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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

OR

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

For the transition period from ____ to _____

Commission File Number 001-36509

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

Delaware **(State or other jurisdiction of incorporation or organization)**	**33-0702205** **(I.R.S. Employer Identification No.)**
11570 6th Street **Rancho Cucamonga, CA** **(Address of principal executive offices)**	**91730** **(zip code)**

(909) 980-9484
(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, par value $0.0001 per share	AMPH	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

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

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

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☒ No ☐

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

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

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant on June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter), based upon the closing price of Common Stock on such date as reported by Nasdaq Global Select Market, was approximately $632,556,518. Shares of common stock known to be held by directors, executive officers and holders of 5% or more of the outstanding common stock of the registrant are not included in the computation. No determination has been made that such persons are "affiliates" of the registrant for any other purpose.

At February 20, 2026, there were 45,370,171 shares of the registrant's common stock outstanding.

Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of its fiscal year to which this report relates in connection with its 2026 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

AMPHASTAR PHARMACEUTICALS, INC.
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SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains "forward-looking statements" that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the following words: "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements relate to future events or future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by the forward-looking statements. These forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the sales and marketing of our products;
- our expectations regarding our manufacturing and production and the integrity of our supply chain for our products, including the risks associated with our single source suppliers;
- our business and operations in general, including: adverse impacts of global conflicts and challenging macroeconomic conditions and market uncertainty on our business, financial condition, operations, cash flows and liquidity;
- our ability to attract, hire, and retain highly skilled personnel;
- interruptions to our manufacturing and production as a result of natural catastrophic events or other causes beyond our control such as power disruptions, pandemics, wars, terrorist attacks or other events;
- the timing and likelihood of U.S. Food and Drug Administration, or the FDA, approvals and regulatory actions on our product candidates, manufacturing activities and product marketing activities;
- our ability to advance product candidates in our platforms into successful and completed clinical trials and our subsequent ability to successfully commercialize our product candidates;
- cost and delays resulting from the extensive pharmaceutical regulations to which we are subject;
- our ability to compete in the development and marketing of our products and product candidates;
- our expectations regarding the business of our Chinese subsidiary, Amphastar Nanjing Pharmaceuticals, Ltd., or ANP;
- the potential for adverse application of environmental, health and safety and other laws and regulations on our operations;
- our expectations for market acceptance of our new products and proprietary drug delivery technologies, as well as those of our active pharmaceutical ingredient, or API, customers;
- the effects of reforms in healthcare regulations and reductions in pharmaceutical pricing, reimbursement and coverage;
- our expectations in obtaining insurance coverage and adequate reimbursement for our products from third-party payers;
- the amount of price concessions or exclusion of suppliers adversely affecting our business;
- variations in intellectual property laws, our ability to establish and maintain intellectual property protection for our products and our ability to successfully defend our intellectual property in cases of alleged infringement;
- the implementation of our business strategies, product development strategies and technology utilization;
- the potential for exposure to product liability claims;
- our ability to successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions, divestitures or investments, including the anticipated benefits of such acquisitions, divestitures or investments;
- our ability to expand internationally;
- economic and industry trends and trend analysis;
- our ability to remain in compliance with laws and regulations that currently apply or become applicable to our business both in the United States and internationally;

- the impact of trade tariffs, export or import restrictions, or other trade barriers;
- the impact of the Patient Protection and Affordable Care Act (as amended) and other legislative and regulatory healthcare reforms in the countries in which we operate including the potential for drug price controls;
- the impact of global and domestic tax reforms;
- the timing for completion and the validation of the new construction at our ANP and Amphastar facilities;
- the timing and extent of share buybacks; and
- our financial performance expectations, including our expectations regarding our backlog, revenue, cost of revenue, gross profit or gross margin, operating expenses, including changes in research and development, sales and marketing and general and administrative expenses, and our ability to achieve and maintain future profitability.

You should read this Annual Report and the documents that we reference elsewhere in this Annual Report completely and with the understanding that our actual results may differ materially from what we expect as expressed or implied by our forward-looking statements. In light of the significant risks and uncertainties to which our forward-looking statements are subject, you should not place undue reliance on or regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. We discuss many of these risks and uncertainties in greater detail in this Annual Report, particularly in Item 1A. “Risk Factors.” These forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report regardless of the time of delivery of this Annual Report, and such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Annual Report.

Unless expressly indicated or the context requires otherwise, references in this Annual Report to “Amphastar,” “the Company,” “we,” “our,” and “us” refer to Amphastar Pharmaceuticals, Inc. and our subsidiaries.

Item 1. Business.

Overview

We are a biopharmaceutical company focusing on developing, manufacturing, and commercializing technically challenging generic and proprietary injectable, inhalation, and intranasal products, as well as active pharmaceutical ingredient, or API products. We currently manufacture and sell over 25 prescription pharmaceutical products, and an over-the-counter product, Primatene MIST®.

Our largest products by net revenues currently include BAQSIMI® glucagon nasal powder, or BAQSIMI®, Primatene MIST®, glucagon, epinephrine, and lidocaine.

In June 2023, we completed our acquisition of BAQSIMI®, the first and only nasally administered glucagon for the treatment of severe hypoglycemia in people with diabetes, and it is currently available in the United States and 26 international markets.

In May 2024, the FDA approved our albuterol sulfate inhalation aerosol, which we launched in August 2024.

In August 2025, the FDA approved our iron sucrose injection, USP 50mg/2.5mL, 100mg/5mL, and 200mg/10mL in single-dose vials, which we launched in the August 2025.

In December 2025, the FDA approved our teriparatide injection, USP 560mcg/2.24mLsingle-patient-use prefilled pen, which we launched in the December 2025.

In February 2026, the FDA approved our Ipratropium Bromide HFA inhalation aerosol, 17 mcg/actuation, which we plan to launch early in the second quarter of 2026.

For the years ended December 31, 2025, 2024, and 2023, we recorded net revenues of $719.9 million, $732.0 million, and $644.4 million, respectively. We recorded net income of $98.1 million, $159.5 million, and $137.5 million for the years ended December 31, 2025, 2024, and 2023, respectively.

We are currently developing a portfolio of generic abbreviated new drug applications, or ANDAs, biologics license applications, or BLAs, including biosimilar insulin product candidates and proprietary product candidates, which are in various stages of development and target a variety of indications. One ANDA and one biosimilar insulin candidate are currently on file with the FDA.

Our multiple technological capabilities enable the development of technically challenging products with limited competition. These capabilities include characterizing complex molecules, analyzing and synthesizing peptides and proteins, conducting immunogenicity studies, engineering particles, and improving drug delivery through sustained-release technology. These technological capabilities have enabled us to produce bioequivalent versions of complex drugs and support the development and manufacture of a broad range of dosage formulations, including solutions, emulsions, suspensions, and lyophilized products, as well as products administered via pre-filled syringes, vials, nasal sprays, or metered-dose inhalers, or MDIs.

Our primary strategic focus is developing and commercializing products with high technical barriers to market entry. We are specifically focused on products that:

- Leverage our proprietary research and development capabilities;
- Require raw materials or APIs for which we believe we have a competitive advantage in sourcing, synthesizing, or manufacturing; and/or
- Improve upon an existing drug’s formulation with respect to drug delivery, safety, and/or efficacy.

Not all of our products will include all of these characteristics. Moreover, we may opportunistically develop and commercialize product candidates with lower technical barriers to market entry if, for example, our existing supply chain and manufacturing infrastructure allow us to pursue a specific product candidate competitively and cost-effectively.

We have made several strategic acquisitions of companies, products, and technologies to complement our internal growth and expertise. These acquisitions have strengthened our core injectable and inhalation product technology infrastructure by providing additional manufacturing, marketing, and research and development capabilities, including the ability to manufacture starting materials, API, and other product components.

Our Markets

We primarily target products with high technical barriers to market entry, with a particular focus on the injectable and inhalation markets. We also manufacture and sell certain APIs.

- *Injectable market.* Based on a December 2025 IQVIA National Sales Perspective Report, the U.S. injectable drug market in 2025 was over $480 billion. Our generic development, including interchangeable biosimilar portfolio, is targeting opportunities in over $7 billion of this market. The injectable market requires highly technical manufacturing capabilities and compliance with strict current Good Manufacturing Practice, or cGMP, requirements, which create high barriers to market entry. Due to these high barriers to market entry, there are a limited number of companies with the technology and experience needed to manufacture injectable products. There have also been a number of quality issues over the past several years that have disrupted the ability of certain injectable manufacturers to produce sufficient product quantity to meet market demand. As such, the supply of injectables has been constrained, even as demand for injectable products has continued to increase.

- *Inhalation market.* Based on a December 2025 IQVIA National Sales Perspective Report, the U.S. inhalation drug market in 2025 was approximately $27 billion. Our generic development portfolio is targeting opportunities in over $1.1 billion of this market. Inhalation drug therapy is used extensively to treat respiratory conditions such as asthma and chronic obstructive pulmonary disease. The MDI is the most widely used device to deliver inhalation therapies. It uses pressurized gas, historically chlorofluorocarbons, or CFCs, and more recently HFAs, to release its dose when the patient activates the device. As in the case of injectables, there are significant technical barriers to manufacturing inhalation products. The evolution of inhalation delivery technologies from nebulizers and CFCs to HFAs has required manufacturers of inhalation products to re-formulate their products, which in many cases may require technical engineering capabilities, additional regulatory approvals and modified delivery devices. Additionally, the development of generic HFA products requires bioequivalence studies for FDA approval.

Our Strengths

We have built our company by integrating the following capabilities and strengths that we believe enable us to compete effectively in the pharmaceutical industry:

- *Robust portfolio of products and product candidates.* We market over 25 commercial products and are developing over 10 product candidates. Our portfolio includes complex generics, biosimilars, and proprietary products at various stages of development. Consistent with our long-term strategy, we continue to expand into higher-value proprietary and biosimilar programs, which we expect will represent an increasing proportion of our pipeline over time.

- *Advanced technical capabilities and multiple delivery technologies.* We have developed multiple advanced technical capabilities that we incorporate into the development of our products and product candidates. These capabilities include characterization of complex molecules, peptide and protein analysis and synthesis, immunogenicity studies, particle engineering, and sustained-release technology. We apply these capabilities across multiple delivery platforms, including injectable, inhalation (MDI), and intranasal delivery technologies. We also develop and utilize prefilled-pen injection delivery systems to support our insulin and other injectable programs, enabling consistent dosing performance and compatibility with a range of biologic and peptide formulations. Our injectable delivery technologies enable us to develop and manufacture generic and proprietary injectables in normal solution, lyophilized, suspension, jelly, emulsion forms, using vials, prefilled pens, and prefilled syringes. Our inhalation technologies cover a variety of delivery methods, including HFA formulations of MDIs. Intranasal technology can offer a non-invasive and convenient route of drug delivery systems. It can offer the advantage of drug bioavailability by bypassing the effect of the first-pass metabolism and can allow drugs to achieve a more rapid and efficient

therapeutic effect. These technical capabilities form the foundation of our strategy to develop products with high barriers to market entry targeting a wide range of indications.

- *Vertically integrated infrastructure.* We are a vertically integrated company with the demonstrated ability to advance a product candidate from the research and development stage through commercialization. Our capabilities include strong research and development expertise, sophisticated pharmaceutical engineering capabilities, comprehensive manufacturing capabilities (including synthesizing and manufacturing API), a strict quality assurance system, extensive regulatory and clinical experience, and established marketing and distribution relationships. We believe our vertical integration allows us to achieve better operating efficiencies, accelerated product development, improved supply chain control, more flexibility in responding to market demands, and internal control over product quality.

- *Experienced management team with deep scientific expertise.* Our management team has a successful track record in product development, project management, quality assurance, acquisitions, sales and marketing and has established relationships with our key customers, partners, and suppliers. Our research and development leadership has deep expertise in areas including pharmaceutical formulation, process development, *in vivo* and *in vitro* studies, analytical chemistry, physical chemistry, drug delivery, and clinical research. We believe that our scientific and technical expertise, coupled with our management team's business, legal, regulatory, and business development experience, will enable us to successfully expand our position with respect to our current products and establish a meaningful market position for our product candidates.

Our Strategy

We aim to be an industry leader in developing, manufacturing, and commercializing technically challenging injectable, inhalation and intranasal pharmaceutical products. In recent years, we have shifted our development focus from primarily complex generics toward proprietary and biosimilar products, reflecting our long-term strategy to expand into higher-value, innovative-driven programs. To achieve this goal, we are pursuing the following key strategies:

- *Diversify our revenues by commercializing our product candidates.* Assuming we successfully develop and obtain regulatory approvals, we plan to commercialize our product candidates and diversify our revenue sources. We have over 10 product candidates in various stages of development, including generic ANDAs, New Drug Applications, NDAs, biosimilar product candidates, and proprietary product candidates. We also expect to expand our internal sales and marketing capabilities and, in some cases, enter into strategic alliances with other pharmaceutical companies to drive market penetration for our product candidates.

- *Complex generic product opportunities.* We believe that we have opportunities for growth driven by our technical expertise in developing generic product candidates with high technical barriers to market entry. We believe that if these product candidates are commercialized, they are likely to face less competition than less technically challenging generic products, which may enable us to earn higher margins for a longer period of time. We believe generic competition for these products will likely be limited because of challenges in product development, manufacturing, or sourcing raw materials or APIs.

- *Develop proprietary products.* We currently have several proprietary product candidates at various stages of development, targeting a broad range of indications. We believe that proprietary products tend to face less competition than generic products due to market exclusivity, intellectual property protection, and other barriers to entry. For these reasons, we believe that our proprietary products will provide us with the opportunity for higher margins and long-term revenue growth.

- *Leverage our vertically integrated infrastructure to drive operational efficiencies.* We believe our vertically integrated infrastructure provides significant benefits, including better operating efficiencies, accelerated product development, and internal control over product quality. Our ability to manufacture APIs allows us to develop products that other companies may not focus on due to the uncertainty of API supply. In addition, our vertically integrated infrastructure, including our research and development capabilities, allows us to conduct technically challenging studies in-house. We believe this vertically integrated infrastructure has led and will continue to lead to a competitive portfolio of products and product candidates.

- *Target and integrate acquisitions of pharmaceutical companies, products, and technologies.* We have a demonstrated ability to identify, acquire and integrate pharmaceutical companies, products, and technologies to complement our internal product development capabilities. Companies we have acquired include, amongst others, (1) International Medication Systems, Limited, or IMS, (2) Armstrong Pharmaceuticals, Inc., or Armstrong, (3) Nanjing Puyan Pharmaceutical Technology Co., Ltd. (which we renamed Amphastar Nanjing Pharmaceuticals Co., Ltd.), or ANP, and (4) Merck Sharpe & Dohme's, or Merck's, API Manufacturing Business in Éragny-sur-Epte, France, in connection with which, we established our French subsidiary, Amphastar France Pharmaceuticals, S.A.S., or AFP. Products we have acquired include BAQSIMI®, Cortrosyn®, and Primatene® MIST. We believe that our scientific and managerial expertise and our integration experience have improved the quality of the product lines and companies that we have acquired, which has had, and we believe will continue to have, a positive effect on our results of operations.

- *Proprietary product licensing.* We have licensed several peptide proprietary product candidates from Nanjing Anji Biotechnology Co., Ltd., or Anji, and Nanjing Hanxin Pharmaceutical Technology Co., Ltd., or Hanxin. We believe we can develop, manufacture and commercialize these product candidates as part of our long-term revenue growth.

Our Technical Capabilities

We develop, manufacture, market, and sell generic and proprietary products that utilize injectable, inhalation, and intranasal delivery systems. We also manufacture and sell insulin API.

- *Injectable.* Our injectable product technologies enable us to develop and manufacture generic and proprietary injectables in liquid, lyophilized, suspension, and emulsion forms, as well as the use of prefilled pens and prefilled syringes to facilitate safety and convenience to users. We have multiple injectable manufacturing facilities that include aseptic filling lines dedicated to the sterile production of injectable products. Additionally, we maintain compliance with cGMP regulations, which has enabled us to obtain regulatory approvals and support commercial supply.

- *Inhalation and Intranasal.* We are focused on developing a broad range of generic and proprietary inhalation and intranasal products utilizing various delivery technologies. We have expertise in formulating HFA-based MDIs, as well as packaging our inhalation drugs in blister packs and other forms that can be used to load our products into various inhalation devices. As with our injectable products, we maintain compliance with cGMP regulations, which we believe will enable us to obtain regulatory approvals and support commercial supply. Additionally, we have extensive formulation and clinical experience in developing complex formulations that can be administered by intranasal delivery. In addition, we are developing formulations using a new environmentally friendly propellant for use in future MDI products as part of our ongoing efforts to advance inhalation technologies.

We have advanced capabilities that enable us to develop technically challenging products.

- *Characterization of complex molecules.* Complex molecule characterization includes determining physicochemical properties, biological activity, immunochemical properties, and purity. Such characterization is important in developing a generic product that is considered the same as a reference drug product, which in turn allows the generic drug developer to demonstrate such "sameness" to the FDA, which ultimately allows for interchangeability with the reference drug product. Complex drugs typically have large molecules composed of a mixture of molecules that differ very slightly from one another. These slight variances make such complex molecules difficult to characterize. We have developed analytical tools that have enabled us to characterize complex molecules in our products and product candidates. We believe that we have the technology to develop a variety of additional analytical tools that will enable us to characterize other complex molecules, including peptide and protein-based products.

- *Immunogenicity.* The ability of an antigen to elicit immune responses is called immunogenicity. Unwanted immunogenicity, which is strongly linked with peptide and protein drug products, occurs when a patient mounts an undesired immune response against drug therapy. As a result, the FDA has signaled that it may require immunogenicity studies as part of the new pathway for biosimilars. In the past, the FDA has required these studies to approve products with complex molecules. We have gained expertise in

immunogenicity by performing immunogenicity studies in connection with the FDA approval process for our enoxaparin product. We believe that our experience conducting these complex immunogenicity studies will be of primary importance in our future efforts to develop complex molecules, and biosimilar product candidates.

- *Peptide and protein product development and production.* The development of peptide and protein drug products utilizes our characterization technology, immunogenicity studies, synthetic capabilities, recombinant DNA, or rDNA, and API manufacturing technology. We have experience using rDNA manufacturing technology, including the genetic engineering of host cells, fermentation to promote cell culture growth, and isolation and purification of the desired protein from the cell culture. Testing is required to ensure that only the desired protein is included in the finished product through each step. We believe that this technology will allow us to develop protein and peptide drug products. In December 2020, we received the first-ever FDA approval for a generic version of Glucagon for Injection Emergency Kit. The FDA determined our approved peptide product to be bioequivalent and therapeutically equivalent to the reference listed drug, which has rDNA origin.

- *Particle engineering.* Particle engineering is important in the field of pulmonary drug delivery as there is a direct relationship between the properties of a particle and its absorption by the lungs. We believe our expertise and technology, which applies to particle engineering and physical chemistry, allow us to engineer particles' size, shape, surface smoothness and distribution to develop inhalation products that are more easily dispersed through targeted areas. We believe this expertise will allow us to formulate difficult-to-disperse inhalation products and demonstrate the sameness of the reference-listed drugs to the FDA.

- *Sustained-release.* We have developed technology to improve drug delivery through sustained-release injectable products. Our sustained-release technology aims to create products that require less dosing frequency, which we believe can lead to diminishing fluctuations of drug concentrations in a patient's bloodstream that would otherwise require more frequent dosing. We plan to use our sustained-release technology to develop generic and proprietary products.

- *Novel formulation.* We have the capability to develop novel formulations to enhance drug delivery. For certain intranasal medications, novel formulations might be required to increase the drug's absorption rate to deliver the medication safely and efficiently. We plan to use our novel formulation with our intranasal epinephrine and other proprietary products.

Pharmaceutical Products

Our Marketed Products

We currently manufacture and sell over 25 products. The following is a description of major and recently launched products in our existing portfolio.

BAQSIMI® (glucagon) nasal powder 3mg

BAQSIMI®, a dry nasal spray used in an emergency for the treatment of severe hypoglycemia in people with diabetes ages four years and above, is the first and only nasally administered glucagon. It is compact, portable and ready to use in a single, fixed 3mg dose.

Primatene MIST®

Primatene MIST®, an over-the-counter epinephrine inhalation product, is indicated for the temporary relief of mild symptoms of intermittent asthma.

Glucagon for Injection Emergency Kit

Glucagon for injection is a difficult to manufacture injectable product. We received the first-ever FDA approval of a generic version of rDNA Glucagon in the fourth quarter of 2020. Using a dedicated process and sophisticated characterization technology, we demonstrated to the FDA that our highly purified synthetic peptide product is

bioequivalent and therapeutically equivalent to the reference listed drug, or RLD, which is an rDNA product. Glucagon for injection emergency kit is indicated for the treatment of severe hypoglycemia and is used as a diagnostic aid.

Enoxaparin

Enoxaparin is a difficult to manufacture injectable form of low molecular weight heparin, which is used as an anticoagulant, and has multiple indications, including the prevention and treatment of deep vein thrombosis. Enoxaparin is difficult to produce in part because the API is not easily manufactured. We manufacture the API for our enoxaparin product and perform all subsequent manufacturing of the finished product in-house.

Naloxone

We sell two versions of naloxone injections for the emergency treatment of known or suspected opioid overdose. We also sell REXTOVY®, our prescription naloxone nasal spray product delivered using our proprietary device, which is intended to be used for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression.

Other Marketed Products

Other pharmaceutical products that we currently market include the following:

- Cortrosyn® (cosyntropin for injection), a lyophilized powder that is indicated for use as a diagnostic agent in the screening of patients with adrenocortical insufficiency;
- Amphadase®, a bovine-sourced hyaluronidase injection that is used as an adjuvant in subcutaneous fluid administration for achieving hydration, to increase absorption and dispersion of other injected drugs, and in subcutaneous urography for improving absorption of radiopaque agents;
- Epinephrine injection, indicated for emergency treatment of allergic reactions, including anaphylaxis, and to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock;
- Lidocaine jelly, a local anesthetic product used primarily for urological procedures;
- Lidocaine topical solution, a local anesthetic used for a variety of procedures;
- Phytonadione injection, an injection of Vitamin K1 that is used for newborn babies;
- Our portfolio of emergency syringe products, including critical care drugs such as atropine, calcium chloride, dextrose, epinephrine, lidocaine, and sodium bicarbonate, are provided in pre-filled syringes and are designed for emergency use in hospital settings;
- Albuterol sulfate inhalation aerosol, indicated for the treatment or prevention of bronchospasm in patients four years of age and older with reversible obstructive airway disease;
- Iron sucrose injection, an iron replacement product indicated for the treatment of iron deficiency anemia in patients with chronic kidney disease;
- Teriparatide injection, USP 560 mcg/2.24mL (250 mcg/mL) single-patient-use prefilled pen. is bioequivalent and therapeutically equivalent to Eli Lilly's FORTEO®, for managing daily osteoporosis therapy; and
- Ipratropium Bromide HFA inhalation aerosol is an anticholinergic indicated for the maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

APIs

We manufacture and sell two API products: Recombinant Human Insulin, or RHI API, and porcine insulin API. These products are part of our vertical integration strategy, as we focus on specific finished products for the injectable insulin market. We also sell RHI API and porcine insulin API to third parties. Additionally, we plan to sell two GLP-1 APIs which were developed and manufactured at our ANP facility to third parties. Sales of small batches for R&D purposes has already begun, but more meaningful sales will require a regulatory approval outside of the U.S.

Our Product Candidates

We seek to develop product candidates with high technical barriers to competitive market entry that leverage our technical capabilities and other competitive advantages. We focus on generic and proprietary product candidates in the injectable, inhalable, topical, and intranasal markets. Our pipeline products are in various stages of development, with a number of these candidates still in the early stages of development. Our pipeline has over 10 product candidates, including generic ANDAs, biosimilar, and proprietary product candidates.

The development, regulatory approval for and commercialization of our product candidates are subject to numerous risks. See Item 1A, “Risk Factors” for additional information.

Generic Product Candidates

We generally employ a strategy of developing generic product candidates that possess a combination of factors that present technical barriers to competition, including difficult formulations, which require complex characterizations, difficult manufacturing requirements and/or limited availability of raw materials. We believe such factors will make these product candidates less susceptible to competition and pricing pressure. We currently have generic ANDAs and biosimilar product candidates at various development stages that leverage our various technical capabilities, including:

- injectable technologies, which include various delivery methods and sizes of pre-filled syringes, vials in solution, suspension and lyophilized forms;
- inhalation technologies, which include MDIs; and
- sophisticated analytical technologies, including characterization and immunogenicity studies for complex molecules, particle engineering, sustained-release technology, peptide, protein and DNA analysis and synthesis.

Biosimilar Product Candidates

Our biosimilar pipeline, with a particular emphasis on interchangeable insulin analogs, targets a high-demand diabetes care sector. Our planned filings use in-house developed technical platforms while navigating a complex regulatory environment with our goal to obtain interchangeable designations.

We are applying our technology platforms to develop product candidates in our biosimilar portfolio, including two interchangeable insulin product candidates: Insulin Aspart (AMP-004), and Recombinant Human Insulin (AMP-005). Developed to meet stringent bioequivalence standards, these candidates are expected to support our vision to effectively and efficiently meet the needs of our target markets.

Additionally, we are developing a biosimilar product outside of our insulin portfolio, AMP-028. This product is expected to leverage our API facilities to participate in a large market without any interchangeable biosimilars.

A rigorous development strategy reinforces our commitment to developing biosimilar products and utilizes our vertically integrated structure when possible. Furthermore, our biosimilar product candidates are developed in accordance with regulatory guidelines for biosimilars, focusing on achieving interchangeability and bioequivalence to their respective reference products through rigorous pharmacokinetic and pharmacodynamics studies, supported by our expertise in areas such as protein engineering, creation of highly purified peptides/proteins, immunogenicity assessments, drug product characterization, and other internal technical platforms. This strategy is designed to deliver high-quality biosimilar

products that meet all regulatory requirements for biosimilarity and interchangeability, thereby maximizing production efficiency.

Proprietary Product Candidates

Our integrated technical skills and expertise provide a strong basis for the development of proprietary drug candidates. These skills include new chemical entity assessment, peptide and protein synthesis technology, complex formulation development, characterization analysis, and immunogenicity studies.

With respect to our proprietary pipeline strategy, we currently have proprietary drug candidates at various development stages that leverage our various technical capabilities including:

Intranasal epinephrine (AMP-019)

Intranasal epinephrine, a prescription epinephrine nasal spray product candidate, is intended to be used for emergency treatment of allergic reactions, including anaphylaxis to stinging insects, allergen immunotherapy, foods, drugs and other allergens.

AMP-105

AMP-105 is a first-in-class peptide targeting a novel mechanism to modulate cell growth and metastasis of multiple poorly treated cancers, offering a new anti-tumor option for patients.

AMP-107

AMP-107 is the first non-injectable anti-vascular endothelial growth factor receptor peptide, which is developed as a topical eye drop for the treatment of wet age-related macular degeneration. It is intended to be an alternative to the routine eye injections used for current treatments.

AMP-109

AMP-109 is a novel peptide-docetaxel conjugate that targets a specific receptor, designed to improve the selectivity and bioavailability of docetaxel. It is designed to reduce docetaxel-induced toxicity, which will improve the efficacy and safety of current taxane therapies.

AMP-110

AMP-110 is a novel synthetic human corticotropin (ACTH) analog. This peptide will target multiple indications.

Other Proprietary Product Candidates

In addition, we have other proprietary product candidates in development. These product candidates incorporate multiple indications utilizing a wide variety of our technical capabilities.

BAQSIMI® Acquisition

In connection with the acquisition of BAQSIMI® in June 2023, we entered into a Transition Service Agreement, or TSA, with Eli Lilly & Company, or Lilly, pursuant to which Lilly agreed to provide certain services to us to support the transition of BAQSIMI® operations, including with respect to the conduct of certain clinical, regulatory, medical affairs, and commercial sales channel activities. Over the course of 2024, we assumed responsibility of these activities from Lilly on a country-by-country basis. As of January 1, 2025, the transition pursuant to the TSA has been completed and we distribute and manage the BAQSIMI® supply chain in all countries where it is available.

The acquisition of BAQSIMI®, builds upon our commercial intranasal product portfolio, provides us with a branded product with growing sales and strong gross margins, and expands our international footprint into 26 new countries.

Research and Development

As of December 31, 2025, we had 163 employees dedicated to research and development with expertise in areas such as pharmaceutical formulation, process development, toxicity studies, analytical, synthetic, and physical chemistry, drug delivery, device development, equipment and engineering, clinical research statistical analysis, etc. Our focus on developing products with high barriers to market entry requires a significant investment in research and development, including clinical development. In particular, developing proprietary products that are reformulations of existing proprietary compounds often requires clinical trials to gain regulatory approval, and we have a team dedicated to designing and managing clinical trials. We have successfully completed several clinical trials for some of our product candidates and are in the process of planning clinical trials for other product candidates under development.

Backlog

A significant portion of our customer shipments in any fiscal year relates to orders received and shipped in that fiscal year, generally resulting in a low product backlog relative to total shipments at any time. We had no significant backlog as of December 31, 2025. Historically, our backlog has not been a meaningful indicator of our ability to achieve any particular level of overall revenue or financial performance.

Manufacturing and Facilities

Our manufacturing facilities are located in Rancho Cucamonga and South El Monte, California; Canton, Massachusetts; Éragny-sur-Epte, France; and Nanjing, China. As of December 31, 2025, we own or lease a total of 69 buildings at six locations in the United States, France and China, that comprise 2.5 million square feet of manufacturing, research and development, distribution, packaging, laboratory, office and warehouse space. Our facilities are regularly inspected by the FDA in connection with our product approvals, and we believe that all of our facilities are being operated in material compliance with the FDA's cGMP regulations.

We continue to expand our facility in Nanjing, China, and expect further significant investment in this facility.

Our API manufacturing facility in Éragny-sur-Epte, France, manufactures porcine insulin API, RHI API, and the API for our AMP-028 biosimilar candidate, and we expect to continue the current site activities.

We believe that our current manufacturing capacity is adequate for the near term. However, we are planning to increase capacity at our plant in Rancho Cucamonga, CA with the goal of allowing us to eventually quadruple the number of units produced at this facility. We are also increasing the capacity of our inhalation facility in Canton, MA and our insulin API production facility at ANP.

Raw Material and Other Suppliers

We depend on suppliers for raw materials, APIs and other components that are subject to stringent FDA requirements. In some cases, we obtain raw materials, components or APIs used in certain of our products from single sources. Currently, we obtain API for certain of our other marketed products from single sources. If we experience difficulties acquiring sufficient quantities of required materials or products from our existing suppliers, or if our suppliers are found to be non-compliant with the FDA's quality system regulation, or QSR, cGMPs or other applicable laws or regulations, we would be required to find alternative suppliers. Obtaining the required regulatory approvals to use alternative suppliers may be a lengthy and uncertain process during which we could lose sales. If our primary suppliers become unable or unwilling to perform, we could experience protracted delays or interruptions in the supply of materials that would ultimately delay our manufacturing of products for commercial sale, which could materially and adversely affect our development programs, commercial activities, operating results and financial condition.

We depend on contract manufacturing organizations, or CMOs, for the supply of BAQSIMI® which are subject to stringent FDA requirements. If our CMOs experience difficulties in acquiring sufficient quantities of required materials or products from their existing suppliers or if our CMOs are found to be non-compliant with the FDA's or other regulatory agencies quality system regulation, cGMP, or other applicable laws or regulations, we would be required to find alternative CMOs. Obtaining the required regulatory approvals to use alternative CMOs may be a lengthy and uncertain process during which we could lose sales. If our CMOs become unable or unwilling to perform, we could

experience protracted delays or interruptions in the supply of BAQSIMI® which could materially and adversely affect our commercial activities, operating results and financial conditions.

If our suppliers or our CMOs encounter problems during manufacturing, establishing additional or replacement suppliers for these materials may take a substantial period of time, as suppliers must be approved by the FDA. Further, a significant portion of our raw materials may be available only from foreign sources, which are subject to the risks of doing business abroad.

The U.S. Department of Agriculture, or USDA, the Animal and Plant Health Inspection Service, or APHIS, and the Veterinary Services regulates the importation of animals and animal-derived materials into the U.S. A USDA veterinary permit is required for importation of materials derived from animals or exposed to animal-source materials. Some of our raw materials sourced from foreign sources are subject to import regulations and permit requirements, including from the USDA. If we are unable to import raw materials, rely upon existing supplies of raw materials or manufacture raw materials in sufficient amounts for our manufacturing needs, we may be required to find alternative suppliers or sources of such materials, which would require prior FDA approval for such alternative suppliers or sources of such materials, which would disrupt or delay the manufacturing of our products.

Similarly, on December 27, 2020, the American Innovation in Manufacturing Act of 2020, or AIM Act, was enacted. The AIM Act directs the United States Environmental Protection Agency to address usage of hydrofluorocarbons, or HFC, by reducing production and consumption of certain HFCs. One of our products, Primatene MIST®, utilizes HFCs subject to the AIM Act's reduction mandate. Moreover, many of our inhalation pipeline assets use HFCs subject to the AIM Act's reduction mandate. There can be no assurance that we will be able to acquire adequate supplies of HFCs for current and future commercialization of our products as a result of the AIM Act or other similar statutes and regulations. Moreover, changes to the ingredients of our proprietary and generic products require FDA approval and there can be no assurance that we will be able to obtain such approval or the timing of such approval.

ANP currently manufactures heparin sodium for our enoxaparin product, isoproterenol, hyaluronidase, and medroxyprogesterone for Amphastar's current products, and we plan to have ANP manufacture APIs and starting materials for APIs for certain other products and product candidates.

Sales and Marketing

Our products are marketed and sold to institutions such as hospitals, long-term care facilities, alternate care sites, clinics, and doctors' offices, and to retail pharmacies. Most institutional customers and retail pharmacies are members of one or more group purchasing organizations, which negotiate collective purchasing agreements on behalf of their members. These facilities purchase products through specialty distributors and wholesalers. We have relationships with the major group purchasing organizations in the United States. We also have relationships with major specialty distributors, wholesalers and retailers who distribute pharmaceutical products nationwide.

The following table provides information regarding the percentage of our net revenues that is derived from each of our major customers and partners:

	% of Net Revenues Year Ended December 31,		
	2025	2024	2023
McKesson	24 %	25 %	25 %
Cencora	22 %	20 %	20 %
Cardinal Health	19 %	19 %	15 %

Our marketing department is responsible for establishing and maintaining contracts and relationships with the group purchasing organizations, distributors, retailers, wholesalers and our sales force is focused on promoting BAQSIMI® and Primatene MIST® with healthcare professionals. One or more of our proprietary product candidates may require deployment of a sales force either directly or through a strategic partner.

Competition

We face and will face significant competition for our products and product candidates from pharmaceutical companies that focus on proprietary and generic injectable and inhalation markets such as Pfizer, Inc., BPI Labs, Lupin Pharmaceuticals, Inc., Viatris Inc., Fresenius Kabi USA, Apotex Corp, American Regent Inc., Hikma Pharmaceuticals USA, Inc., Par Pharmaceuticals, Cipla USA Inc., Meitheal Pharmaceuticals, Dr. Reddy's Laboratories, Inc., Xeris Pharmaceuticals, Medefil Inc., Accord Healthcare, and Teva Pharmaceutical USA Inc. Competition in the generic pharmaceutical industry has increased as producers of branded products have entered the business by creating generic drug subsidiaries, purchasing generic drug companies, or licensing their products to generic manufacturers prior to patent expiration and/or as their patents expire. Therefore, our competitors also include the innovator companies of our generic drug products. The presence of these current and prospective competitive products may have an adverse effect on our market share, revenue and gross profit from our products.

Similarly, we will face significant competition for our proprietary product candidates. Our competitors vary depending upon product categories, and within each product category, upon dosage strengths and drug-delivery systems. Based on total assets, annual revenues and market capitalization, we are smaller than some of our competitors with respect to both our generic and proprietary products and product candidates. Some of our competitors have been in business for a longer period of time, have a greater number of products on the market and have greater financial and other resources than we do. It is also possible that developments by our competitors will make our generic or proprietary products and product candidates noncompetitive or obsolete.

For pharmaceutical companies, the most important competitive factors are scope of product line, ability to timely develop new products and relationships with group purchasing organizations, retailers, wholesalers and customers. Sales of generic pharmaceutical products tend to follow a pattern based on regulatory and competitive factors. As patents for brand-name products and related exclusivity periods expire, the first generic pharmaceutical manufacturer to receive regulatory approval for generic versions of products is typically able to achieve significant market penetration and higher margins. As competing generic manufacturers receive regulatory approval on the same products, market size, revenue and gross profit typically decline. The level of market share and price will be affected, which will in turn affect the revenue and gross profit attributable to a particular generic pharmaceutical product. This impact is normally related to the number of competitors in that product's market and the timing of that product's regulatory approval. We must develop and introduce new products in a timely and cost-effective manner and identify products with significant barriers to market entry in order to grow our business.

Government Regulation

In the United States

General

Our operations and many of the products manufactured or sold by the company are subject to extensive regulation by a number of government agencies, both within and outside the United States. In the United States, the federal agencies that regulate the company's facilities, operations, employees, products (including their manufacture, sale, import and export) and services include: the U.S. Food and Drug Administration, the Drug Enforcement Agency, the Environmental Protection Agency, the Occupational Health & Safety Administration, the Department of Agriculture, the Department of Labor, the Department of Defense, Customs and Border Protection, the Department of Commerce, the Department of Treasury and others. International government agencies also regulate public health, product registration, manufacturing, environmental conditions, exports, imports, and other aspects of the company's global operations and products.

Pharmaceutical companies and their prescription brand and generic pharmaceutical products are subject to extensive pre- and post-market regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, or FFDCA, the Public Health Service Act of 1944, or PHSA, and regulations implementing those statutes, with regard to the testing, manufacturing, safety, efficacy, labeling, storage, record-keeping, advertising and promotion of such products, and by comparable agencies and laws in foreign countries. For many drugs (drugs falling within the definition of "new drug" in the FFDCA), FDA approval is required before the product can be marketed in the United States. All applications for FDA approval must contain, among other things, comprehensive and scientifically reliable information relating to pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling and quality control. These applications must also contain data and information related to safety, effectiveness, bioavailability and/or bioequivalence.

Many of our activities are subject to the jurisdiction of other federal regulatory and enforcement departments and agencies, such as the Department of Health and Human Services, or HHS, Office of the Inspector General, or OIG, the Federal Trade Commission (which also has the authority to regulate the advertising of consumer healthcare products, including over-the-counter drugs), the Department of Justice, the Drug Enforcement Administration, or DEA, the Veterans Administration, the Centers for Medicare and Medicaid Services and the Securities and Exchange Commission, or SEC. Individual states, acting through their attorneys general, have become active as well, seeking to regulate the marketing of prescription drugs under state consumer protection and false advertising laws.

FDA Approval and Regulatory Considerations

Prescription generic and branded pharmaceutical products are subject to extensive regulation by the FDA under the FFDCA and PHSA and regulations implementing those statutes, with regard to the testing, manufacturing, safety, efficacy, labeling, storage, record-keeping, advertising and promotion of such products, and regulation by other state, federal and foreign agencies under the laws that they enforce. For many drugs (drugs falling within the definition of "new drug" in the FFDCA), including the drugs in our current drug portfolio, FDA approval is required before marketing in the U.S. Applications for FDA drug approval must generally contain, among other things, information relating to pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling, quality control and either safety and effectiveness or bioequivalence. There are two drug approval processes under the FFDCA — an ANDA approval process for generic drugs and an NDA approval process for new drugs that cannot be approved in ANDAs. For drugs that are "biological products" within the meaning of the PHSA, there are two different approval processes — a biological license application, or BLA, approval process for original biological products and a biosimilar application approval process for biosimilar products that are approved based on their similarity to biologicals that were previously approved in BLAs.

The ANDA Approval Process

Our pipeline generic drug product candidates cannot be lawfully marketed unless we obtain FDA approval. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as "the Hatch-Waxman Act," established abbreviated FDA approval procedures for drugs that are shown to be bioequivalent to drugs previously approved by the FDA through its NDA process, which are commonly referred to as the "innovator" or "reference" drugs. Approval to market and to distribute these bioequivalent drugs is obtained by filing an ANDA with the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the API, drug product formulation, specifications, stability, analytical methods, manufacturing process validation data, quality control procedures and bioequivalence. Rather than demonstrating safety and effectiveness, an ANDA applicant must demonstrate that its product is bioequivalent to an approved reference drug. In certain situations, an applicant may submit an ANDA for a product with a strength or dosage form that differs from a reference drug based upon FDA approval of an ANDA Suitability Petition. The FDA will approve an ANDA Suitability Petition if it finds that the product does not raise questions of safety and efficacy requiring new clinical data. ANDAs generally cannot be submitted for products that are not bioequivalent to the referenced drug or that are labeled for a use that is not approved for the reference drug. Applicants seeking to market such products can submit an NDA under Section 505(b)(2) of the FFDCA with supportive data from clinical trials.

The Generic Drug User Fee Act, or GDUFA, was enacted by Congress in 2012 and was reauthorized as GDUFA II in 2017 and GDUFA III in 2022. GDUFA is designed to provide funding to the FDA to expedite timelines for the FDA's review of ANDA applications. GDUFA funding is intended to increase the ability of the FDA to perform critical program functions and to reduce costs. Under the GDUFA, the FDA has specific goals for reviewing ANDA applications. For example, as part of GDUFA II and GDUFA III, the goal of the FDA is to complete the review of 90% of original ANDA applications within 10 months from filing of the ANDA. Under previous GDUFA authorizations, the average time for sponsors to obtain FDA approval of ANDAs was 32-34 months post-filing. As newer GDUFA reauthorizations occur in 5 year increments, it is expected that these ANDA timelines will also change.

