Purchase Agreement, dated as of June 27, 2025, by and among BioCryst Pharmaceuticals, Inc., BioCryst Ireland Limited and Neopharmed Gentili S.p.A. Incorporated by reference to Exhibit 2.1 to the Company's Form 8-K filed June 30, 2025.
(19)	BioCryst Pharmaceuticals, Inc. Insider Trading Policy.
(21)	Subsidiaries of the Registrant.
(23)	Consent of Ernst & Young, LLP, Independent Registered Public Accounting Firm.

(31.1)	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
(31.2)	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
(32.1)*	Certification of the 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)*	Certification of the 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	BioCryst Pharmaceuticals, Inc. Rule 10D-1 Clawback Policy. Incorporated by reference to Exhibit 97 to the Company's Form 10-K filed on February 27, 2024.
(101)	Financial statements from the Annual Report on Form 10-K of BioCryst Pharmaceuticals, Inc. for the fiscal year ended December 31, 2025, formatted in Inline XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive Income (Loss), (iii) Consolidated Statements of Cash Flows, (iv) Consolidated Statements of Stockholders' Equity and (v) Notes to Consolidated Financial Statements.
(104)	Cover Page Interactive Data File – The cover page from this annual report on Form 10-K for the fiscal year ended December 31, 2025 is formatted in Inline XBRL (contained in Exhibit 101).
†	Certain identified information has been omitted pursuant to Item 601(b)(10) of Regulation S-K because it is both not material and would likely cause competitive harm to the Company if publicly disclosed.
*	The certification is being furnished solely to accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, and will not be deemed "filed" for purposes of Section 18 of the Exchange Act, except to the extent that the Company specifically incorporates it by reference.
&	Management contracts.
( )	Filed herewith.

ITEM 16. ***FORM 10-K SUMMARY.***

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on February 26, 2026.

BIOCRYST PHARMACEUTICALS, INC.

By: /s/ Charles Gayer
Charles Gayer
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on February 26, 2026:

Signature	Title(s)
/s/ Charles Gayer Charles Gayer	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ Babar Ghias Babar Ghias	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
/s/ Vincent Milano Vincent Milano	Chairperson of the Board, Director
/s/ Steven Frank Steven Frank	Director
/s/ Steven Galson Steven Galson, M.D.	Director
/s/ Theresa Heggie Theresa Heggie	Director
/s/ Alan Levin Alan Levin	Director
/s/ Amy McKee Amy McKee, M.D.	Director
/s/ Jill Milne, Ph.D. Jill Milne, Ph.D.	Director
/s/ Machelle Sanders Machelle Sanders	Director
/s/ Jon Stonehouse Jon Stonehouse	Director