Upon approval of an NDA or ANDA, the FDA lists the product in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," which is commonly known as the "Orange Book." In the case of an NDA, the FDA also lists patents identified by the NDA applicant as claiming the drug or an approved method of using the drug. Any applicant who files an ANDA must certify to the FDA with regard to each relevant patent that (1) no patent information has been submitted to the FDA; (2) the patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the patent is invalid or will not be

infringed upon by the manufacture, use or sale of the drug product for which the ANDA is submitted. This last certification is known as a Paragraph IV certification. A notice of the Paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA refers. If the NDA holder submits the patent information to the FDA prior to submission of the ANDA and the NDA holder or patent owner(s) sues the ANDA applicant for infringement within 45 days of its receipt of the certification notice, the FDA is prevented from approving that ANDA until the earlier of 30 months from the receipt of the notice of the Paragraph IV certification, the expiration of the patent or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. An ANDA applicant that is sued for infringement may file a counterclaim to challenge the listing of the patent or information submitted to the FDA about the patent.

Generally, the ANDA applicant that (1) files a substantially complete ANDA using a Paragraph IV certification on the first day prior to any other ANDA applicant filing an application with such a certification, based on the same reference drug and (2) provides appropriate notice to the NDA holder, and all patent owner(s) for a particular generic product, the applicant may be awarded a delay in the approval of other subsequently filed ANDAs with Paragraph IV certifications based on the same reference drug. This statutory delay is commonly referred to as 180-day exclusivity. A substantially complete ANDA is one that contains all the information required by the statute and the FDA's regulations, including the results of any required bioequivalence studies. The FDA may refuse to accept the filing of an ANDA that is not substantially complete or may determine during substantive review of the ANDA that additional information, such as an additional bioequivalence study, is required to support approval. Such a determination may affect an applicant's first to file status and eligibility for 180-day exclusivity. The Medicare Prescription Drug Improvement and Modernization Act of 2003, or the MMA, provides that the 180-day exclusivity delay ends 180 days after the first commercial marketing of the ANDA product. This exclusivity may be forfeited under a number of different circumstances, including: (1) failure to market within certain prescribed periods of time following certain events related to submission of the application, approval of the application, court decisions and settlements and patent withdrawals from the Orange Book; (2) an amendment or withdrawal of the Paragraph IV certification or certifications upon which the exclusivity was based; (3) failure to obtain tentative approval within certain prescribed time periods (30, 36, or 40 months after submission of the ANDA); (4) an agreement with the NDA holder, patent owner or another ANDA applicant that is determined by a court or the FTC to violate provisions of antitrust laws; (5) withdrawal of the ANDA; or (6) expiration of patent or patents upon which exclusivity is based. The 180-day exclusivity provisions described above were passed in the MMA, and do not apply where the first ANDA with a Paragraph IV certification submitted for the reference drug was filed before December 8, 2003.

ANDA approvals can be delayed by exclusivities awarded to the holder of the NDA for the reference drug. The FFDCA provides five-year exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, or NCE, meaning that the FDA has not previously approved any other drug containing the same active moiety. This exclusivity generally prohibits the submission of an ANDA for any drug product containing the same active moiety during the five-year exclusivity period. However, submission of an ANDA with a Paragraph IV certification is permitted after four years, and if a patent infringement lawsuit is brought within 45 days after such certification, FDA approval of the ANDA is delayed until 7.5 years after the NCE approval date. The FFDCA also provides three-year exclusivity for the approval of new and supplemental NDAs for product changes that require new clinical investigations (other than bioavailability studies) that were conducted or sponsored by the applicant. These changes include, among other things, new indications, dosage forms, routes of administration or strengths of an existing drug and new uses.

ANDA approvals can also be delayed by orphan drug exclusivity, pediatric exclusivity and exclusivity for certain new antibiotic drugs. The FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for this type of disease or condition will be recovered from sales in the U.S. for that drug. Seven-year orphan drug exclusivity is available to a product that has orphan drug designation and that receives the first FDA approval for the indication for which the drug has such designation. Orphan drug exclusivity prevents approval of another application for the same drug, for the same orphan indication, for a period of seven years, regardless of whether the application is a full NDA or an ANDA, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Pediatric exclusivity, if granted, provides an additional six months to an existing exclusivity or statutory delay in approval resulting from a patent certification. This six-month exclusivity, which runs from the end of other exclusivity protection or patent delay, 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 FFDCA also provides exclusivity

for certain antibiotic drugs for serious or life-threatening infections that the FDA designates as "qualified infectious disease products." This exclusivity extends other exclusivities for the same drug by five years, but does not extend patent-related delays in approval.

In 2017, the FDA Reauthorization Act of 2017, or FDARA, was passed, which created a new pathway to allow the FDA to expedite the development and review of an ANDA for a drug that is designated as a Competitive Generic Therapy, or CGT. To qualify for the designation, the FDA must confirm that the ANDA is for a generic drug in which there is inadequate generic competition. Inadequate generic competition is defined to mean, that there is not more than one approved drug in the active section of the Orange Book.

Once assigned CGT designation by the FDA, the FDA may take various actions to help expedite the development and review process. This includes priority granting and expediting review during Product Development and Pre-Submission Meetings, Mid-Review Cycle Meetings and providing for a more coordinated review of ANDA's with CGT.

As part of the FDARA, a new type of 180-day marketing exclusivity period for ANDA applicants with CGT designation has been created. Broadly, this exclusivity applies when the ANDA applicant is considered as the first approved applicant, and there is no other exclusivity period eligibility.

Many of the products that we are developing qualify for CGT. Having a generic product designated as CGT provides for certain actions which the FDA may take in order to expedite the development and review of an ANDA.

The NDA Approval Process

The NDA approval process is generally far more demanding than the ANDA process, depending on whether the applicant is submitting a "full NDA" containing all of the data and information required for approval of a new drug or a "Section 505(b)(2) NDA" which is a more limited submission that is generally utilized for modifications to previously approved products.

The Prescription Drug User Fee Act, or PDUFA, was enacted by Congress in 1992. It authorizes the FDA to collect fees from companies that produce certain new human drug and biological products. The fees collected are designed to play an important role in expediting the new drug approval process. Like GDUFA, PDUFA must be reauthorized every 5 years. It is currently authorized as PDUFA VII through September of 2027. As part of the PDUFA, the FDA has specific goals for reviewing NDA/BLA applications. For example, as part of PDUFA VII, the goal of the FDA is to complete the review of 90% of original NDAs that are not new molecular entities within 10 months of the date of filing the NDA.

The Full NDA

The approval process for a full NDA generally involves:

- completion of preclinical laboratory and animal testing to demonstrate safety, in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, for human clinical testing that must satisfy the FDA and become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the efficacy of the proposed drug product for each intended use;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is produced to assess compliance with the FDA's cGMP regulations; and
- submission to and approval by the FDA of an NDA.

Before human clinical trials can begin on a new drug, the results of preclinical tests, together with manufacturing information and analytical data, must be submitted to the FDA as part of an IND and the FDA must permit the IND to become effective. Each clinical trial under an IND must be reviewed and approved by an independent Institutional

Review Board, or IRB. Human clinical trials are typically conducted in three sequential phases that may overlap. These phases generally include:

- Phase 1, during which the drug is introduced into healthy human subjects, or on occasion, patients and is tested for safety, stability, dose tolerance and metabolism;
- Phase 2, during which the drug is introduced into a limited patient population to determine the efficacy of the product in specific targeted indications, to determine dosage tolerance and optimal dosage and to identify possible adverse effects and safety risks; and
- Phase 3, during which the clinical trial is expanded to a larger and more diverse patient group at geographically dispersed clinical trial sites to further evaluate the drug and ultimately to demonstrate effectiveness.

The IND sponsor, the FDA or the IRB may suspend a clinical trial at any time for various reasons, including failure to follow appropriate ethical trial protocols, failure to provide adequate protections for trial participants or a belief that the subjects are being exposed to an unacceptable health risk.

The results of preclinical animal studies and human clinical studies, together with other detailed information (e.g., relating to pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling, quality control) are submitted to the FDA in the NDA.

The Section 505(b)(2) NDA

For modifications to products previously approved by the FDA, an applicant may file an NDA under Section 505(b)(2) of the FFDCA. This section permits the filing of an NDA where some or all of the data 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. Under this section, an applicant may rely on the approval of another NDA or on studies published in the scientific literature. The applicant may be required to conduct additional studies or provide additional information to fully demonstrate the safety and effectiveness of its modification to the approved product.

Where a Section 505(b)(2) applicant relies on the FDA's approval of another NDA, the applicant is required to submit the same types of patent certifications as are required for an ANDA. As in the case of an ANDA, a Paragraph IV certification challenging one or more of the patents listed for the reference drug will require notice to the patent owner(s) and NDA holder and will permit a patent infringement suit that may result in a 30-month stay in the approval of the Section 505(b)(2) NDA. The approval of a Section 505(b)(2) NDA may also be delayed by the NCE, three-year, orphan drug, pediatric and new antibiotic exclusivities that are applicable to ANDAs as discussed above.

The Biosimilar Application Approval Process

The BPCIA, passed by Congress in 2010, amended the PHSA to create an abbreviated approval pathway for follow-on biologics. This approval pathway is available for "biosimilar" products, which are products that are highly similar to biologics that have been approved in BLAs under the PHSA notwithstanding minor differences in clinically inactive components. A biosimilar application must contain information demonstrating (1) biosimilarity to the reference product, (2) sameness of strength, dosage form, route of administration and mechanism(s) of action with the reference product (where known), (3) approval of the reference product for the indication(s) proposed for the biosimilar product and (4) appropriate manufacturing facilities. The FDA will approve the application based on a finding of biosimilarity or interchangeability with the reference product. A finding of biosimilarity must be based on (1) a demonstration that the products are "highly similar" notwithstanding minor differences in clinically inactive components, (2) animal studies, including an assessment of toxicity, and (3) a clinical study or studies (including an assessment of immunogenicity and pharmacokinetics or pharmacodynamics) sufficient to show the safety, purity and potency of the proposed product for one or more "appropriate" conditions of use for which licensure is sought and for which the reference product is licensed, unless the FDA waives a specific requirement. The definition of "biosimilar" requires that there be no clinically meaningful differences between the biosimilar and reference product with regard to safety, purity and potency.

An applicant with a pending or approved biosimilar application may seek an FDA determination that its product is interchangeable with the reference drug. In addition to demonstrating biosimilarity to the reference product, the

biosimilar applicant must demonstrate that its product can be expected to yield the same clinical result as the reference product in any given patient. If the biosimilar product may be administered more than once to a patient, the applicant must demonstrate that the risk in terms of safety or diminished efficacy of alternating or switching between the biosimilar and reference products is not greater than the risk of continued administration of the reference product. The PHSA provides that a determination of interchangeability means that the biosimilar product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. The first biosimilar determined to be interchangeable with a particular reference product for any condition of use is protected by an exclusivity that delays an FDA determination of interchangeability with regard to any other biosimilar application. The exclusivity delays the subsequent interchangeability determination until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable biosimilar biological product, if an expedited patent action was commenced against the applicant under section 351(l)(6) and the litigation is still pending; or (4) 18 months after approval of the first interchangeable product if the reference product sponsor did not sue the biosimilar applicant for infringement under the patent resolution provisions of the PHSA.

The PHSA provides a number of exclusivity protections for reference products that may delay submission and approval of biosimilar applications. The PHSA delays submission of a biosimilar application until four years after the date on which the reference product was first licensed and delays final approval of a biosimilar application until 12 years after the first licensure of the reference product. The first-licensure requirement precludes an additional period of exclusivity for a supplement to the original application for the reference product. It also precludes exclusivity for an entirely new BLA in certain circumstances. A new BLA submitted by a sponsor or manufacturer of a previously approved biologic would not be protected by exclusivity for (1) a non-structural change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength or (2) a structural change that does not result in a change in safety, purity or potency. As in the case of NDAs approved under the FFDCA, BLAs may be entitled to orphan exclusivity and to pediatric exclusivity.

The BPCIA amended the definition of biological product to include proteins (other than synthetic polypeptides). Applications for biological products, including proteins, must now be approved under the PHSA rather than under the FFDCA. The BPCIA provides a grandfather exception for biologics falling within a product class for which the FDA has approved an application under the FFDCA.

Under the PHSA, patents are not listed in the Orange Book and companies submitting biosimilar applications are not required to submit patent certifications. Patent disputes are resolved outside of the FDA regulatory process. The biosimilar applicant must share the contents of its biosimilar application and information on its manufacturing processes with counsel for the company holding the BLA for the reference drug. The biosimilar applicant and BLA holder must exchange information about relevant patents and seek agreement on patents to be litigated under an expedited litigation procedure.

The BLA Approval Process

The BLA approval process is similar to the Full NDA approval process and generally involves:

- completion of preclinical laboratory and animal testing in compliance with the FDA's GLP regulations;
- submission to the FDA of an IND for human clinical testing, which must satisfy the FDA and become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the efficacy of the proposed drug product for each intended use;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is produced to assess compliance with the FDA's cGMP regulations; and
- submission to and approval by the FDA of a BLA.

Combination Products

- A combination product is a product comprising of two or more regulated components (e.g., a drug and device) that are combined into a single product, co-packaged, or sold separately but intended for co-administration, as evidenced by the labeling for the products. A drug that is administered using an inhaler is an example of a combination drug/device product.

- The FDA is divided into various Centers, which each have authority over a specific type of product. NDAs are reviewed by personnel within the Center for Drug Evaluation and Research, or CDER, while device applications and premarket notifications are reviewed by the Center for Devices and Radiological Health, or CDRH. For biologic products, the BLAs are generally reviewed by personnel within the Center for the Biologic Evaluation and Research, or CBER. When reviewing a drug (biologic)/device combination product, the FDA must assign a lead Center to review the product, based on the combination product's primary mode of action, or PMOA, which is the single mode of a combination product that provides the most important therapeutic action of the combination product. The Center that regulates that portion of the product that generates the PMOA becomes the lead evaluator. If there are two independent modes of action, neither of which is subordinate to the other, the FDA makes a determination as to which Center to assign the product based on consistency with other combination products raising similar types of safety and effectiveness questions or to the Center with the most expertise in evaluating the most significant safety and effectiveness questions raised by the combination product.

- When evaluating an application, a lead Center may consult other Centers and apply the standards that would be applicable but still retain complete reviewing authority, or it may collaborate with another Center, by which the Center assigns review of a specific section of the application to another Center, delegating its review authority for that section. Typically, the FDA requires a single marketing application submitted to the Center selected to be the lead evaluator, although the agency has the discretion to require separate applications to more than one Center. One reason to submit multiple applications is if the applicant wishes to receive some benefit that accrues only from approval under a particular type of application, like new drug product exclusivity. If multiple applications are submitted, each may be evaluated by a different lead Center.

- Our inhalers, intranasal delivery systems, and prefilled syringes, which deliver a specific drug or biologic, are regulated by the FDA as combination products. We believe the combination products will be regulated by the FDA as a drug or biologic (and not a device) because the primary mode of action of the combination will be a drug (or biological) action. As such, we will need to submit a marketing application to the CDER (or CBER) for our inhalers or prefilled syringes that deliver a specific drug. CDRH will provide input to CDER (or CBER) on the device aspects of the combination. We can provide no assurance that any of our combination products will be approved by the FDA in a timely fashion, if at all.

- Like their constituent products—e.g., drugs/biologics and devices—combination products are highly regulated and subject to a broad range of post marketing requirements including cGMPs, adverse event reporting, periodic reports, labeling and advertising and promotion requirements and restrictions, market withdrawal and recall.

FDA Action on an Application for Approval

If applicable statutory or regulatory requirements are not satisfied, the FDA may deny approval of an NDA, ANDA, BLA, or biosimilar application, or the FDA may require additional data or information. After approval of the application (or license), the FDA may suspend or withdraw the approval based on various criteria, including new information related to safety or effectiveness or failure to comply with post-approval requirements. In addition, the FDA may in some instances require post-marketing studies on approved products and may take actions to limit marketing of the product based on the results of those studies.

The new drug and biological product approval processes may take years, and the time may vary substantially based upon the type of application and the type, complexity and novelty of the product or disease. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon a manufacturer’s activities. Success in early stage clinical trials does not assure success in later stage clinical trials. Data

obtained from clinical activities are not always conclusive and may be subject to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product may result in restrictions on the product or complete withdrawal of the product from the market.

Manufacturing (cGMP) Requirements

We and our suppliers are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. These cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facilities for our products must meet cGMP requirements to the satisfaction of the FDA before the FDA will approve our products and we must continue to meet these requirements after our products are approved. We and our suppliers are subject to periodic inspections of facilities by the FDA and other authorities to assess our compliance with applicable regulations.

Other Regulatory Requirements

Maintaining substantial compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Drug and biologic manufacturers are required to register their establishments with the FDA and certain state agencies. After approval, the FDA and these state agencies conduct periodic unannounced inspections to ensure continued compliance with ongoing regulatory requirements.

In addition, after approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. The FDA may require post-approval testing and surveillance programs to monitor safety and effectiveness of approved products that have been commercialized. Any drug or biologic products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including:

- record-keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;
- reporting on advertisements and promotional labeling;
- drug sampling and distribution requirements; and
- complying with electronic record and signature requirements.

In addition, the FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. There are numerous regulations and policies that govern various means for disseminating information to health-care professionals, as well as consumers, including industry sponsored scientific and educational activities, information provided to the media and information provided over the Internet. Drugs or biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label.

FDA Enforcement Authority

The FDA has very broad enforcement authority and the failure to comply with applicable regulatory requirements can result in administrative or judicial sanctions being imposed on us or on the manufacturers and distributors of our approved products, including warning letters, refusals of government contracts, clinical holds, civil penalties, injunctions (which may in some circumstances involve restitution, disgorgement or profits, recalls and/or total or partial suspension of production or distribution), seizure of products, withdrawal of approvals, refusal to approve pending applications and criminal prosecution of the company and company officials that may result in fines and incarceration. The FDA has authority to inspect manufacturing facilities as well as other facilities in which drug products are held, packaged or stored, to determine compliance with cGMP and other requirements under the FDCA. 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. In addition, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products and withdraw approvals, any one or more of which could have a materially adverse effect on us.

Foreign Regulatory Requirements

Outside the United States, our ability to market a product is contingent upon receiving marketing authorization from the appropriate regulatory authorities. The requirements governing marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Union, or EU, registration procedures are available to companies wishing to market a product in more than one EU member state. The regulatory authority generally will grant marketing authorization if it is satisfied that we have presented it with adequate evidence of safety, quality and efficacy.

USDA Animal and Plant Health Inspection Service

USDA-APHIS regulates the importation of certain animals and animal-derived materials into the U.S. In particular, a USDA veterinary permit is required for importation of materials derived from animals or exposed to animal-source materials. Recently, USDA enhanced its African swine fever, or ASF, surveillance efforts, including restrictions on importation of pig-derived products from affected countries and testing for the ASF virus. While ASF does not affect human health, it is a highly contagious and deadly disease to local pig populations. ASF is currently widespread and endemic in various parts of Africa and Sardinia. In recent years, ASF has been reported in parts of the EU and in China, where the first cases of ASF were reported in August 2018. Complying with additional requirements, such as additional analytical data and documentation of processing flow, may be required for obtaining an import permit for certain materials from affected countries. Changes made to suppliers or sources of raw materials for drug products will require prior FDA approval, which would disrupt or delay the manufacturing of our products.

Fraud and Abuse Laws

Because of the significant federal funding involved in Medicare and Medicaid, Congress and the states have enacted, and actively enforce, a number of laws to eliminate fraud and abuse in federal health care programs. Our business is subject to compliance with these laws.

Federal False Claims Act

The False Claims Act, or FCA, imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program. The *qui tam* provisions of the FCA allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government and to share in any monetary recovery. In recent years, the number of suits brought against health care providers by private individuals has increased dramatically. In addition, various states have enacted false claims laws analogous to the FCA, and many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal or other governmental health care program.

When an entity is determined to have violated the FCA, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of up to $25,595 under 42 CFR 1003.210(a)(1) for each violation, subject to adjustment for inflation. There are many potential bases for liability under the FCA. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The federal government has used the FCA to assert liability on the basis of inadequate care, kickbacks and other improper referrals, and improper use of Medicare numbers when detailing the provider of services, in addition to the more predictable allegations of misrepresentations with respect to the services rendered. In addition, the federal government has prosecuted companies under the FCA in connection with off-label promotion of products. Our current and future activities relating to the reporting of wholesale or estimated retail prices of our products, the reporting of

discount and rebate information and other information affecting federal, state and third-party reimbursement of our products, and the sale and marketing of our products may be subject to scrutiny under these laws. While we are unaware of any current matters, we are unable to predict whether we will be subject to actions under the FCA or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly affect our financial performance.

The Open Payment Act

The Physician Payment Sunshine Act, or the Open Payment Act, which was enacted as part of the Affordable Care Act, requires all pharmaceutical manufacturers that participate in Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Secretary of the Department of Health and Human Services payments or other transfers of value made in the previous year by that entity, or by a third party as directed by that entity, to covered recipients, including physicians (defined to include doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, as defined by law, or to third parties on behalf of such covered recipients, as well as ownership and investment interests held by physicians and their immediate family members. The payments and transfer of value required to be reported include the cost of meals provided to a physician, travel reimbursements and other transfers of value provided as part of contracted services, including speaker programs, advisory boards, consultation services and clinical trial services. The statute requires the federal government to make reported information available to the public. Failure to comply with the reporting requirements can result in significant civil monetary penalties. Additionally, there are criminal penalties if an entity intentionally makes false statements in such reports. We are subject to the Open Payment Act and the information we disclose may lead to greater scrutiny, which may result in modifications to established practices and additional costs. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering adopting similar laws requiring transparency of interactions with health care professionals.

The Anti-kickback Statute

As a life sciences company, we are subject to the federal anti-kickback statute, or AKS. The AKS prohibits payments or providing anything of "value" (remuneration) for the purpose of inducing or rewarding the referral or generation of healthcare business. The intent is to protect the independence and clinical judgment of providers. There are numerous exceptions, or safe harbors, the most notable of which are that it is permissible to provide a discount or rebate to a healthcare provider based upon volume, and that manufacturers can pay administrative fees to GPOs or buying groups.

As a result of the AKS, the company pays particular attention to interactions with healthcare providers and how it structures sales. Any and all discounts that are offered are appropriately disclosed and documented to promote compliance with the AKS. At present, we employ our own salespeople and do not utilize a third-party sales force.

Both consulting relationships with healthcare providers and educational and research activities with healthcare providers and teaching hospitals receive considerable enforcement scrutiny. As a result, the company also pays particular attention to these relationships.

The Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA arguably includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anticorruption laws and/or regulations. Failure by our employees, agents, contractors, vendors, licensees, partners or collaborators to comply with the FCPA and other anticorruption laws and/or regulations could result in significant civil or criminal penalties.

Environmental Considerations

We are subject to federal, state and local environmental laws and regulations, both U.S. and foreign, including those promulgated by the Occupational Safety and Health Administration, the Environmental Protection Agency, the Department of Health and Human Services and the Air Quality Management District, which govern activities and operations that may have adverse environmental effects such as discharges to air, soil and water, as well as handling and

disposal practices for solid and hazardous wastes. Because we own and operate real property, these laws impose strict liability for the costs of cleaning up, and for damages resulting from, sites of past spills, disposals or other releases of hazardous substances and materials. These laws and regulations may also require us to pay for the investigation and remediation of environmental contamination at properties operated by us and at off-site locations where we have arranged for the disposal of hazardous substances. If it is determined that our operations or facilities are not in compliance with current environmental laws, we could be subject to fines and penalties, the amount of which could be material.

The costs of complying with various applicable environmental requirements, as they now exist or as may be altered in the future, could adversely affect our financial condition and results of operations.

Similarly, on December 27, 2020, the American Innovation in Manufacturing Act of 2020, or AIM Act, was enacted. The AIM Act directs the United States Environmental Protection Agency to address usage of hydrofluorocarbons, or HFC, by reducing production and consumption of certain HFCs. One of our products, Primatene MIST®, utilizes HFCs subject to the AIM Act's reduction mandate. Moreover, many of our inhalation pipeline assets use HFCs subject to the AIM Act's reduction mandate. There can be no assurance that we will be able to acquire adequate supplies of HFCs for current and future commercialization of our products as a result of the AIM Act or other similar statutes and regulations. Moreover, changes to the ingredients of our proprietary and generic products requires FDA approval and there can be no assurance that we will be able to obtain such approval or the timing of such approval.

We have made and will continue to make expenditures to comply with current and future U.S. and foreign environmental laws and regulations. We anticipate that we will incur additional capital and operating costs in the future to comply with existing environmental laws and new requirements arising from new or amended statutes and regulations. We cannot accurately predict the impact and costs that future regulations will impose on our business.

Other Regulations

We are subject to various national, regional and local laws of general applicability, such as laws regulating working conditions. We are also subject to country specific data protection laws and regulations relating to the collection and processing of personal data around the world. In addition, we are subject to various national, regional and local environmental protection laws and regulations, including those governing the emission of material into the environment. We are also subject to various national, regional and local laws regulating how we interact with healthcare professionals and representatives of government that impact our promotional and other commercial activities.

We also must comply with data protection and data privacy requirements such as HIPAA, GDPR, CCPA, and the upcoming CPRA. Compliance with these laws, rules and regulations regarding privacy, security and protection of employee data could result in higher compliance and technology costs for us, as well as significant fines, penalties and damage to our global reputation and our brand as a result of non-compliance.

In 2013, the federal Drug Supply Chain Security Act, or the DSCSA, became effective in the United States, mandating an industry-wide, national serialization system for pharmaceutical packaging with a ten-year phase-in process. By 2018, all manufacturers and re-packagers were required to mark each prescription drug package with a unique serialized code. Each of Amphastar and our U.S.-based subsidiaries is subject to or covered by DSCSA and is required to comply and continue to comply with such requirements. Additionally, should any subsidiary that is not subject to or covered by the DSCSA become subject to or covered by the DSCSA, we may be required to modify our manufacturing sites to comply with the rules and regulations.

Coverage and Reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payers, such as government health programs, commercial insurance, and managed healthcare organizations. In the U.S., for example, principal decisions about government reimbursement for new products are typically made by CMS, the agency that administers the Medicare program through regional contractors, state Medicaid programs, third-party payers, and insurance plans for certain patient populations. These entities decide whether and to what extent a new product will be covered and reimbursed based on clinical needs and economic impact. To date, no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payer-by-payer basis.

Increasingly, third-party payers are requiring that drug companies provide them with discounts usually in the form of rebates from list prices and are challenging the prices charged for medical products. Further, such payers are examining the medical necessity and reviewing the cost effectiveness of newly launched drugs. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payers may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct additional expensive pharmaco-economic Phase 4 real-world studies to demonstrate the medical necessity and cost effectiveness of our products. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products, with no assurance that coverage and adequate reimbursement will be obtained. Additionally, maintaining coverage for a product is often evaluated annually by payers and additional barriers may be placed impacting access. We are committed to partnering with payers to ensure broad access and affordability.

Pharmaceutical Pricing

We participate in the Medicaid Drug Rebate Program and Medicare Part D Coverage Gap Discounts Program, or Medicare Part D. Participation is required for federal funds to be available for our covered outpatient drugs under Medicaid and Medicare Part B, or Medicare Part B, and under Medicare Part D, respectively. Under the Medicaid Drug Rebate Program, we are required to pay a mandatory rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid. Those rebates are based on pricing data reported by the manufacturer on a monthly and quarterly basis to CMS. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug, which, in general, represents the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts, and other price concessions. Under the Medicare Part D Coverage Gap Discount Program, manufacturers, including us, are currently required to provide to CMS a 70% discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries are in the coverage gap phase of the Medicare Part D benefit design. The IRA sunsets the coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program.

The Affordable Care Act, or ACA, made significant changes to the Medicaid Drug Rebate Program, and CMS issued a final regulation to implement the changes to the Medicaid Drug Rebate Program under the ACA. CMS also issued a final regulation that modified prior Medicaid Drug Rebate Program regulations to permit reporting multiple best price figures with regard to value-based purchasing arrangements; and provide definitions for “line extension,” “new formulation,” and related terms, with the practical effect of expanding the scope of drugs considered to be line extensions that are subject to an alternative rebate formula.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service’s 340B drug pricing program in order for federal funds to be available for the manufacturer’s drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B ceiling price for the manufacturer’s covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program.

Further, the Inflation Reduction Act, or IRA, of 2022 established a Medicare Part D inflation rebate schemes and a drug price negotiation program, with the first negotiated prices to take effect in 2026. It also makes several changes to the Medicare Part D benefit, including the creation of a new manufacturer discount program in place of the current coverage gap discount program that began in 2025. Under IRA, only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, CMS selected 10 high-cost Medicare Part D drugs. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, up to an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, up to 20 additional Part B or Part D drugs will be selected. Various industry stakeholders have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. Further,

the current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of HHS to establish a mechanism through which American patients can buy drugs directly from manufacturers who sell at a most-favored-nation price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the U.S. In November 2025, CMS announced a voluntary initiative called the GENEROUS Model (GENErating cost Reductions fOr U.S. Medicaid Model) to introduce the option of most-favored-nation pricing to the Medicaid program, whereby a drug manufacturer may voluntarily offer supplemental rebates to participating state Medicaid programs for a manufacturer's covered outpatient drugs. Government agreements with pharmaceutical companies and other measures that use most-favored-nation pricing targets for prescription drugs or that increase generic and biosimilar drug entry sooner than expected can have a material adverse effect on our industry, ability to set adequate pricing for new drugs to recover R&D costs, ability to attract potential investors and potential buyers in the future, or the pricing of our approved product in the U.S. and in foreign countries.

In addition, to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, a manufacturer also must participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. Under this program, the manufacturer is obligated to make its innovator and single source products available for procurement on an FSS contract and charge a price to four federal agencies, the VA, U.S. Department of Defense, or DoD, Public Health Service and U.S. Coast Guard - that is no higher than the statutory Federal Ceiling Price, or FCP. Manufacturers also are obligated to calculate and submit to the VA on a quarterly and annual basis, their Non-Federal Average Manufacturer Price, or Non-FAMP, which the VA uses to calculate the FCP. Moreover, pursuant to regulations issued by the DoD Defense Health Agency to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, manufacturers are required to provide rebates on utilization of their innovator and single source products that are dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies.

The requirements under the Medicaid, 340B, FSS, and TRICARE programs could reduce the revenue we may generate from any products that are commercialized in the future and could adversely affect our business and operating results. If we fail to comply with any applicable obligations under governmental pricing programs that we participate in, we could be subject to additional reimbursement requirements, significant civil monetary penalties, sanctions and fines, and those could negatively impact our business, financial condition, results of operations and growth prospects.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing.

Healthcare Reform

The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products and/or lower cost over the counter alternatives for branded prescription drugs. For example, the ACA substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits.

There have been judicial challenges to certain aspects of the ACA, as well as efforts by Congress to modify, and by agencies to alter the implementation of, certain aspects of the ACA. For example, Congress eliminated the tax penalty for not complying with the ACA's individual mandate to carry health insurance. Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In 2025, the IRA sunsets the coverage gap discount program and replaces it with a new manufacturer discount.

It is possible that the ACA, as currently enacted or may be amended in the future, as well as other healthcare reform measures including those that may be adopted in the future, may result in more rigorous coverage criteria, and less favorable payment methodologies, or other downward pressure on coverage and payment and the price that we receive for any approved product. Any reduction in reimbursement or restriction on coverage under Medicare or other government programs may result in a similar reduction or restriction by private payers.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year required by the Budget Control Act of 2021, as amended by the American Taxpayer Relief Act of 2012, or ATRA. Subsequent legislation extended the 2% reduction, generally to FY 2032. ATRA, among other things, also reduced Medicare payments to several types of providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Other new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Moreover, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private third-party payers often follow Medicare coverage policy and payment limitations in setting their own payment rates and in establishing their formulary placement.

Further, the IRA introduces several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs and a change in manufacturer liability under the program which could negatively affect the profitability of our product candidates. The IRA sunsets the current Part D coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program. Failure to pay a discount under this new program will be subject to a civil monetary penalty. In addition, the IRA established a Medicare Part B inflation rebate scheme effective January 2023 and a Medicare Part D inflation rebate scheme effective October 2022, under which, generally speaking, manufacturers will owe rebates if the price of a Part B or Part D drug increases faster than the pace of inflation. Failure to timely pay a Part B or D inflation rebate is subject to a civil monetary penalty. The IRA also creates a drug price negotiation program under which the prices for Medicare units of certain high Medicare spend drugs and biologicals without generic or biosimilar competition will be capped by reference to, among other things, a specified non-federal average manufacturer price starting in 2026. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and/or a civil monetary penalty. Congress continues to examine various policy proposals that may result in pressure on the prices of prescription drugs with respect to the government health benefit programs and otherwise. The IRA or other legislative changes could impact the market conditions for our product candidates. The One Big Beautiful Bill Act of 2025, or the OBBB Act, includes provisions that impact the United States healthcare system in various ways, including cuts to Medicaid and introducing new participant eligibility requirements for Medicaid coverage, which are expected to significantly change the administration and applicability of Medicaid coverage.

Additionally, there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and

state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Finally, some states have established Prescription Drug Affordability Boards (or similar entities) to review high-cost drugs and, in some cases, set upper payment limits.

Intellectual Property

Our success depends on our ability to operate without infringing the patents and proprietary rights of third parties. However, we cannot determine with certainty whether patents or patent applications of other parties will have a materially adverse effect on our ability to make, use, or sell any products. A number of pharmaceutical companies, biotechnology companies, universities and research institutions may have filed patent applications or may have been granted patents that cover aspects of our, or our licensors' products, product candidates, or other technologies.

With respect to our existing generic products and generic product candidates, we primarily rely on trade secrets, unpatented proprietary know-how and continuing technological innovation to protect our products and technologies, especially where we do not believe patent protection is appropriate or obtainable. Although in some cases, we seek patent protection to preserve our competitive position, our current patent portfolio does not cover the majority of our existing products and product candidates. We own several U.S. and foreign patents covering processes and equipment used in the manufacture of a few of our products. The expiration dates of these patents range from 2026 to 2041. We also own several trademarks registered with the USPTO.

We currently own more than 100 issued patents globally, including several patents covering BAQSIMI®, including U.S. Patent Number 10,213,487, which is listed in the U.S. FDA Orange Book, and we own a U.S. patent covering the HFA version of Primatene MIST®, U.S. Patent Number 8,367,734, which is listed in the U.S. FDA Orange Book. We have several patent applications that are currently pending. For our product candidates that are not intended to be generic products, we may seek to obtain patent rights or rely on trade secret protection. We may not be able to obtain patent or other forms of protection for inventions or other intellectual property developed by our officers, employees, or consultants because we might not have been the first to file or to invent the patentable technology or others may have independently developed similar or alternative technology.

The majority of our products and product candidates are not currently covered by any U.S. or foreign patents owned by us. Indeed, many of our products and product candidates are generic products, and therefore may not be eligible for patent protection. For example, our enoxaparin product is a generic product, and as such, our enoxaparin product is not covered by any U.S. or foreign patents. Other of our products, including Amphadase®, are based on compounds for which any applicable patents have expired, or which were not patented by Amphastar in the first instance because they are older compounds.

Despite our efforts to protect our proprietary information through the use of confidentiality and non-disclosure agreements, unauthorized parties may copy aspects of our products or obtain and use information that we regard as proprietary. Other parties may also independently develop know-how or obtain unauthorized access to our technologies.

Intellectual property protection is highly uncertain and involves complex legal and factual questions. Our patents and those for which we have or will license rights may be challenged, invalidated, infringed or circumvented, and the rights granted in those patents may not provide proprietary protection or competitive advantages to us. We and our licensors may not be able to develop patentable products. Even if a patent application is filed, some or all of the patent claims may not be allowed, the patent itself may not issue, or in the event of issuance, the issued claims may not be sufficient to protect the technology owned by or licensed to us.

Third-party patent applications and patents could reduce the coverage of the patents licensed, or that may be licensed to, or owned by us. If patents containing competitive or conflicting claims are issued to third parties, we may be enjoined from the commercialization of products or be required to obtain licenses to these patents or to develop or obtain alternative technology. In addition, other parties may duplicate, design around or independently develop similar or alternative technologies to ours or those of our licensors.

Litigation may be necessary to enforce patents issued or licensed to us or to determine the scope or validity of another party's proprietary rights. USPTO interference proceedings may be necessary if we and another party both claim to have invented the same subject matter. Even if we ultimately prevail, we could incur substantial costs and our management's attention would be diverted if:

- litigation is required to defend against patent suits brought by third parties;
- we participate in patent suits brought against or initiated by our licensors;
- we initiate suits against third parties who are infringing on our patents; or
- we participate in an interference or other similar USPTO proceeding.

However, even if we pursue litigation or other action to protect our intellectual property rights, we may not prevail in any of these actions or proceedings.

Human Capital

As of December 31, 2025, we had 1,976 full-time employees in the United States, China, and France. Of these employees, approximately 170 employees hold post-graduate degrees. We consider our employees' intellectual capital an essential driver of our business and key to our future prospects. None of our U.S. employees are subject to a collective bargaining agreement or represented by a trade or labor union.

The following table summarizes our employees by category and location:

	United States	China	France	Total
Manufacturing	1,169	104	93	1,366
QA/QC and Regulatory Affairs	162	75	34	271
Sales and Marketing	20	—	—	20
General and Administrative	112	20	24	156
Research and Development	110	48	5	163
Total employees	1,573	247	156	1,976

Talent Acquisition and Retention

We recognize that our employees largely contribute to our success. To this end, we support business growth by attracting and retaining best-in-class talent. Our talent acquisition team uses internal and external resources to recruit highly skilled candidates globally.

Total Rewards

Our total rewards philosophy recognizes the contributions of our workforce by offering competitive compensation and benefits packages. We provide employees with compensation packages that include base salary and annual incentive bonuses. Certain employees are also eligible for long-term equity awards. We also provide comprehensive employee benefits, which vary by country and region, such as life and health insurance, health savings accounts, paid time off, an Employee Stock Purchase Program, and a 401(k) plan.

Health, Safety, and Wellness

Our employees' health, safety, and wellness are a priority in which we have always invested and will continue to do so. We provide our employees and their families with access to various innovative, flexible, and convenient health and wellness programs. Program benefits are intended to provide protection and security, so employees can have peace of mind concerning events that may require time away from work or impact their financial well-being. These programs are highlighted regularly in our monthly human resources newsletters.

Corporate Information

We incorporated in California under the name Amphastar Pharmaceuticals, Inc. in 1996 and merged our California corporation into Amphastar Pharmaceuticals, Inc., a newly formed Delaware corporation, in 2004. Our corporate offices are located at 11570 6th Street, Rancho Cucamonga, CA 91730. Our telephone number is (909) 980-9484. 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 Securities Exchange Act of 1934, as amended, or the Exchange Act, are available free of charge as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. You can access our filings with the SEC by visiting http://www.amphastar.com. The SEC also maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is http://www.sec.gov.

We use our website as a channel of distribution for important company information. Important information, including press releases, analyst presentations and financial information regarding us, as well as corporate governance information, is routinely posted and accessible on the "Investors" section of the website, which is accessible by clicking on the tab labeled "Investors" on our website home page. The contents of the websites provided above are not intended to be incorporated by reference into this Annual Report on Form 10-K or in any other report or document we file with the SEC. Further, our reference to the URLs for these websites are intended to be inactive textual references only.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes thereto. Our future operating results may vary substantially from anticipated results due to a number of risks and uncertainties, many of which are beyond our control. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. The following discussion highlights some of these risks and uncertainties and the possible impact of these risks on future results of operations. If any of the following risks occur, our business, financial condition or results of operations could be materially and adversely affected. In that case, the market value of our common stock could decline substantially and you could lose part or all of your investment.

Summary of Risk Factors

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

- our success depends on our ability to develop and/or acquire and commercialize additional pharmaceutical products;
- our BAQSIMI®, Primatene MIST®, glucagon, epinephrine, and lidocaine, products collectively represent a significant portion of our net revenues; if the sales volume or pricing of these products decline, or if we are unable to satisfy market demand for these products, this could have a material adverse effect on our business, financial position and results of operations;
- our actual financial and operating results could differ materially from any expectations or guidance provided by us concerning future results;
- our success depends on the integrity of our supply chain, including multiple single source suppliers, and reliance on a third party for the manufacture of BAQSIMI® the disruption of which could negatively impact our business;
- our ability to develop new products and additional revenue streams depends upon a variety of factors including being able to invest ongoing revenue and borrow funds or raise additional capital when needed;
- we face significant competition in the pharmaceutical industry with respect to both our proprietary and generic drugs, which may result in others developing or commercializing products before or more successfully than we do, which could significantly limit our growth and materially and adversely affect our financial results;
- health care providers may not be receptive to our products, particularly those that incorporate our proprietary drug delivery platforms;
- sales of our products may be adversely affected by the continuing consolidation of our customer base;
- we depend upon our key personnel, the loss of whom could adversely affect our operations. If we fail to attract and retain the talent required for our business, our business could be materially harmed;
- our business may be adversely affected by challenging macroeconomic conditions globally;
- because a portion of our manufacturing takes place in China, a significant disruption in the construction or operation of our manufacturing facility in China, political unrest in China, tariffs, impacts of outbreaks of health epidemics, or changes in social, political, trade, health, economic, environmental, or climate-related conditions or in laws, regulations and policies governing foreign trade could materially and adversely affect our business, financial condition and results of operations;

- we may be exposed to product liability claims and may not be able to obtain or maintain adequate product liability insurance;
- we are exposed to risks related to our international operations and failure to manage these risks may adversely affect our operating results and financial condition;
- the FDA approval process is time-consuming and complicated, and we may not obtain the FDA approval required for a product within the timeline we desire, or at all; additionally, we may lose FDA approval and/or our products may become subject to foreign regulations;
- the novel use of particle engineering or synthetic APIs for any of our product candidates, may not receive regulatory approval, and without regulatory approval we will not be able to market our product candidates;
- if clinical studies for our product candidates are unsuccessful or significantly delayed, we will be unable to meet our anticipated development and commercialization timelines, which would have an adverse impact on our business;
- if branded pharmaceutical companies are successful in limiting the use of generics through their legislative, regulatory and/or other efforts, our sales of generic products may suffer; and
- our success depends on our ability to obtain, protect, and enforce our intellectual property.

Risks Relating to our Business and Industry

Our success depends on our ability to develop and/or acquire and commercialize additional pharmaceutical products.

Our financial results depend upon our ability to commercialize additional generic and proprietary pharmaceutical products, and whether our products are accepted by patients and physicians and are reimbursed by payers. Commercialization requires that we successfully and cost-effectively develop, test and manufacture or otherwise acquire both generic and proprietary products. All of our products must receive regulatory approval and meet (and continue to comply with) regulatory standards and requirements, including continued safety and efficacy standards. If health, safety, or environmental concerns arise with respect to a product, we may be forced to withdraw it from the market and be exposed to greater liability, including product liability lawsuits. There can be no guarantee that our investment in research and development activities will result in FDA approval or produce commercially viable new products.

The development and commercialization process, particularly with respect to our proprietary products, is time-consuming, costly and involves a high degree of business risk. Our products currently under development, if and when fully developed and tested, may not perform as we expect. Necessary regulatory approvals may not be obtained in a timely manner, if at all, and we may not be able to produce and market such products successfully and profitably. Delays in any part of the process, or our inability to obtain regulatory approval of our products, including litigation with competitors and regulatory compliance of our suppliers and contractors, could adversely affect our operating results by restricting or delaying our introduction of new products, which could adversely impact our ability to market a prospective product. The FDA and similar regulatory agencies may change or impose new regulatory requirements on our products, which could require us to perform additional studies, expand additional resources on regulatory compliance, or delay our commercialization plan. To the extent that we expend significant resources on research and development efforts and are not able, ultimately, to introduce successful new products as a result of those efforts, our business, financial position and results of operations may be materially and adversely affected, and the market value of our common stock could decline.

Our ability to introduce new generic products also depends upon our success in challenging patent rights held by third parties or in developing non-infringing products. Due to the emergence and development of competing products over time, our overall profitability depends on, among other things, our ability to introduce new products in a timely manner, to continue to manufacture products cost-effectively and to manage the life cycle of our product portfolio. If we are unable to cost-effectively maintain an adequate flow of successful generic and proprietary products and new indications and/or delivery methods for existing products sufficient to cover our substantial research and development costs and the decline in sales of older products that either become subject to generic competition, or are displaced by competing products or therapies, it could have a material adverse effect on our business, financial condition or results of operations.

Our BAQSIMI®, Primatene MIST®, glucagon, epinephrine, and lidocaine products collectively represent a significant portion of our net revenues. If the sales volume or pricing of these products decline, or if we are unable to satisfy market demand for these products, they could have a material adverse effect on our business, financial position and results of operations.

Sales from our BAQSIMI® product that we acquired in June 2023 represented 26%, 20%, and 8% of our total net revenues for the years ended December 31, 2025, 2024, and 2023, respectively. Sales from our Primatene MIST® product represented 15%, 14%, and 14% of our total net revenues for the years ended December 31, 2025, 2024, and 2023, respectively. Sales from our glucagon product, represented 10%, 15% and 18% of our total net revenues for the years ended December 31, 2025, 2024, and 2023, respectively. Sales from our epinephrine product represented 10%, 13%, and 13% of our total net revenues for the years ended December 31, 2025, 2024, and 2023, respectively. Sales from our lidocaine products represented 8%, 8%, and 9% of our total net revenues for the years ended December 31, 2025, 2024, and 2023, respectively. We have experienced declining revenue from glucagon and some of our other existing products in the past. If the sales volume or pricing of glucagon and epinephrine multi-dose vial continues to decline, or if the sales volume or pricing of lidocaine declines, or if we are unable to satisfy market demand for these products, our business, financial position and results of operations could be materially and adversely affected, and the market value of our common stock could decline. For example, our glucagon and our epinephrine multi-dose vial products continue to see increased competition in the market, which could result in declining per unit prices as well as lower market share due to intense pricing competition in the pharmaceutical industry. We have experienced significant declines in the per unit pricing and gross margins attributable to our glucagon product since its commercial launch. Our BAQSIMI®, Primatene MIST®, glucagon, epinephrine, and lidocaine, products could be rendered obsolete or negatively impacted by numerous factors, many of which are beyond our control, including:

- decreasing average sales prices;
- development by others of new pharmaceutical products that are more effective than ours;
- entrance of new competitors into our markets;
- loss of key relationships with suppliers, group purchasing organizations or end-user customers;
- manufacturing or supply interruptions;
- increase in material input costs;
- changes in the prescribing practices of physicians;
- changes in third-party reimbursement practices;
- implementation of prescription drug cost containment measures;
- changes in applicable FDA, health care, and environmental law;
- product liability claims; and
- product recalls or safety alerts.

Any factor adversely affecting the sale of these products may cause our revenues to decline, and we may not be able to achieve and maintain profitability.

Our ability to develop new products and additional revenue streams depends upon our ability to invest ongoing revenue, borrow funds or raise additional capital when needed.

Developing a single product in the pharmaceutical industry is a very expensive proposition with no certainty of regulatory clearance or commercial success. Considerable amounts are invested into the research and development process. Our research and development expense was $85.8 million, $73.9 million, and $73.7 million for the years ended December 31, 2025, 2024, and 2023, respectively. As noted elsewhere herein, ongoing revenue from current operations is a critical component of being able to adequately fund ongoing research and development efforts in our product

pipeline. We may also fund our research and development using borrowed funds or funds raised through the capital markets. Our ability to obtain such funds on favorable terms, if at all, may be affected by market volatility, changes in the interest rate environment and general economic instability. If any one, or all, of these sources become unavailable, our research and development projects may become delayed or negatively impacted.

Our success depends on the integrity of our supply chain, including multiple single source suppliers, and reliance on a third party for the manufacture of BAQSIMI®, the disruption of which could negatively impact our business.

Some of our products are the result of complex manufacturing processes, and some require highly specialized raw materials, and BAQSIMI® relies on CMOs. Because our business requires outsourcing in some instances, we are subject to inherent uncertainties related to product safety, availability and security. We depend on CMOs and suppliers to perform manufacturing activities effectively and on a timely basis for our API and drug products. These third parties are independent entities subject to their own unique operational and financial risks that are out of our control. For some of our key raw materials, components and APIs used in certain of our products, we have only a single, external source of supply, and alternate sources of supply may not be readily available.

For example, in 2023, our API supplier for medroxyprogesterone discontinued making the active ingredient, which resulted in a halt in sales of the product after the third quarter of 2023. We were only able to relaunch this product in September 2024 following FDA qualification of our subsidiary ANP to manufacture this API. In the future, it is possible that our suppliers will receive warning letters from the FDA and be unsuccessful in their efforts to address the issues raised in such warning letters on a timely basis, or at all, or may discontinue production of raw materials, components or APIs used in our products or product candidates and would result in delays in commercialization and/or manufacturing of our products or product candidates if FDA approval for such products or product candidates is received. Furthermore, we may be unable to replace such supplier with an alternate supplier on a commercially reasonable and timely basis, or at all.

If we fail to maintain relationships with our current suppliers, including our CMOs, we may not be able to complete development, commercialization or marketing of our products, which would have a material and adverse effect on our business. Third-party suppliers may not perform as agreed, may discontinue production, or may terminate their agreements with us. For example, because these third parties provide materials to a number of other pharmaceutical companies, they may experience capacity constraints or choose to prioritize one or more of their other customers over us. Any significant problem that our suppliers experience could delay or interrupt our supply of materials until the supplier cures the problem or until we locate, negotiate for, validate and receive FDA approval for an alternative source of supply, if one is available. In the near term, we do not anticipate that the FDA will approve alternative sources to back up our primary suppliers. Therefore, if our primary suppliers become unable or unwilling to manufacture or deliver materials, we could experience protracted delays or interruptions in the supply of materials. This would ultimately delay our manufacture of products for commercial sale, which could materially and adversely affect our development programs, commercial activities, operating results and financial condition.

Additionally, any failure by us to forecast demand for, or to maintain an adequate supply of, the raw material and finished product could result in an interruption in the supply of certain products and a decline in sales of that product.

Underutilization of our manufacturing capacity could negatively impact our gross margins.

We have invested significantly in our manufacturing capacity in order to vertically integrate our business, contain the costs of raw materials and reduce the risks imposed by relying on third-party single source suppliers. We currently own and operate facilities that manufacture raw materials and APIs for our products and product candidates and those of our customers and partners, including insulin API for MannKind. However, if market demand decreases or if market supply surpasses demand, whether because of macroeconomic factors, pharmaceutical industry volatility, or deficiencies specific to our customers, we may not be able to reduce manufacturing expenses or overhead costs proportionately. For example, a significant portion of our manufacturing capacity in our facility in Éragny-sur-Epte, France is utilized for the manufacturing of insulin API for MannKind, and, until recently, a significant portion of our manufacturing capacity in Rancho Cucamonga was utilized for the manufacture of enoxaparin. We have amended our supply agreement with MannKind, or the Supply Agreement and our option purchase agreement with MannKind, or the Option Agreement, multiple times to modify and extend the annual minimum purchase commitments under the Supply Agreement and the Option Agreement. This lowers the annual minimum quantities and lowers the production levels at AFP. Mannkind will not be purchasing RHI for at least the next two years as they are in the process of qualifying our upgraded RHI, which uses our internally produced inclusion bodies made at AFP.

If an increase in supply outpaces the increase in market demand, or if demand decreases, such as a further reduction in sales of insulin API for MannKind, the resulting oversupply could adversely impact our sales and result in the underutilization of our manufacturing capacity, high inventory levels, changes in revenue mix and rapid price erosion, which would lower our margins and adversely impact our financial results. In addition, in order to offset fixed manufacturing overhead costs and utilize our current facilities and personnel, it may at times be in our best interest to continue to produce and sell products that are not profitable in the near term, although this would negatively impact our gross margins.

We face significant competition in the pharmaceutical industry with respect to both our proprietary and generic drugs, which may result in others developing or commercializing products before or more successfully than we do, which could significantly limit our growth and materially and adversely affect our financial results.

We face and will face significant competition for our products and product candidates from pharmaceutical companies that focus on proprietary and generic injectable and inhalation markets such as Pfizer, Inc., BPI Labs, Lupin Pharmaceuticals, Inc., Viatris Inc., Fresenius Kabi USA, Apotex Corp., American Regent, Inc., Hikma Pharmaceuticals USA Inc., Par Pharmaceuticals, Cipla USA Inc., Meitheal Pharmaceuticals, Dr. Reddy's Laboratories, Inc., Xeris Pharmaceuticals, Medefil Inc., Accord Healthcare, and Teva Pharmaceuticals USA Inc. Competition in the generic pharmaceutical industry has increased as producers of branded products have entered the business by creating generic drug subsidiaries, purchasing generic drug companies, or licensing their products to generic manufacturers prior to patent expiration and/or as their patents expire.

We face similar competition with respect to our over-the-counter product. Our product competes with other products that are owned and marketed by companies with much greater financial resources to reach consumers and market their products to influence end-customer buying decisions. There can be no assurance that we will be able to profitably market our over-the-counter product and money spent on such marketing efforts may reduce our ability to focus on and develop our pharmaceutical products.

Our business operates in the pharmaceutical industry, which is an industry characterized by intense competition. Many of our competitors have longer operating histories and greater financial, research and development, marketing and other resources than we do. Consequently, many of our competitors may be able to develop products and/or processes competitive with, or superior to, our own. We are concentrating the majority of our efforts and resources on developing product candidates utilizing our proprietary technologies. The commercial success of products utilizing such technologies will depend, in large part, on the intensity of competition, labeling claims approved by the FDA for our products compared to claims approved for competitive products and the relative timing and sequence for commercial launch of new products by other companies that compete with our new products. If alternative technologies or other therapeutic approaches are adopted prior to our new product approvals, then the market for our new products may be substantially decreased, thus reducing our ability to generate future profits.

This intensely competitive environment requires an ongoing, extensive search for technological innovations and the ability to market products effectively, including the ability to communicate the effectiveness, safety and value of our products to healthcare professionals in private practice, group practices and managed care organizations. Our competitors vary depending upon product categories and, within each product category, upon dosage strengths and upon drug-delivery systems. Based on total assets, annual revenues and market capitalization, we are smaller than many of our national and international competitors with respect to both our generic and proprietary pharmaceutical products and product candidates. Many of our competitors have been in business for a longer period of time than us, have a greater number of products on the market and have greater financial and other resources than we do. Furthermore, recent trends in this industry are toward further market consolidation of large drug companies into a smaller number of very large entities, further concentrating financial, technical and market strength and increasing competitive pressure in the industry. If we directly compete with large entities for the same markets and/or products, their financial strength could prevent us from capturing a profitable share of those markets. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. It is possible that developments by our competitors will make our products or technologies noncompetitive or obsolete.

Our current and future indebtedness has and may continue to adversely affect our operating results and cash flows.

The acquisition of BAQSIMI® was financed with proceeds of the senior secured term loan, or the Wells Fargo Term Loan, provided by the syndicated credit agreement, or the Credit Agreement, by and among the Company, certain subsidiaries of the Company, as guarantors, certain lenders, and Wells Fargo Bank, National Association, or Wells

Fargo, as Administrative Agent (in such capacity, Agent), Swing line Lender and L/C Issuer. The material increase in our indebtedness as a result of the Credit Agreement and the 2.00% Convertible Senior Notes due 2029, or the 2029 Convertible Notes, has and may continue to adversely affect our operating results, cash-flows and our ability to use cash generated from operations as we satisfy our materially increased underlying interest and principal payment obligations under the Credit Agreement and the 2029 Convertible Notes, as applicable.

Specifically, our materially increased indebtedness could have important consequences to investors in our common stock, including any or all of the following:

- we could be subject to substantial variable interest rate risk because interest rates applicable to certain of our indebtedness are based on a fixed margin over an indexed rate or an adjusted base rate. If interest rates were to further increase substantially it could have a material adverse effect on our operating results and could affect our ability to service the indebtedness;

- our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements, or other purposes may be limited or financing may be unavailable;

- a substantial portion of our cash flows must be dedicated to the payment of principal and interest on our indebtedness and other obligations and will not be available for use in our business;

- our level of indebtedness could limit our flexibility in planning for, or reacting to, changes in our business and the markets in which we operate or place us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital;

- our high degree of indebtedness will make us more vulnerable to changes in general economic conditions and/or a downturn in our business, thereby making it more difficult for us to satisfy our obligations; and

- any conversion of the 2029 Convertible Notes could dilute the interests of existing investors in our common stock.

Our ability to make scheduled payments of the principal and interest when due, or to refinance our borrowings under the Credit Agreement and/or the 2029 Convertible Notes, will depend on our future performance, which is subject to economic, financial, competitive and other factors beyond our control.

Our business may not continue to generate cash flow from operations in the future sufficient to satisfy our obligations under our indebtedness, and any future indebtedness we may incur and to make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as reducing or delaying investments or capital expenditures, selling assets, refinancing or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our existing or future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default under the Credit Agreement, the 2029 Convertible Notes or future indebtedness.

If we fail to make required payments under our existing or future indebtedness, we would be in default under the terms of these agreements. Subject to customary cure rights, any default would permit the holders of the indebtedness to accelerate repayment of this debt and could cause defaults under other indebtedness that we have, any of which could have a material adverse effect on the trading price of our common stock.

Our outstanding loan agreements contain restrictive covenants that may limit our operating flexibility.

Our loan agreements are collateralized by substantially all of our presently existing and subsequently acquired assets and subject us to certain affirmative and negative covenants, including limitations on our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates. For example, the Credit Agreement contains financial and operational covenants that may adversely affect our operational freedom or ability to pursue strategic transactions that we would otherwise consider to be in the best interests of stockholders, including obtaining additional indebtedness to finance such transactions.

We are also subject to certain covenants that require us to maintain certain financial ratios and are required under certain conditions to make mandatory prepayments of outstanding principal. As a result of these covenants and ratios, we have certain limitations on the manner in which we can conduct our business, and we may be restricted from engaging in favorable business activities or financing future operations or capital needs until our current debt obligations are paid in full or we obtain the consent of our lenders, which we may not be able to obtain. For example, the Credit Agreement contains financial and operational covenants that may adversely affect our ability to engage in certain activities, including certain financing and acquisition transactions, stock repurchases, guarantees, and similar transactions, without obtaining the consent of the lenders, which may or may not be forthcoming including without limitation, covenants requiring compliance with a maximum consolidated net leverage ratio test and a minimum consolidated interest coverage ratio test.

We may not be able to generate sufficient cash flow or revenue to pay the principal and interest on our debt. In addition, upon the occurrence of an event of default, our lenders, among other things, can declare all indebtedness due and payable immediately, which would adversely impact our liquidity and reduce the availability of our cash flows to fund working capital needs, capital expenditures and other general corporate purposes. An event of default includes our failure to pay any amount due and payable under the loan agreements, the occurrence of a material adverse change in our business as defined in the loan agreements, our breach of any covenant in the loan agreements, subject to a grace period in some cases, or an involuntary insolvency proceeding. Additionally, a lender could exercise its lien on substantially all of our assets and our future working capital, borrowings or equity financing may not be available to repay or refinance any such debt.

We may not have sufficient cash to settle conversions of the 2029 Convertible Notes in cash, to repurchase the 2029 Convertible Notes upon a fundamental change, or to repay the principal amount of the 2029 Convertible Notes in cash at their maturity, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the 2029 Convertible Notes.

Holders of the 2029 Convertible Notes will have the right to require us to repurchase all or a portion of the 2029 Convertible Notes upon the occurrence of a fundamental change, as defined in the indenture governing the 2029 Convertible Notes, or the Indenture, before the applicable maturity date at a repurchase price equal to 100% of the principal amount of such 2029 Convertible Notes to be repurchased, plus accrued and unpaid interest or special interest, if any, as described in the Indenture. In addition, upon conversion of the 2029 Convertible Notes, we will be required to settle a portion or all of the conversion obligation in respect of the 2029 Convertible Notes being converted in cash, as described in the Indenture. Moreover, we will be required to repay the 2029 Convertible Notes in cash at their maturity unless earlier converted, redeemed or repurchased. However, we may not have enough available cash on hand or be able to obtain financing at the time we are required to make repurchases of the 2029 Convertible Notes surrendered therefor or pay cash with respect to the 2029 Convertible Notes being converted or at their respective maturity.

In addition, our ability to repurchase the 2029 Convertible Notes or to pay cash upon conversions of the 2029 Convertible Notes or at their maturity may be limited by law, regulatory authority or agreements governing our future indebtedness. Our failure to repurchase the 2029 Convertible Notes at a time when the repurchase is required by the Indenture or to pay cash upon the conversion of the 2029 Convertible Notes or at their maturity as required by the Indenture would constitute a default under the Indenture. A default under the Indenture or the fundamental change itself could also lead to a default under agreements governing our existing and future indebtedness. Moreover, the occurrence of a fundamental change under the Indenture could constitute an event of default under any such agreement. If the payment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness, which would have a material adverse effect on our business, results of operations and financial condition.

The conditional conversion feature of the 2029 Convertible Notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of the 2029 Convertible Notes is triggered, holders of the 2029 Convertible Notes will be entitled under the Indenture to convert the 2029 Convertible Notes at any time during the specified periods at their option. Upon such event, if one or more holders elect to convert their 2029 Convertible Notes, we would be required to settle a portion or all of the conversion obligation in cash, which could adversely affect our liquidity. In addition, even if holders of the 2029 Convertible Notes do not elect to convert their 2029 Convertible Notes,

we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of such 2029 Convertible Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

If we fail to obtain exclusive marketing rights for our generic pharmaceutical products or fail to introduce these generic products on a timely basis, our revenues, gross margin and operating results may decline significantly.

The Hatch-Waxman amendments to the Federal Food, Drug, and Cosmetic Act, or FFDCA, provide for a period of 180 days of generic marketing exclusivity for any applicant that is first-to-file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to the corresponding brand drug, which we refer to as a Paragraph IV certification. The holder of an approved ANDA containing a Paragraph IV certification that is successful in challenging the applicable brand drug patent(s) is often able to price the applicable generic drug to yield relatively high gross margins during this 180-day marketing exclusivity period, however, there is no certainty that we will be the first-to-file and granted the 180-day marketing exclusivity period or, if we are granted the 180-day marketing exclusivity period, that we will not forfeit such period. In addition, ANDAs that contain Paragraph IV certifications challenging patents generally become the subject of patent litigation that can be both lengthy and costly and there are no certainty that we would prevail if there were any such litigation. Even where we are awarded marketing exclusivity, we may be required to share our exclusivity period with other ANDA applicants who submit Paragraph IV certifications. In addition, brand companies often authorize a generic version of the corresponding brand drug to be sold during any period of marketing exclusivity that is awarded, which reduces gross margins during the marketing exclusivity period. Brand companies may also reduce the price of their brand product to compete directly with generics entering the market, which similarly would have the effect of reducing gross margins. Furthermore, timely commencement of litigation by the patent owner imposes an automatic stay of ANDA approval by the FDA for 30 months, unless the case is decided in the ANDA applicant's favor during that period. Finally, if the court's decision is adverse to the ANDA applicant, the ANDA approval will be delayed until the challenged patent expires, and the applicant will not be granted the 180-day marketing exclusivity.

Accordingly, our revenues and future profitability are dependent, in large part, upon our ability or the ability of our development partners to file ANDAs with the FDA timely and effectively or to enter into contractual relationships with other parties that have obtained marketing exclusivity. We may not be able to develop and introduce successful products in the future within the time constraints necessary to be successful. If we or our development partners are unable to continue to timely and effectively file ANDAs with the FDA or to partner with other parties that have obtained marketing exclusivity, our revenues, gross margin and operating results may decline significantly, and our prospects and business may be materially adversely affected.

Our generic products face, and our generic product candidates will face, additional competitive pressures that are specific to the generic pharmaceutical industry.

With respect to our generic pharmaceutical business, revenues and gross profit derived from the sales of generic pharmaceutical products tend to follow a pattern based on certain regulatory and competitive factors. As patents and exclusivities protecting a brand name product expire, the first manufacturer to receive regulatory approval for a generic version of the product is generally able to achieve significant market penetration. Therefore, our ability to increase or maintain revenues and profitability in our generics business is largely dependent on our success in challenging patents and developing non-infringing formulations of proprietary products. As competing manufacturers receive regulatory approvals on generic products or as brand manufacturers launch generic versions of their products (for which no separate regulatory approval is required), market share, revenues and gross profit typically decline, often significantly and rapidly. Accordingly, the level of market share, revenue and gross profit attributable to a particular generic product normally is related to the number of competitors in that product's market and the timing of that product's regulatory approval and launch, in relation to competing approvals and launches. For example, glucagon is also marketed by Viatris, Inc., Cipla Limited, Lupin Pharmaceuticals, Inc., and others also either market or plan to market a generic version of glucagon. Other companies may have received FDA approval of glucagon but have not launched the product, while other companies may have filed ANDAs for glucagon with the FDA. The presence of these current and prospective competitive products has had, and may continue to have, an adverse effect on our market share, revenue and gross profit from our glucagon product. Since the commercial launch of our glucagon product, we have experienced significant declines in sales volume, per unit pricing and gross margins attributable to this product. Consequently, we must continue to develop and introduce new generic products in a timely and cost-effective manner to maintain our revenues and gross margins. We may have fewer opportunities to launch significant generic products in the future, as the number and size of proprietary products that are subject to patent challenges is expected to decrease in the next several

years compared to historical levels. Additionally, as new competitors enter the market, there may be increased pricing pressure on certain products, which may result in lower gross margins. In addition to our enoxaparin product, we have experienced pricing pressure on many of our other products, including naloxone, and we expect this trend to continue in the future.

Competition in the generic drug industry has also increased due to the proliferation of authorized generic pharmaceutical products. "Authorized generics" are generic pharmaceutical products that are introduced by brand companies, either directly or through partnering arrangements with other generic companies. Authorized generics are equivalent to the brand companies' brand name drugs, but are sold at relatively lower prices than the brand name drugs. An authorized generic product can be marketed during the 180-day exclusivity granted to the first manufacturer or manufacturers to submit an ANDA with a Paragraph IV certification for a generic version of the brand product. The sale of authorized generics adversely impacts the market share of a generic product that has been granted 180-day exclusivity. Because authorized generics may be sold during our exclusivity periods, if any, they can materially decrease the profits that we could otherwise receive as an exclusive marketer of a generic alternative. Such actions have the effect of reducing the potential market share and profitability of our generic products and may inhibit us from developing and introducing generic pharmaceutical products corresponding to certain brand name drugs.

Such competition can also result from the entry of generic versions of another product in the same therapeutic class as one of our drugs, or in another competing therapeutic class, or from the compulsory licensing of our products by governments, or from a general weakening of intellectual property laws in certain countries around the world.

In addition, the goals established under the Generic Drug User Fee Act, and increased funding of the FDA's Office of Generic Drugs, have led to more and faster generic approvals, and consequently increased competition for some of our products. The FDA has stated that it has established new steps to enhance competition, promote access and lower drug prices and is approving record-breaking numbers of generic applications. While these FDA improvements are expected to benefit our generic product pipeline, they will also benefit competitors that seek to launch products in established generic markets where we currently offer products.

If the market for any of our reference brand products significantly declines, sales or potential sales of our generic and biosimilar products and product candidates may suffer and our business would be materially impacted.

Proprietary products face competition on numerous fronts as technological advances are made or new products are introduced. As new products are approved that compete with the reference proprietary product to our generic products and generic or biosimilar product candidates, sales of the reference brand products may be significantly and adversely impacted and may render the reference brand product obsolete. In addition, brand companies may pursue life cycle management strategies that also impact our generic products.

If the market for a reference brand product is impacted, we in turn may lose significant market share or market potential for our generic or biosimilar products and product candidates, and the value for our generic or biosimilar pipeline could be negatively impacted. As a result, our business, including our financial results and our ability to fund future discovery and development programs, would suffer.

Health care providers may not be receptive to our products, particularly those that incorporate our proprietary drug delivery platforms.

The commercial success of our products will depend on acceptance by health care providers and others that such products are clinically effective, affordable and safe. Our products utilizing our proprietary drug delivery technologies may not be accepted by health care providers and others. Factors that may materially affect market acceptance of our products include but are not limited to:

- the relative therapeutic advantages and disadvantages of our products compared to competitive products;
- the relative timing of the commercial launch of our products compared to competitive products;
- the relative safety and efficacy of our products compared to competitive products;
- the product labeling approved by the FDA for our products and for competing products;
- the willingness of third-party payers to reimburse for our prescription products and the level of any

reimbursement provided for our prescription products;

- the willingness of pharmacy chains to stock our new products;
- the willingness of consumers to pay for our products; and
- legislative and regulatory efforts implemented by federal, state, or foreign governments to contain health care costs and prescription drug pricing, including measures that increase our reporting obligations to regulatory authorities and that impact how our customers purchase our drug products.

Our products, if successfully developed and commercially launched, will compete with both currently marketed products and new products launched in the future by other companies. Health care providers may not accept or utilize some of our products. Physicians and other prescribers may not be inclined to prescribe our prescription products unless our products demonstrate commercially viable advantages over other products currently marketed for the same indications. Pharmacy chains may not be willing to stock certain of our new products, and pharmacists may not recommend such products to consumers. Further, consumers may not be willing to purchase some of our products. If our products do not achieve market acceptance, we may not be able to generate significant revenues or become profitable.

If we are unable to maintain our group purchasing organization relationships, our revenues could decline and future profitability could be jeopardized.

Many of the existing and potential customers for our products have combined to form group purchasing organizations in an effort to lower costs. Group purchasing organizations negotiate pricing arrangements with medical supply manufacturers and distributors, and these negotiated prices are made available to a group purchasing organization's affiliated hospitals and other members. Group purchasing organizations provide end-users access to a broad range of pharmaceutical products from multiple suppliers at competitive prices and, in certain cases, exercise considerable influence over the drug purchasing decisions of such end-users. Hospitals and other end-users contract with the group purchasing organization of their choice for their purchasing needs. We currently derive, and expect to continue to derive, our revenue from end-user customers that are members of group purchasing organizations. Maintaining our strong relationships with these group purchasing organizations will require us to continue to be a reliable supplier, offer a broad product line, remain price competitive, comply with FDA regulations and provide high-quality products. Although our group purchasing organization pricing agreements are typically multi-year in duration, most of them may be terminated by either party with 60 or 90 days' notice. The group purchasing organizations with which we have relationships may have relationships with manufacturers that sell competing products, and such group purchasing organizations may earn higher margins from these competing products or combinations of competing products or may prefer products other than ours for other reasons. If we are unable to maintain our group purchasing organization relationships, sales of our products and revenue could decline.

Consolidation in the health care industry could lead to demands for price concessions or for the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, financial condition or results of operations.

Because health care costs have risen significantly, numerous initiatives and reforms by legislatures, regulators and third-party payers to curb these cost increases have resulted in a trend in the health care industry to consolidate product suppliers and purchasers. As the health care industry consolidates, competition among suppliers to provide products to purchasers has become more intense. This in turn has resulted and will likely continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations and large single accounts continue to use their market power to influence product pricing and purchasing decisions. As the U.S. payer market concentrates further and as more drugs become available in generic form, biopharmaceutical companies may face greater pricing pressure from private third-party payers, who will continue to drive more of their patients to use lower cost generic alternatives. This drive towards generic alternatives could adversely affect sales of our proprietary products and increase competition among generic manufacturers.

Sales of our products may be adversely affected by the continuing consolidation of our customer base.

A significant proportion of our sales are made to relatively few U.S. wholesalers and group purchasing organizations. These customers are continuing to undergo significant consolidation. Sales to three of these customers for the years ended December 31, 2025, 2024, and 2023, respectively, accounted for approximately 65%, 64%, and 60% of our total

net revenues, respectively. Such consolidation has provided and may continue to provide them with additional purchasing leverage, and consequently may increase the pricing pressures that we face.

Moreover, we are exposed to a concentration of credit risk as a result of this concentration among our customers. If one or more of our major customers experienced financial difficulties, the effect on us would be substantial. This could have a material adverse effect on our business, financial condition and results of operations.

Our net sales and quarterly growth comparisons may also be affected by fluctuations in the buying patterns of retail chains, major distributors and other trade buyers, whether resulting from seasonality, pricing, wholesaler buying decisions or other factors. In addition, because a significant portion of our U.S. revenues is derived from relatively few customers, any financial difficulties experienced by a single customer, or any delay in receiving payments from a single customer, could have a material adverse effect on our business, financial condition and results of operations.

At the same time, the traditional model for distribution of pharmaceutical products is also undergoing disruption as a result of the entry or potential entry of new competitors and significant mergers among key industry participants. These changes to the traditional supply chain could lead to our customers having increased negotiation leverage and to additional pricing pressure and price erosion.

If our business partners do not fulfill their obligations with respect to our distribution or collaboration agreements, our revenues and our business will suffer.

Pursuant to certain distribution or collaboration agreements, the success of some of our products or product candidates also depends on the success of the collaboration with our business partners, who are responsible for certain aspects of researching, developing, marketing, distributing or commercializing our products or product candidates. If any such agreement were to be terminated in accordance with its terms, including due to a party's failure to perform its obligations or responsibilities under the agreement, revenues could be delayed or diminished from these products and our revenues and/or profit share for these products could be adversely impacted.

We depend upon our key personnel, the loss of whom could adversely affect our operations. If we fail to attract and retain the talent required for our business, our business could be materially harmed.

We depend to a significant degree on our key management employees, including our Chief Executive Officer and Chief Science Officer, Jack Y. Zhang, and our Chief Operating Officer and Chief Scientist, Mary Z. Luo. The loss of services from any of these persons may significantly delay or prevent the achievement of our product development or business objectives. We do not carry key man life insurance on any key personnel. Competition among pharmaceutical companies for qualified employees is intense, and the ability to attract and retain qualified individuals is critical to our success. We have experienced attrition among our executive officers in the past, and any future loss of key members of our organization or any inability to continue to attract high-quality employees may delay or prevent the achievement of major business objectives. Our productivity may be adversely affected if we do not integrate or train our new employees quickly and effectively.

Competition for highly-skilled personnel is often intense, especially in Southern California, where we have a substantial presence and need for highly-skilled personnel. We may not be successful in attracting, integrating or retaining qualified personnel to fulfill our current or future needs. Also, to the extent we hire personnel from competitors, we may be subject to allegations that we have improperly solicited, or that they have divulged proprietary or other confidential information, or that their former employers own their inventions or work product.

Our business may be adversely affected by challenging macroeconomic conditions globally.

General conditions in the global economy and in the global financial markets could adversely affect our results of operations, and the overall demand for our products. Downturns in economic conditions and recessions, including inflationary pressures and changes in interest rates could continue to decrease spending and adversely affect demand for our products and harm our business and results of operations. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including weakened demand for our products and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our products. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

We may be exposed to product liability claims and may not be able to obtain or maintain adequate product liability insurance.

Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. Product liability claims might be made by patients, health care providers or others who sell or consume our products. These claims may be made even with respect to those products that possess regulatory approval for commercial sale.

Our reputation is the foundation of our relationships with physicians, patients, group purchasing organizations and other customers. If we are unable to effectively manage real or perceived issues that could negatively impact sentiments toward us, our business could suffer. Our customers may have a number of concerns about the safety of our products whether or not such concerns have a basis in generally accepted science or peer-reviewed scientific research. These concerns may be increased by negative publicity, even if the publicity is inaccurate. Any negative publicity, whether accurate or inaccurate, about the efficacy, safety or side effects of our products or product categories, whether involving us, a competitor or a reference drug, could materially reduce market acceptance of our products, cause consumers to seek alternatives to our products, result in product withdrawals and cause our stock price to decline. Negative publicity could also result in an increased number of product liability claims, whether or not these claims have a basis in scientific fact.

We currently maintain a $20.0 million product liability insurance policy, which covers Amphastar, IMS, Armstrong, and AFP, products, but our insurance coverage is subject to deductibles and may not reimburse us or may not be sufficient to reimburse us for all expenses or losses we may suffer from any product liability claims. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. Large judgments have been awarded in class action lawsuits based on drug products that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

If serious adverse events or deaths are identified relating to any of our products once they are on the market, we may be required to withdraw our products from the market, which would hinder or preclude our ability to generate revenues.

We are required to report to relevant regulatory authorities adverse events or deaths associated with our product candidates or approved products. Based on such events, regulatory authorities may withdraw their approvals of such products or take enforcement actions. We may be required to reformulate our products, and/or we may have to recall the affected products from the market and may not be able to reintroduce them into the market. Furthermore, our reputation in the marketplace may suffer and we may become the target of lawsuits, including class actions suits. Any of these events could harm or prevent sales of the affected products and could have a material adverse effect upon our business and financial condition.

Any acquisitions of technologies, products and businesses may be difficult to integrate, could adversely affect our relationships with key customers and/or could result in significant charges to earnings.

We plan to regularly review potential acquisitions of technologies, products and businesses complementary to our business. For example, in 2023 we acquired BAQSIMI® from Eli Lilly & Company. Acquisitions typically entail many risks and could result in difficulties in integrating operations, personnel, technologies and products. If we are not able to successfully integrate our acquisitions, we may not obtain the advantages and synergies that the acquisitions were intended to create, which may have a material adverse effect on our business, results of operations, financial condition and cash flows, our ability to develop and introduce new products and the market price of our stock. In addition, some acquisitions may require regulatory approvals before products may be sold by us, which may not be obtained on a timely basis, or at all. It is possible that the integration of some acquired technologies, information systems and data could increase our risk of experiencing a data security or privacy incident. In addition, in connection with acquisitions, we could experience disruption in our business, technology and information systems, customer or employee base, including diversion of management's attention from our continuing operations. There is also a risk that key employees of companies that we acquire or key employees necessary to successfully commercialize technologies and products that we acquire may seek employment elsewhere, including with our competitors. Furthermore, there may be overlap between our products or customers and the companies that we acquire that may create conflicts in relationships or other commitments detrimental to the integrated businesses. If we are unable to successfully integrate technologies, products, businesses or personnel that we acquire, we could incur significant impairment charges or other adverse financial

consequences.

Identifying, executing and realizing attractive returns on acquisitions is highly competitive and involves a high degree of uncertainty. We expect to encounter competition for potential target businesses from both strategic and financial buyers. Some of these competitors may be well established and have extensive experience in identifying and consummating business combinations. Some of these competitors may possess greater technical, human and other resources than us, and our financial resources may be relatively limited when contrasted with those of our competitors. We may lose acquisition opportunities if we do not match our competitors' pricing, terms and structure criteria for such acquisitions. If we are forced to match these criteria to make acquisitions, we may not be able to achieve acceptable returns on our acquisitions or may bear substantial risk of capital loss. In addition, target companies may not be willing to sell assets at valuations which are attractive to us. Furthermore, the terms of our existing or future indebtedness may hinder or prevent us from making additional acquisitions of technologies, products or businesses. Because of these factors, we may not be able to consummate an acquisition on attractive terms, if at all.

We intend to conduct an extensive due diligence investigation for any business we consider acquiring. Intensive due diligence is often time consuming and expensive due to the operations, finance and legal professionals who may be involved in the due diligence process. Even if we conduct extensive due diligence on a target business which we acquire, we may not identify all material issues that are present inside a particular target business. If our due diligence fails to discover or identify material issues relating to a target business, industry or the environment in which the target business operates, we may be forced to later write-down or write-off assets, restructure the target business' operations or incur impairment or other charges that could result in losses to us.

We may engage in acquisitions or strategic partnerships that could disrupt our business, cause dilution to our stockholders, reduce our financial resources, cause or to incur debt or assume contingent liabilities, and subject us to other risks.

In the future, we may enter into transactions to acquire other businesses, products or technologies or enter into strategic partnerships, including licensing. If we do identify suitable acquisition or partnership candidates, we may not be able to make such acquisitions or partnerships on favorable terms, or at all. Any acquisitions or partnerships we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. For example, our Term Loan may restrict our ability to pursue certain mergers, acquisitions or consolidations without obtaining the prior consent of a majority of lenders in our existing syndicate or repaying our outstanding loan amounts. We could incur losses resulting from undiscovered liabilities of the acquired business or partnership that are not covered by the indemnification we may obtain from the seller or our partner. In addition, we may not be able to successfully integrate any acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions or partnerships may also divert management attention from day-to-day responsibilities, lead to a loss of key personnel, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or partnerships or the effect that any such transactions might have on our operating results.

Charges to earnings resulting from acquisitions could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Under U.S. generally accepted accounting principles, or GAAP, business combination accounting standards, we recognize the identifiable assets acquired, the liabilities assumed and any non-controlling interests in acquired companies generally at their acquisition date fair values and, in each case, separately from goodwill. Goodwill as of the acquisition date is measured as the excess amount of consideration transferred, which is also generally measured at fair value, and the net of the acquisition date amounts of the identifiable assets acquired and the liabilities assumed. Our estimates of fair value are based upon assumptions believed to be reasonable but which are inherently uncertain. After we complete an acquisition, the following factors could result in material charges and adversely affect our operating results and may adversely affect our cash flows:

- costs incurred to combine the operations of companies we acquire, such as transitional employee expenses and employee retention, redeployment or relocation expenses;

- impairment of goodwill or intangible assets, including acquired in-process research and development;

- amortization of intangible assets acquired;
- a reduction in the useful lives of intangible assets acquired;
- identification of or changes to assumed contingent liabilities, including, but not limited to, contingent purchase price consideration, income tax contingencies and other non-income tax contingencies, after our final determination of the amounts for these contingencies or the conclusion of the measurement period (generally up to one year from the acquisition date), whichever comes first;
- charges to our operating results to eliminate certain duplicative pre-acquisition activities, to restructure our operations or to reduce our cost structure; and
- charges to our operating results resulting from expenses incurred to effect the acquisition.

A significant portion of these adjustments could be accounted for as expenses that will decrease our net income and earnings per share for the periods in which those costs are incurred. Such charges could cause a material adverse effect on our business, financial position and results of operations and could cause the market value of the common stock to decline.

We may evaluate asset dispositions and other transactions that may impact our results of operations, and we may not achieve the expected results from these transactions.

From time to time, we may enter into agreements to dispose of certain assets. However, we cannot assure you that we will be able to dispose of any such assets at any anticipated prices, or at all, or that any such sale will occur during any anticipated time frame. In addition, we may engage in business combinations, purchases of assets or contractual arrangements or joint ventures. Subject to the agreements governing our existing debt or otherwise, some of these transactions may be financed with our additional borrowings. We may suffer a loss of key employees, customers or suppliers, loss of revenues, increases in costs or other difficulties in connection with these transactions. Other transactions may advance future cash flows from some of our businesses, thereby yielding increased short-term liquidity, but consequently resulting in lower cash flows from these operations over the longer term. The failure to realize the expected long-term benefits of any one or more of these transactions could have a material adverse effect on our financial condition or results of operations.

Significant balances of intangible assets, including goodwill, are subject to impairment testing and may result in impairment charges, which may materially and adversely affect our results of operations and financial condition.

A significant amount of our total assets is related to goodwill and intangible assets. As of December 31, 2025, the value of our goodwill and intangible assets net of accumulated amortization was $566.0 million. Goodwill and other intangible assets are tested for impairment annually when events occur or circumstances change that could potentially reduce the fair value of the reporting unit or intangible asset. Impairment testing compares the fair value of the reporting unit or intangible asset to its carrying amount. Any future goodwill or other intangible asset impairment, if any, would be recorded in operating income and could have a material adverse effect on our results of operations and financial condition.

Counterfeit versions of our products could harm our patients and reputation.

Our industry has been increasingly challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Counterfeit products are frequently unsafe or ineffective, and can be potentially life-threatening. To distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product, and harm the business of companies such as ours. Additionally, it is possible that adverse events caused by unsafe counterfeit products would mistakenly be attributed to the authentic product. If a product of ours was the subject of counterfeits, we could incur substantial reputational and financial harm in the longer term.

Our business and operations have been impacted in the past, and may be impacted in the future, in the event of system breach or failure.

We and our third-party service providers and other third parties with whom we do business, including our collaborators, third-party providers, distributors, customers and other contractors utilize information technology systems and networks to transmit, store and otherwise process electronic data in connection with our business activities, including our supply chain processes, operations and communications including, in some cases, our clinical data and business proprietary information, and electronic data interchange, on purchase orders, invoices, chargebacks, among other things. We and such third parties, including our collaborators, third-party service providers, distributors and other contractors, also collect, transmit, store and otherwise process certain data relating to individuals, including about our personnel, business partners, and others, which may be subject to applicable data protection, security and privacy laws and regulations that require adoption of minimum information security standards. The cost of compliance with applicable data protection, security and privacy laws and regulations have increased and may increase in the future.

Despite our implementation of security measures to protect the confidentiality, integrity, and availability of the systems, networks and data within our control from various threats (e.g., threats of cyber-attacks, system breaches, and other security breaches and incidents, malware, viruses, hacking, fraudulent use, social engineering attacks, phishing attacks, ransomware attacks, credential-stuffing attacks, denial-of-service attacks, unauthorized access, insider threats, accidental disclosures, intellectual property theft and economic espionage, exploitable vulnerabilities, defects or bugs in our or our third-party service providers' systems, natural disasters, war, terrorism, telecommunications and electrical outages, breakdowns, damage, outages, interruptions, and other cyber-events), we and certain of our third-party service providers have experienced and may continue to experience cyber-attacks, outages, interruptions, and other cyber-events of varying degrees from time to time. For example, in the past we have been subject to security incidents that resulted in a temporary disruption to some of its internal computer systems. Our systems and networks and the systems and networks of our third-party service providers, have been, and in the future may be, breached or disrupted due to the threats described above or otherwise. The size and complexity of our systems may make them potentially vulnerable to breakdown or interruption, whether due to computer viruses or other causes, which may result in loss of data or the impairment of production and other supply chain processes, adversely affecting our business.

Techniques used to sabotage or obtain unauthorized access to systems and networks are constantly evolving and, in some instances, are not identified until or after they are launched against a target. We and our third-party service providers may be unable to anticipate these techniques, discover threats and react in a timely manner, or implement adequate preventative or mitigating measures. Further, system breaches, malware, ransomware, computer hacking, and insider threats have become more prevalent. For example, companies have experienced an increase in phishing and social engineering attacks from third parties in connection with the increase in employees working remotely in recent years. We and our third-party service providers who may be operating with personnel in remote work environments may have increased security risks, due to increased use of home Wi-Fi networks and virtual private networks, as well as increased disbursement of physical machines. Also, due to political uncertainty and military actions, we and our third-party service providers are vulnerable to heightened risks of cyber threats and cyber-attacks from or affiliated with nation-state actors, including attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products and services. While we implement security measures designed to reduce these risks, there is no guarantee that these measures will be adequate to safeguard all systems and networks. Any failure of ourselves or our third-party service providers to maintain performance, reliability, security and availability of our systems and networks, or other systems or networks on which our data is stored or processed, may result in accidental or unlawful destruction, damage, loss, unavailability, alteration, impairment, misuse, unauthorized disclosure of, or unauthorized access to our data, including personal information.

In addition, potential legal, regulatory, contractual, financial, operational, and reputational harm may arise from the accidental or unlawful destruction, damage, loss, unavailability, alteration, impairment, misuse, unauthorized disclosure of, or unauthorized access to our systems, networks, or data, including data which is transmitted, stored or otherwise processed by us or by third parties, including collaborators, third-party service providers, distributors, and other contractors on our behalf. For example:

- The accidental or unlawful loss, unavailability, or alteration of clinical trial data from completed or ongoing clinical trials for any of our product candidates could affect our ability to operate, result in delays in our development and regulatory approval efforts, and significantly increase our costs to recover or reproduce the data.

- Any security incident may require costly response and remediation efforts, trigger notification obligations under breach notification laws or contractual notification requirements, result in litigation or adverse regulatory action arising from or related to such an incident or event, damage our reputation, and result in significant additional expense to implement further data protection measures. Integrating the systems and data of any acquired entity may increase these risks due to unforeseen threats and vulnerabilities.

- Similarly, any security incident experienced by our collaborators, third-party providers, distributors and other contractors may hinder our product development, supply chain, other business operations, or our regulatory and contractual obligations to others and could also give rise to litigation or adverse regulatory action.

In an effort to ensure appropriate oversight of cyber security issues and risks, management updates the Board of Directors on cyber security matters on a quarterly basis, and the Board of Directors has assigned oversight of cyber security to the Audit Committee. Additionally, the Company has a security training and compliance program, which employees with access to information technology, must complete annually or more often, if deemed necessary or appropriate.

There can be no assurance that we will be successful in preventing security incidents nor that we will be successful in mitigating their effects, despite the implementation of security measures for systems, networks and data within our control. Similarly, there can be no assurance that our collaborators, third-party service providers, distributors and other contractors will be successful in protecting our data on their systems or in protecting other systems upon which we may rely. Furthermore, breach notification laws are not consistent among jurisdictions, and compliance and other measures in the event of a security incident could result in a substantial cost and diversion of resources and distract management and technical personnel in efforts to investigate or correct the security incident, address and eliminate vulnerabilities and prevent future security incidents, and remediate the security incident, which repairing systems and responding to claims of damages for actual or asserted contract breaches. Any such security incident could have a material adverse effect on our business and prospects.

Although we maintain cyber insurance coverage that may cover certain of our losses in connection with a security incident, we cannot be certain our insurance coverage will be adequate for losses actually incurred, that insurance will continue to be available to us on commercially reasonable terms (if at all) or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, or denials of coverage, could have a material adverse effect on our business, including our financial condition, results of operations and reputation.

We have incurred losses in the past and we may operate at a loss in future years while continuing to invest in developing and acquiring new products.

Although we achieved net income in the years ended December 31, 2025, 2024, and 2023, we may incur operating and net losses and negative cash flow from operations in the future. Our business may generate operating losses if we do not successfully commercialize our product candidates, maintain sales of and profits from existing products, and generate sufficient revenues to support our level of operating expenses, especially as we continue our investments in developing and, to the extent applicable, acquiring new products. Because of the numerous risks and uncertainties associated with our commercialization efforts and future product development, we are unable to predict whether we will be able to maintain profitability.

Risks Relating to Regulatory Matters

The FDA approval process for changes to existing products (such as change of components or API supplier) is time-consuming and complicated, and we may not obtain the FDA approval required for such changes within the timeline we desire, or at all.

The development, testing, manufacturing, marketing and sale of generic and proprietary pharmaceutical products and biological products are subject to extensive federal, state and local regulation in the U.S. and other countries. Satisfaction of all regulatory requirements, which typically takes years for drugs that require regulatory approval in ANDAs, NDAs, biological license applications, or BLAs, or biosimilar applications is dependent upon the type, complexity and novelty of the product candidate and requires the expenditure of substantial resources for research (including qualification of suppliers and their supplied materials), development, in vitro and in vivo (including nonclinical and clinical trials)

studies, manufacturing process development and commercial scale up. Some of our products are drug-device combination products that are regulated as drug products by the FDA, with consultation from the FDA's Center for Device and Radiological Health. These combination products require the submission of drug applications to the FDA. All of our products are subject to compliance with the FFDCA and/or the Public Health Service Act, or PHSA, and with the FDA's implementing regulations. Failure to adhere to applicable statutory or regulatory requirements by us or our business partners would have a material adverse effect on our operations and financial condition. In addition, in the event we are successful in developing product candidates for distribution and sale in other countries, we would become subject to regulation in such countries. Such foreign regulations and product approval requirements are expected to be time consuming and expensive as well.

We have in the past and may in the future encounter delays or agency rejections during any stage of the regulatory review and approval process based upon a variety of factors, including without limitation the failure to provide clinical data demonstrating compliance with the FDA's requirements for safety, efficacy and quality. Those requirements may become more stringent prior to submission of our applications for approval or during the review of our applications due to changes in the law or changes in FDA policy or the adoption of new regulations. After submission of an application, the FDA may refuse to file the application, deny approval of the application or require additional testing or data. The FDA can convene an Advisory Committee to assist the FDA in examining specific issues related to the application.

Under various user fee enactments, the FDA has committed to timelines for its review of NDAs, ANDAs, BLAs and biosimilar applications. However, the FDA's timelines described in its guidance on these statutes are flexible and subject to changes based on workload and other potential review issues that may delay the FDA's review of an application. Further, the terms of approval of any applications may be more restrictive than our expectations and could affect the marketability of our products.

The FDA also has the authority to revoke or suspend approvals of previously approved products for cause, to debar companies and individuals from participating in the approval process for ANDAs, to request recalls of allegedly violative products, to seize allegedly violative products, to obtain injunctions that may, among other things, close manufacturing plants that are not operating in conformity with cGMP and stop shipments of potentially violative products and to prosecute companies and individuals for violations of the FFDCA.

One of our API suppliers discontinued manufacturing an API included in one of our commercial products. We qualified one of our subsidiaries to supply the necessary API, and obtained FDA approval of our new API supply. However, the approval process for the API supply was delayed, causing us to temporarily stop manufacturing and selling the product for several months. Similar situations could happen with other suppliers in the future. If we are forced to stop manufacturing any of our commercial products in the future, for any length of time, it could have a material effect on our operating results and financial condition.

FDA regulations and policies are subject to change, especially in view of changes under a new Presidential administration and new leadership at the agency, which can delay regulatory approval or have a material adverse effect on our operations. In June 2024, the U.S. Supreme Court overruled the *Chevron* doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite various stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, 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 uncertainty in the industry, and disrupt the FDA's normal operations.

Clinical failure can occur at any stage of clinical development. The results of earlier clinical trials are not necessarily predictive of future results and any product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Clinical failure can occur at any stage of our clinical development. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in Phase 3 clinical trials, even after seeing promising results in earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. If any of our product candidates are found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for them and our business would be harmed.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Our clinical trials may not demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If we are unable to bring any of our current or future product candidates to market, or to acquire any marketed, previously approved products, our ability to create long-term stockholder value will be limited.

If clinical studies for our product candidates are unsuccessful or significantly delayed, we will be unable to meet our anticipated development and commercialization timelines, which would have an adverse impact on our business.

Some of our new drug candidates must be approved in NDAs based on clinical studies demonstrating safety and/or effectiveness. For these types of studies, we rely on our investigational teams, who mainly are medical experts working in multicenter hospitals, to execute our study protocols with our product candidates. As a result, we have less control over our development program than if we were to perform the studies entirely on our own. Third parties may not perform their responsibilities according to our anticipated schedule. Delays in our development programs could significantly increase our product development costs and delay product commercialization.

The commencement of clinical trials on our product candidates may be delayed for several reasons, including but not limited to delays in demonstrating sufficient pre-clinical safety required to obtain regulatory clearance to commence a clinical trial, reaching agreements on acceptable terms with prospective contract research organizations, clinical trial sites and licensees, manufacturing and quality assurance release of a sufficient supply of a product candidate for use in our clinical trials, delays in recruiting sufficient subjects for a clinical trial and/or obtaining institutional review board approval to conduct a clinical trial at a prospective clinical site. Once a clinical trial has begun, it may be delayed, suspended or terminated by us or by regulatory authorities for a variety of reasons, including without limitation ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials, a determination by us or regulatory authorities that continuing a trial presents an unreasonable health risk to participants, failure to conduct clinical trials in accordance with regulatory requirements, lower than anticipated recruitment or retention rate of patients in clinical trials, inspection of the clinical trial operations or trial sites by regulatory authorities, the imposition of a clinical hold by the FDA, lack of adequate funding to continue clinical trials and/or negative or unanticipated results of clinical trials.

Patient enrollment, a significant factor in the time required to complete a clinical study, is affected by many factors, including the size and nature of the study subject population, the proximity of patients to clinical sites, the eligibility criteria for the study, the design of the clinical study, competing clinical studies and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to available alternatives, including without limitation therapies being investigated by other companies. Further, completion of a clinical study and/or the results of a clinical study may be adversely affected by failure to retain subjects who enroll in a study but withdraw due to, among other things, adverse side effects, lack of efficacy, improvement in condition before treatment has been completed or for personal issues or who fail to return for or complete post-treatment follow-up.

Changes in governmental regulations and guidance relating to clinical studies may occur and we may need to amend study protocols to reflect these changes. Protocol amendments may require us to resubmit protocols to institutional review boards for reexamination or renegotiate terms with contract research organizations and study sites and investigators, all of which may adversely impact the costs or timing of or our ability to successfully complete a trial.

Clinical trials required by the FDA for approval of our products may not produce the results we need to move forward in product development or to submit or obtain approval of an NDA. Success in pre-clinical testing and early phase clinical trials does not assure that late phase clinical trials will be successful. Even if the results of any future Phase 3 clinical trials are positive, we may have to commit substantial time and additional resources to conduct further pre-clinical and clinical studies before we can submit NDAs or obtain FDA approval for our product candidates.

Clinical trials are expensive and at times difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Further, if participating subjects or patients in clinical studies suffer drug-related adverse reactions during the course of such trials, or if we or the FDA believes that participating patients are being exposed to unacceptable health risks, we may suspend the clinical trials. Failure can occur at any stage of the trials, and we could encounter problems that would cause us to abandon clinical trials and/or require additional clinical studies relating to a product candidate.

Even if our clinical trials and laboratory testing are completed as planned, their results may fail to provide support for approval of our products or for label claims that will make our products commercially viable.

Positive results in nonclinical testing and early phase clinical studies do not ensure that late phase clinical studies will be successful or that our product candidates will be approved by the FDA. To obtain FDA approval of our proprietary product candidates, we must demonstrate through nonclinical testing and clinical studies that each product is safe and effective for each proposed indication. Further, clinical study results frequently are susceptible to varying interpretations. Medical professionals, investors and/or regulatory authorities may analyze or weigh study data differently than we do. In addition, determining the value of clinical data typically requires application of assumptions and extrapolations to raw data. Alternative methodologies may lead to differing conclusions, including with respect to the safety or efficacy of our product candidates.

In addition, if we license rights to third parties to develop our product candidates in other geographic areas or for other indications, we may have limited control over nonclinical testing or clinical studies that may be conducted by such third-party licensees in those territories or for those indications. If data from third-party testing identifies a safety or efficacy concern, such data could adversely affect our or another licensee's development of such product.

There is significant risk that our products could fail to show anticipated results in nonclinical testing and/or clinical studies and, as a result, we may elect to discontinue the development of a product for a particular indication or altogether. A failure to obtain requisite regulatory approvals or to obtain approvals of the scope requested may delay or preclude us from marketing our products or limit the commercial use of the products, and would have a material adverse effect on our business, financial condition and results of operations.

The novel use of particle engineering or synthetic APIs for any of our product candidates, may not receive regulatory approval, and without regulatory approval we will not be able to market our product candidates.

We are engaging in particle engineering for certain product candidates and there is no guarantee that we will obtain regulatory approval or, upon commercialization, market acceptance of these products.

The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulations by the FDA in the U.S. and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the U.S. until we receive approval of an NDA from the FDA. NDA approvals may require extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. NDAs must include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. If we submit an NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. Any submissions may not be accepted for filing and review by the FDA. Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require additional expensive and time-consuming post-approval clinical trials or reporting as conditions of approval. Regulators of other countries and jurisdictions have their own procedures for approval of product candidates with which we must comply prior to marketing in those countries or jurisdictions. Obtaining regulatory approval for marketing of a product candidate in one country does not necessarily ensure that we will be able to obtain regulatory approval in any other country.

In addition, delays in approvals or rejections of marketing applications in the U.S. or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidates or other products. Also, regulatory approval for any of our product candidates may be withdrawn.

We also have plans to develop synthetic APIs. Our ongoing trials and studies may not be successful or regulators may

not agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date or approve the use of such synthetic APIs.

If we are unable to obtain approval from the FDA or other regulatory agencies for our product candidates or synthetic APIs, we will not be able to market such product candidates and our ability to achieve profitability may be materially impaired.

A fast track designation by the regulatory agencies, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We do not currently have fast track designation for any of our product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for fast track designation. The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional procedures adopted by the FDA. In addition, the FDA may withdraw fast track designation if they believe that the designation is no longer supported by data from our clinical development program or if a competitor's product candidate is approved. For example, we were granted a fast track designation for our intranasal naloxone product, but this designation was withdrawn after a competitor's intranasal naloxone was approved. Many drugs that have received fast track designation have failed to obtain FDA approval.

The commercial success of our NDA product candidates will depend in significant measure on the scope of the indication(s) and claims that the FDA approves for such products.

The scientific foundation of our NDA product candidates will be based on our various proprietary technologies and the commercial success of these product candidates will depend in significant measure upon our ability to obtain FDA approval of labeling describing such products' indication(s) and expected features or benefits. Failure to achieve FDA approval of product labeling containing adequate information on features or benefits will prevent or substantially limit our advertising and promotion of such features in order to differentiate our proprietary technologies from those products that already exist in the market. This failure would have a material adverse impact on our business.

Our ANDA products are also subject to FDA approval of their labeling and the labeling of the referenced drug products.

Even if we are able to obtain regulatory approval for our generic products, state pharmacy boards or state agencies may conclude that our products are not substitutable at the pharmacy level for the reference listed drug. If our generic products are not substitutable at the pharmacy level for their reference listed drugs, or if our drug products do not gain the acceptance of healthcare providers, payors, and patients, this could materially reduce sales of our products and our business would suffer.

Although the FDA may determine that a generic product is therapeutically equivalent to a brand product and indicate this therapeutic equivalence by providing it with an "A" rating in the FDA's Orange Book, this designation is not binding on state pharmacy boards or state agencies. As a result, in states that do not deem our product candidates substitutable at the pharmacy level, physicians may be required to specifically prescribe our product or a generic product alternative in order for our product to be dispensed. Should this occur with respect to one of our generic product candidates, it could materially reduce sales in those states, which would substantially harm our business. Further, to the extent patients or their physicians are slow to adopt our generic products or do not consider our generic products as therapeutically equivalent, physicians may prescribe the branded products or otherwise instruct pharmacists to not substitute for our generic products, which would substantially harm our business.

Our investments in biosimilar products may not result in products that are approved by the FDA or other foreign regulatory authorities and, even if approved by such authorities, may not result in commercially successful products.

We plan to build on our existing platforms to produce biosimilar products in the future. In 2010, Congress amended the PHSA to create an abbreviated approval pathway for follow-on biologics. This approval pathway is available for "biosimilar" products, which are products that are highly similar to previously approved biologics notwithstanding minor differences in inactive components. The process for bringing a biosimilar product to market is uncertain and may be drawn out for an extended period of time. Approval of biosimilar applications may be delayed by exclusivity on the BLA

for the reference product for up to 12 years. Biosimilar applicants are also subjected to a patent resolution process that will require biosimilar applicants to share the contents of their application and information concerning its manufacturing processes with counsel for the company holding the BLA for the reference drug and to engage in a patent litigation process that could delay or prevent the commercial launch of a product for many years.

Biosimilar products are not presumed to be substitutable for the reference drug under the Biologics Price Competition and Innovation Act, or BPCIA. Biosimilar applicants must seek a separate FDA determination that they are "interchangeable" with the reference drug, meaning that they can be expected to produce the same clinical result in any given patient without an increase in risk due to switching from the brand product. The first interchangeable biosimilar product, an insulin glargine product, was approved in July 2021. The statutory standards for determining biosimilarity and interchangeability are broad and subject to change, and the FDA has broad discretion to determine the nature and extent of product characterization, nonclinical testing and clinical testing on a product-by-product basis.

Products approved based on biosimilarity without an FDA determination of interchangeability may not be substitutable at the retail pharmacy level. Some states have passed laws limiting pharmacy substitution to biosimilar products that the FDA has determined to be interchangeable, as well as restrictions on the substitution of interchangeable biosimilar products. These restrictions include, among other things, requirements for informing the patient and the prescribing physician of the substitution or proposed substitution, authority for the prescribing physician and the patient to preclude substitution and recordkeeping requirements. There is no certainty that other states will not impose similar restrictions or that states will not impose further restrictions or preclude substitution of interchangeable biosimilar products entirely.

Our competitive advantage in this area will depend on our success in demonstrating to the FDA that platform technology provides a level of scientific assurance that facilitates determinations of interchangeability, reduces the need for expensive clinical or other testing and raises the scientific quality requirements for our competitors to demonstrate that their products are highly similar to a brand product. Our ability to succeed will depend in part on our ability to invest in new programs and develop data in a timeframe that enables the FDA to consider our approach as the FDA begins to implement the new law. BLA holders will develop strategies and precedents for delaying or impeding approvals of biosimilar products and determinations of interchangeability. For example, the lengthy 12-year exclusivity protection provides the BLA holder for the reference drug with an opportunity to develop and replace its original product with a modified product that may avoid a determination of interchangeability and that may qualify for an additional 12-year marketing exclusivity period, reducing the potential opportunity for substitution at the retail pharmacy level for interchangeable biosimilars. As brand and biosimilar companies gain greater understanding of and experience with the new regulatory pathway, we expect to see new and unexpected company strategies, FDA decisions and court decisions that will pose unexpected challenges that will prevent, delay or make more difficult biosimilar approvals.

In addition, the BPCIA was passed as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the Affordable Care Act. If the Affordable Care Act is amended or is repealed with respect to the biosimilar approval pathway, our opportunity to develop biosimilars (including interchangeable biologics) could be materially impaired and our business could be materially and adversely affected.

Some of our products are used with drug delivery or companion diagnostic devices which have their own regulatory, manufacturing, reimbursement and other risks.

Some of our products or product candidates may be used in combination with a drug delivery device, such as an injector, inhaler or other delivery system. Although the drug delivery devices we currently use in our products and product candidates are provided by third parties, we have entered into collaboration agreements with various medical device manufacturers to develop drug delivery systems to be used for our pipeline products. These drug-device combination products are particularly complex, expensive and time-consuming to develop due to the number of variables involved in the final product design, including ease of patient and doctor use, establishing clinical efficacy, reliability and cost of manufacturing, regulatory approval requirements and standards and other important factors. We will be responsible for any regulatory filings arising from this collaboration and, although we have significant in-house and external regulatory expertise, we have never prepared or submitted an NDA to the FDA for a drug-device combination product. Our product candidates intended for use with such drug delivery, or expanded indications that we may seek for our products used with such devices, may not be approved or may be substantially delayed in receiving approval if the devices do not gain and/or maintain their own regulatory approvals or clearances. Where approval of the drug product and device is sought under a single application, the increased complexity of the review process may delay approval.

Some of the drug delivery devices utilized in our products and product candidates are provided by single source

unaffiliated third-party companies. We are dependent on the sustained cooperation and effort of those third-party companies both to supply the devices and to maintain regulatory compliance with the FDA quality system regulations applicable to medical device, and, in some cases, to conduct the studies required for approval or other regulatory clearance of the devices. We are also dependent on those third-party companies continuing to maintain such approvals or clearances once they have been received. Failure of third-party companies to supply the devices, to successfully complete studies on the devices in a timely manner, or to obtain or maintain required approvals or clearances of the devices could result in increased development costs, delays in or failure to obtain regulatory approval and delays in product candidates reaching the market or in gaining approval or clearance for expanded labels for new indications. In addition, loss of regulatory approval or clearance of a device that is used with our product may result in the removal of our product from the market.

The drug delivery devices used with our products are also subject to many of the same reimbursement risks and challenges to which our products are subject. A reduction in the availability of, or the coverage and/or reimbursement for, drug delivery devices used with our products could have a material adverse effect on our product sales, business and results of operations.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. Failure to obtain regulatory approval in foreign jurisdictions would prevent our product candidates from being marketed abroad.

In addition to regulations in the United States, to market and sell our products in the EU and in many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements, both from a clinical and manufacturing perspective. Approval by the FDA does not ensure approval by regulatory or payor authorities in other countries or jurisdictions, and approval by one regulatory or payor authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country. We may not be able to obtain approvals from regulatory authorities or payor authorities outside the United States on a timely basis, if at all.

Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we are unable to obtain approval of any of our product candidates by regulatory or payor authorities in the EU, Asia or elsewhere, or if we fail to comply with the regulatory requirements in foreign jurisdictions, the commercial prospects of that product candidate may be significantly diminished, and our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials, which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries.

Further, in Europe, the implementation of the Clinical Trials Regulation depends on confirmation of full functionality of the Clinical Trials Information System through an independent audit. This clinical trial portal and database is maintained by the EMA in collaboration with the European Commission and the EU Member States. Information on the conduct and

results of each clinical trial carried out in the EU is made publicly available. In addition, this database is complementary to the database established for pharmacovigilance (Regulation (EC) No 726/2004 with respect to centrally authorized medicinal products). The Commission Implementing Regulation (EU) No 520/2012 outlines the practical implications for marketing authorization holders, national competent authorities, and the EMA. Also, Commission Delegated Regulation (EU) No 357/2014 on post-authorization efficacy studies specifies the situations in which such studies may be required. Post-authorization efficacy studies may be required where concerns relating to some aspects of efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed, or where the understanding of the disease, the clinical methodology or the use of the medicinal product under real-life conditions indicate that previous efficacy evaluations might have to be revised significantly. Since Brexit, although the rules around GMP and pharmacovigilance in the UK currently remain similar to the EU requirements, UK-specific requirements or changes to current requirements could be implemented in the future, which could expose us to liability under UK-specific laws and regulations and increased costs associated with compliance with such new laws and regulations. Within the UK, requirements for clinical trials, marketing authorization, and post-approval compliance in Great Britain may differ from those of Northern Ireland, Scotland, and/or Wales. Satisfying these and other regulatory requirements can be costly, time consuming, uncertain and subject to unanticipated delays.

In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any foreign jurisdiction, and we do not have experience in obtaining regulatory approval in such jurisdictions. If we fail to comply with regulatory requirements in international markets or fail to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

Uncertainty in the regulatory framework and future legislation can lead to disruption in the execution of international multi-center clinical trials, the monitoring of adverse events through pharmacovigilance programs, the evaluation of the benefit-risk profiles of new medicinal products, and determination of marketing authorization across different jurisdictions. There could also be disruption to the supply and distribution as well as the import/export both of active pharmaceutical ingredients and finished product. Such a disruption could create supply difficulties for ongoing clinical trials and may damage the integrity of the pharmacovigilance database for the safety of new products. The cumulative effects of the disruption to the regulatory framework, uncertainty in future regulation, and changes to existing regulations may add considerably to the development lead time to marketing authorization and commercialization of products in the EU and/or the United Kingdom and increase our costs. We cannot predict the impact of such changes and future regulation on our business or the results of our operations.

If branded pharmaceutical companies are successful in limiting the use of generics through their legislative, regulatory and/or other efforts, our sales of generic products may suffer.

Many pharmaceutical companies producing proprietary drugs have increasingly used state and federal legislative and regulatory means to delay, impede and/or prevent generic competition. These efforts have included but are not limited to the following:

- making changes to the formulation of their product and arguing that potential generic competitors must demonstrate bioequivalence and/or comparable abuse-resistance to the reformulated brand product;
- pursuing new patents for existing products which may be granted immediately prior to the expiration of earlier patents, which could extend patent protection for additional years or otherwise delay the launch of generics;
- selling the brand product as an authorized generic, either by the brand company directly, through an affiliate, or by a marketing partner;
- using the FDA's Citizen Petition process to request amendments to FDA standards or otherwise delay generic drug approvals;
- challenging FDA denials of Citizen Petitions in court and seeking injunctive relief to reverse approval of generic drug applications;
- seeking changes to standards in the U.S. Pharmacopeia/National Formulary, which are compendial drug standards that are recognized by industry and, in some instances, are enforceable under the FFDCA;

- attempting to use the legislative and regulatory process to have drugs reclassified or rescheduled by the DEA;
- using the legislative and regulatory process to set standards and requirements for abuse deterrent formulations that are patented or that will otherwise impede or prevent generic competition;
- seeking special patent-term extensions through amendments to non-related federal legislation;
- engaging in initiatives to enact state legislation that would restrict the substitution of certain generic drugs, including products that we are developing;
- entering into agreements with pharmacy benefit management companies that block the dispensing of generic products;
- seeking patents on methods of manufacturing certain API;
- settling patent lawsuits with generic companies in a manner that leaves the patent as an obstacle for approval of other companies' generic drugs;
- settling patent litigation with generic companies in a manner that avoids forfeiture of or otherwise protects or extends the exclusivity period;
- providing medical education or other information to physicians, third-party payers and federal and state regulators that take the position that certain generic products are inappropriate for approval or for substitution after approval;
- seeking state law restrictions on the substitution of generic and biosimilar products at the pharmacy level without the instruction or permission of a physician; and
- seeking federal or state regulatory restrictions on the use of the same non-proprietary name as the reference brand product for a biosimilar or interchangeable biologic.

If pharmaceutical companies or other third parties are successful in limiting the use of generic products through these or other means, our sales of generic products may decline. If we experience a material decline in generic product sales, our results of operations, financial condition and cash flows will suffer.

Our revenues may be adversely affected if we fail to obtain insurance coverage or adequate reimbursement for our products from third-party payers and administrators.

Our ability to successfully commercialize our products may depend in part on the availability of reimbursement for and insurance coverage of our prescription products from government health administration authorities, private health insurers and other third-party payers and administrators, including Medicaid and Medicare. Third-party payers and administrators, including state Medicaid programs and Medicare, have been challenging the prices charged for pharmaceutical products. Government and other third-party payers increasingly are limiting both coverage and the level of reimbursement for new drugs. Third-party insurance coverage may not be available to patients for some of our product candidates. The continuing efforts of government and third-party payers to contain or reduce the costs of health care may limit our commercial opportunity. If government and other third-party payers do not provide adequate coverage and reimbursement for certain of our products, health care providers may not prescribe them or patients may ask their health care providers to prescribe competing products with more favorable reimbursement.

Managed care organizations and other private insurers frequently adopt their own payment or reimbursement reductions. Consolidation among managed care organizations has increased the negotiating power of these entities. Private third-party payers, as well as governments, increasingly employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. While these approaches generally favor generic products over brands, generic competition is stronger. Our existing products and our product candidates include proprietary products and generic products. Failure to obtain timely or adequate pricing or formulary placement for our products or obtaining such pricing or placement at unfavorable pricing could adversely impact revenue. In addition to formulary tier co-pay differentials, private health insurance companies and self-insured employers have been raising co-payments required from

beneficiaries, particularly for proprietary pharmaceuticals and biotechnology products. Private health insurance companies also are increasingly imposing utilization management tools, such as requiring prior authorization for a proprietary product if a generic product is available or requiring the patient to first fail on one or more generic products before permitting access to a proprietary medicine. We currently have managed care organization agreements for BAQSIMI®.

We must manufacture our drug products at our facilities in conformity with cGMP regulations; failure to maintain compliance with cGMP regulations may prevent or delay the manufacture or marketing of our products or product candidates and may prevent us from gaining approval of our products.

All of our products and product candidates for use in clinical studies must be manufactured, packaged, labeled and stored in accordance with cGMP. For our approved products, modifications, enhancements, or changes in manufacturing processes and sites may require supplemental FDA approval, which may be subject to a lengthy application process or which we may be unable to obtain.

All facilities of Amphastar, our subsidiaries and our CMOs and suppliers are periodically subject to inspection by the FDA and other governmental entities, and operations at these facilities could be interrupted or halted if the FDA or another governmental entity deems such inspections as unsatisfactory. For example, our facilities in Rancho Cucamonga, CA, Éragny Sur Epte, France, and Nanjing, China have previously been subject to FDA cGMP inspections since 2019 as well as pre-approval, routine and other inspections by the FDA, state, and other regulatory authorities and may be again in the future per applicable law. Compliance with cGMP standards requires substantial expenditures of time, money and effort in such areas as production and quality control to ensure full technical compliance. Failure to comply with cGMP or with other state, federal, or foreign requirements may result in unanticipated compliance expenditures, total or partial suspension of production or distribution, suspension of review of applications submitted for approval of our product candidates, termination of ongoing research, disqualification of data derived from studies on our products and/or enforcement actions such as recall or seizure of products, injunctions, civil penalties and criminal prosecutions of the company and company officials. There can be no assurance that we will be able to remedy any deficiencies cited by FDA or other regulatory agencies in their inspections.

Our operations are subject to environmental, health and safety and other laws and regulations, with which compliance is costly and which exposes us to penalties for non-compliance.

Our business, products and product candidates are subject to federal, state and local laws and regulations relating to the protection of the environment, natural resources and worker health and safety and the use, management, storage and disposal of hazardous substances, waste and other regulated materials. Because we own and operate real property, various environmental laws also may impose liability on us for the costs of cleaning up and responding to hazardous substances that may have been released on our property, including releases unknown to us. These environmental laws and regulations also could require us to pay for environmental remediation and response costs at third-party locations where we dispose of or recycle hazardous substances. The costs of complying with these various environmental requirements, as they now exist or as may be altered in the future, have in the past and could in the future adversely affect our financial condition and results of operations. For example, as a result of environmental concerns about the use of CFCs, the FDA issued a final rule in 2009 that required the phase-out of the CFC version of our Primatene MIST® product by the end of 2011. This phase out caused us to discontinue sales of the CFC version of our Primatene MIST® product subsequent to December 31, 2011 and write off our inventory for the product, which had an adverse effect on our financial results.

Similarly, on December 27, 2020, the American Innovation in Manufacturing Act of 2020, or AIM Act, was enacted. The AIM Act directs the United States Environmental Protection Agency to address usage of hydrofluorocarbons, or HFC, by reducing production and consumption of certain HFCs. Two of our products, Primatene MIST® and Albuterol, utilize HFCs subject to the AIM Act's reduction mandate. Moreover, many of our inhalation pipeline assets use HFCs subject to the AIM Act's reduction mandate. There can be no assurance that we will be able to acquire adequate supplies of HFCs for current and future commercialization of our products as a result of the AIM Act or other similar statutes and regulations. Moreover, changes to the ingredients of our proprietary and generic products require FDA approval and there can be no assurance that we will be able to obtain such approval or the timing of such approval.

The Affordable Care Act and certain legislation and regulatory proposals may increase our costs of compliance and negatively impact our profitability over time.

In March 2010, former President Barack Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, which we refer to collectively as the Affordable Care Act. The Affordable Care Act made extensive changes to the delivery of health care in the United States. We expect that the rebates, discounts, taxes and other costs resulting from the Affordable Care Act over time will have a negative effect on our expenses and profitability in the future. Furthermore, the Independent Payment Advisory Board created by the Affordable Care Act to reduce the per capita rate of growth in Medicare spending could potentially limit access to certain treatments or mandate price controls for our products. Moreover, expanded government investigative authority and increased disclosure obligations may increase the cost of compliance with new regulations and programs.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, or ACA. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. It is unclear how this Supreme Court decision, future litigation, or healthcare measures promulgated by the current administration will impact our business, financial condition and results of operations. Complying with any new legislation or changes in healthcare regulation could be time-intensive and expensive, resulting in a material adverse effect on our business.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. For example, in November 2013, Congress passed the Drug Quality and Security Act, or the DQSA. The DQSA establishes federal pedigree tracking standards requiring drugs to be labeled and tracked at the lot level, preempts state drug pedigree requirements, and, since November 27, 2024, requires all supply-chain stakeholders to participate in an electronic, interoperable prescription drug track and trace system. The DQSA also establishes new requirements for drug wholesale distributors and third-party logistics providers, including licensing requirements in states that had not previously licensed such entities. Recently, the FDA promulgated enhanced drug distribution security requirements under the Drug Supply Chain Security Act, including requiring trading partners to provide, receive and maintain documentation about products and ownership only electronically using interoperable systems and processes. If we or our partners fail to comply with these and other regulatory requirements that apply to our operations, our business may be materially impacted. As a result of these and other new requirements implemented by the government, 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.

Former President Barack Obama also signed into law the Food and Drug Administration Safety and Innovation Act. The law and related agreements make several significant changes to the FFDCA and FDA's processes for reviewing marketing applications that could have a significant impact on the pharmaceutical industry, including, among other things, the following:

- reauthorizes the Prescription Drug User Fee Act, which increases the amount of associated user fees, and, for certain types of applications, increases the expected time frame for FDA review of NDAs;
- permanently reauthorizes and makes some revisions to the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, which provide for pediatric exclusivity and mandated pediatric assessments for certain types of applications, respectively;
- revises certain standards and requirements for FDA inspections of manufacturing facilities and the importation of drug products from foreign countries;
- creates incentives for the development of certain antibiotic drug products;
- modifies the standards for accelerated approval of certain new medical treatments;
- expands the reporting requirements for potential and actual drug shortages;
- requires the FDA to issue a report on, among other things, ensuring the safety of prescription drugs that have the potential for abuse;

- requires the FDA to hold a public meeting regarding the potential rescheduling of drug products containing hydrocodone, which was held in October 2012; and
- requires electronic submission of certain marketing applications following the issuance of final FDA regulations.

The full impact of new laws and regulations and changes to any existing regulations by the current administration is uncertain. Some changes may have an adverse effect on our results of operations.

There has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In August 2022, Congress passed the Inflation Reduction Act of 2022 (the "IRA"), which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, manufacturers are required to pay higher rebates on brand-name drugs once a patient reaches their out-of-pocket spending limit, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, CMS selected 10 high-cost Medicare Part D drugs in 2023 and the negotiated maximum fair price for each drug has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, up to an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, up to 20 additional Part B or Part D drugs will be selected. Various industry stakeholders have initiated lawsuits against the federal government asserting that the price negotiation provision of the Inflation Reduction Act are unconstitutional. Further, the current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of Health and Human Services to establish a mechanism through which American patients can buy drugs directly from manufacturers who sell at a most-favored-nation ("MFN") price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the United States. The One Big Beautiful Bill Act (the "OBBB Act"), which was signed into law in July 2025, includes provisions that will impact the U.S. healthcare system in various ways, including by cuts to Medicaid and introducing new participant work and eligibility requirements for Medicaid coverage, which are expected to significantly change the administration and applicability of Medicaid coverage. In November 2025, CMS announced a voluntary initiative called the GENEROUS Model (GENErating cost Reductions fOr U.S. Medicaid Model) to introduce the option of most-favored-nation pricing to the Medicaid program, whereby a drug manufacturer may voluntarily offer supplemental rebates to participating state Medicaid programs for a manufacturer's covered outpatient drugs. We cannot predict the full impact of these initiatives, executive orders, and new laws focused on reducing prescription drug prices or increasing domestic drug manufacturing capacity, or other measures that may be implemented by the current administration related to drug pricing, drug supply chain and manufacturing in the United States. The impact of these judicial challenges, legislative, executive, and administrative actions, including future healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our approved products.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, in September 2020, the Governor of California signed legislation that brings California one step closer to establishing its own generic drug label, which could have significant impact on the generic drug industry and generic drug pricing. A number of states are also

considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws.

Additionally, we encounter similar regulatory and legislative issues in most other countries. In the EU, and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. This international system of price regulations may lead to inconsistent prices.

If significant additional reforms are made to the U.S. health care system, or to the health care systems of other markets in which we operate, those reforms could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Complying with laws in the U.S., Europe, and other jurisdictions that impose restrictive regulations addressing the collection, use, and other processing of personal information may be expensive, and failure to comply with such laws and regulations could cause substantial harm to our business.

We also must comply with data protection, security and privacy requirements. Compliance with laws, rules and regulations regarding privacy, security and protection of personal information, including about our personnel, business partners, and others, could result in higher compliance and technology costs for us. Significant fines, penalties, damages and harm to our global reputation and our brand could result from actual or perceived non-compliance.

We collect, process, use, store, transmit and transfer personal information from individuals located in the EU and the United Kingdom in connection with our business. The collection, storage, transmission, transfer, use, and other processing of personal information in the EU are governed by the provisions of the General Data Protection Regulation ((EU) 2016/679), or the GDPR. In the UK, the applicable legislation is the UK General Data Protection Regulation, or the UK GDPR. This legislation imposes requirements relating to having legal bases for processing personal information relating to identifiable individuals, transferring such information outside of the UK or the European Economic Area, to third countries that have not been found to provide adequate protection to such personal information, including to the U.S., providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal information to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments and record-keeping. Failure to comply with the requirements of the GDPR, the UK GDPR and related national data protection laws of the UK and the member states of the EU may result in investigations, substantial fines up to the greater of €20 million or 4% of annual global turnover, civil claims, and damages being brought against us, which could have a material adverse effect on our business, financial condition and results of operations.

While the GDPR applies uniformly across the EU, each EU member state is permitted to issue nation-specific data protection legislation, which has created inconsistencies on a country-by country basis. The United Kingdom made certain modifications to its data protection regime in the UK Data (Use and Access) Act 2025, which could require us to modify our compliance measures and incur costs.

The European Commission issued an adequacy decision to the United Kingdom under the GDPR on June 28, 2021, pursuant to which personal information generally may be transferred from the EU to the United Kingdom without restriction; however, this adequacy decision requires renewal in 2025. The European Commission may intervene at any time with respect to its adequacy decision. The United Kingdom's adequacy determination therefore is subject to future uncertainty and may be subject to modification or revocation, with the United Kingdom potentially being considered an inadequate third country under the GDPR, meaning that transfers of personal information from the European Economic Area to the United Kingdom would require an alternative transfer mechanism. Furthermore, there will be increasing scope for divergence in application, interpretation and enforcement of the data protection law as between the United Kingdom and European Economic Area.

In addition, U.S. states are adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements related to personal information. For example, California enacted the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020. The CCPA gives California residents, among other things, expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA also

provides for civil penalties for violations, as well as a private right of action for certain data breaches that may increase data breach litigation. The CCPA was expanded substantially on January 1, 2023 when the California Privacy Rights Act of 2020, or the CPRA, which was approved by California voters in November 2020, became fully operative. The CPRA among other things, gives consumers the ability to limit use of information deemed to be sensitive and establishes the California Privacy Protection Agency to implement and enforce the CPRA and impose administrative fines. Aspects of the CCPA and CPRA, and their interpretation and enforcement remain uncertain. The potential effects of the CCPA and CPRA are far-reaching and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

The CCPA and CPRA could mark the beginning of a trend toward more stringent data protection, security and privacy legislation in the U.S. The CCPA has prompted a number of proposals for federal and state privacy legislation. For example, Virginia, Colorado, Utah and Connecticut have each passed laws similar to but different from the CCPA and CPRA that took effect in 2023; Florida, Montana, Oregon and Texas have enacted similar laws that went into effect in 2024; Tennessee, Delaware, Iowa, Maryland, Minnesota, Nebraska, New Hampshire, and New Jersey have enacted similar laws that went into effect in 2025; and Indiana, Kentucky, and Rhode Island have enacted similar laws that go into effect in 2026. Similar laws have been proposed in other states and at the federal level, reflecting a trend toward more stringent data protection, security and privacy legislation in the U.S. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. Further, several states have enacted laws that provide additional protection to consumer health data, including Washington, which enacted the My Health, My Data Act, which, among other things, provides for a private right of action, and Nevada and Connecticut, which have enacted similar laws. Additionally, the U.S. Department of Justice recently issued a final rule that took effect in April 2025, which places limitations, and in some cases prohibitions, on certain transfers of sensitive personal data to business partners located in certain "countries of concern" or with other specified links to such countries. Responsibilities and liabilities under, and other potential impacts of, the GDPR, the UK GDPR, the CCPA, and other U.S. laws are significant, and we may be required to put in place additional measures designed to comply with these regimes.

We may also publicly post privacy policies and other documentation regarding our collection, use, storage, transmission, transfer, and other processing of personal information. Although we endeavor to comply with our public policies and documentation, we may at times fail to do so or be alleged to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or contractors fail to comply with our published policies and documentation. Such failures can subject us to potential regulatory action if they are found to be deceptive, unfair, or misrepresentative of our actual practices.

Additionally, other jurisdictions are considering new or expanded laws or regulations relating to privacy, security and data protection. We expect laws, regulations, industry standards and other obligations worldwide relating to privacy, data protection, and cybersecurity to continue to evolve, and that there will continue to be new, modified, and re-interpreted laws, regulations, standards, and other obligations in these areas. For example, the Network and Information Security Directive II, or NIS2, adopted in 2023, aims to enhance cybersecurity across critical infrastructure and essential services in the EU. It expands the scope of the 2016 NIS Directive to include additional sectors while enforcing stricter governance and accountability requirements. NIS2 requires all 27 EU member states to issue implementing legislation by October 2024; however, several EU member states have not finalized their respective legislation and guidance.

With laws, regulations and other obligations relating to privacy, security and data protection imposing new and relatively burdensome obligations, which may be inconsistent between jurisdictions or in conflict with each other due to differing applications and interpretations, and with substantial uncertainty over further interpretation and application of these and other obligations, we may face challenges in addressing their requirements, putting in place additional compliance mechanisms and making necessary changes to our policies, contracts and practices, and may incur significant costs and expenses in an effort to do so. Additionally, if we or third parties we work with, such as our third-party providers, violate applicable laws or regulations or our policies, such violations may also put our data at risk and could in turn have an adverse effect on our business. Any failure or perceived failure by us or our service providers to comply with our applicable policies or notices relating to privacy, security or data protection, our contractual or other obligations to third parties, or any of our other legal obligations relating to privacy, security or data protection, may result in public criticism, governmental investigations or enforcement actions, litigation, claims and other proceedings, and could result in significant fines, penalties, and other liability. Additionally, defending against any claims, litigation, regulatory proceedings, or other proceedings can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions or proceedings that may be brought against us, our business may be impaired, and we may suffer reputational and other harm.

Our products may be subject to federal and state laws and certain initiatives relating to cost control, which may decrease our profitability.

In the U.S., we expect there may be federal and state proposals for cost controls. We expect that increasing emphasis on managed care in the U.S. will continue to put pressure on the pricing of pharmaceutical products. In addition, we are required to pay rebates to states, which are generally calculated based on the prices for our products that are paid by state Medicaid programs. Cost control initiatives could decrease the price that we charge, and increase the rebate amounts that we must provide, for any of our products in the future. Further, cost control initiatives could impair our ability to commercialize our products and our ability to earn significant revenues from commercialization. The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our products, if we obtain regulatory approval;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

In the U.S., all of our pharmaceutical products are subject to increasing pricing pressures. Such pressures have increased as a result of the Medicare Prescription Drug Improvement and Modernization Act of 2003, or the MMA, due to the enhanced purchasing power of the private sector plans that negotiate on behalf of Medicare beneficiaries. For example, in November 2021, the Biden administration also announced a prescription drug plan in Build Back Better framework, which proposes allowing Medicare to negotiate prescription drug prices, imposing a tax penalty if drug companies increase their prices faster than inflation, and directly lowering out-of-pocket costs for seniors. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, manufacturers are required to pay higher rebates on brand-name drugs once a patient reaches their out-of-pocket spending limits, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. With the transition to the current administration, including changes in the leadership of various federal government agencies, the impact of these legislative, executive, and administrative actions and future healthcare measures and agency rules implemented by the current administration on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our approved products.

Our reporting and payment obligations under the Medicare and/or Medicaid drug rebate programs and other governmental purchasing and rebate programs are complex and may involve subjective decisions that could change as a result of new business circumstances, new regulatory guidance or advice of legal counsel. Any determination of failure to comply with those obligations could subject us to penalties and sanctions which could have a material adverse effect on our business, financial position and results of operations and the market value of our common stock could decline.

The regulations regarding reporting and payment obligations with respect to Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material changes.

In January 2016, the Centers for Medicare and Medicaid Services, or CMS, issued a final rule that helped to clarify many of the changes made to the Medicaid Drug Rebate Program by the Affordable Care Act. The final rule attempts to provide drug manufacturers with the regulatory guidance necessary to ensure proper calculation and reporting of drug product and pricing information. Specifically, the final rule attempts to clarify the definition of what constitutes a manufacturer's "best price" and aligns it, where appropriate, to the definition of "Average Manufacturer Price", which is

used to calculate drug rebates. Notwithstanding the final rule's guidance, a number of state and federal government agencies have continued to conduct investigations of manufacturers' reporting practices with respect to Average Wholesale Prices, or AWP, in which reports of inflated AWP may lead to excessive payments for prescription drugs. These investigations could have a material adverse effect on our business, financial position and results of operations. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries. The impact of these legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the current administration on us and the pharmaceutical industry as a whole is unclear.

Any governmental agencies that have commenced, or may commence, an investigation of our business relating to the sales, marketing, pricing, quality or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs including Medicare and/or Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments — and even in the absence of any such ambiguity — a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions. Any such penalties or sanctions could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

We may be subject to enforcement action if we engage in the off-label promotion of our products.

Our promotional materials and training methods must comply with the FFDCA and other applicable laws and regulations, including restraints and prohibitions on the promotion of off-label, or unapproved, use. Physicians may prescribe our products for off-label use without regard to these prohibitions, as the FFDCA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including but not limited to the issuance of an untitled letter or warning letter, and a judicial action seeking injunction, product seizure and civil or criminal penalties. It is also possible that other federal, state or non-U.S. enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us and harm our reputation.

The pharmaceutical industry is highly regulated and pharmaceutical companies are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act.

Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

- the federal Anti-kickback statue, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new

federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of individually identifiable health information;

- the FFDCA and similar laws regulating advertisement and labeling;

- the federal Physician Payment Sunshine Act, created under the ACA, and its implementing regulations, require applicable manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services under the Open Payments Program, information related to certain payments and other transfers of value made in the previous year to physicians (defined to include doctors of medicine and osteopathy, dentists, podiatrists, optometrists and licensed chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members;

- the U.S. Foreign Corrupt Practices Act, which prohibits corrupt payments, gifts or transfers of value to non-U.S. officials;

- non-U.S. and U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers;

- state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources;

- state and local laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration, and items of value provided to healthcare professionals and entities;

- state and local laws that require the registration of pharmaceutical sales representatives; and

- state and foreign laws also govern the privacy, protection and security of personal information (including health information) in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The federal false claims laws have been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers or formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Most states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the type of payer. Administrative, civil and criminal sanctions may be imposed under these federal and state laws. In addition, we are also subject to federal and state consumer protection and unfair competition laws that broadly regulate marketplace activities and activities that potentially harm consumers.

Further, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity can now be found guilty under the Affordable Care Act without actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, imprisonment, exclusion from federal health care programs and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

To enforce compliance with the federal laws, the U.S. Department of Justice, or DOJ, has increased its scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, if a healthcare provider settles an investigation with the DOJ or other law enforcement agencies, we may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates.

In addition, there has been a trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of commercial compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may run afoul of one or more of the requirements.

If the activities of any of our business partners are found to be in violation of these laws or any other federal and state fraud and abuse laws, they may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of its activities with regard to the commercialization of our products, which could harm the commercial success of our products and materially affect our business, financial condition and results of operations. While we have implemented numerous risk mitigation measures to comply with such regulations in this complex operating environment, we cannot guarantee that we will be able to effectively mitigate all operational risks. While we have developed and instituted a corporate compliance program, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws, all potentially applicable foreign regulations and/or laws and/or all requirements of the corporate integrity agreement. Because of the far-reaching nature of these laws, we may be required to alter or discontinue one or more of our business practices to be in compliance with these laws. If we fail to adequately mitigate our operational risks or if we or our agents fail to comply with any of those regulations, laws and/or requirements, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Such occurrences could have a material and adverse effect on our product sales, business and results of operations.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal or state regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. In addition, efforts to ensure that our business arrangements with third parties will comply with these laws and regulations and will involve substantial costs. Any state or federal regulatory review of us or the third parties with whom we contract, regardless of the outcome, would be costly and time-consuming.

Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct, or other illegal activity by our employees, independent contractors, consultants, commercial partners, and vendors. Misconduct by these parties could include intentional, reckless, and negligent conduct that fails to:

- comply with the laws of the FDA, EMA, and other comparable foreign regulatory authorities;
- provide true, complete, and accurate information to the FDA, EMA, and other comparable foreign regulatory authorities;
- comply with manufacturing standards we have established;
- comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or
- report financial information or data accurately or to disclose unauthorized activities to us.

Our business operations, including research, sales, marketing, education, and other business arrangements, in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs, and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. While we have a code of conduct and ethics, it is not always possible to identify and deter misconduct by employees and third parties, 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. 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, including the imposition of significant fines or other sanctions.

Risks Relating to our International Business

Because a portion of our manufacturing takes place in China, a significant disruption in the construction or operation of our manufacturing facility in China, political unrest in China, tariffs, impacts of outbreaks of health epidemics, or changes in social, political, trade, health, economic, environmental, or climate-related conditions or in laws, regulations and policies governing foreign trade could materially and adversely affect our business, financial condition and results of operations.

We currently manufacture the starting material for Amphadase® and enoxaparin as well as the APIs for isoproterenol, nitroprusside, and medroxyprogesterone at our manufacturing facility in China, and we plan to use this facility to manufacture several of the APIs for products in our pipeline. Additionally, we intend to continue to invest in the expansion of this manufacturing facility. Our manufacturing facility and operations in China involve significant risks, including:

- disruptions in the construction of the manufacturing facility;
- interruptions to our operations in China or the inability of our manufacturing facility to produce adequate quantities of raw materials or APIs to meet our needs as a result of natural catastrophic events or other causes beyond our control such as power disruptions or widespread disease outbreaks, including the recent outbreaks that impact animal-derived products, such as the importation of pig-derived crude heparin from countries impacted by the African swine flu, and the COVID-19 pandemic, which resulted in import and export complications, and otherwise cause shortages in the supply of raw materials or cause disruptions in our manufacturing capability;
- product supply disruptions and increased costs as a result of heightened exposure to changes in the policies of the Chinese government, political unrest or unstable economic conditions in China;

- the imposition of additional tariffs, export controls or other trade barriers as a result of changes in social, political, and economic conditions or in laws, regulations, and policies governing foreign trade, including U.S. export controls impacting the ability to send certain products and technology, specifically related to semi-conductor manufacturing and supercomputing (including a prohibition on exports, reexports, and transfers to and within China without an export license, and the addition of new China-based entities to certain U.S. restricted party lists including the Entity List and Unverified List, trade sanctions and import laws and regulations, tariffs on various imports into the U.S. from China including those previously implemented and additional tariffs that may in the future be implemented by the U.S. government (including on imports of pharmaceutical products into the United States currently under investigation by the U.S. Department of Commerce, among other potential tariffs), the implementation, scope, and duration of which remain uncertain;

- the imposition of retaliatory trade measures by China or other countries in response to new or escalated tariffs, export controls, or other trade measures by the United States (including those previously implemented by China and other countries, such as tariffs on U.S.-origin items and export controls on certain rare earth materials), which may affect the availability and/or price of materials used in our supply chain, and the implementation, scope, and duration of which remain uncertain;

- the nationalization or other expropriation of private enterprises or intellectual property by the Chinese government, which could result in the total loss of our investment in China; and

- interruptions to our manufacturing or business operations resulting from geo-political actions, global conflicts, natural disasters including earthquakes, typhoons, floods, and fires, or outbreaks of health epidemics or outbreaks in livestock or animals that impact or restrict importation, use, or distribution of animal-derived products.

Any of these matters could materially and adversely affect our business and results of operations. These interruptions or failures could impair our ability to operate our business, impede the commercialization of our product candidates or delay the introduction of new products, impact our product quality, or impair our competitive position. Any material adverse effect on our employees, suppliers, and logistics providers could have a material adverse effect on our manufacturing operations in China or the supply of raw materials or APIs originating from China.

We are exposed to risks related to our international operations and failure to manage these risks may adversely affect our operating results and financial condition.

We have operations both inside and outside the U.S. For example, we have suppliers in Asia and Europe, and we own manufacturing facilities in Nanjing, China, and Éragny-sur-Epte, France. As a result, a significant portion of our operations is conducted by and/or rely on entities outside the markets in which our products are sold, and, accordingly, we import a substantial number of products into such markets. We may, therefore, be denied access to our customers or suppliers or denied the ability to ship products from any of our sites as a result of a closing of the borders of the countries in which we sell our products, or in which our operations are located, due to economic, legislative, political and military conditions in such countries.

International operations are subject to a number of other inherent risks, and our future results could be adversely affected by a number of factors, including:

- requirements or preferences for domestic products or solutions, which could reduce demand for our products;

- differing existing or future regulatory and certification requirements;

- management communication and integration problems resulting from cultural and geographic dispersion;

- greater difficulty in collecting accounts receivable and longer collection periods;

- difficulties in enforcing contracts;

- difficulties and costs of staffing and managing non-U.S. operations;

- difficulty hiring and retaining appropriate personnel due to intense competition for such resources and resulting wage inflation in the cities where our operations are located;
- different labor regulations, especially in the European Union, where labor laws are generally more advantageous to employees as compared to the United States, including deemed hourly wage and overtime regulations in these locations;
- the uncertainty of protection for intellectual property rights in some countries and resulting exposure to misappropriation of intellectual property or information that is proprietary to us, our customers and other third parties;
- tariffs and trade barriers, export regulations and other regulatory and contractual limitations on our ability to sell our products;
- changes in social, political, and economic conditions or in laws, regulations and policies governing foreign trade, manufacturing, development and investment both domestically as well as in other countries and jurisdictions into which we manufacture or sell our products;
- exposure to liabilities under both U.S. and foreign laws, including export and antitrust regulations, anti-corruption and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, and similar applicable laws and regulations in other jurisdictions, and any trade regulations ensuring fair trade practices;
- uneven electricity supply that can negatively impact manufacturing;
- heightened risk of unfair or corrupt business practices in certain geographies and of improper or fraudulent sales arrangements that may impact financial results and result in restatements of, or irregularities in, financial statements;
- fluctuations in currency exchange rates and regulatory compliance;
- delays, inefficiencies, and other challenges inherent to efficiently managing an increased number of employees over large geographic distances, including the need to implement appropriate systems, policies, benefits, and compliance programs;
- potentially adverse tax consequences, including multiple and possibly overlapping tax structures; and
- interruptions to our manufacturing or business operations resulting from trade restrictions, political and economic instability, political unrest, war, terrorism, natural disasters including earthquakes, typhoons, floods, and fires, or outbreaks of health epidemics such as the coronavirus and African swine flu outbreaks.

Furthermore, weak domestic or global economic conditions or fear or anticipation of such conditions could adversely affect our business, financial condition, results of operations and prospects in a number of ways, including lower prices for our products, reduced sales and lower or no growth. For example, the global macroeconomic environment could be negatively affected by, among other things, instability in global economic markets resulting from increased U.S. trade tariffs and trade disputes between the U.S. and other countries, instability in the global credit markets, the impact and uncertainty regarding global central bank monetary policy, high interest rates and inflation rates, instability in the geopolitical environment, economic challenges in China and ongoing U.S. and foreign governmental debt concerns. Such challenges have caused, and are likely to continue to cause, uncertainty and instability in local economies and in global financial markets, particularly if any future sovereign debt defaults or significant bank failures or defaults occur. Market uncertainty and instability in Europe or Asia could intensify or spread further, particularly if ongoing stabilization efforts prove insufficient. Continuing or worsening economic instability could adversely affect sales of our products. Continued turmoil in the geopolitical environment in many parts of the world may also affect the overall demand for our products. Although we do not believe that our business, financial condition, results of operations and prospects have been significantly adversely affected by economic and political uncertainty in Europe, Asia or other countries to date, deterioration of such conditions may harm our business, financial condition, results of operations and prospects in the future. A prolonged period of economic uncertainty or a downturn may also significantly affect financing markets, the availability of capital and the terms and conditions of financing arrangements, including the

overall cost of financing. Circumstances may arise in which we need, or desire, to raise additional capital, and such capital may not be available on commercially reasonable terms, or at all.

In addition, any further expansion of our existing international operations or entry into additional international markets, would require significant management attention and financial resources. These and other factors could harm our ability to gain future revenues and, consequently, materially impact our business, results of operations and financial condition.

Adverse changes to import restrictions relating to certain animal-derived products or raw materials we use from affected countries could disrupt our supply chain and result in delays in the manufacturing of our products.

Some of our raw materials, such as certain animal-derived materials, sourced from foreign sources are subject to import regulations and permit requirements, including from the USDA. The APHIS within the USDA has regulatory oversight over certain animals and animal-derived products that could pose a risk to domestic agriculture. In 2020, USDA increased its African swine flu surveillance efforts, including additional testing and enhanced restrictions on importation of certain porcine products from affected countries, like China. If we are unable to import raw materials, rely upon existing supplies of raw materials or manufacture raw materials in sufficient amounts for our manufacturing needs, we may be required to find alternative suppliers or sources of such materials, which could disrupt or delay the manufacturing of our products. The success of our business operations and sales with respect to our heparin products will also depend on our continued efforts to maintain the proper product quality and safety profile of the crude heparin obtained either from China or an alternative source.

Enhanced trade tariffs, import restrictions, export restrictions, Chinese regulations or other trade barriers may materially harm our business.

We are continuing to expand our international operations as part of our growth strategy. There is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, government regulations and tariffs. There is a possibility that the United States could continue to impose greater restrictions on international trade and significant increases in tariffs on goods imported into the United States. For example, since September 2018, the U.S. Trade Representative (the "USTR") enacted Section 301 tariffs on certain commodities from certain U.S. trading partners, most prominently China and Brazil, affecting hundreds of billions of dollars of imports. In addition, between February 4, 2025 and February 23, 2026, the U.S. government imposed "fentanyl-related" tariffs of 10% to 35% on the import of almost all Chinese-, Mexican-, and Canadian-origin items with an exception for items qualifying for duty-free treatment under the U.S.-Mexico-Canada Agreement, as well as additional "reciprocal" tariffs of 10% to 125% on certain products of most other U.S. trading partners, including China, after April 2025, with exemptions for certain pharmaceutical products, semiconductors, and consumer electronics. Since March 2025, the U.S. government has also implemented new Section 232 tariffs of 10% to 50% on various commodities based on findings by the U.S. government that imports of these items threaten to impair U.S. national security, including with regard to imports of certain articles of steel and aluminum; passenger vehicles, trucks, and automotive components; certain articles of copper; and timber, lumber, and certain article of wood. Following a Supreme Court ruling on February 20, 2026, the U.S. government ceased collecting the fentanyl-related and reciprocal tariffs on February 24, 2026. On the same day, the U.S. government implemented a "temporary import surcharge" under authorities provided in Section 122 of the Trade Acts of 1974, currently set at 15% and scheduled to last for a period of 150 days. This temporary import surcharge, like the reciprocal tariffs preceding it, excludes certain items, including pharmaceutical products, certain electronics, and other items specified in Annexes to the President's February 20, 2026 executive order "Imposing a Temporary Import Surcharge to Address Fundamental International Payments Problems." These trade policies, including applicable items, tariff rates, countries, and exceptions, are subject to change. Additional tariffs may in the future also be implemented by the U.S. government (including on imports of pharmaceutical products into the United States, which are currently under Section 232 investigation by the U.S. Department of Commerce), the implementation, scope, and duration of which remain uncertain. Tariffs on imports of APIs and starting materials used in our products, or retaliatory trade measures taken by China or other countries, which could potentially include restricted access to APIs or starting materials used in our products, could result in us needing to raise prices, make changes to our products, or otherwise materially harm our business, financial condition and results of operations. Further, the continued threats of tariffs, trade restrictions, and trade barriers could have a generally disruptive impact on the global economy and, therefore, negatively impact our sales. Given the focus of the U.S. government on issues related to China, including the imposition of additional restrictions on exports related to semi-conductor manufacturing and supercomputing, the imposition of outbound investment controls affecting U.S. persons' ability to invest in certain enterprises in China, and the addition of entities based in China to various restricted party lists, along with uncertainty regarding how the U.S. or foreign governments will act with respect to tariffs, international trade

agreements and policies, a trade war, further governmental action related to tariffs or international trade policies, or additional tax or other regulatory changes in the future could occur and could directly and adversely impact our financial results and results of operations.

We are subject to various governmental export control and trade sanctions laws and regulations that could impair our ability to compete in international markets or subject us to liability if we violate these controls.

In some cases, our products are subject to export control laws and regulations, including the Export Administration Regulations administered by the U.S. Department of Commerce, and our activities may be subject to trade and economic sanctions, including those administered by the United States Department of the Treasury's Office of Foreign Assets Control, or OFAC (collectively, "Trade Controls"). As such, a license may be required to export or re-export our products, or provide related services, to certain countries and end-users, and for certain end-uses. The process for obtaining necessary licenses may be time-consuming or unsuccessful, potentially causing delays in sales or losses of sales opportunities and these licenses may not be issued.

Trade Controls are complex and dynamic regimes and monitoring and ensuring compliance can be challenging. Although we have procedures in place designed to ensure our compliance with Trade Controls, any failure to comply could subject us to both civil and criminal penalties, including substantial fines, possible incarceration of responsible individuals for willful violations, possible loss of our export or import privileges, and reputational harm. Although we have no knowledge that our activities have resulted in violations of Trade Controls, any failure by us or our partners to comply with applicable laws and regulations could have negative consequences for us, including reputational harm, government investigations, and penalties.

The Chinese government may exert substantial influence over the manner in which we conduct our business operations in China.

The Chinese government has exercised, and continues to exercise, substantial control over virtually every sector of the Chinese economy through regulation and state ownership. Our ability to conduct our proposed manufacturing operations in China may be harmed by changes in its laws and regulations, including those relating to taxation, tariffs and other trade restrictions, environmental regulations, land use rights, property ownership and other matters. We believe that our operations in China are in material compliance with all applicable legal and regulatory requirements. However, the central or local governments of the jurisdictions in which we operate may impose new, stricter regulations or interpretations of existing regulations that would require additional expenditures and efforts on our part to ensure our compliance with such regulations or interpretations. Accordingly, government actions in the future, including any decision not to continue to support economic reforms and to return to a more centrally planned economy or regional or local variations in the implementation of economic policies, could have a significant effect on economic conditions in China or particular regions thereof and could require us to divest ourselves of any interest we then hold in Chinese properties or entities, including our Chinese operating subsidiary, ANP.

The Chinese legal system can be uncertain and could limit the legal protections available to us.

Unlike common law systems, such as the United States, the Chinese legal system is based on written statutes and decided legal cases have little precedential value. Our Chinese operating subsidiary, ANP, is subject to laws and regulations applicable to foreign investments in China in general and laws and regulations applicable to foreign invested enterprises in particular. ANP is also subject to laws and regulations governing the formation and conduct of domestic Chinese companies. Relevant Chinese laws, regulations and legal requirements may change frequently, and their interpretation and enforcement involve uncertainties. For example, we may have to resort to administrative and court proceedings to enforce the legal protections under law or contract. However, since Chinese administrative and court authorities have significant discretion in interpreting and implementing statutory and contract terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and our level of legal protection in China compared to other legal systems. Such uncertainties, including the inability to enforce our contracts and intellectual property rights, could materially and adversely affect our business and operations. In addition, confidentiality protections in China may not be as effective as in the U.S. or other countries. Accordingly, future developments in the Chinese legal system, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, or the preemption of local requirements by national laws, could limit the legal protections available to us.

Our financial performance is impacted by the financial performance of our Chinese operating subsidiary, ANP.

Because we consolidate ANP's financial results in our results of operations, our financial performance is impacted by the financial performance of ANP. ANP's financial performance may be affected by a number of factors, including, but not limited to:

- ANP's ability to execute on its expansion plans;
- the commercial success of ANP's APIs, starting materials and finished pharmaceutical products;
- results of clinical trials of our product candidates or those of ANP's customers;
- pricing actions by competitors;
- the timing of orders or any cancellation of orders from ANP's customers;
- manufacturing or supply interruptions;
- actions taken by current and potential business partners;
- actions by regulatory bodies, such as the FDA or the CFDA;
- changes or developments in laws or regulations;
- disputes or other developments relating to patents or other proprietary rights;
- litigation or investigations involving ANP, our industry, or both; and
- ANP's ability to control costs, including its operating expenses.

Our business may be affected by increasing sanctions and export controls targeting Russia and other responses to Russia's invasion of Ukraine.

As a result of Russia's invasion of Ukraine, the U.S., the U.K. and the EU governments, among others, developed coordinated sanctions and export-control measure packages that continue to include increasing controls.

Based on the public statements to date, these packages include:

- comprehensive financial sanctions against major Russian banks (including SWIFT cut off);
- designation of individuals and entities seen to support Russian military activities;
- additional designations of Russian individuals including but not limited to those with significant business interests and government connections; and
- enhanced export controls and trade sanctions targeting Russia's imports of a wide range of goods and services as a whole, including potentially tighter controls on exports and reexports of items previously subject to only a low level of control, stricter licensing policy with respect to issuing export licenses, increased restrictions on services, and/or increased use of additional "end-use" controls to block or impose licensing requirements on exports.

Although we do not export any items to Russia, depending on the extent and breadth of any new sanctions or export controls, it is possible that our business, results of operations and financial condition could be adversely affected.

Risks Relating to our Intellectual Property

Our success depends on our ability to obtain, protect, and enforce our intellectual property.

In addition to obtaining FDA approval for our generic and proprietary drug candidates, our success also depends on our ability to obtain and maintain patent protection for new products developed utilizing our technologies, in the U.S. and in other countries, and to enforce these patents. The patent positions of pharmaceutical firms, including us, are generally uncertain and involve complex legal and factual issues. Any of our patent claims in our approved and pending non-provisional and provisional patent applications relating to our technologies may not be issued or, if issued, any of our existing and future patent claims may not be held valid and enforceable against third-party infringement. Moreover, any patent claims relating to our technologies may not be sufficiently broad to protect our products. In addition, issued patent claims may be challenged, potentially invalidated, or potentially circumvented. Our patent claims may not afford us protection against our competitors. We currently have a number of U.S. and foreign patents issued. However, issuance of a patent is not conclusive evidence of its validity or enforceability. We may not be granted patents for any of our pending patent applications or any patent applications that we may file in the future and our issued patents may not be upheld if challenged. Further, we may not be able to detect an unauthorized use of our intellectual property rights if a competitor uses our intellectual property confidentially, in-house, with no public disclosure.

The U.S. uses a first inventor to file system in which, assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to receive a patent (rather than the first to invent as was the case under prior U.S. law). Accordingly, it is possible that potentially invalidating prior art may become available in between the time that we develop an invention and file a patent application that covers the invention. In addition, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, reexamination, inter parties review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights.

Past enforcement of intellectual property rights in countries outside the U.S., including China in particular, has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries will likely be problematic or unpredictable, particularly in other countries where intellectual property rights are not highly developed or protected. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Patent claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions.

Enforcement of our intellectual property rights may not be pursued in some situations in which an alleged infringer may have a more dominant intellectual property position or for other business reasons.

We also rely on, or intend to rely on, our trademarks, trade names and brand names to distinguish our products from the products of our competitors and have registered or applied to register our own trademarks. However, our trademark applications may not be granted. Third parties may also oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition and could require us to devote significant resources to advertising and marketing these new brands. Further, our competitors may infringe our trademarks or we may not have adequate resources to enforce our trademarks.

We have in the past and in the future may become involved in patent litigations or other intellectual property proceedings relating to our future product approvals, which could result in liability for damages or delay or stop our development and commercialization efforts.

The pharmaceutical industry has been characterized by significant litigation and other proceedings regarding patents, patent applications and other intellectual property rights. The situations in which we may become parties to such litigation or proceedings may include any third parties initiating litigation claiming that our products infringe their patent or other intellectual property rights; in such case, we will need to defend against such proceedings. For example, the field of generic pharmaceuticals is characterized by frequent litigation that occurs in connection with generic pharmaceutical companies filing ANDAs, Paragraph IV certifications and attempting to invalidate the patents of the proprietary reference drug. Any non-generic products that we successfully develop may be subject to such challenge by third parties.

As a generic pharmaceutical company, we also expect to file ANDAs and Paragraph IV certifications and to attempt to invalidate patents of third party reference drugs for which we seek to develop generic versions.

The costs of resolving any patent litigation or other intellectual property proceeding, even if resolved in our favor, could be substantial. Many of our potential competitors will be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other intellectual property proceedings may also consume significant management time.

In the event that a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult and time-consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time-consuming and could divert our management's attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patent or other intellectual property rights against a challenge. If we are unsuccessful in enforcing and protecting our intellectual property rights and protecting our products, it could materially harm our business.

For example, we have been involved in patent litigation and antitrust litigation related to our sales of enoxaparin and other products, including albuterol. The protracted litigations involved, and may continue to involve, large legal expenses and the diversion of management's time and effort away from the business. Any future adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses, whether in these litigations or in other litigations, could result in substantial monetary damage awards and could prevent us from manufacturing and selling our products, which could have a material and adverse effect on our financial condition.

There may also be situations where we use our business judgment and decide to market and sell products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts, a situation commonly referred to as an at-risk launch. The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent owner and not necessarily by the profits earned by the infringer as well as injunctive relief, which would halt our ability to market and sell such products altogether. In the case of a willful infringement, the definition of which is subjective, such damages may be increased up to three times. Moreover, because of the discount pricing typically involved with generic products, patented proprietary products generally realize a substantially higher profit margin than generic products. An adverse decision in a case such as this or in other similar litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

With respect to our proprietary products, if we fail to adequately protect or enforce our intellectual property rights, we could lose sales to generic versions of our proprietary products which could cause a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

The success of our proprietary products depends in part on our ability to obtain, maintain and enforce patents and trademarks, and to protect trade secrets, know-how and other proprietary information and technologies. Our ability to commercialize any proprietary product successfully will largely depend upon our ability to obtain and maintain patents of sufficient scope to prevent third parties from developing substantially equivalent products. In the absence of patent and trade secret protection, competitors may adversely affect our proprietary products business by independently developing and marketing substantially equivalent products. It is also possible that we could incur substantial costs if we are required to initiate litigation against others to protect or enforce our intellectual property rights.

We have filed patent applications covering compositions of, methods of making and/or methods of using, our proprietary products and proprietary product candidates. We may not be issued patents based on patent applications already filed or that we may file in the future, and if patents are issued, they may be insufficient in scope to cover our proprietary products. The issuance of a patent in one country does not ensure the issuance of a similar patent in any other country, or that we will even seek patent protection in all countries worldwide. Furthermore, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions and has been and remains the subject of much litigation. Legal standards relating to scope and validity of patent claims are evolving and may differ in various countries. Any patents we have obtained, or will obtain in the future, may be challenged, invalidated or circumvented. Moreover, the USPTO or any other governmental agency, as well as third parties, may commence interference,

opposition or other related third-party proceedings involving our patents or patent applications. Any challenge to, or invalidation or circumvention of, our patents or patent applications would be costly, would require significant time and attention of our management, could cause a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Our unpatented trade secrets, know-how, confidential and proprietary information and technology may be inadequately protected.

We rely on unpatented trade secrets, know-how and technology. This intellectual property is difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be submitted to regulatory authorities during the regulatory approval process. We seek to protect trade secrets, know-how, confidential or proprietary information and technologies, in part, by entering into confidentiality and invention assignment agreements with employees, consultants and others. These parties may breach or terminate these agreements, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets, know-how, or other confidential or proprietary information and technologies or result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other breaches of the agreements. Despite our efforts to protect our trade secrets, know-how, and our other confidential and proprietary information and technologies, we or our collaboration partners, board members, employees, consultants, contractors, or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors. In addition, we may not be able to detect any unauthorized disclosure of our trade secrets, know-how and our other confidential and proprietary information and technologies if such disclosure was conducted confidentially without public disclosure.

There is a risk that our trade secrets, know-how, and other confidential and proprietary information and technologies could have been, or could, in the future, be shared by any of our former employees with, and be used to the benefit of, any company that competes with us.

If we fail to maintain trade secret protection or fail to protect the confidentiality of our know-how, and other confidential and proprietary information and technologies, our competitive position may be adversely affected. Enforcement of claims that a third party has illegally obtained and is using trade secrets, know-how, and other confidential and proprietary information and technologies, is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods, know-how and trade secrets, we may not be able to prevail in an intellectual property litigation against them, which could have a material adverse effect on our business.

There can be no assurance of timely patent and trademark review and approval to minimize competition and generate sufficient revenues.

There can be no assurance that the USPTO will have sufficient resources to review and grant our patent and trademark applications in a timely manner. Consequently, our patent and trademark applications may be delayed for many years (if they issue at all), which would prevent intellectual property protection for our products. If we fail to successfully commercialize our products due to the lack of intellectual property protection, we may be unable to generate sufficient revenues to meet or grow our business according to our expected goals and this may have a materially adverse effect on our profitability, financial condition and operations.

We may be subject to claims that we, our board members, employees or consultants have used or disclosed alleged trade secrets or other proprietary information belonging to third parties and any such individuals who are currently affiliated with one of our competitors may disclose our proprietary technology or information.

As is commonplace in the biotechnology and pharmaceutical industries, some of our board members, employees and consultants are or have been employed at, or associated with, other biotechnology or pharmaceutical companies that compete with us. While employed at or associated with these companies, these individuals may become exposed to or involved in research and technology similar to the areas of research and technology in which we are engaged. We may be subject to claims that we, or our employees, board members or consultants have inadvertently, willfully or otherwise used or disclosed alleged trade secrets or other proprietary information of those companies. Litigation may be necessary to defend against such claims.

We have entered into confidentiality agreements with our executives and key consultants. However, we do not have, and are not planning to enter into, any confidentiality agreements with our non-executive directors because they have a

fiduciary duty of confidentiality as directors. Our former board members, employees or consultants who are currently employed at, or associated with, one of our competitors may unintentionally or willfully disclose our proprietary technology or information.

Risks Related to Ownership of our Common Stock

Sales of substantial amounts of our common stock, or indications of an intent to sell, may cause our stock price to decline.

If we or our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. We may also issue shares of common stock or securities convertible into our common stock from time to time in connection with financings, acquisitions, investments or otherwise. Any such issuances would result in dilution to our existing stockholders and could cause our stock price to fall.

In addition, we have registered approximately 15.1 million shares subject to options and RSUs outstanding or reserved for future issuance under our equity compensation plans. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Jack Y. Zhang and Mary Z. Luo, each of whom serves as a director and an executive officer, own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2025, Jack Y. Zhang and Mary Z. Luo, or Drs. Zhang and Luo, each of whom serves as one of our directors and executive officers, and their affiliates beneficially own approximately 26.2% of our outstanding common stock, including shares of common stock subject to options exercisable within 60 days of December 31, 2025. Our directors, executive officers and each of our stockholders who own greater than 5% of our outstanding common stock and their affiliates, in the aggregate, own approximately 28.8% of the outstanding, including shares of our common stock, based on the number of shares outstanding and shares of our common stock subject to options exercisable within 60 days of December 31, 2025. As a result, these stockholders, if acting together, will be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, depriving our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the Company and might ultimately affect the market price of our common stock.

Jack Y. Zhang and Mary Z. Luo have each pledged shares of our common stock to secure funds borrowed under existing credit lines from three financial institutions. Each of the lenders has varying rights as a lender, including one which has the right to conduct a forced sale at its sole discretion. An action by one of the lenders could include a sale of certain shares of our common stock pledged as collateral, the sale of which could cause the price of our common stock to decline. An action to cure and cover indebtedness by any one of the lenders could also have other negative impacts on our business.

Jack Y. Zhang and Mary Z. Luo have each pledged shares of our common stock to secure funds borrowed under existing credit lines by UBS Group and its affiliates, or UBS, East West Bank, or East West, and Cathay Bank. As of December 31, 2025, UBS had extended combined credit lines of $15.0 million to Applied Physics & Chemistry Laboratories, Inc., or APCL, which is controlled by Dr. Zhang and Dr. Luo, East West had agreed to a loan of up to $12.0 million to Drs. Zhang and Luo, and Cathay Bank had agreed to a loan of up to $30.0 million to APCL and Dr. Luo. The UBS credit lines are secured by a pledge of 801,156 shares of our common stock currently held by APCL, the East West loan is secured by a pledge of 800,000 shares of our common stock held by Dr. Zhang and the Cathay Bank loan is secured by a pledge of 2,000,000 shares of our common stock held by APCL and Dr. Luo. Interest on each of these loans accrues at market rates. UBS has an unlimited and unilateral right to call each of the credit lines for any reason whatsoever, and each of East West and Cathay Bank has acceleration rights to protect itself in the event of a default.

We have a pledging policy to restrict the pledging of shares by our executive officers and directors, which was created in 2021 and most recently amended in 2025. The policy prohibits our executive officers and directors from entering into any transaction whereby the executive officer or director, directly or indirectly, pledges, hypothecates, or otherwise encumbers more than forty (40) percent of shares of common stock held by the individual or more than ten (10) percent

of our total outstanding shares of common stock as of the date of the transaction, whichever is lower, as collateral for indebtedness. This restriction extends to any hedging or similar transaction designed to decrease the risks associated with holding our securities.

While we are not a party to these loans, which are full recourse against APCL and each of Drs. Zhang and Luo, respectively, and are secured by pledges of a portion of the shares of our common stock currently held by APCL and each of Drs. Zhang and Luo, if the price of our common stock declines, Drs. Zhang and Luo may be forced by these financial institutions to provide additional collateral for the loans or to sell shares of our common stock held by them in order to remain within the margin limitations imposed under the terms of their loans. Furthermore, the pledged shares of our common stock may be acquired and sold by the lenders. These factors may limit Drs. Zhang and Luo's ability to either pledge additional shares of our common stock or sell shares of our common stock held by them as a means to avoid or satisfy a margin call with respect to their pledged shares of our common stock in the event of a decline in our stock price that is large enough to trigger a margin call. Any significant sales of shares of our common stock by one or more of these three lenders could cause the price of our common stock to decline further.

We do not intend to pay dividends for the foreseeable future.

The continued operation and expansion of our business will require substantial funding. Accordingly, we do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our Board of Directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our Board of Directors deems relevant. In addition, our existing loan agreements restrict, and any future indebtedness may restrict, our ability to pay dividends. Investors seeking cash dividends should not purchase our common stock. Accordingly, realization of a gain on your investment will depend on the appreciation of the price of our common stock, which may never occur.

While we have engaged in repurchases of our common stock, any future decisions to reduce or discontinue repurchasing our common stock pursuant to our previously announced repurchase program could cause the market price for our common stock to decline.

Although our Board has authorized a share repurchase program, and we repurchased approximately 2.9 million of our shares during 2025 for $75.4 million, any determination to continue to execute our stock repurchase program as planned will be subject to, among other things, our financial position and results of operations, available cash and cash flow, capital requirements, and other factors, as well as our Board's continuing determination that the repurchase program is in the best interests of our shareholders and is in compliance with all laws and agreements applicable to the repurchase program. Our stock repurchase program does not obligate us to acquire any specific number of shares. If we fail to meet any expectations related to stock repurchases, the market price of our stock could decline significantly, and could have a material adverse impact on investor confidence. Additionally, price volatility of our stock over a given period may cause the average price at which we repurchase our own stock to exceed the stock market price at a given point in time.

We may further increase or decrease the amount of repurchases of our common stock in the future. Any reduction or discontinuance by us of repurchases of our common stock pursuant to our current share repurchase authorization program could cause the market price of our common stock to decline. Moreover, in the event repurchases of our common stock are reduced or discontinued, our failure or inability to resume repurchasing common stock at historical levels could result in a lower market valuation of our common stock.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws, as well as provisions of the Delaware General Corporation Law, or the DGCL, could depress the trading price of our common stock by making it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions include:

- authorizing the issuance of undesignated preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;

- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;
- establishing a classified Board of Directors, whereby only one-third of the members of our Board of Directors are elected at one time;
- providing that vacancies on our board of directors may be filled only by a majority of directors then in office; and
- establishing advance notice procedures and requirements for stockholders to nominate candidates for election as directors or to bring matters before meetings of stockholders.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors, which is responsible for appointing the members of our management. Furthermore, our amended and restated certificate of incorporation provides 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 breach of fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; or (iv) any action asserting a claim against us that is governed by the internal affairs doctrine. This provision is not intended to apply to actions arising under the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act, or any claim for which the federal courts have exclusive jurisdiction. In addition, our amended and restated bylaws provide that, unless the Company consents in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act against any person in connection with any offering of the Company's securities, including, without limitation, any auditor, underwriter, expert, control person or other defendant. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to these provisions. These exclusive-forum provisions may discourage lawsuits against us or our directors, officers, and employees. In addition, we are subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our Board of Directors. This provision could delay or prevent a change of control, whether or not it is desired by or beneficial to our stockholders, which could also affect the price that some investors are willing to pay for our common stock.

General Risk Factors

Global macroeconomic conditions may negatively affect us and may magnify certain risks that affect our business.

Our business is sensitive to general economic conditions, both inside and outside the U.S. Slower global economic growth, credit market crises, high levels of unemployment, reduced levels of capital expenditures, government deficit reduction, changes in inflation and interest rate environments, sequestration and other austerity measures and other challenges affecting the global economy adversely affects us and our distributors, customers and suppliers. It is uncertain how long these effects will last or whether economic and financial trends will worsen or improve. Changes in economic conditions and supply chain constraints and steps taken by governments and central banks could lead to higher inflation than previously experienced or expected, which could, in turn, lead to an increase in costs. In an inflationary environment, we may be unable to raise the prices of our products sufficiently to keep up with the rate of inflation. Such uncertain economic times may have a material adverse effect on our revenues, results of operations, financial condition and, if circumstances worsen, our ability to raise capital at reasonable rates. If slower growth in the global economy or in any of the markets we serve continues for a significant period, if there is significant deterioration in the global economy or such markets or if improvements in the global economy do not benefit the markets we serve, our business and financial statements could be adversely affected.

Additionally, as a result of any future global economic downturn, our third-party payers may delay or be unable to satisfy their reimbursement obligations. Sales of our principal products are dependent, in part, on the availability and

extent of reimbursement from third-party payers, including government programs such as Medicare and Medicaid and private payer healthcare and insurance programs. A reduction in the availability or extent of reimbursement from government and/or private payer healthcare programs could have a material adverse effect on the sales of our products, our business and results of operations.

Current economic conditions may adversely affect the ability of our distributors, customers, suppliers and service providers to obtain the liquidity required to pay for our products or to buy necessary inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations, and could negatively impact our business and cash flow. Although we make efforts to monitor these third parties' financial condition and their liquidity, our ability to do so is limited, and some of them may become unable to pay their bills in a timely manner, or may even become insolvent, which could negatively impact our business and results of operations. These risks may be elevated with respect to our interactions with third parties with substantial operations in countries where current economic conditions are the most severe, particularly where such third parties are themselves exposed to sovereign risk from business interactions directly with fiscally-challenged government payers.

At the same time, significant changes and volatility in the financial markets, in the consumer and business environment, in the competitive landscape and in the global political and security landscape make it increasingly difficult for us to predict our revenues and earnings into the future. As a result, any revenue or earnings guidance or outlook which we have given or might give may be overtaken by events, or may otherwise turn out to be inaccurate. Though we endeavor to give reasonable estimates of future revenues and earnings at the time we give such guidance, based on then-current conditions, there is a significant risk that such guidance or outlook will turn out to be, or to have been, incorrect.

We could be materially and adversely affected by violations of the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws.

The U.S. Foreign Corrupt Practices Act of 1977, as amended and similar applicable laws and regulations in other jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Our policies mandate compliance with these anti-bribery laws, which often carry substantial penalties. We are currently expanding our operations abroad, including expanding our facilities in China, a country which has experienced governmental and private sector corruption to some degree, and in certain circumstances, strict compliance with anti-bribery laws may conflict with certain local customs and practices. Our internal control policies and procedures may not always protect us from acts committed by our affiliates, employees or agents which may violate these laws and regulations. Violations of foreign and U.S. laws and regulations could result in fines and penalties, criminal sanctions against us, our officers or our employees, prohibitions on the conduct of our business and on our ability to offer our products in one or more countries, and could also materially affect our brand, our international growth efforts, our ability to attract and retain employees, our business, and our operating results. There can be no assurance that our partners, our employees, contractors, or agents will not subject us to potential claims or penalties. Any violations of these laws, or allegations of such violations, could have a material adverse effect on our business, financial position, and results of operations and could cause the market value of our common stock to decline.

Movements in foreign currency exchange rates could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

A portion of our revenues, indebtedness and other liabilities and our costs are denominated in foreign currencies, including the Chinese yuan and the euro. We report our financial results in U.S. dollars. Our results of operations and, in some cases, cash flows may in the future be adversely affected by certain movements in exchange rates. We also expect that certain exchange rates may be more volatile than normal as a result of political and civil unrest, global conflicts, tariff policies, supply chain disruptions, heightened inflationary pressures, and fluctuating interest rates, as well as other uncertain macroeconomic conditions. From time to time, we may implement currency hedges intended to reduce our exposure to changes in foreign currency exchange rates. However, any such hedging strategies may not be successful, and any of our unhedged foreign exchange exposures will continue to be subject to market fluctuations. These risks could cause a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Our results of operations can be adversely affected by labor shortages, turnover and labor cost increases.

Labor is a primary component of operating our business. A number of factors may adversely affect the labor force available to us or increase labor costs, including high employment levels and government regulations. A sustained labor

shortage or increased turnover rates within our employee base could lead to increased costs, such as increased overtime to meet demand and increased wage rates to attract and retain employees, and could negatively affect our ability to efficiently operate our manufacturing and distribution facilities and overall business. If we are unable to hire and retain employees capable of performing at a high-level, or if mitigation measures we may take to respond to a decrease in labor availability, such as overtime and third-party outsourcing, have negative effects, our business could be adversely affected. An overall labor shortage, lack of skilled labor, increased turnover or labor inflation could have a material adverse impact on our business, financial condition or operating results.

Complications with the design or implementation of our new enterprise resource planning system could adversely impact our business and operations.

We rely extensively on information systems and technology to manage our business and summarize operating results. We are in the process of a multi-year implementation of a new global enterprise resource planning ("ERP") system. The ERP system is designed to accurately maintain the Company's financial records, enhance operational functionality and provide timely information to the Company's management team related to the operation of the business and is intended to replace our existing operating and financial systems. The ERP system implementation process has required, and will continue to require, the investment of significant personnel and financial resources. We may not be able to successfully implement the ERP system without experiencing delays, increased costs and other difficulties. If we are unable to successfully design and implement the new ERP system as planned, our financial positions, results of operations and cash flows could be negatively impacted. Additionally, if we do not effectively implement the ERP system as planned or the ERP system does not operate as intended, and accordingly, the effectiveness of our internal control over financial reporting could be adversely affected or our ability to assess those controls adequately could be further delayed.

Failure to maintain adequate internal controls or to implement new or improved controls could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. We have in the past, identified a material weakness in our internal control over financial reporting, which was remediated; however, our remediation efforts may not enable us to avoid a material weakness in the future. Ensuring that we have adequate internal financial and accounting controls and procedures in place to help produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be evaluated frequently.

We are required to disclose certain changes made in our internal control and procedures on a quarterly basis. Our independent registered public accounting firm is required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. Our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. In addition, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation by our independent registered public accounting firm.

In the event that our Chief Executive Officer, Chief Financial Officer, or independent registered public accounting firm determines that our internal control over financial reporting is not effective as defined under Section 404, we could be subject to one or more investigations or enforcement actions by state or federal regulatory agencies, stockholder lawsuits, breaches of the covenants under our credit facilities, or other adverse actions requiring us to incur defense costs, pay fines, make settlements or seek judgments, which may adversely affect investor perceptions and potentially result in a decline in our stock price.

There are inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with GAAP. Any future changes in estimates, judgments and assumptions used or necessary revisions to prior estimates, judgments or assumptions or changes in accounting standards could lead to a restatement or revision to previously consolidated financial statements, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as discussed in greater detail in "Part II – Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations." the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our operating results may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our operating results to fall below the expectations of securities analysts and investors, resulting in a decline in our stock price. Significant assumptions and estimates used in preparing our consolidated financial statements include those related to revenue recognition, provision for chargebacks and rebates, accruals for product returns, valuation of inventory, impairment of intangibles and long-lived assets, accounting for income taxes and share-based compensation. Furthermore, although we have recorded reserves for litigation related contingencies based on estimates of probable future costs, such litigation related contingencies could result in substantial further costs. Also, any new or revised accounting standards may require adjustments to previously issued financial statements. Any such changes could result in corresponding changes to the amounts of liabilities, revenues, expenses and income. Any such changes could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Changes in financial accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our business and financial results.

Changes in tax laws, tax rulings and other factors may have a significantly adverse impact on our effective tax rate and tax expense, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Changes in tax laws, tax rulings, or the way in which such laws and rulings are interpreted or implemented, could adversely affect our effective tax rate and tax expense. For example, in 2022 the U.S. government enacted the Inflation Reduction Act of 2022, which imposes a 1% excise tax on certain stock repurchases (including potentially pursuant to our stock repurchase program) and a 15% alternative minimum tax on adjusted financial statement income. In addition, the OBBB Act was signed into law on July 4, 2025 and introduced significant changes to U.S. federal tax law. We are continuing to evaluate the full impact of the OBBB Act on us. Further, many countries, and organizations such as the Organization for Economic Cooperation and Development have proposed implementing changes to existing tax laws ("Pillar 2"), including a proposed 15% global minimum tax that has been and is being adopted by several countries. The United States has withdrawn support for Pillar 2, but the G7 and the U.S. Treasury Department announced an agreement that the U.S. international tax regime will operate "side-by-side" with Pillar 2 rules. We are continuing to monitor the enactment and implementation of Pillar 2 legislation, and the impact on our financial position and results of operations.

In addition to income taxes in the United States, we are subject to income taxes in many foreign jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes. In the ordinary course of business, there are many transactions and calculations where the ultimate tax determination is uncertain. The final determination of any tax audits or related litigation could be materially different from our historical income tax provisions and accruals.

In addition, tax laws are dynamic and subject to change. As new laws are passed and new interpretations of the law are issued or applied, our provision for income taxes may be affected. Changes to U.S. tax laws now or in the future could impact the tax treatment of our earnings, as well as cash and cash equivalent balances we currently maintain. Furthermore, due to shifting economic and political conditions, tax policies or rates in various jurisdictions may be subject to significant change.

Additionally, increases in our effective tax rate as a result of a change in the mix of earnings in countries with differing

statutory tax rates, changes in our overall profitability, changes in the valuation of deferred tax assets and liabilities, the results of audits and the examination of previously filed tax returns by various taxing authorities and continuing assessments of our tax exposures could impact our tax liabilities and affect our income tax expense, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

The facilities we use for our headquarters, laboratory and research and development activities are located in earthquake-prone areas of California. A significant percentage of the facilities we use for our manufacturing, packaging, warehousing, distribution and administration offices are also located in these areas. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. Additionally, we currently rely on third parties whose operations may be disrupted by natural disasters. For example, in the aftermath of Hurricane Helene we experienced delays in shipments of certain products.

If a natural disaster, power outage or other event occurred that prevented us or the third parties upon whom we depend from using all or a significant portion of our facilities, that damaged critical infrastructure, such as our or third parties' manufacturing facilities, or that otherwise disrupted operations of ours or those of third parties, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans.

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our operating results may be subject to quarterly and annual fluctuations as a result of a number of factors, including the following:

- the commercial success of our key products and those of our customers;
- results of clinical trials of our product candidates or those of our competitors;
- pricing actions by competitors;
- the timing of orders or any cancellation of orders from our customers;
- manufacturing or supply interruptions;
- actions by regulatory bodies, such as the FDA, that have the effect of delaying or rejecting approvals of our product candidates;
- changes in the prescription practices of physicians;
- changes or developments in laws or regulations applicable to our product candidates;
- introduction of competitive products or technologies;
- failure to meet or exceed financial projections we provide to the public;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of securities analysts or investors;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures,

capital commitments or achievement of significant milestones;

- changes in, or termination of our agreements with our business partners;
- developments concerning our sources of manufacturing supply;
- disputes or other developments relating to patents or other proprietary rights;
- litigation or investigations involving us, our industry, or both;
- additions or departures of key scientific or management personnel;
- announcements or issuances of debt, equity or convertible securities;
- sales of our common stock by our stockholders;
- changes in the market valuations of similar companies;
- major catastrophic events;
- major changes in our Board of Directors or management or departures of key personnel;
- our overall effective tax rate, including impacts caused by any reorganization in our corporate structure, and any new legislation or regulatory developments, including the OBBB Act;
- changes in accounting principles;
- general economic and market conditions and overall fluctuations in U.S. equity markets; or
- the other factors described in this "Item 1A, Risk Factors" section.

Any one of the factors above, or the cumulative effect of some of the factors referred to above, may result in significant fluctuations in our quarterly or annual operating results. This variability and unpredictability could result in our failing to meet our revenue, billings or operating results expectations or those of securities analysts or investors for any period. In addition, a significant percentage of our operating expenses are fixed in nature and based on forecasted revenue trends. Accordingly, in the event of revenue shortfalls, we are generally unable to mitigate the negative impact on operating results in the short term. If we fail to meet or exceed such expectations for these or any other reasons, our business could be materially adversely affected and our stock price could fluctuate or decline substantially.

In addition, if the market for pharmaceutical company stocks or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, operating results or financial condition. The trading price of our common stock might also decline in reaction to events that affect other companies in our industry even if these events do not directly affect us. Our stock price may also be affected by sales of large blocks of our stock or an interruption or change in our stock buyback program.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. If our stock price is volatile, we may become the target of securities litigation. Securities litigation could result in substantial costs and divert our management's attention and resources from our business, and this could have a material adverse effect on our business, operating results and financial condition.

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain executive management and qualified board members.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of the Nasdaq Stock Market LLC and other applicable securities rules and regulations. Compliance with these rules and regulations imposes significant legal and financial compliance costs and may divert management's attention from other business concerns, which could adversely affect our business and operating results.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices, including increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

Failure to comply with these requirements could also subject us to enforcement actions by the SEC, further increase costs and divert management's attention, damage our reputation and adversely affect our business, operating results or financial condition.

We also believe that being a public company and these rules and regulations make it more expensive for us to obtain director and officer liability insurance.

We may become involved in securities class action litigation that could divert management's attention from our business and adversely affect our business and could subject us to significant liabilities.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations as well as a broad range of other factors, including the realization of any of the risks described in this section, may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies generally experience significant stock price volatility. We may become involved in this type of litigation in the future. Litigation is often expensive and could divert management's attention and resources from our primary business, which could adversely affect our business. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

We may become involved in litigation that may materially adversely affect us.

From time to time, we may be involved in a variety of claims, lawsuits, investigations and proceedings relating to securities laws, product liability, patent infringement, contract disputes, employment-related claims, and other matters relating to various claims that arise in the normal course of our business in addition to governmental and other regulatory investigations and proceedings. For example, former employees have filed claims against us under California's Private Attorneys General Act, or PAGA. PAGA allows an aggrieved staff member to bring a lawsuit on behalf of other current and former staff members for labor code violations. In addition, third parties may, from time to time, assert claims against us in the form of letters and other communications. Such matters can be time-consuming, divert management's attention and resources, cause us to incur significant expenses in defense and/or attorneys' costs or liability and/or require us to change our business practices. Because of the potential risks, expenses and uncertainties of litigation, we may, from time to time, settle disputes, even where we have meritorious claims or defenses, by agreeing to settlement agreements. Because litigation is inherently unpredictable, we cannot assure you that the results of any of these actions will not have a material adverse effect on our business, financial condition, results of operations and prospects.

As a result of disclosure of information in this Annual Report on Form 10-K and in filings required of a public company, our business and financial condition are more visible, which we believe may result in threatened or actual litigation by competitors and other third parties. If such claims are successful, our business and operating results could be adversely affected. Even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our business and operating results.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein.

We conduct periodic risk assessments to identify cybersecurity threats, as well as assessments in the event of a material change in our business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems, and safeguards in place to manage such risks.

Following these risk assessments, we re-design, implement, and maintain reasonable safeguards to minimize identified risks; reasonably address any identified gaps in existing safeguards; and regularly monitor the effectiveness of our safeguards. We devote significant resources and designate high-level personnel, including our Head of the Information Technology Systems, or ITS, department, who reports to our Chief Executive Officer, to manage the risk assessment and mitigation process. As part of our overall risk management system, we monitor and test our safeguards and train our employees on these safeguards, in collaboration with human resources, IT, and management. Personnel at all levels and departments are made aware of our cybersecurity policies through training.

We engage consultants in connection with our risk assessment processes. These service providers assist us in designing and implementing our cybersecurity policies and procedures, as well as to monitor and test our safeguards. We require each third-party service provider to certify that it has the ability to implement and maintain appropriate security measures, consistent with all applicable laws, to implement and maintain reasonable security measures in connection with their work with us, and to promptly report any suspected breach of its security measures that may affect our business.

For additional information regarding whether any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect our company, including our business strategy, results of operations, or financial condition, please refer to Item 1A, “Risk Factors,” in this annual report on Form 10-K, including the risk factors entitled “Our business and operations have been impacted in the past, and may be impacted in the future, in the event of system breach or failure” and “Complying with laws in the U.S., Europe, and other jurisdictions that impose restrictive regulations addressing the collection, use, and other processing of personal information may be expensive, and failure to comply with such laws and regulations could cause substantial harm to our company.”

Governance

One of the key functions of our board of directors is informed oversight of our risk management process, including risks from cybersecurity threats. Our board of directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks we face. Our board of directors administers its cybersecurity risk oversight function through the audit committee. The chairperson of our audit committee has received a certificate in Cybersecurity Oversight from Carnegie Mellon University.

Our head of the ITS Department and our executive management are primarily responsible for assessing and managing our material risks from cybersecurity threats.

Our head of the ITS Department oversees our cybersecurity policies and processes, including those described in “Risk Management and Strategy” above. We have set up processes by which our executive management are informed about and monitor the prevention, detection, mitigation, and remediation of cybersecurity incidents.

Our head of the ITS Department and our executive management provide quarterly briefings to the audit committee of the

board regarding our company's cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third parties, and the like. Our audit committee provides regular updates to the board of directors on such reports. In addition, our head of the ITS Department provides periodic briefings to the board of directors on cybersecurity risks and activities.

Item 2. Properties.

Our manufacturing facilities are located in Rancho Cucamonga and South El Monte, California; Canton, Massachusetts; Éragny-sur-Epte, France; and Nanjing, China. As of December 31, 2025, we own or lease a total of 69 buildings at six locations in the U.S., France and China, that comprise 2.5 million square feet of manufacturing, research and development, distribution, packaging, laboratory, office and warehouse space. Our facilities are regularly inspected by the FDA in connection with our product approvals, and we believe that all of our facilities are being operated in material compliance with the FDA's cGMP regulations.

The following table provides a summary of our owned properties:

Location	Aggregate Facility Size (in square feet)	Primary Use
Rancho Cucamonga, CA	267,674	Headquarters, research and development, laboratories, manufacturing, packaging, warehousing and administrative offices
Éragny-sur-Epte, France	251,983	Manufacturing, laboratories, warehousing and administrative offices
Canton, MA	216,590	Manufacturing, packaging, warehousing, distribution and administrative offices
Nanjing, China	1,103,737	Manufacturing, procurement, research and development, warehousing, and administrative offices
Chino, CA	57,968	Research and development, and laboratories
South El Monte, CA	21,200	Manufacturing

The properties leased by us have expiration dates ranging from 2026 to 2035 (including certain renewal options). The following table provides a summary of our leased properties:

Location	Aggregate Facility Size (in square feet)	Primary Use
Rancho Cucamonga, CA	191,180	Warehousing, distribution and administrative offices
South El Monte, CA	343,413	Manufacturing, packaging, warehousing, distribution and administrative offices

We believe that our current manufacturing capacity is adequate for the near term. However, we are planning to increase capacity at our plant in Rancho Cucamonga, CA which should allow us to eventually quadruple the number of units produced at this facility. We are also increasing the capacity of our inhalation facility in Canton, MA and our insulin API production facility at ANP. We have in the past approached capacity at one of our facilities largely as a result of the FDA's request that we reintroduce certain previously discontinued products to help cope with a nationwide shortage of these products. We believe that these capacity issues have been ameliorated as a result of certain other manufacturers re-entering the market and increasing the production of the products that were subject to the shortage.

Item 3. Legal Proceedings.

From time to time, we may also be involved in a variety of other claims, lawsuits, investigations, and proceedings related to securities laws, product liability, patent infringement, contract disputes, employment, and other matters that arise in the normal course of our business. In addition, third parties may, from time to time, assert claims against us in the form of letters and other communications.

The results of any litigation cannot be predicted with certainty, and an unfavorable resolution in any legal proceedings could materially affect our future business, results of operations, or financial condition. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

For information on legal proceedings, see "Part II – Item 8. Financial Statements and Supplementary Data – Notes to Consolidated Financial Statements – Note. 19 Litigation."

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.

Our common stock is listed on the Nasdaq Global Select Market and has traded under the symbol "AMPH" since our initial public offering on June 25, 2014. Prior to this date, there was no public market for our common stock.

Dividend Policy

We have not declared or paid any dividends on our common stock since our initial public offering. We currently anticipate that we will retain future earnings, if any, for the development, operation and expansion of our business and do not anticipate declaring or paying any dividends in the foreseeable future. Additionally, our ability to pay dividends on our common stock is limited by restrictions under the terms of our existing credit facilities. Any future determinations related to dividend policy will be made at the discretion of our Board of Directors.

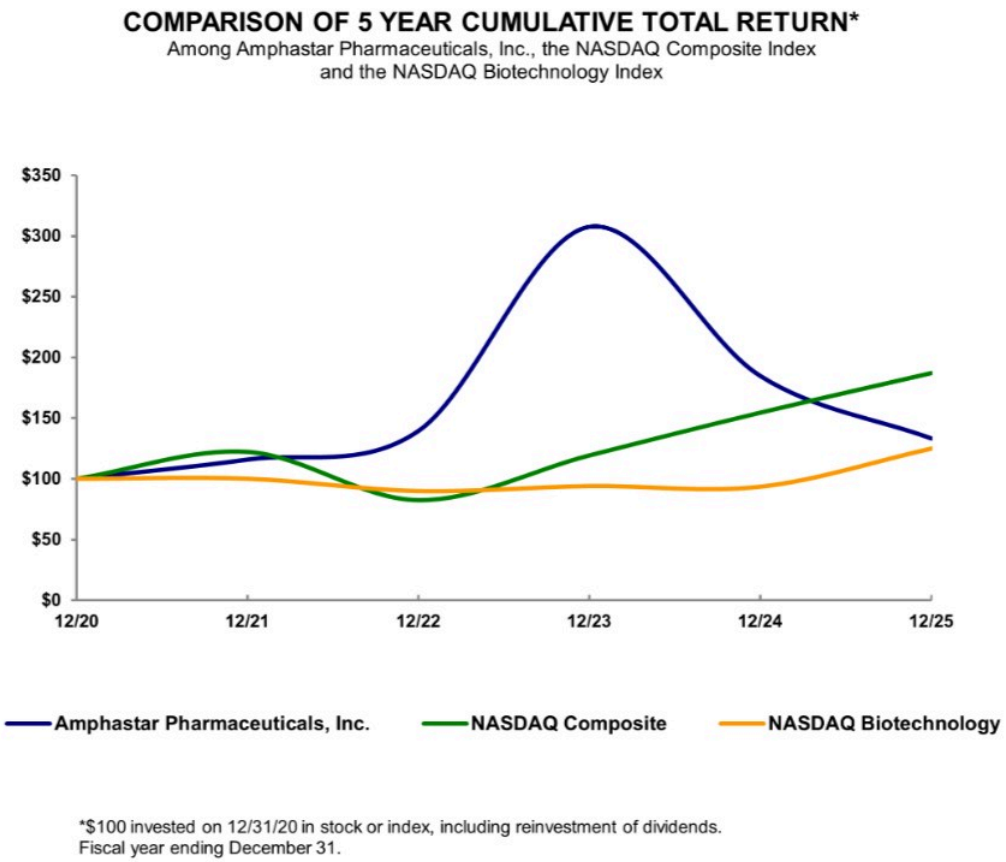
Holders of Record

At February 20, 2026, we had 45,370,171 shares of common stock outstanding held by approximately 115 stockholders of record of our common stock. We believe the actual number of stockholders is greater than this number of record holders, including stockholders who are beneficial owners but whose shares are held in "street" name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Stock Performance Graph

This graph shall not be deemed "soliciting material" or to be "filed" with the Securities and Exchange Commission for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any filing of Amphastar Pharmaceuticals, Inc. under the Securities Act or the Exchange Act.

The following graph illustrates a comparison of the total cumulative stockholder return on our common stock since December 31, 2020, with the cumulative stockholder return since December 31, 2020, on two indices: the Nasdaq Composite Index and the Nasdaq Biotechnology Index. The graph assumes an initial investment of $100 on December 31, 2020, both in our common stock and each index. It also assumes reinvestment of dividends, if any. Historical stockholder return shown is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.



Issuer Purchases of Equity Securities During the Quarter Ended December 31, 2025

The table below provides information with respect to repurchases of our common stock.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs[1]	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs[1] (in millions)
October 1 - October 31, 2025	396,845	$ 24.55	396,845	$ 35.4
November 1 - November 30, 2025	203,261	25.89	203,261	30.1
December 1 - December 31, 2025	206,858	26.57	206,858	24.6

(1) These repurchases were made under our previously authorized share buyback program (see "Part II – Item 8. Financial Statements and Supplementary Data – Notes to Consolidated Financial Statements – Note 15. Stockholders' Equity – Share Buyback Program").

Recent Sales of Unregistered Securities

None.

Item 6. [Reserved]

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

The following is a discussion and analysis of the consolidated operating results, financial condition, liquidity and cash flows of our company as of and for the periods presented below. The following discussion and analysis should be read in conjunction with the audited consolidated financial statements and the related notes thereto included in Item 8 under the heading "Financial Statements and Supplementary Data." This discussion contains forward-looking statements that are based on the beliefs of our management, as well as assumptions made by and information currently available to, our management. Actual results could differ materially from those discussed in or implied by forward-looking statements. These risks, uncertainties and other factors include among others, those identified under the "Special Note About Forward-Looking Statements," above and described in greater detail elsewhere in this Annual Report on Form 10-K, particularly in Item 1A, under the heading "Risk Factors."

In this section, we generally discuss the results of our operations for the year ended December 31, 2025, compared to the year ended December 31, 2024. For a discussion of the year ended December 31, 2024, to the year ended December 31, 2023, please refer to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 3, 2025, which discussion is hereby incorporated herein by reference.

Overview

We are a biopharmaceutical company focusing on developing, manufacturing, and commercializing technically challenging generic and proprietary injectable, inhalation, and intranasal products, as well as active pharmaceutical ingredient, or API products. We currently manufacture and sell over 25 prescription pharmaceutical products, and an over-the-counter product, Primatene MIST®.

Our largest products by net revenues currently include BAQSIMI®, Primatene MIST®, epinephrine, glucagon, and lidocaine.

We are currently developing a portfolio of generic abbreviated new drug applications, or ANDAs, biologics license applications, or BLAs, including biosimilar insulin product candidates, and proprietary product candidates, which are in various stages of development and target a variety of indications. One ANDA and one biosimilar insulin candidate are currently on file with the FDA.

To complement our internal growth and expertise, we have in-licensed several early-stage proprietary products and have made several strategic acquisitions of companies, products and technologies. These acquisitions collectively have strengthened our core injectable and inhalation product technology infrastructure by providing additional manufacturing, marketing, and research and development capabilities, including the ability to manufacture raw materials, APIs, and other components for our products.

Macroeconomic Trends and Uncertainties

Recent worldwide events and macroeconomic factors, such as international trade relations, tariffs, new legislation and regulations, changes in administration, taxation or monetary policy changes, public sector budgetary cycles and funding authorization in the United States, political and civil unrest, global conflicts, supply chain disruptions, heightened inflationary pressures, and fluctuating interest rates, as well as rising healthcare costs among other factors, also increase volatility in the global economy and continue to pose challenges to our business. For example, there is significant uncertainty relating to tariffs. While all of our finished products and four of our APIs are manufactured in the United States, we import APIs, starting materials for APIs, and components from various countries.

See "Part I – Item 1A, Risk Factors" for further discussion of the potential adverse impact of unfavorable global and geopolitical economic conditions on our business, results of operations and financial conditions.

Recent Developments

In August 2025, the FDA approved our Iron Sucrose Injection, USP 50mg/2.5mL, 100mg/5mL, and 200mg/10mL in single-dose vials, which we launched in the third quarter of 2025.

In August 2025, we entered into a License Agreement with Nanjing Anji Biotechnology Co., Ltd., or Anji, pursuant to which Anji has granted an exclusive license to certain intellectual property controlled by Anji to develop, make, use and commercialize products incorporating or comprising certain compounds, including three identified products, or Licensed Products, in the United States and Canada. During the year ended December 31, 2025, we made an earnest payment and upfront payment totaling $6.0 million to Anji upon the signing of the License agreement. The agreement is also subject to potential development milestone payments, as well as sales milestone and royalty payments. For more information regarding the Anji license agreement, see "Part II – Item 8. Financial Statements and Supplementary Data – Notes to Consolidated Financial Statements – Note 17. Commitments and Contingencies."

In December 2025, the FDA approved our Teriparatide Injection, USP 560mcg/2.24mL in single-patient-use prefilled pen, which we launched in December 2025.

In January 2026, we entered into a License Agreement with Nanjing Hanxin Pharmaceutical Technology Co., Ltd., or Hanxin, pursuant to which Hanxin has granted an exclusive license to a fully synthetic corticotropin (ACTH) analog, now designated AMP-110, in the United States and Canada. AMP-110 is designed to address inflammatory and autoimmune conditions with a potentially improved safety profile compared to porcine-derived ACTH products. In January 2026, we made an upfront payment of $2.0 million to Hanxin upon signing the License Agreement. The agreement is also subject to potential development milestone payments, as well as sales milestone and royalty payments. For more information regarding the Hanxin license agreement, see "Part II – Item 8. Financial Statements and Supplementary Data – Notes to Consolidated Financial Statements – Note 20. Subsequent Events."

In February 2026, the FDA approved our Ipratropium Bromide HFA inhalation aerosol, 17 mcg/actuation, which we plan to launch early in the second quarter of 2026.

Business Segments

Our performance is assessed and resources are allocated based on one reportable segment, pharmaceutical products.

For more information regarding our segments, see "Part II – Item 8. Financial Statements and Supplementary Data – Notes to Consolidated Financial Statements – Note 5. – Segment Reporting."

Results of Operations

Year ended December 31, 2025 compared to year ended December 31, 2024

Net revenues

	Year Ended December 31,		Change	
	2025	2024	Dollars	%
		(in thousands)		
Net revenues				
Product revenues, net	$ 719,887	$ 712,814	$ 7,073	1 %
Other revenues	—	19,153	(19,153)	(100)%
Total net revenues	$ 719,887	$ 731,967	$ (12,080)	(2)%
Cost of revenues	$ 363,830	$ 358,112	$ 5,718	2 %
Gross profit	$ 356,057	$ 373,855	$ (17,798)	(5)%
as % of net revenues	*49 %*	*51 %*		

The increase in product revenues, net, for 2025 was primarily due to the following changes:

	Year Ended December 31,		Change	
	2025	2024	Dollars	%
		(in thousands)		
Product revenues, net:				
BAQSIMI®	$ 185,358	$ 126,898	$ 58,460	46 %
Primatene MIST®	108,669	102,012	6,657	7 %
Epinephrine	70,643	94,090	(23,447)	(25)%
Glucagon	69,084	108,319	(39,235)	(36)%
Lidocaine	56,479	55,854	625	1 %
Other products	229,654	225,641	4,013	2 %
Total product revenues, net	$ 719,887	$ 712,814	$ 7,073	1 %

Product Revenues, net

BAQSIMI® sales increased primarily due to an increase in unit volume, as we assumed full distribution responsibilities globally at the beginning of 2025. Total BAQSIMI® sales growth, including units sold by Lilly in 2024 which were accounted for in other revenues, was 12%. Primatene MIST® sales increased primarily due to an increase in unit volumes driven by our continued marketing efforts. The decrease in sales of epinephrine was due to a decrease in unit volume, impacting sales by $13.4 million, as well as a lower average selling price, which impacted sales by $10.0 million, primarily as a result of increased competition for our multi-dose epinephrine vial product. The decrease in sales of glucagon was due to a lower average selling price, which impacted sales by $24.3 million, as well as a decrease in unit volumes, impacting sales by $14.9 million, as a result of competition and the continued shift to ready to use glucagon products such as BAQSIMI®. The increase in other products was primarily due to an increase in albuterol sales of $14.7 million and iron sucrose sales of $4.4 million, which were launched in August 2024 and August 2025, respectively, as well as an increase in sales for several other products including sodium bicarbonate and atropine due to an increase in demand caused by other supplier shortages. This increase was partially offset by a decrease in sales of enoxaparin of $9.9 million and dextrose of $9.6 million due to increased competition.

We anticipate that sales of glucagon will continue to decline in the future due to competitive dynamics. We also anticipate that sales of epinephrine and other products will continue to fluctuate depending on the ability of our competitors to supply market demands.

Other Revenues

As we completed the assumption of distribution responsibilities globally for BAQSIMI® at the beginning of 2025, all BAQSIMI® related revenues in the current period are recognized in product revenues, net. Other revenues in the previous period include the portion of BAQSIMI® sales made by Lilly on our behalf under the TSA, which amounted to $19.2 million during the year ended December 31, 2024, based on total BAQSIMI® sales of $37.6 million as reported to us by Lilly, which was recognized on a net basis, similar to a royalty arrangement.

Backlog

A significant portion of our customer shipments in any period relate to orders received and shipped in the same period, generally resulting in low product backlog relative to total shipments at any time. We had no significant backlog as of December 31, 2025. Historically, our backlog has not been a meaningful indicator in any given period of our ability to achieve any particular level of overall revenue or financial performance.

Gross Margins

In 2024, under the TSA, the portion of revenues relating to BAQSIMI® sales made by Lilly on our behalf were reported on a net basis, similar to a royalty arrangement with no amount reported as cost of revenues resulting in increased gross margins for that period. Gross margins were also impacted by lower pricing for glucagon and epinephrine multi-dose vials, both of which are higher-margin products, as well as an increase in labor costs.

The decrease in gross margins was partially offset by the increase in sales of Primatene MIST®, which is a higher-margin

product. Additionally, cost control efforts across the business partially offset the impact of pricing declines.

Selling, distribution, and marketing, and general and administrative

	Year Ended December 31,		Change	
	2025	2024	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 43,885	$ 37,802	$ 6,083	16 %
General and administrative	85,925	56,720	29,205	51 %

The increase in selling, distribution and marketing expenses was primarily due to expenses related to the expansion of our sales and marketing efforts related to BAQSIMI®, including expenses related to our co-promotion contract with MannKind, and sales efforts related to Primatene MIST®. The increase in general and administrative expense was primarily related to a legal settlement, which increased expenses by $23.1 million.

We expect that selling, distribution and marketing expenses will continue to increase due to the increase in marketing expenditures for BAQSIMI® and Primatene MIST®. Legal fees may fluctuate from period to period due to the timing of patent challenges and other litigation matters.

Research and development

	Year Ended December 31,		Change	
	2025	2024	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 34,027	$ 31,634	$ 2,393	8 %
Pre-launch inventory	960	483	477	99 %
Clinical trials	3,038	594	2,444	411 %
FDA fees	1,568	1,715	(147)	(9)%
Materials and supplies	15,157	16,813	(1,656)	(10)%
Depreciation	14,603	12,486	2,117	17 %
Other expenses[(1)]	16,491	10,189	6,302	62 %
Total research and development expenses	$ 85,844	$ 73,914	$ 11,930	16 %

(1) Includes the earnest payment and upfront payment totaling $6.0 million relating to the licensing agreement with Anji.

Research and development expenses consist primarily of costs associated with the research and development of our product candidates including the cost of developing APIs. We expense research and development costs as incurred.

Research and development expenses increased primarily due to the $6.0 million payment for the licensing agreement that we entered into with Anji in the third quarter of 2025. Additionally, we had an increase in clinical trial expense, primarily for our insulin and inhalation pipeline products, as well as an increase in depreciation expense. This was partially offset by a decrease in material and supply expenses.

We have made, and expect to continue to make, substantial investments in research and development to expand our product portfolio and grow our business. We expect that research and development expenses will increase on an annual basis due to increased clinical trials costs related to our insulin and inhalation product candidates. These expenditures will include costs of APIs developed internally as well as APIs purchased externally for use in research and development, the cost of purchasing reference listed drugs and the costs of performing the clinical trials. As we undertake new and challenging research and development projects, we anticipate that the associated costs will increase significantly over the next several quarters and years.

Non-operating expenses, net

	Year Ended December 31,		Change	
	2025	2024	Dollars	%
		(in thousands)		
Non-operating expenses:				
Interest income	$ 8,679	$ 10,612	$ (1,933)	(18)%
Interest expense	(25,481)	(30,343)	4,862	(16)%
Other income (expenses), net	23	4,076	(4,053)	(99)%
Total non-operating expenses, net	$ (16,779)	$ (15,655)	$ (1,124)	7 %

The change in non-operating expenses, net is primarily a result of:

- A decrease in interest income resulting from a decrease in interest rates on our cash and investments accounts.
- A decrease in interest expense as a result of the repayment of the mortgage loan with East West Bank, as well as the accretion of the interest on the deferred payment for BAQSIMI®, both of which were paid in full in June 2024. For more information regarding our debt, see "Part II – Item 8. Financial Statements and Supplementary Data – Notes to Consolidated Financial Statements – Note 13. Debt."
- A change to other income (expenses), net primarily as a result of foreign currency fluctuation, as well as mark-to-market adjustments relating to our interest rate swap contracts during the year ended December 31, 2025.

Income tax provision

	Year Ended December 31,		Change	
	2025	2024	Dollars	%
		(in thousands)		
Income tax provision	$ 25,530	$ 29,672	$ (4,142)	(14)%
Effective tax rate	*21 %*	*16 %*		

Our effective tax rate for the year ended December 31, 2025 increased in comparison to the year ended December 31, 2024, primarily due to lower excess tax benefit from share-based compensation. For more information regarding our income taxes, see "Part II – Item 8. Financial Statements and Supplementary Data – Notes to Consolidated Financial Statements – Note 14. – Income Taxes."

On July 4, 2025, the One Big Beautiful Bill Act, or OBBB Act, was enacted into law. The OBBB Act includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, modifications to the international tax framework and the restoration of favorable tax treatment for certain business provisions. The OBBB Act did not result in any material adjustments to our total income tax provision for the year ended December 31, 2025.

Liquidity and Capital Resources

Cash Requirements and Sources

We need capital resources to maintain and expand our business. We expect our cash requirements to increase significantly as we sponsor clinical trials for, seek regulatory approvals of, and develop, manufacture and market our current development stage product candidates and pursue strategic acquisitions of businesses or assets. Our future capital expenditures include projects to upgrade, expand, and improve our manufacturing facilities in the United States and China, including a significant increase in capital expenditures over the next few years. We plan to fund this facility expansion with cash flows from operations.

Our cash obligations include the principal and interest payments due on our existing loans, and finance and operating lease payments. In addition, upon the achievement of various development, regulatory and commercial milestones for agreements, we have entered into with third parties, we are contractually obligated to pay additional amounts that, in the aggregate, are significant. These payments are contingent upon the occurrence of various future events, substantially all

of which have a high degree of uncertainty of occurring, and any resulting cash requirements are managed through our operating budgeting processes. These obligations are not recorded on our consolidated balance sheets. As of December 31, 2025, the maximum amount that may be payable in the future for agreements we have entered into with third parties is approximately $1.0 billion. These obligations are further described below and throughout this Annual Report on Form 10-K.

As of December 31, 2025, our foreign subsidiaries collectively held $15.7 million in cash and cash equivalents. Cash or cash equivalents held at foreign subsidiaries are not available to fund the parent company's operations in the United States. We believe that our cash reserves, operating cash flows, and borrowing availability under our credit facilities will be sufficient to fund our operations for at least the next 12 months from the filing of this Annual Report on Form 10-K. We expect additional cash flows to be generated in the longer term from future product launches, although there can be no assurance as to the receipt of regulatory approval for any product candidates that we are developing or the timing of any product launches, which could be lengthy or ultimately unsuccessful.

Working capital increased $117.6 million to $477.9 million at December 31, 2025, compared to $360.3 million at December 31, 2024.

Debt and Borrowing Capacity

Our outstanding debt obligations are summarized as follows:

	December 31,		
	2025	2024	Change
		(in thousands)	
Short-term debt and current portion of long-term debt	$ 1,641	$ 234	$ 1,407
Long-term debt	608,749	601,630	7,119
Total debt	$ 610,390	$ 601,864	$ 8,526

As of December 31, 2025, we had $219.5 million in unused borrowing capacity under revolving lines of credit with Wells Fargo Bank, China Merchant Bank, and Industrial and Commercial Bank of China Limited.

The weighted average interest rates on lines of credit as of December 31, 2025 and 2024 were 3.4% and 4.0%, respectively. For our loans with Wells Fargo Bank, we have entered into fixed interest rate swap contracts to exchange the variable interest rates for fixed interest rates.

For more information regarding our outstanding indebtedness, see "Part II – Item 8. Financial Statements and Supplementary Data – Notes to Consolidated Financial Statements – Note 13. – Debt."

Contractual Obligations and Commitments

Operating Lease Obligations

As of December 31, 2025 we had a total of $55.2 million of minimum rental payments due under operating leases. Of that amount, $10.6 million is due within 12 months as of December 31, 2025. For more information regarding our operating lease obligations see "Part II – Item 8. Financial Statements and Supplementary Data – Notes to Consolidated Financial Statements –Note. 17 – Commitments and Contingencies."

Milestone Obligations

BAQSIMI®

The terms of our Purchase Agreement with Lilly require us to make future sales-based milestone payments aggregating up to $575.0 million based on achievement of specified net sales amounts. As of December 31, 2025, we have not triggered any milestones and therefore no amounts have been recognized or paid. The amount and timing of such future obligations are unknown and uncertain.

Licensing Agreement with Anji

The terms of the license agreement with Anji require us to make cash payments to Anji of up to $42.0 million in development-based milestone payments and up to $225.0 million in sales-based milestone payments, subject to the achievement of the applicable development and sales milestone events respectively. Additionally, we are obligated to make royalty payments of 5% on net sales, not to exceed a maximum annual amount of $22.5 million each calendar year for each Licensed Product and a maximum accumulated amount of $60.0 million for each of the three Licensed Products. We are also required to pay Anji a certain percentage of sublicense income received from the sublicense transactions. As of December 31, 2025, we have not triggered any milestones and therefore no amounts have been recognized or paid. The amount and timing of such future obligations are unknown and uncertain.

Purchase Obligations

We have certain purchase obligations under which we are required to make minimum payments for items including, but not limited to inventory and raw materials. As of December 31, 2025, we had an aggregate amount of approximately $37.5 million of purchase obligations.

Cash Flows

The following table summarizes our cash flow activities for the years ended December 31, 2025 and 2024.

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Statement of Cash Flow Data:		
Net cash provided by (used in)		
Operating activities	$ 156,115	$ 213,386
Investing activities	(70,332)	(124,930)
Financing activities	(67,425)	(80,953)
Effect of exchange rate changes on cash	210	(190)
Net increase in cash, cash equivalents, and restricted cash	$ 18,568	$ 7,313

Sources and Use of Cash

Operating Activities

Net cash provided by operating activities was $156.1 million for the year ended December 31, 2025, which included net income of $98.1 million. Non-cash items comprised primarily of $66.6 million of depreciation and amortization, which includes $31.6 million related to depreciation of property, plant and equipment; $25.1 million related to amortization of intangible assets; $6.5 million related to amortization of operating lease right-of-use assets; $3.4 million related to amortization of discounts, premiums, and debt issuance costs; and share-based compensation expense of $27.3 million.

Additionally, for the year ended December 31, 2025, there was a net cash outflow from changes in operating assets and liabilities of $66.0 million, which resulted primarily from increases in inventories and accounts receivable, and the net change in income tax. The increase in inventories was primarily due to the increased purchases of finished product, raw materials and components for BAQSIMI®, as we assumed full responsibility for the supply chain from Lilly. The increase in accounts receivables was primarily due to the timing of sales.

Net cash provided by operating activities was $213.4 million for the year ended December 31, 2024, which included net income of $159.5 million. Non-cash items comprised primarily of $63.2 million of depreciation and amortization, which includes $28.2 million related to depreciation of property, plant and equipment; $24.7 million related to amortization of intangible assets; $4.2 million related to amortization of operating lease right-of-use assets; $6.0 million related to amortization of discounts, premiums, and debt issuance costs; and share-based compensation expense of $24.4 million. Additionally, for the year ended December 31, 2024, there was a net cash outflow from changes in operating assets and liabilities of $14.5 million, which resulted primarily from an increase in accounts receivables, an increase in inventories, as well as an increase in prepaid expenses and other assets, which was partially offset by an increase in accounts payable and accrued liabilities. The increase in accounts receivables was primarily due to the increase in sales. The increase in

inventories was primarily due to the increased purchases of finished product, raw materials and components for BAQSIMI®. Accounts payable and accrued liabilities increased primarily due to the increase in accrued customer fees and rebates associated with BAQSIMI® sales, as we continued to assume distribution responsibilities for BAQSIMI® from Lilly to our customers in the United States and certain other countries throughout 2024.

Investing Activities

Net cash used in investing activities was $70.3 million for the year ended December 31, 2025, primarily as a result of $34.9 million in purchases of property, plant, and equipment, which included $22.3 million incurred in the United States, $3.0 million in France, and $9.6 million in China, as well as a net cash outflow of $28.8 million from sales and purchases of investments during the period.

Net cash used in investing activities was $124.9 million for the year ended December 31, 2024, primarily due to the payment of $129.0 million relating to the BAQSIMI® acquisition, $41.0 million in purchases of property, plant, and equipment, which included $16.6 million incurred in the United States, $2.9 million in France, and $21.5 million in China. This was partially offset by a net cash inflow of $49.2 million from sales and purchases of investments during the period.

Financing Activities

Net cash used in financing activities was $67.4 million for the year ended December 31, 2025, primarily as a result of $75.6 million used to purchase treasury stock. This was partially offset by $2.9 million in net proceeds from the settlement of share-based compensation awards under our equity plan, as well as $6.2 million of net proceeds from borrowings on our line of credit in China.

Net cash used in financing activities was $81.0 million for the year ended December 31, 2024, primarily as a result of $85.5 million used to purchase treasury stock and $4.9 million used to settle share-based compensation awards under our equity plan and for tax payments related to the net share settlement of options exercised. Additionally, we made $8.3 million in principal payments on our long-term debt, primarily as a result of paying off the mortgage loan with East West Bank. This was partially offset by $18.4 million of net proceeds from borrowings on our line of credit in China.

Critical Accounting Policies

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates. In some cases, changes in the accounting estimates are reasonably likely to occur from period to period. Accordingly, actual results could differ materially from our estimates. To the extent that there are material differences between these estimates and actual results, our financial condition and results of operations will be affected. We base our estimates on past experience and other assumptions that we believe are reasonable under the circumstances, and we evaluate these estimates on an ongoing basis. We refer to accounting estimates of this type as critical accounting policies, which we discuss further below. While our significant accounting policies are more fully described in Part II – Item 8. Financial Statements and Supplementary Data – Notes to Consolidated Financial Statements – Note 2. – Summary of Significant Accounting Policies", we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our audited consolidated financial statements.

Revenue Recognition

Product revenues, net

Our net revenues consist principally of revenues generated from the sale of our pharmaceutical products. Generally, we recognize revenues at the time of product delivery to our customers in accordance with ASC, 606 *Revenue from Contracts with Customers*. In some cases, revenues are recognized at the time of shipment when stipulated by the terms of the sale agreements. Revenues derived from contract manufacturing services are recognized when third-party products are shipped to customers, after the customer has accepted test samples of the products to be shipped.

The consideration we receive in exchange for our goods or services is only recognized when it is probable that a significant reversal will not occur. The consideration to which we expect to be entitled includes a stated list price, less various forms of variable consideration. We make significant estimates for related variable consideration at the point of sale, including chargebacks, rebates, product returns, other discounts and allowances.

We establish allowances for estimated chargebacks, rebates and product returns based on a number of qualitative and quantitative factors, including:

- contract pricing and return terms of our agreements with customers;
- wholesaler inventory levels and turnover;
- historical chargeback and product return rates;
- shelf lives of our products, which is generally two years;
- direct communication with customers;
- anticipated introduction of competitive products or authorized generics; and
- anticipated pricing strategy changes by us and/or our competitors.

Although we believe that our estimates and assumptions are reasonable as of the date when made, actual results may differ significantly from these estimates. Our financial position, results of operations and cash flows may be materially and negatively impacted if actual returns exceed our estimated allowances for returns.

The following table summarizes activity in each of our product revenue allowance categories for the years ended December 31, 2025 and 2024:

	Chargebacks and Rebates[1]	Product Returns[2]	Management fees and Incentives[3]
	(in thousands)		
Balance as of December 31, 2023	$ 27,920	$ 17,179	$ 14,483
Provisions	298,230	9,597	62,939
Credits and payments issued to third parties	(260,361)	(6,917)	(60,166)
Balance as of December 31, 2024	$ 65,789	$ 19,859	$ 17,256
Provisions	452,070	19,963	72,581
Credits and payments issued to third parties	(433,828)	(15,746)	(71,612)
Balance as of December 31, 2025	$ 84,031	$ 24,076	$ 18,225

(1) Chargeback and Rebates include chargebacks, managed care rebates, GPO rebates, government rebates, and co-pay program incentives. Chargeback and rebates were deducted from gross revenue at the time revenues were recognized and were recorded as a reduction to accounts receivables, net and accounts payable and accrued liabilities on our consolidated balance sheets.

(2) Estimated provisions for product returns were deducted from gross revenues at the time revenues were recognized and are included in accounts payable and accrued liabilities and other long-term liabilities on our consolidated balance sheets.

(3) Management fees and incentives include management and GPO fees and sales incentives and allowances, which were deducted from gross revenues at the time revenues were recognized and were recorded as accounts payable and accrued liabilities on our consolidated balance sheets.

Recent Accounting Pronouncements

In December 2023, the Financial Accounting Standard Board, or FASB, issued Accounting Standard Update, or ASU, 2023-09, *Income taxes (Topic 740): Improvements to Income Tax Disclosures,* which requires entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation table, as well as disclosure of income taxes paid disaggregated by jurisdiction. The disclosure requirements will be applied prospectively. We adopted this guidance on December 31, 2025 and updated our disclosures to conform to this tax disclosure requirements. The adoption of this guidance did not have a material impact on our consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement Reporting-Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40), Disaggregation of Income Statement Expenses.* The standard update improves the disclosures about a public business entity's expenses by requiring more detailed information about the types of expenses (including purchases of inventory, employee compensation, depreciation and amortization) included within income statement expense captions. The guidance will be effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. The standard updates are to be applied prospectively with the option for retrospective application. We are currently evaluating the impact of disclosure requirements related to the new standard on our consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-04, *Debt– Debt with Conversion and Other Options, (subtopic 470-20).* The update is intended to improve the relevance and consistency in application of the induced conversion guidance in Subtopic 470-20 for (a) convertible debt instruments with cash conversion features and (b) debt instruments that are not currently convertible. ASU 2024-04 is effective for annual reporting periods beginning after December 15, 2025. We are currently evaluating the impact of the new standard on our consolidated financial statements and related disclosures.

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.* The ASU amends the existing standard to remove all references to prescriptive and sequential software development project stages. Under this guidance, eligible software development costs will begin to be capitalized when management has authorized and committed to funding the software project, and it is probable that the project will be completed and the software will be used to perform the function intended. In evaluating whether it is probable the project will be completed; management is required to consider whether there is significant uncertainty associated with the development activities of the software. This guidance is effective for all annual periods beginning after December 15, 2027, and for interim periods within those annual reporting periods, with early adoption permitted. The guidance may be applied on a prospective basis, a modified basis for in-process projects, or a retrospective basis. We are currently evaluating the impact of the new standard on our consolidated financial statements and related disclosures.

Government Regulation

Our products and facilities are subject to regulation by a number of federal and state governmental agencies. The FDA in particular, maintains oversight of the formulation, manufacture, distribution, packaging, and labeling of all of our products. The Drug Enforcement Administration, or DEA, maintains oversight over our products that are considered controlled substances.

Our manufacturing facilities as well as our CMOs are subject to periodic inspection by the FDA to ensure that they are operating in compliance with cGMP requirements. We believe that as of December 31, 2025, all of our manufacturing facilities and our CMOs are in compliance with all applicable regulations of federal and state governmental agencies, including all those of the FDA and DEA. Throughout 2025, we had inspections conducted by various regulatory agencies at some of our manufacturing facilities, which resulted in no critical observations.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

The following discussion provides forward-looking quantitative and qualitative information about our potential exposure to market risk. Market risk represents the potential loss arising from adverse changes in the value of financial instruments. The risk of loss is assessed based on the likelihood of adverse changes in fair values, cash flows or future earnings. We are exposed to market risk for changes in the market values of our investments (Investment Risk), the impact of interest rate changes (Interest Rate Risk), and the impact of foreign currency exchange changes (Foreign Currency Exchange Risk).

Investment Risk

We regularly review the carrying value of our investments and identify and recognize losses, for income statement purposes, when events and circumstances indicate that any declines in the fair values of such investments below our accounting basis are other than temporary. As of December 31, 2025, none of our investments experienced any declines in fair value that we believe are other than temporary. We do not enter into investments for trading or speculative purposes.

As of December 31, 2025, we had $11.2 million deposited in six banks located in China, $3.8 million deposited in one bank located in France, and $0.7 million deposited in one bank located in the United Kingdom. We also maintained $111.4 million in cash equivalents that include money market accounts as of December 31, 2025. Additionally, we maintain approximately $96.1 million in investment grade corporate and municipal bonds as of December 31, 2025. The remaining amounts of our cash equivalents as of December 31, 2025, are in non-interest bearing accounts.

As of December 31, 2024, we had $6.7 million deposited in six banks located in China, $1.8 million deposited in one bank located in France, and $0.7 million deposited in one bank located in the United Kingdom. We also maintained $102.1 million in cash equivalents that include money market accounts as of December 31, 2024. Additionally, we maintain approximately $54.4 million in investment grade corporate and municipal bonds as of December 31, 2024. The remaining amounts of our cash equivalents as of December 31, 2024, are in non-interest bearing accounts.

We maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits. Interest bearing and non-interest bearing accounts we hold at banking institutions are guaranteed by the Federal Deposit Insurance Corporation, or FDIC, up to $250,000. Substantially all of our cash balances held at banking institutions are in excess of FDIC coverage. We consider this to be a normal business risk.

Interest Rate Risk

Our primary exposure to market risk is interest rate sensitive investments and credit facilities, which are affected by changes in the general level of U.S. interest rates. Due to the nature of our short-term investments, we believe that we are not subject to any material interest rate risk with respect to our short-term investments. In an effort to manage interest-rate exposures, we may enter into derivative contracts to achieve an acceptable balance between fixed- and floating-rate debt.

As of December 31, 2025, we had $610.4 million in long-term debt and finance leases outstanding, all of which have either a fixed interest rate or are locked-in fixed interest rates through swap contracts.

As of December 31, 2024, we had $601.9 million in long-term debt and finance leases outstanding, all of which have either a fixed interest rate or are locked-in fixed interest rates through swap contracts.

For more information regarding our debt agreements and interest rate swap contracts, see “Part II – Item 8. Financial Statements and Supplementary Data – Notes to Consolidated Financial Statements – Note 13. – Debt.”

Foreign Currency Exchange Risk

Our products are primarily sold in the U.S. domestic market, and have little exposure to foreign currency price fluctuations. Our operations in France are exposed to market risk related to changes in foreign currency exchange rates, because our sales contracts are frequently denominated in euros, which are subject to fluctuations relative to the USD.

Our Chinese subsidiary, ANP, maintains its books of record in Chinese yuan. These books are remeasured into the functional currency of USD, using the current or historical exchange rates. The resulting currency remeasurement adjustments and other transactional foreign exchange gains and losses are reflected in our consolidated statement of operations.

Our French subsidiary, AFP, maintains its books of record in euros. AUK's subsidiary, IMS UK, maintains its books of record in British pounds. These local currencies have been determined to be the subsidiaries' respective functional currencies. Activities in the statements of operations are translated to USD using average exchange rates during the period. Assets and liabilities are translated at the rate of exchange prevailing on the balance sheet date. Equity is translated at the prevailing rate of exchange at the date of the equity transactions. Translation adjustments are reflected in stockholders' equity and are included as a component of other accumulated comprehensive income (loss). The unrealized gains or losses of intercompany foreign currency transactions that are of a long-term investment nature are reported in other accumulated comprehensive income (loss).

We are also exposed to the potential earnings effects from intercompany foreign currency assets and liabilities that arise from normal trade receivables and payables and other intercompany loans.

As of December 31, 2025, a theoretical 10% unfavorable change in the exchange rate of the U.S. dollar strengthening against the foreign currencies to which we have exposure would result in approximately $0.1 million reduction of foreign currency gains, and approximately $3.6 million reduction in other comprehensive income.

As of December 31, 2024, a theoretical 10% unfavorable change in the exchange rate of the U.S. dollar strengthening against the foreign currencies to which we have exposure would result in approximately $1.2 million reduction of foreign currency gains, and approximately $3.1 million reduction in other comprehensive income.

As of December 31, 2025 and 2024, our foreign subsidiaries had cash balances denominated in foreign currencies in the amount of $7.7 million and $6.6 million, respectively.

Item 8. Financial Statements and Supplementary Data.

Index to Amphastar Pharmaceuticals, Inc. Consolidated Financial Statements

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Amphastar Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Amphastar Pharmaceuticals, Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive income, stockholders' equity 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.

Reserves for chargebacks and rebates

Description of the Matter	The Company's reserves for chargebacks and rebates totaled $79.2 million at December 31, 2025. As described in Note 3 to the consolidated financial statements, the Company estimates chargebacks and rebates using the expected value method at the time of sale to customers based on inventory stocking levels, historical chargeback and rebate rates, and current contract pricing. Auditing the estimates for chargebacks and rebates was complex due to the judgmental nature of the assumptions used. In particular, for product that remains in the distribution channel at December 31, 2025, management is required to estimate the applicable rates that are utilized to calculate the ending chargebacks and rebate reserves.

How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls over the chargebacks reserve estimation process. This included testing controls over management's review of significant assumptions and inputs used for the chargebacks reserve estimate, including actual sales, historical experience, wholesaler inventory levels, and contract pricing. To test the reserve for chargebacks, we evaluated the reasonableness of the applicable chargebacks rate by comparing rates at different time periods, including historical and subsequent periods, and performing sensitivity analyses over those rates. We evaluated subsequent activity to assess whether there was any new information that would require adjustment to the reserve. To test the reserve for rebates, we assessed the reasonableness of management's rebate rates assumptions by evaluating the historical trends, developing an independent range of the assumptions, and testing a sample of rebate payments. We also evaluated subsequent activity to assess whether there was any new information that would require adjustment to the reserve.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1998.

Irvine, California

February 26, 2026

AMPHASTAR PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 170,177	$ 151,609
Restricted cash	235	235
Short-term investments	112,635	70,036
Restricted short-term investments	2,200	2,200
Accounts receivable, net	143,560	136,289
Inventories	176,890	153,741
Income tax refunds and deposits	17,167	1,747
Prepaid expenses and other assets	13,152	18,214
Total current assets	636,016	534,071
Property, plant, and equipment, net	310,567	297,345
Finance lease right-of-use assets	221	383
Operating lease right-of-use assets	42,931	46,899
Goodwill and intangible assets, net	565,965	590,660
Long-term investments	—	10,996
Other assets	31,135	25,992
Deferred tax assets	42,464	71,124
Total assets	$ 1,629,299	$ 1,577,470
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 148,348	$ 157,057
Income taxes payable	239	9,664
Current portion of long-term debt	1,641	234
Current portion of operating lease liabilities	7,928	6,804
Total current liabilities	158,156	173,759
Long-term reserve for income tax liabilities	5,926	6,957
Long-term debt, net of current portion and unamortized debt issuance costs	608,749	601,630
Long-term operating lease liabilities, net of current portion	37,684	41,881
Other long-term liabilities	29,979	20,945
Total liabilities	840,494	845,172
Commitments and contingencies (see Note 17)		
Stockholders' equity:		
Preferred stock: par value $0.0001; 20,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock: par value $0.0001; 300,000,000 shares authorized; 61,779,883 and 45,645,497 shares issued and outstanding, respectively, as of December 31, 2025 and 60,847,124 and 47,617,691 shares issued and outstanding, respectively, as of December 31, 2024	6	6
Additional paid-in capital	535,380	505,400
Retained earnings	666,881	568,787
Accumulated other comprehensive loss	(5,314)	(9,181)
Treasury stock	(408,148)	(332,714)
Total stockholders' equity	788,805	732,298
Total liabilities and stockholders' equity	$ 1,629,299	$ 1,577,470

See accompanying notes to consolidated financial statements.

AMPHASTAR PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Year Ended December 31,		
	2025	2024	2023
Net revenues:			
Product revenues, net	$ 719,887	$ 712,814	$ 593,238
Other revenues	—	19,153	51,157
Total net revenues	719,887	731,967	644,395
Cost of revenues	363,830	358,112	293,274
Gross profit	356,057	373,855	351,121
Operating expenses:			
Selling, distribution, and marketing	43,885	37,802	28,853
General and administrative	85,925	56,720	51,540
Research and development	85,844	73,914	73,741
Total operating expenses	215,654	168,436	154,134
Income from operations	140,403	205,419	196,987
Non-operating expenses:			
Interest income	8,679	10,612	5,459
Interest expense	(25,481)	(30,343)	(27,158)
Other income (expenses), net	23	4,076	(3,929)
Total non-operating expenses, net	(16,779)	(15,655)	(25,628)
Income before income taxes	123,624	189,764	171,359
Income tax provision	25,530	29,672	31,833
Income before equity in losses of unconsolidated affiliate	98,094	160,092	139,526
Equity in losses of unconsolidated affiliate	—	(573)	(1,981)
Net income	$ 98,094	$ 159,519	$ 137,545
Net income per share:			
Basic	$ 2.10	$ 3.29	$ 2.85
Diluted	$ 2.03	$ 3.06	$ 2.60
Weighted-average shares used to compute net income per share:			
Basic	46,743	48,429	48,265
Diluted	48,215	52,058	53,001

See accompanying notes to consolidated financial statements.

AMPHASTAR PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(in thousands)

	Year Ended December 31,		
	2025	2024	2023
Net income	$ 98,094	$ 159,519	$ 137,545
Other comprehensive income (loss), net of income taxes			
Foreign currency translation adjustment	3,867	(695)	298
Change in pension obligations	—	(8)	(152)
Total other comprehensive income (loss)	3,867	(703)	146
Total comprehensive income	$ 101,961	$ 158,816	$ 137,691

See accompanying notes to consolidated financial statements.

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

	Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive loss	Treasury Stock		Total
	Shares	Amount				Shares	Amount	
Balance as of December 31, 2022	58,110,231	$ 6	$ 455,077	$ 271,723	$ (8,624)	(9,998,162)	$ (189,524)	$ 528,658
Net income	—	—	—	137,545	—	—	—	137,545
Other comprehensive income	—	—	—	—	146	—	—	146
Purchase of treasury stock	—	—	—	—	—	(1,338,757)	(58,144)	(58,144)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(237)	—	—	15,606	237	—
Issuance of common stock in connection with the Company's equity plans	1,279,963	—	10,974	—	—	—	—	10,974
Share-based compensation expense	—	—	20,242	—	—	—	—	20,242
Balance as of December 31, 2023	59,390,194	$ 6	$ 486,056	$ 409,268	$ (8,478)	(11,321,313)	$ (247,431)	$ 639,421
Net income	—	—	—	159,519	—	—	—	159,519
Other comprehensive loss	—	—	—	—	(703)	—	—	(703)
Purchase of treasury stock	—	—	—	—	—	(1,919,670)	(85,458)	(85,458)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(175)	—	—	11,550	175	—
Issuance of common stock in connection with the Company's equity plans	1,456,930	—	(4,849)	—	—	—	—	(4,849)
Share-based compensation expense	—	—	24,368	—	—	—	—	24,368
Balance as of December 31, 2024	60,847,124	$ 6	$ 505,400	$ 568,787	$ (9,181)	(13,229,433)	$ (332,714)	$ 732,298
Net income	—	—	—	98,094	—	—	—	98,094
Other comprehensive income	—	—	—	—	3,867	—	—	3,867
Purchase of treasury stock	—	—	—	—	—	(2,915,580)	(75,586)	(75,586)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(152)	—	—	10,627	152	—
Issuance of common stock in connection with the Company's equity plans	932,759	—	2,855	—	—	—	—	2,855
Share-based compensation expense	—	—	27,277	—	—	—	—	27,277
Balance as of December 31, 2025	61,779,883	$ 6	$ 535,380	$ 666,881	$ (5,314)	(16,134,386)	$ (408,148)	$ 788,805

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2025	**2024**	**2023**
Cash Flows From Operating Activities:			
Net income	$ 98,094	$ 159,519	$ 137,545
Reconciliation to net cash provided by operating activities:			
Loss on disposal of assets	39	9	475
Impairment of long-lived assets	—	—	2,700
Loss (gain) on interest rate swaps and foreign currency transactions, net	2,492	(2,792)	5,330
Depreciation of property, plant, and equipment	31,647	28,249	25,205
Amortization of intangible assets	25,048	24,718	12,830
Operating lease right-of-use asset amortization	6,506	4,238	3,742
Amortization of discounts, premiums, and debt issuance costs	3,355	6,032	11,399
Equity in losses of unconsolidated affiliate	—	573	1,981
Share-based compensation expense	27,277	24,368	20,242
Changes in reserve for uncertain tax positions	(1,032)	891	(1,159)
Changes in deferred taxes, net	28,660	(17,872)	(12,578)
Changes in operating assets and liabilities:			
Accounts receivable, net	(6,367)	(21,671)	(26,086)
Inventories	(21,063)	(48,797)	(1,724)
Prepaid expenses and other assets	(3,530)	(10,726)	(2,728)
Income tax refunds, deposits, and payable, net	(24,843)	6,834	(3,319)
Operating lease liabilities	(5,609)	(3,750)	(3,589)
Accounts payable and accrued liabilities	(4,559)	63,563	13,237
Net cash provided by operating activities	156,115	213,386	183,503
Cash Flows From Investing Activities:			
BAQSIMI® acquisition	—	(129,000)	(506,406)
Purchases and construction of property, plant, and equipment	(34,882)	(41,041)	(38,166)
Purchase of intangible assets	(2,250)	—	—
Purchase of investments	(119,130)	(76,792)	(144,556)
Maturity of investments	90,291	126,022	38,622
Deposits and other assets	(4,361)	(4,119)	1,390
Net cash used in investing activities	(70,332)	(124,930)	(649,116)
Cash Flows From Financing Activities:			
Proceeds from equity plans, net of withholding tax payments	2,855	(4,849)	10,974
Purchase of treasury stock	(75,586)	(85,458)	(58,144)
Debt issuance costs	(687)	(816)	(25,079)
Proceeds from borrowing under lines of credit	6,216	18,433	—
Proceeds from issuance of long-term debt	—	—	845,000
Principal payments on long-term debt	(223)	(8,263)	(318,658)
Net cash provided by (used in) financing activities	(67,425)	(80,953)	454,093
Effect of exchange rate changes on cash	210	(190)	(282)
Net increase (decrease) in cash, cash equivalents, and restricted cash	18,568	7,313	(11,802)
Cash, cash equivalents, and restricted cash at beginning of period	151,844	144,531	156,333
Cash, cash equivalents, and restricted cash at end of period	$ 170,412	$ 151,844	$ 144,531
Noncash Investing and Financing Activities:			
Deferred payment for BAQSIMI® acquisition	$ —	$ —	$ 121,699
Capital expenditures included in accounts payable	$ 7,741	$ 5,622	$ 4,454
Operating lease right-of-use assets in exchange for operating lease liabilities	$ 2,537	$ 18,804	$ 10,521
Supplemental Disclosures of Cash Flow Information:			
Interest paid, net of capitalized interest	$ 23,218	$ 26,811	$ 17,573
Income taxes paid	$ 22,710	$ 40,104	$ 49,001

See accompanying notes to consolidated financial statements

AMPHASTAR PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Business

Amphastar Pharmaceuticals, Inc., a Delaware corporation (together with its subsidiaries, hereinafter referred to as the "Company"), is a biopharmaceutical company that focuses on developing, manufacturing, and commercializing technically challenging generic and proprietary injectable, inhalation, and intranasal products, including products with high technical barriers to market entry. Additionally, the Company sells active pharmaceutical ingredient, or API, products. Most of the Company's products are contracted and distributed through group purchasing organizations, drug wholesalers, and drug retailers. The Company's insulin API products are sold to other pharmaceutical companies for use in their own products and are being used by the Company in the development of injectable pharmaceutical products.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its subsidiaries, and are prepared in accordance with United States generally accepted accounting principles, or GAAP. All intercompany activity has been eliminated in the preparation of the consolidated financial statements. In the opinion of management, the accompanying consolidated financial statements include all adjustments, which are of a normal recurring nature, necessary to present fairly the consolidated financial position, results of operations, and cash flows of the Company.

The Company's subsidiaries include: (1) International Medication Systems, Limited, or IMS, (2) Armstrong Pharmaceuticals, Inc., or Armstrong, (3) Amphastar Nanjing Pharmaceuticals Inc., or ANP, (4) Amphastar France Pharmaceuticals, S.A.S., or AFP, (5) Amphastar UK Ltd., or AUK, and (6) International Medication Systems (UK) Limited, or IMS UK.

Investment in Unconsolidated Affiliate

The Company applies the equity method of accounting for investments when it has significant influence, but not controlling interest in the investee. The Company's proportionate share of the earnings or losses resulting from these investments is reported as "Equity in losses of unconsolidated affiliate" in the accompanying consolidated statements of operations. Investments accounted for using the equity method may be reported on a lag of up to three months if financial statements of the investee are not available in sufficient time for the investor to apply the equity method as of the current reporting date.

The Company's equity method investments are reported at cost and adjusted each period for the Company's share of the investee's earnings or losses and dividends paid, if any.

Use of Estimates

The preparation of the consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates. The principal accounting estimates include: fair value of financial instruments, allowance for credit losses, discounts, chargebacks and rebates, product returns, adjustment of inventory to its net realizable value, impairment of investments, long-lived and intangible assets and goodwill, litigation reserves, stock price volatility for share-based compensation expense, valuation allowances for deferred tax assets, and liabilities for uncertain income tax positions.

Foreign Currency

The functional currency of the Company, its domestic subsidiaries, its Chinese subsidiary ANP, and its U.K. subsidiary, AUK, is the U.S. Dollar, or USD. ANP maintains its books of record in Chinese yuan. These books are remeasured into the functional currency of USD using the current or historical exchange rates. The resulting currency remeasurement

adjustments and other transactional foreign currency exchange gains and losses are reflected in the Company's accompanying consolidated statements of operations.

The Company's French subsidiary, AFP, maintains its books of record in euros. AUK's subsidiary, IMS UK, maintains its books of record in British pounds. These local currencies have been determined to be the subsidiaries' respective functional currencies. Activities in the statements of operations are translated to USD using average exchange rates during the period. Assets and liabilities are translated at the rate of exchange prevailing on the balance sheet date. Equity is translated at the prevailing rate of exchange at the date of the equity transactions. Translation adjustments are reflected in stockholders' equity and are included as a component of other comprehensive income. The unrealized gains or losses of intercompany foreign currency transactions that are of a long-term investment nature are reported in other accumulated comprehensive income.

The unrealized gains and losses of intercompany foreign currency transactions that are of a long-term investment nature for the years ended December 31, 2025, 2024, and 2023 were a $4.0 million gain, a $1.9 million loss, and a $1.1 million gain, respectively.

Comprehensive Income

The Company's comprehensive income includes its foreign currency translation gains and losses and changes in pension obligations.

Acquisitions

The Company evaluates acquisitions and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether or not the Company has acquired inputs and substantive processes that have the ability to create outputs, which would meet the definition of a business.

Acquisitions meeting the definition of business combinations are accounted for using the acquisition method of accounting, which requires that the purchase price be allocated to the net assets acquired at their respective fair values. In a business combination, any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

For asset acquisitions, a cost accumulation model is used to determine the cost of an asset acquisition. Direct transaction costs are recognized as part of the cost of an asset acquisition. The cost of an asset acquisition, including transaction costs, is allocated to identifiable assets acquired and liabilities assumed based on a relative fair value basis, with the exception of non-qualifying assets. Goodwill is not recognized in an asset acquisition. When a transaction accounted for as an asset acquisition includes an in-process research and development, or IPR&D, asset, the IPR&D asset is only capitalized if it has an alternative future use other than in a particular research and development project. Asset acquisitions may include contingent consideration arrangements that encompass obligations to make future payments to sellers contingent upon the achievement of future financial targets. Contingent consideration, including assumed contingent considerations, is not recognized until all contingencies are resolved and the consideration is paid or becomes payable (unless contingent considerations meets the definition of a derivative, in which case the amount becomes part of the basis in the asset acquired), at which point the consideration is allocated to the assets acquired based on their relative fair values at the acquisition date, with the exception of non-qualifying assets.

Judgments are used in determining estimates of useful lives of long-lived assets. Useful life estimates are based on, among other factors, estimates of expected future net cash flows, the assessment of each asset's life cycle, and the impact of competitive trends on each asset's life cycle and other factors. These judgments can materially impact the estimates used to allocate purchase consideration to assets acquired and liabilities assumed, and the resulting timing and amounts

charged to or recognized in current and future operating results. For these and other reasons, actual results may vary significantly from estimated results.

Shipping and Handling Costs

For the years ended December 31, 2025, 2024, and 2023, the Company included shipping and handling costs of approximately $8.1 million, $8.0 million and $7.0 million, respectively, in selling, distribution and marketing expenses in the accompanying consolidated statements of operations.

Advertising Expense

Advertising expenses, primarily associated with Primatene MIST®, are recorded as they are incurred, except for expenses related to the development of a major commercial or media campaign, which are expensed in the period in which the commercial or campaign is first presented, and are reflected as a component of selling, distribution and marketing in the Company's consolidated statements of operations. For the years ended December 31, 2025, 2024, and 2023, advertising expenses were $10.2 million, $10.5 million, and $10.4 million, respectively.

Research and Development Costs

Research and development costs are charged to expense as incurred and consist of costs incurred to further the Company's research and development activities. These include salaries and related employee benefits, costs associated with clinical trials, nonclinical research and development activities, regulatory activities, license fees, milestone payments upon the achievement of clinical, or regulatory events, materials, supplies, research-related overhead expenses and fees paid to external service providers.

The Company has entered into, and may continue to enter into, license agreements to access and utilize certain technology. In each case, the Company evaluates if the license agreement results in the acquisition of an asset or a business. To date, none of the Company's license agreements have been considered an acquisition of a business. For asset acquisitions, the upfront payments to acquire such licenses, as well as any future milestone payments made before product approval that do not meet the definition of a derivative, are immediately recognized as research and development expense in the statements of operations when paid or become payable, provided there is no alternative future use of rights in other research and development projects.

Financial Instruments

The Company's accompanying consolidated balance sheets include the following financial instruments: cash and cash equivalents, restricted cash, accounts receivable, accounts payable, accrued liabilities, short-term borrowings and long-term obligations. The Company considers the carrying amounts of current assets and liabilities on the consolidated balance sheets to approximate the fair value of these financial instruments due to the short maturity of these items. The carrying value of the Company's long-term obligations, with the exception of the convertible debt (See Note 13) approximates their fair value, as the stated borrowing rates are comparable to rates currently offered to the Company for instruments with similar maturities. The Company at times enters into interest rate swap contracts to manage its exposure to interest rate changes and its overall cost of long-term debt. The Company's interest rate swap contracts exchange the variable interest rates for fixed interest rates.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash, money market accounts, certificates of deposit and highly liquid investments with original maturities of three months or less.

AMPHASTAR PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Investments

Investments as of December 31, 2025 and 2024 consisted of certificates of deposit and investment grade corporate, agency, and municipal bonds with original maturity dates between three and thirty-six months.

Restricted Cash

Restricted cash is collateral required for the Company to guarantee certain vendor payments in France. As of December 31, 2025 and 2024, the restricted cash balance was $0.2 million.

Restricted Short-Term Investments

Restricted short-term investments consist of certificates of deposit that are collateral for standby letters of credit to qualify for workers' compensation self-insurance. The certificates of deposit have original maturities greater than three months, but less than one year. As of December 31, 2025 and 2024, the balance of restricted short-term investments was $2.2 million.

Accounts receivable and Allowance for Credit Losses

Accounts receivable generally consists of amounts due from the Company's customers, which primarily includes pharmaceutical wholesalers and drug retailers. Accounts receivable is recorded net of discounts, chargebacks, allowances and other adjustments. The Company evaluates the collectability of accounts receivable based on a combination of factors. When the Company is aware of circumstances that may impair a customer's ability to pay subsequent to the original sale, the Company records a specific allowance to reduce the amounts receivable to the amount that the Company reasonably believes to be collectable. For all other customers, the Company recognizes an allowance for credit losses based on factors that include the length of time the receivables are past due, industry and geographic concentrations, the current economic conditions and historical collection experience. As of December 31, 2025 and 2024, the Company's allowance for credit losses was $3.3 million and $3.5 million, respectively.

Inventories

Inventories consist of currently marketed products. The Company states inventory at the lower of cost or net realizable value. Cost is determined in a manner that approximates the first-in, first-out method. Provisions are made for slow moving, unsellable, or obsolete items. Net realizable value is determined using the estimated selling price, in the ordinary course of business, less estimated costs to complete and dispose.

The Company may produce or purchase inventories prior to or with the expectation of receiving regulatory approval in the near term, based on operational decisions about the most effective use of existing resources. This inventory is referred to as pre-launch inventory. It is the Company's accounting policy that the pre-launch inventory is capitalized if it has a probable future economic benefit at the time it is purchased or manufactured. If regulatory approval is received and previously expensed pre-launch inventory is sold, such sales may contribute up to a 100% margin to the Company's operating results. Pre-launch inventory costs include cost of work in process, materials, and finished drug products. For the years ended December 31, 2025, 2024, and 2023, the Company did not have material capitalized pre-launch inventory.

AMPHASTAR PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Property, Plant and Equipment

Property, plant and equipment are stated at cost or, in the case of assets acquired in a business combination, at fair value on the purchase date. Depreciation and amortization expense is computed using the straight-line method over the estimated useful lives of the related assets as follows:

Buildings	20 - 31 years
Machinery and equipment	3 - 12 years
Furniture and fixtures	3 - 7 years
Automobiles	4 - 5 years
Leasehold improvements	Lesser of remaining lease term or useful life

Intangible Assets, net

The evaluation of intangible assets includes assessing the amortization period for which the asset is expected to contribute to future cash flows of the Company. Intangible assets with finite lives are amortized primarily on a straight-line basis over the period the asset is expected to contribute directly or indirectly to the future cash flows of the Company as follows:

Product rights	10 - 24 years
Land-use rights	37 - 50 years
Other intangibles	6 - 20 years

Impairment of Long-Lived Assets, including Identifiable Definite-Lived Intangible Assets

The Company assesses long-term and identifiable definite-lived intangible assets or asset groups for impairment when events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. If the sum of the expected future undiscounted cash flows is less than the carrying amount of the asset or asset group, further impairment analysis is performed. An impairment loss is measured as the amount by which the carrying amount of the asset or asset groups exceeds the fair value (assets to be held and used) or fair value less cost to sell (assets to be disposed of). The Company also assesses the useful lives of its assets periodically to determine whether events and circumstances warrant a revision to the remaining useful life. Changes in the useful life are adjusted prospectively by revising the remaining period over which the asset is amortized.

Deferred Income Taxes

The Company utilizes the liability method of accounting for income taxes, under which deferred taxes are determined based on the temporary differences between the financial statements and the tax basis of assets and liabilities using enacted tax rates. A valuation allowance is recorded when it is more likely than not that the deferred tax assets will not be realized.

Debt Issuance Costs

Debt issuance costs related to non-revolving debt are recognized as a reduction to the related debt balance in the accompanying consolidated balance sheets and amortized to interest expense over the contractual term of the related debt using the effective interest method. Debt issuance costs associated with revolving debt are capitalized within other long-term assets on the consolidated balance sheets and are amortized to interest expense over the term of the related revolving debt.

Convertible Debt

The Company accounts for its convertible debt instruments as a single unit of account, a liability, because the Company

AMPHASTAR PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

concluded that the conversion features do not require bifurcation as a derivative under Accounting Standards Codification, or ASC, 815-15, *Derivatives and Hedging* and the Company did not issue its convertible debt instruments at a substantial premium.

In accordance with Accounting Standards Update, or ASU, 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)*: *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, the Company evaluates convertible debt instruments to determine if the conversion feature is freestanding or embedded. If the conversion feature does not require derivative treatment under ASC 815, the instrument is evaluated under ASC 470-20, "*Debt with Conversion and Other Options"* for consideration of any beneficial conversion features. If no beneficial conversion features exist that require separate recognition, convertible debt instruments are accounted for as a single liability measured at its amortized cost as long as no other features require separation and recognition as derivatives.

Capitalized Software Implementation Costs

The Company capitalizes certain software implementation costs incurred under a cloud computing arrangement that is a service contract. Costs incurred during the preliminary project phase or planning and research phase are expensed as incurred. Costs incurred during the application development stage related to the implementation of the hosting arrangement are capitalized and included within other assets on the accompanying consolidated balance sheets. Capitalized implementation costs are amortized on a straight-line basis over the term of the associated hosting arrangement when ready for its intended use. Capitalized implementation costs were $6.8 million as of December 31, 2025 and are included in other long-term assets in the Company's consolidated balance sheet. As of December 31, 2024, the Company did not have any capitalized implementation costs. For the years ended December 31, 2025 and 2024, the Company did not record any amortization expense for capitalized implementation costs.

Impairment of Indefinite-Lived Intangible Asset and Goodwill

The Company assesses indefinite lived intangible asset and goodwill for impairment in the fourth quarter of each year or more frequently if indicators of impairment are present. When the Company chooses to perform a qualitative assessment, it evaluates economic, industry and company-specific factors as an initial step. If the Company determines it is more likely than not that the indefinite-lived intangible asset is impaired or the fair value of a reporting unit is less than its carrying amount, further quantitative impairment testing is then performed; otherwise, no further testing is required. An impairment loss is recorded if the asset's fair value is less than its carrying value. The Company also periodically assesses its indefinite-lived intangible asset to determine if events and circumstances continue to support an indefinite useful life. If the life is no longer indefinite, the asset is tested for impairment. The carrying value, after recognition of any impairment loss, is amortized over its remaining useful life.

Self-Insured Claims

The Company is self-insured, up to certain limits, for workers' compensation claims. The Company has purchased stop-loss insurance, which will reimburse the Company for individual claims in excess of $350,000 or aggregate minimum attachment of $5.4 million annually. The cost of claims reported and an estimate of claims incurred but not reported are charged to operating expenses. A liability for unpaid claims and the associated claim expenses, including incurred but not reported losses, is actuarially determined and reflected in accrued liabilities in the accompanying consolidated balance sheets. Total expense under the program was approximately $2.7 million, $2.0 million, and $1.7 million, for the years ended December 31, 2025, 2024, and 2023, respectively. The self-insured claims liability was $6.4 million and $5.2 million at December 31, 2025 and 2024, respectively. The determination of such claims and expenses and the appropriateness of the related liability is reviewed periodically and updated, as necessary. Changes in estimates are recorded in the period identified.

AMPHASTAR PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Litigation, Commitments and Contingencies

Litigation, commitments and contingencies are accrued when management, after considering the facts and circumstances of each matter as then known, has determined it is probable a liability will be found to have been incurred and the amount of the loss can be reasonably estimated. When only a range of amounts is reasonably estimable and no amount within the range is more likely than another, the low end of the range is recorded. Legal fees are expensed as incurred. Due to the inherent uncertainties surrounding gain contingencies, the Company generally does not recognize potential gains until they are realized.

Recent Accounting Pronouncements

In December 2023, the Financial Accounting Standard Board, or FASB, issued ASU 2023-09, *Income taxes (Topic 740): Improvements to Income Tax Disclosures,* which requires entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation table, as well as disclosure of income taxes paid disaggregated by jurisdiction. The disclosure requirements will be applied prospectively. The Company adopted this guidance on December 31, 2025 and updated its disclosures to conform to this tax disclosure requirements. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement Reporting-Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40), Disaggregation of Income Statement Expenses.* The standard update improves the disclosures about a public business entity's expenses by requiring more detailed information about the types of expenses (including purchases of inventory, employee compensation, depreciation and amortization) included within income statement expense captions. The guidance will be effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The standard updates are to be applied prospectively with the option for retrospective application. The Company is currently evaluating the impact of disclosure requirements related to the new standard on the Company's consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-04, *Debt– Debt with Conversion and Other Options, (subtopic 470-20).* The update is intended to improve the relevance and consistency in application of the induced conversion guidance in Subtopic 470-20 for (a) convertible debt instruments with cash conversion features and (b) debt instruments that are not currently convertible. ASU 2024-04 is effective for annual reporting periods beginning after December 15, 2025. The Company is currently evaluating the impact of the new standard on the Company's consolidated financial statements and related disclosures.

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.* The ASU amends the existing standard to remove all references to prescriptive and sequential software development project stages. Under this guidance, eligible software development costs will begin to be capitalized when management has authorized and committed to funding the software project, and it is probable that the project will be completed and the software will be used to perform the function intended. In evaluating whether it is probable the project will be completed; management is required to consider whether there is significant uncertainty associated with the development activities of the software. This guidance is effective for all annual periods beginning after December 15, 2027, and for interim periods within those annual reporting periods, with early adoption permitted. The guidance may be applied on a prospective basis, a modified basis for in-process projects, or a retrospective basis. The Company is currently evaluating the impact of the new standard on the Company's consolidated financial statements and related disclosures.

AMPHASTAR PHARMACEUTICALS, INC.
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Note 3. Revenue Recognition

Product revenues, net

In accordance with ASC *606 Revenue from Contracts with Customers*, revenue is recognized at the time that the Company's customers obtain control of the promised goods and we satisfy the Company's performance obligations, which is generally at the time of product delivery to the Company's customers. In some cases, the Company's performance obligation is satisfied and revenue is recognized at the time of shipment when stipulated by the terms of the sale agreements.

The consideration to which the Company expects to be entitled includes a stated list price, less various forms of variable consideration including chargebacks and rebates, product returns, prompt pay discounts, distributor fees, patient co-pay assistance, and other related deductions. These deductions to product sales are referred to as gross-to-net deductions and are estimated and recorded in the period in which the related product sales occur. Payment terms offered to customers generally range from 30 to 75 days; however, payment terms differ by jurisdiction, by customer and, in some instances, by type of product. Revenues from product sales, net of gross-to-net deductions, are recorded only to the extent a significant reversal in the amount of cumulative revenue recognized is not probable of occurring when the uncertainty associated with gross-to-net deductions is subsequently resolved. Taxes assessed by governmental authorities and collected from customers are excluded from product sales. If the Company expects, at contract inception, that the period between the transfer of control and corresponding payment from the customer will be one year or less, the amount of consideration is not adjusted for the effects of a financing component. Shipping and handling activities are considered to be fulfillment activities rather than a separate performance obligation and are recorded within selling, distribution and marketing expenses in the accompanying consolidated statements of operations.

Chargebacks and Rebates: Wholesaler chargebacks relate to sales terms under which the Company agrees to reimburse wholesalers for differences between the gross sales prices at which the Company sells its products to wholesalers and the actual prices of such products that wholesalers resell under the Company's various contractual arrangements with third parties such as hospitals, group purchasing organizations and pharmacy benefit managers in the United States. Rebates include primarily amounts paid to retailers, payers, and providers in the United States, including those paid to Medicare and state Medicaid programs, and are based on contractual arrangements or statutory requirements. The Company estimates chargebacks and rebates using the expected value method at the time of sale to customers based on inventory stocking levels, historical chargeback and rebate rates, and current contract pricing.

Chargebacks and rebates are reflected as a component of product revenues, net. The following table is an analysis of the chargeback and rebate activities and ending balances:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Beginning balance	$ 60,331	$ 27,920
Provision for chargebacks and rebates	445,183	289,332
Credits and payments issued to third parties	(426,332)	(256,921)
Ending balance	$ 79,182	$ 60,331

Changes in the chargeback provision from period to period are primarily dependent on the Company's sales to its wholesalers, the level of inventory held by wholesalers, and the wholesalers' customer mix. Changes in the rebate provision from period to period are primarily dependent on retailers' and other indirect customers' purchases. The approach that the Company uses to estimate chargebacks and rebates has been consistently applied for all periods presented. Variations in estimates have been historically small. The Company continually monitors chargebacks and rebates and makes adjustments when it believes that the actual chargebacks and rebates may differ from the estimates. Accounts receivable and/or accounts payable and accrued liabilities are reduced and/or increased by the chargebacks and rebate amounts depending on whether the Company has the right to offset with the customer.

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Chargebacks and rebates are included in the following balance sheet accounts:

	December 31,	
	2025	2024
	(in thousands)	
Reduction to accounts receivable, net	$ 43,820	$ 26,258
Accounts payable and accrued liabilities	35,362	34,073
Total	$ 79,182	$ 60,331

Accrual for Product Returns: The Company offers certain customers the right to return qualified excess or expired inventory for full or partial credit. The Company's product returns primarily consist of the returns of expired products from sales made in prior periods. Returned products cannot be resold. At the time product revenue is recognized, the Company records an accrual for product returns estimated using the expected value method. The accrual is based, in part, upon the historical relationship of product returns to sales and customer contract terms. The Company also assesses other factors that could affect product returns including market conditions, product obsolescence, and new competition.

The provision for product returns is reflected as a component of net revenues. The following table is an analysis of the product return liability:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Beginning balance	$ 19,859	$ 17,179
Provision for product returns	19,963	9,597
Credits issued to third parties	(15,746)	(6,917)
Ending balance	$ 24,076	$ 19,859

The provision for product returns is included in the following balance sheet accounts:

	December 31,	
	2025	2024
	(in thousands)	
Accounts payable and accrued liabilities	$ 18,568	$ 14,559
Other long-term liabilities	5,508	5,300
Total	$ 24,076	$ 19,859

Prompt Pay Discounts: The Company provides its customers with a percentage discount on their invoice if the customers pay within the agreed upon timeframe. The Company generally expects that its customers will earn such prompt pay discounts. The Company estimates the probability of customers paying promptly based on the percentage of discount outlined in the purchase agreement between the two parties, and deducts the full amount of these discounts from gross product sales and accounts receivable at the time revenue is recognized.

Distributor Fees: The Company engages with wholesalers to distribute its products to end customers. The Company pays the wholesalers a fee for services such as: inventory management, chargeback administration, and service level commitments. The Company estimates the amount of distribution services fees to be paid and adjusts the transaction price with the amount of such estimate at the time of sale to the customer. An accrued liability is recorded for unpaid distribution service fees.

Patient Co-Pay Assistance: Co-pay assistance represents financial assistance to qualified patients, assisting them with prescription drug co-payments required by insurance. The accrued liability for co-pay is based on an estimate of claims and the cost per claim that the Company expects to receive associated with inventory that exists in the distribution channel at period end.

AMPHASTAR PHARMACEUTICALS, INC.
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Revenues derived from contract manufacturing services are recognized when third-party products are shipped to customers. The Company's accounting policy is to review each agreement involving contract development and manufacturing services to determine if there are multiple revenue-generating activities that constitute more than one unit of account. Revenues are recognized for each unit of account based on revenue recognition criteria relevant to that unit.

Service revenues derived from research and development contracts are recognized over time based on progress toward satisfaction of the performance obligation. For each performance obligation satisfied over time, the Company assesses the proper method to be used for revenue recognition, either an input method to measure progress toward the satisfaction of services or an output method of determining the progress of completion of performance obligation. Revenue from research and development services at ANP was $3.2 million, $4.2 million, and $4.5 million for the years ended December 31, 2025, 2024, and 2023, respectively.

Other revenues

Revenues related to BAQSIMI® sales made by Lilly under the TSA during the years ended December 31, 2024, and 2023, were recorded on a net basis, similar to a royalty arrangement.

Note 4. Net Income per Share

Basic net income per share is calculated based upon the weighted-average number of shares outstanding during the period. Diluted net income per share gives effect to all potentially dilutive shares outstanding during the period, such as stock options, non-vested restricted stock units, and shares issuable under the Company's Employee Stock Purchase Plan, or ESPP, and potential shares of common stock issuable upon conversion of Convertible Notes of the Company, due March 2029, or the 2029 Convertible Notes.

For the year ended December 31, 2025, options to purchase 3,200,705 shares of stock with a weighted-average exercise price of $35.00 per share were excluded in the computation of diluted net income per share because their effect would be anti-dilutive. The 2029 Convertible Notes had no impact on the computation of diluted net income per share as the average stock price during the period was less than the conversion price.

For the year ended December 31, 2024, options to purchase 618,973 shares of stock with a weighted-average exercise price of $46.63 per share were excluded in the computation of diluted net income per share because their effect would be anti-dilutive. The 2029 Convertible Notes had no impact on the computation of diluted net income per share as the average stock price during the period was less than the conversion price.

For the year ended December 31, 2023, the Company did not have any options that were excluded in the computation of diluted net income per share because the effect would be anti-dilutive. The 2029 Convertible Notes had no impact on the computation of diluted net income per share as the average stock price during the period was less than the conversion price.

AMPHASTAR PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The following table provides the calculation of basic and diluted net income per share for each of the periods presented:

	Year Ended December 31,		
	2025	2024	2023
	(in thousands, except per share data)		
Basic and dilutive numerator:			
Net income	$ 98,094	$ 159,519	$ 137,545
Denominator:			
Weighted-average shares outstanding — basic	46,743	48,429	48,265
Net effect of dilutive securities:			
Incremental shares from equity awards	1,472	3,629	4,736
Weighted-average shares outstanding — diluted	48,215	52,058	53,001
Net income per share — basic	$ 2.10	$ 3.29	$ 2.85
Net income per share — diluted	$ 2.03	$ 3.06	$ 2.60

Note 5. Segment Reporting

The Company's business is the development, manufacture, and marketing of pharmaceutical products (see Note 1). The Company's Chief Executive Officer, is the Chief Operating Decision Maker, or CODM.

The CODM uses consolidated information to assess the Company's performance. As a result, the Company has one reportable segment, pharmaceutical products.

The measure of segment assets is reported on the consolidated balance sheets as total assets.

Selected segment financial information is presented below:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Net revenues:	$ 719,887	$ 731,967	$ 644,395
Less:			
Payroll expense	191,787	191,274	173,818
Materials and supplies	43,314	46,111	46,134
Clinical trials expense	3,038	594	5,216
Depreciation and amortization expense	56,695	52,967	38,035
Stock-based compensation expense	27,277	24,368	20,242
Consulting and outside services expense	39,771	27,772	17,698
Advertising and promotional expense	13,138	11,559	11,123
Other segment items[(1)]	204,441	167,827	139,071
Interest income	(8,679)	(10,612)	(5,459)
Interest expense	25,481	30,343	27,158
Income tax provision	25,530	29,672	31,833
Equity in losses of unconsolidated affiliate	—	573	1,981
Net income	$ 98,094	$ 159,519	$ 137,545

(1) Other segment items primarily include maintenance and repairs expense, travel expense, professional services expense, legal expense, rent expense, product costs, certain overhead expenses, manufacturing cost absorption and variances, inventory provisions, miscellaneous expenses, and foreign currency exchange gains and losses.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Net revenues by product are presented below:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Product revenues, net:			
BAQSIMI®	$ 185,358	$ 126,898	$ —
Primatene MIST®	108,669	102,012	89,321
Epinephrine	70,643	94,090	81,650
Glucagon	69,084	108,319	113,684
Lidocaine	56,479	55,854	58,162
Other products	229,654	225,641	250,421
Total product revenues, net	719,887	712,814	593,238
Other revenues	—	19,153	51,157
Total net revenues	$ 719,887	$ 731,967	$ 644,395

Net revenues and carrying values of long-lived assets, which includes property, plant and equipment, as well as finance and operating lease right-of-use assets, by geographic region, based on where the Company conducts its operations, are as follows:

	Net Revenues Year Ended December 31,			Long-Lived Assets December 31,	
	2025	2024	2023	2025	2024
			(in thousands)		
United States	$ 681,422	$ 707,681	$ 635,192	$ 206,697	$ 202,328
China	3,184	4,339	4,505	110,055	107,887
France	35,281	19,947	4,698	36,967	34,412
Total	$ 719,887	$ 731,967	$ 644,395	$ 353,719	$ 344,627

Note 6. Customer and Supplier Concentration

Customer Concentrations

The following table provides accounts receivable and net revenue information for the Company's three major customers:

	% of Total Accounts Receivable		% of Net Revenues		
	December 31,	December 31,	Year Ended December 31,		
	2025	2024	2025	2024	2023
McKesson	28 %	34 %	24 %	25 %	25 %
Cencora	28 %	23 %	22 %	20 %	20 %
Cardinal Health	12 %	16 %	19 %	19 %	15 %

Supplier Concentrations

The Company depends on suppliers for raw materials, APIs, and other components and depends on a contract manufacturing organization, or CMO, for the supply of BAQSIMI® that are all subject to stringent FDA requirements. Some of these materials may only be available from one or a limited number of sources. Establishing additional or replacement suppliers for these materials may take a substantial period of time, as suppliers must be approved by the FDA. Furthermore, a significant portion of raw materials may only be available from foreign sources. If the Company is unable to secure, on a timely basis, sufficient quantities of the materials it depends on to manufacture and market its products, or if the Company's CMO is found to be non-compliant with the FDA's or other regulatory agencies quality

system regulation, cGMP, or other applicable laws or regulations, it could have a materially adverse effect on the Company's business, financial condition, and results of operations.

Note 7. Fair Value Measurements

GAAP defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the principal or most advantageous market for the asset or liability at the measurement date (an exit price). These standards also establish a hierarchy that prioritizes observable and unobservable inputs used in measuring fair value of an asset or liability, as described below:

- *Level 1* – Inputs to measure fair value are based on quoted prices (unadjusted) in active markets on identical assets or liabilities;
- *Level 2* – Inputs to measure fair value are based on the following: (a) quoted prices in active markets on similar assets or liabilities, (b) quoted prices for identical or similar instruments in inactive markets, or (c) observable (other than quoted prices) or collaborated observable market data used in a pricing model from which the fair value is derived; and
- *Level 3* – Inputs to measure fair value are unobservable and the assets or liabilities have little, if any, market activity; these inputs reflect the Company's own assumptions about the assumptions that market participants would use in pricing the assets or liabilities based on best information available in the circumstances.

As of December 31, 2025 and 2024, cash equivalents include money market accounts and corporate and municipal bonds with original maturities of less than three months. Investments consist of certificates of deposit as well as investment-grade corporate, agency and municipal bonds with original maturity dates between three and thirty-six months. The certificates of deposit are carried at amortized cost in the Company's consolidated balance sheets, which approximates their fair value determined based on Level 2 inputs. The corporate, agency and municipal bonds are classified as held-to-maturity and are carried at amortized cost net of allowance for credit losses. The fair value of such bonds is disclosed in Note 8 and was determined based on Level 2 inputs. The restrictions on restricted cash and investments have an immaterial effect on the fair value of these financial assets.

The fair values of the Company's financial assets and liabilities measured on a recurring basis as of December 31, 2025 and 2024, are as follows:

	Total	Level 1	Level 2	Level 3
		(in thousands)		
Cash equivalents	$ 111,350	$ 111,350	$ —	$ —
Restricted cash	235	235	—	—
Short-term investments	16,530	—	16,530	—
Restricted short-term investments	2,200	—	2,200	—
Interest rate swaps related to variable rate loans	(4,566)	—	(4,566)	—
Total assets and liabilities measured at fair value as of December 31, 2025	$ 125,749	$ 111,585	$ 14,164	$ —

	Total	Level 1	Level 2	Level 3
		(in thousands)		
Cash equivalents	$ 102,059	$ 102,059	$ —	$ —
Restricted cash	235	235	—	—
Short-term investments	26,629	—	26,629	—
Restricted short-term investments	2,200	—	2,200	—
Interest rate swaps related to variable rate loans	(234)	—	(234)	—
Total assets and liabilities measured at fair value as of December 31, 2024	$ 130,889	$ 102,294	$ 28,595	$ —

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The Company does not hold any Level 3 instruments that are measured at fair value on a recurring basis.

Nonfinancial assets and liabilities are not measured at fair value on a recurring basis but are subject to fair value adjustments in certain circumstances. These items primarily include investments in unconsolidated affiliates, long-lived assets, goodwill, and intangible assets for which the fair value is determined as part of an impairment test. As of December 31, 2025 and 2024, there were no significant adjustments to fair value for nonfinancial assets or liabilities.

The Company's deferred compensation plan assets are valued using the cash surrender value of the life insurance policies and are not included in the table above.

Note 8. Investments

The following is a summary of the Company's investments that are classified as held-to-maturity:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
Corporate and agency bonds (due within 1 year)	$ 95,981	$ 39	$ (60)	$ 95,960
Municipal bonds (due within 1 year)	124	—	—	124
Total investments as of December 31, 2025	$ 96,105	$ 39	$ (60)	$ 96,084
Corporate and agency bonds (due within 1 year)	$ 42,907	$ 34	$ (25)	$ 42,916
Corporate and agency bonds (due within 1 to 3 years)	10,867	—	(6)	10,861
Municipal bonds (due within 1 year)	199	—	(1)	198
Total investments as of December 31, 2024	$ 53,973	$ 34	$ (32)	$ 53,975

At each reporting period, the Company evaluates securities for impairment when the fair value of the investment is less than its amortized cost. The Company evaluated the underlying credit quality and credit ratings of the issuers, identifying neither a significant deterioration since purchase nor any other factors that would indicate a material credit loss.

The Company measures expected credit losses on held-to-maturity investments on a collective basis. All the Company's held-to-maturity investments were considered to be one pool. The estimate for credit losses considers historical loss information that is adjusted for current conditions and reasonable and supportable forecasts. Expected credit losses on held-to-maturity investments were not material to the consolidated financial statements.

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Note 9. Goodwill and Intangible Assets

The table below shows the weighted-average life, original cost, accumulated amortization, and net book value by major intangible asset classification:

	Weighted-Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
		(in thousands)		
Definite-lived intangible assets				
BAQSIMI® product rights	24	$ 591,338	$ 61,597	$ 529,741
Land-use rights	39	2,540	947	1,593
Other intangibles	7	2,443	439	2,004
Subtotal	24	596,321	62,983	533,338
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill	*	3,402	—	3,402
Subtotal	*	32,627	—	32,627
As of December 31, 2025	*	$ 628,948	$ 62,983	$ 565,965

	Weighted-Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
		(in thousands)		
Definite-lived intangible assets				
BAQSIMI® product rights	24	$ 591,338	$ 36,958	$ 554,380
Land-use rights	39	2,540	881	1,659
Other intangibles	7	2,443	96	2,347
Subtotal	24	596,321	37,935	558,386
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill	*	3,049	—	3,049
Subtotal	*	32,274	—	32,274
As of December 31, 2024	*	$ 628,595	$ 37,935	$ 590,660

* Intangible assets with indefinite lives have an indeterminable average life.

Goodwill

The changes in the carrying amounts of goodwill are as follows:

	December 31, 2025	December 31, 2024
	(in thousands)	
Beginning balance	$ 3,049	$ 3,216
Currency translation	353	(167)
Ending balance	$ 3,402	$ 3,049

Amortization

Included in cost of revenues for the years ended December 31, 2025, 2024, and 2023 is product rights amortization expense of $25.0 million, $24.7 million, and $15.5 million, respectively.

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As of December 31, 2025, the expected amortization expense for all amortizable intangible assets during the next five fiscal years ending December 31 and thereafter is as follows:

	(in thousands)
2026	$ 25,078
2027	25,078
2028	25,078
2029	25,078
2030	25,078
Thereafter	407,948
Total amortizable intangible assets	533,338
Indefinite-lived intangibles	32,627
Total intangibles (net of accumulated amortization)	$ 565,965

Note 10. Inventories

Inventories consist of the following:

	December 31,	
	2025	2024
	(in thousands)	
Raw materials and supplies	$ 106,832	$ 81,511
Work in process	40,440	32,807
Finished goods	29,618	39,423
Total inventories	$ 176,890	$ 153,741

Charges of $6.0 million, $14.0 million, and $18.8 million were included in the cost of revenues in the Company's consolidated statements of operations for the years ended December 31, 2025, 2024, and 2023, respectively, to adjust the Company's inventory and related firm purchase commitments to their net realizable value. For the year ended December 31, 2025, these charges included $0.6 million in the cost of revenues to adjust the Company's enoxaparin inventory and related firm purchase commitments to their net realizable value. For the year ended December 31, 2024, these charges included $7.4 million in the cost of revenues to adjust the Company's enoxaparin inventory and related firm purchase commitments to their net realizable value. For the year ended December 31, 2023, these charges included $9.1 million in the cost of revenues to adjust the Company's enoxaparin inventory and related firm purchase commitments to their net realizable value.

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Note 11. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	December 31,	
	2025	2024
	(in thousands)	
Buildings	$ 196,675	$ 169,429
Leasehold improvements	46,098	42,012
Land	7,554	7,422
Machinery and equipment	302,330	277,408
Furniture, fixtures, and automobiles	39,769	35,976
Construction in progress	24,407	36,685
Total property, plant, and equipment	616,833	568,932
Less accumulated depreciation	(306,266)	(271,587)
Total property, plant, and equipment, net	$ 310,567	$ 297,345

The Company incurred depreciation expense of $31.6 million, $28.2 million, and $25.2 million for the years ended December 31, 2025, 2024, and 2023, respectively.

Interest expense capitalized was approximately $1.2 million, $0.8 million, and $2.0 million for the years ended December 31, 2025, 2024, and 2023, respectively.

Note 12. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following:

	December 31,	
	2025	2024
	(in thousands)	
Accrued customer fees and rebates	$ 56,362	$ 53,993
Accrued payroll and related benefits	26,318	26,010
Accrued product returns, current portion	18,568	14,559
Accrued loss on firm purchase commitments	200	413
Accrued litigation and settlements	232	8,472
Other accrued liabilities	14,076	23,096
Total accrued liabilities	115,756	126,543
Accounts payable	32,592	30,514
Total accounts payable and accrued liabilities	$ 148,348	$ 157,057

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Note 13. Debt

Debt consists of the following:

	December 31,	
	2025	2024
	(in thousands)	
Convertible Debt		
2029 Convertible Notes	$ 345,000	$ 345,000
Term Loan		
Wells Fargo Term Loan due June 2028	250,000	250,000
Other Loans and Payment Obligations		
French government loans due December 2026	56	99
Line of Credit Facilities		
Line of credit facility with China Merchant Bank due October 2026	—	—
Wells Fargo Revolving line of credit facility due June 2028	—	—
Line of credit facility with ICBC Bank due November 2033	24,649	18,433
Equipment under Finance Leases	264	432
Total debt	619,969	613,964
Less: current portion of long-term debt	1,641	234
Less: loan issuance costs	9,579	12,100
Long-term debt, net of current portion and unamortized debt issuance costs	$ 608,749	$ 601,630

Credit Agreement

2029 Convertible Notes

In September 2023, the Company issued the 2029 Convertible Notes, in the aggregate principal amount of $345.0 million in a private offering pursuant to Section 4(a)(2) and Rule 144A under the Securities Act of 1933, as amended. The Company used portions of the net proceeds from the 2029 Convertible Notes to (i) repay approximately $200.0 million of the Company's borrowings under the Wells Fargo Term Loan and (ii) repurchase $50.0 million of the Company's common stock.

In connection with the issuance of the 2029 Convertible Notes, the Company incurred approximately $10.8 million of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees. Unamortized debt issuance costs related to the 2029 Convertible Notes were $6.3 million and $8.3 million as of December 31, 2025 and 2024, respectively. The fair value of the 2029 Convertible Notes was approximately $319.1 million as of December 31, 2025 based on Level 2 inputs.

For the years ended December 31, 2025, 2024, and 2023, the total interest expense related to the 2029 Convertible Notes was $8.9 million, $8.9 million, and $2.6 million, with coupon interest expense of $6.9 million, $6.9 million, and $2.0 million, and the amortization of debt issuance cost of $2.0 million, $2.0 million, and $0.6 million, respectively.

The 2029 Convertible Notes are general senior, unsecured obligations and bear an interest rate of 2.0% per year. The

AMPHASTAR PHARMACEUTICALS, INC.
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2029 Convertible Notes were issued pursuant to an indenture, dated September 15, 2023, or the Indenture, between the Company and U.S. Bank Trust Company, National Association, as trustee.

The 2029 Convertible Notes will rank senior in right of payment to all of the Company's indebtedness that is expressly subordinated in right of payment to the 2029 Convertible Notes; equal in right of payment to all of the Company's unsecured indebtedness that is not so subordinated; effectively junior to any of the Company's secured indebtedness to the extent of the value of the assets securing such indebtedness, including any amount outstanding under the Company's credit facilities; and structurally junior to all indebtedness and other liabilities of the Company's current or future subsidiaries, including trade payables.

Interest is payable semi-annually in arrears on March 15 and September 15 of each year. The 2029 Convertible Notes may bear additional interest under specified circumstances relating to the Company's failure to comply with its reporting obligations under the Indenture or if the 2029 Convertible Notes are not freely tradeable as required by the Indenture.

The 2029 Convertible Notes will mature on March 15, 2029, unless earlier converted, repurchased or redeemed.

Conversions of the 2029 Convertible Notes will be settled in cash up to the aggregate principal amount of the 2029 Convertible Notes to be converted, and cash, shares of common stock or a combination of cash and shares of common stock, at the Company's election, with respect to the remainder, if any, of the Company's conversion obligation in excess of the aggregate principal amount.

Holders may convert their 2029 Convertible Notes at their option prior to the close of business on the business day immediately preceding December 15, 2028, in multiples of $1,000 principal amount, only under the following circumstances: (i) during any calendar quarter commencing after the calendar quarter ending on December 31, 2023 (and only during such calendar quarter), if the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price for the 2029 Convertible Notes on each applicable trading day, (ii) during the five business day period after any five consecutive trading day period in which the trading price, as defined in the Indenture, per $1,000 principal amount of the 2029 Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day, (iii) if the Company calls the 2029 Convertible Notes for redemption, at any time prior to the close of business on the second scheduled trading day immediately preceding the redemption date, and (iv) upon the occurrence of specified corporate events defined in the Indenture.

On or after December 15, 2028, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert all or any portion of their 2029 Convertible Notes, in multiples of $1,000 principal amount, at the option of the holder regardless of the foregoing circumstances.

The Company may redeem the 2029 Convertible Notes, at its option, in whole or in part (subject to certain limitations), on or after September 20, 2026 and prior to the 41st scheduled trading day preceding the maturity date, if the last reported sale price of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on and including the trading day immediately preceding the date on which the Company provides notice of redemption at a redemption price equal to 100% of the principal amount of the 2029 Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

The initial conversion rate is 15.8821 shares of the Company's common stock per $1,000 principal amount of the 2029 Convertible Notes, which represents an initial conversion price of approximately $62.96 per share of common stock. The initial conversion price of $62.96 represents a premium of approximately 35.0% over the last reported sale price of the Company's common stock on Nasdaq Global Select Market on September 12, 2023. The conversion rate is subject to adjustment under certain circumstances in accordance with the terms of the Indenture.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

If a fundamental change, as defined in the Indenture, occurs at any time prior to the maturity date, then, subject to certain conditions, holders of the 2029 Convertible Notes may require the Company to repurchase for cash all or any portion of their 2029 Convertible Notes at a repurchase price equal to 100% of the principal amount of the 2029 Convertible Notes to be repurchased, plus any accrued and unpaid interest. In addition, following certain specified corporate events or if the Company issues a notice of redemption, the Company will, under certain circumstances, increase the conversion rate for holders who convert their 2029 Convertible Notes in connection with such corporate event or during a redemption period.

Syndicated Credit Agreement with Wells Fargo Bank, National Association - Due June 2028

In June 2023, in connection with the BAQSIMI® acquisition, the Company entered into a syndicated credit agreement with Wells Fargo, or the Credit Agreement. Under the terms of the Credit Agreement, the Company borrowed $500.0 million in the form of a term loan, or the Wells Fargo Term Loan. Proceeds from the Wells Fargo Term Loan were used to finance the acquisition of BAQSIMI®, repay certain of the Company's and its subsidiaries' existing third-party indebtedness, and pay fees and expenses incurred in connection with each of the foregoing. Outstanding borrowings with respect to the Wells Fargo Term Loan initially accrue interest, at the Company's option, at a per annum rate equal to either (i) a base rate equal to the highest of (x) the federal funds rate, plus 0.50%, (y) the prime rate then in effect and (z) an adjusted daily one-month Secured Overnight Financing Rate, or SOFR, rate determined on the basis of a one-month interest period plus 1.00%, in each case, plus an applicable margin of 1.25%, or (ii) an adjusted Term SOFR rate, subject to a floor of 0.00%, plus an applicable margin of 2.25%. Following delivery of financial statements for the Company's first fiscal quarter following payment in full of a $125.0 million guaranteed payment owed to Lilly on June 30, 2024, the applicable margin for outstanding borrowings with respect to the Wells Fargo Term Loan will range from 0.50% to 1.50% in the case of base rate loans and 1.50% to 2.50% in the case of Term SOFR rate loans, in each case, depending on the Company's consolidated net leverage ratio as of the most recently ended fiscal quarter. The Wells Fargo Term Loan matures in June 2028.

The Wells Fargo Term Loan requires principal payments of $12.5 million for the first year, which increases to $25.0 million during the second year, and $37.5 million during the third, fourth and fifth years, with the remaining balance due at maturity. The loan is secured by substantially all of the Company's and certain of its subsidiaries' assets, subject to certain exceptions and limitations. In the third quarter of 2023, the Company repaid approximately $200.0 million of the borrowings under the Wells Fargo term Loan with the proceeds from the 2029 Convertible Notes, thereby satisfying all of the current and future loan amortization payments required by the Wells Fargo Term Loan until maturity. In the fourth quarter of 2023, the Company made a principal payment of $50.0 million, reducing the balance to $250.0 million.

The Credit Agreement also provides for a $200.0 million Revolving Credit Facility and bears the same interest rate as the Wells Fargo Term Loan.

In conjunction with the Credit Agreement, the Company entered into an interest rate swap contract with Wells Fargo, with a notional amount of $250.0 million to exchange the variable rate on the Wells Fargo Term Loan for a fixed rate of 4.04%. The interest swap contract liability had a fair value of $4.6 million as of December 31, 2025.

The Company incurred approximately $14.3 million in issuance costs in connection with the Credit Agreement, of which $3.0 million represented debt modification costs and were charged to interest expense in the Company's consolidated statement of operations for year ended December 31, 2023.

Debt issuance costs associated with the Credit Agreement (other than its Revolving Credit Facility component) are presented as a reduction to the carrying value of the related debt, while debt issuance costs associated with the Revolving Credit Facility are capitalized within other long-term assets on the consolidated balance sheets. Unamortized debt issuance costs related to the Credit Agreement as of December 31, 2025 and 2024 were $4.3 million and $6.0 million, respectively, which are being amortized over the term of the Credit Agreement using the effective interest rate method.

AMPHASTAR PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

As a result of the $250.0 million repayment of the principal balance of the Wells Fargo Term Loan, approximately $3.8 million of unamortized debt issuance costs were written off during the year ended December 31, 2023.

Line of Credit Facilities

Line of Credit Facility with China Merchant Bank – Due October 2026

In March 2020, the Company entered into a credit agreement with China Merchant Bank. The credit agreement allows the Company to borrow up to $14.6 million secured by buildings and land use rights held by ANP. The interest rate and other terms will be determined at the time of the borrowing, depending on the type of loan requested. The credit period was for 36 months and expired in March 2023.

In October 2023, the Company renewed the credit agreement with China Merchant Bank, and allows the Company to borrow up to $4.1 million. The credit period is for 36 months and expires in October 2026.

Syndicated Line of Credit Facility with ICBC Bank – Due November 2033

In January 2024, the Company entered into a credit agreement with Industrial and Commercial Bank of China Limited, or ICBC Bank, acting as a lender and as agent for other lenders. The credit agreement allows the Company to borrow up to $40.0 million secured by equipment and buildings at ANP. The interest rate and other terms will be determined at the time of the borrowing, depending on the type of loan requested. The credit agreement expires in November 2033.

The loan bears interest at the prime rate as published by The People's Bank of China minus 0.2%. Interest payments are due quarterly and repayment of the principal amount is biannual and begins in May 2026. As of December 31, 2025, the Company had $24.6 million of principal outstanding under this loan, which is recorded net of loan issuance costs of $1.3 million.

Interest Rate Swap Contract

As of December 31, 2025, the fair value of the loans listed above approximated their carrying amount based on Level 2 inputs, with the exception of the 2029 Convertible Notes. For the Wells Fargo Term Loan, the Company has entered into a fixed interest rate swap contract to exchange the variable interest rates for fixed interest rates. The interest rate swap contract is recorded at fair value in the other long-term liabilities line in the consolidated balance sheets. Changes in the fair values of interest rate swaps were $4.3 million, $5.0 million, and $5.9 million for the years ended December 31, 2025, 2024, and 2023, respectively.

Covenants

At December 31, 2025 and 2024, the Company was in compliance with all of its debt covenants.

AMPHASTAR PHARMACEUTICALS, INC.
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Long-Term Debt Maturities

As of December 31, 2025, the principal amounts of long-term debt maturities during each of the next five fiscal years ending December 31 are as follows:

	Long-term Debt
	(in thousands)
2026	$ 1,479
2027	5,692
2028	255,692
2029	353,538
2030	3,304
	$ 619,705

Note 14. Income Taxes

The Company's income (loss) before income taxes generated from its operations were:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Income (loss) before income taxes:			
United States	$ 128,952	$ 195,178	$ 181,922
Foreign	(5,328)	(5,414)	(10,563)
Total income before income taxes	$ 123,624	$ 189,764	$ 171,359

The Company's provision for income taxes consisted of the following:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Current provision:			
Federal	$ (2,874)	$ 44,251	$ 42,689
State	227	589	1,912
Foreign	(482)	1,974	1,089
Total current provision	(3,129)	46,814	45,690
Deferred provision (benefit):			
Federal	26,338	(17,126)	(13,134)
State	3,402	363	1,537
Foreign	(1,081)	(379)	(2,260)
Total deferred provision	28,659	(17,142)	(13,857)
Total provision for income taxes	$ 25,530	$ 29,672	$ 31,833

The lower federal current provision in 2025 reflects the impact of a tax deduction for certain previously deferred capitalized research and development expenditures under the One Big Beautiful Bill Act, or the OBBB Act.

For the year ended December 31, 2025, the Company adopted ASU 2023-09 on a prospective basis.

AMPHASTAR PHARMACEUTICALS, INC.
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A reconciliation of the US federal statutory income tax rate of 21% to the Company's effective tax rate after the adoption of ASU 2023-09 is as follows:

	Year Ended December 31, 2025	
	(in thousands)	Percent
US federal statutory tax rate	$ 25,961	21.0 %
State and local income taxes, net of federal income tax effect*	2,376	1.9
Foreign tax effects	522	0.4
Effect of cross-border tax laws	(43)	—
Tax credits		
Research and development tax credits	(4,464)	(3.6)
Nontaxable or nondeductible items		
Executive compensation	2,992	2.4
Other	(266)	(0.2)
Changes in unrecognized tax benefits	(1,491)	(1.2)
Other adjustments	(57)	—
Effective tax rate	$ 25,530	20.7 %

* State taxes in California made up the majority (greater than 50%) of the tax effect in this category.

A reconciliation of the US federal statutory income tax rate of 21% to the Company's effective tax rate before the adoption of ASU 2023-09 is as follows:

	Year Ended December 31,	
	2024	2023
Statutory federal income tax	21.0 %	21.0 %
State tax expense, net of federal tax benefit	0.4	1.6
Foreign tax rate differences	—	(0.1)
Foreign valuation allowance	1.4	0.1
Research and development credits	(3.7)	(4.2)
Share-based compensation	(5.1)	(3.2)
Executive compensation	1.7	2.4
Intercompany transfer of assets other than inventory	—	0.6
Other	(0.1)	0.4
Effective tax rate	15.6 %	18.6 %

The Company's effective tax rate for 2025 increased in comparison to 2024 primarily due to lower excess tax benefit from share-based compensation.

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Income Taxes Paid

The following table presents income taxes paid (net of refunds received) for the year ended December 31, 2025:

	Year Ended December 31, 2025 (in thousands)
Federal	$ 20,700
State & Local	
California	1,223
Other state & local jurisdictions	(611)
Foreign	
China	1,504
Other foreign jurisdictions	(106)
Total Income Taxes Paid	$ 22,710

Deferred Tax Assets and Liabilities

Deferred income taxes reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, tax credit carryforwards, and the tax effects of net operating loss carryforwards.

The significant components of the Company's deferred tax assets and liabilities are as follows:

	December 31, 2025	December 31, 2024
	(in thousands)	
Deferred tax assets:		
Research and development credits	$ 9,374	$ 12,300
Net operating loss carryforward	24,032	22,047
Inventory capitalization and reserve	13,957	16,523
Share-based compensation	5,278	5,067
Operating leases	11,028	11,996
Accrued expenses	7,897	6,969
Accrued chargebacks and rebates	13,556	9,080
Product return allowance	6,922	5,749
Intangibles	2,124	2,124
Research and development capitalization	19,967	48,411
Total deferred tax assets	114,135	140,266
Deferred tax liabilities:		
Depreciation/amortization	22,473	22,771
Intangibles	12,176	7,849
Operating leases	10,637	11,622
Federal impact of state deferred taxes	2,919	3,522
Other	193	984
Total deferred tax liabilities	48,398	46,748
Valuation allowance	(23,273)	(22,394)
Net deferred tax assets	$ 42,464	$ 71,124

Tax Law Updates

On July 4, 2025, the OBBB Act, was enacted into law. The OBBB Act includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, modifications to the international tax

framework and the restoration of favorable tax treatment for certain business provisions. The OBBB Act did not result in any material adjustments to the Company's total income tax provision for the year ended December 31, 2025 and the Company's deferred tax balances were adjusted to reflect impacts of the OBBB Act enactment.

Net Operating Loss Carryforwards and Tax Credits

At December 31, 2025, the Company had no material U.S. federal or state net operating loss carryforwards, or NOL carryforwards. The Company had China, France and United Kingdom foreign NOL carryforwards of approximately $0.8 million, $91.9 million, and $2.9 million, respectively. The China NOL has a 5-year carryforward period and the France and United Kingdom NOLs have indefinite carryforward periods.

At December 31, 2025, the Company had California research and development tax credit carryforwards of approximately $18.8 million. The California research and development tax credit has an indefinite carryforward period.

Valuation Allowance

In assessing the need for a valuation allowance, management considers whether it is more likely than not that some portion or all of the deferred income tax assets will be realized. Ultimately, realization depends on the existence of future taxable income. Management considers sources of taxable income such as income in prior carryback periods, future reversal of existing deferred taxable temporary differences, tax-planning strategies, and projected future taxable income.

The Company continues to record a full valuation allowance on the net deferred income tax assets of its French subsidiary, AFP, and its U.K. subsidiaries, AUK and IMS UK and will continue to do so until the subsidiaries generate sufficient taxable income to realize their respective deferred income tax assets. As of December 31, 2025 and 2024, the Company had a full valuation allowance against the net deferred tax assets of AFP, which totaled $22.4 million and $20.7 million, respectively, and a full valuation allowance against the net deferred tax assets of its UK subsidiaries of immaterial amounts.

The Company also records a valuation allowance on net deferred income tax assets in states where it files separately and will continue to do so until sufficient taxable income is generated to realize these state deferred income tax assets.

Uncertain Income Tax Positions

A reconciliation of the beginning and ending balances of unrecognized tax benefits is as follows:

	December 31,		
	2025	2024	2023
		(in thousands)	
Balance at the beginning of the year	$ 13,738	$ 12,493	$ 12,895
Additions based on tax positions related to prior years	357	—	—
Additions based on tax positions related to the current year	1,896	2,659	2,074
Deductions based on statute of limitations	(1,676)	(1,414)	(2,476)
Balance at the end of the year	$ 14,315	$ 13,738	$ 12,493

Included in the balance of unrecognized tax benefits as of December 31, 2025 and 2024, was $13.2 million and $12.7 million, respectively that represents the portion that would impact the effective income tax rate if recognized.

The Company recognizes interest and penalties related to unrecognized tax benefits in its income tax provision. For the years ended December 31, 2025, 2024, and 2023, the Company accrued interest of approximately $1.4 million, $1.3 million and $1.0 million, respectively, related to its uncertain tax positions.

The Company and/or one or more of its subsidiaries files income tax returns in the U.S. federal jurisdiction and various U.S. states and foreign jurisdictions. As of December 31, 2025, the Company is under U.S. federal examination for the

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2022 tax year, California for the 2019-2021 tax years, and New York for the 2023 tax year. The Company does not have a tax examination in progress for Massachusetts, other states, or foreign jurisdictions. The Company is subject to income tax audit by tax authorities for tax years 2022 to 2024 for federal, 2019 to 2024 for states, and 2015 to 2024 for foreign.

Note 15. Stockholders' Equity

Equity Plans

As of December 31, 2025, the Company has two equity plans: the Amended and Restated 2015 Equity Incentive Plan, or the Amended 2015 Plan, and the 2014 Employee Stock Purchase Plan or ESPP. Upon termination of the predecessor plans, the shares available for grant at the time of termination, and shares subsequently returned to the plans upon forfeiture or option termination, were transferred to the successor plan in effect at the time of share return. The Company issues new shares of common stock upon exercise of stock options, vesting of restricted stock units, or RSU, and settlement of ESPP, with the exception of the awards granted to employees at AFP, which are settled through re-issuance of the Company's treasury shares.

Amended and Restated 2015 Equity Incentive Plan

In March 2015, the Board of Directors adopted the Company's 2015 Equity Incentive Plan, or the Original 2015 Plan, which was approved by the Company's stockholders in May 2015 and was set to expire in March 2025. The Original 2015 Plan was designed to meet the needs of a publicly traded company, including the requirements for granting "performance-based compensation" under Section 162(m) of the Internal Revenue Code. The Original 2015 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units, performance shares, and other stock or cash awards to employees of the Company and its subsidiaries, members of the Board of Directors and consultants.

In November 2020, the Board of Directors approved the Amendment and Restated 2015 Equity Incentive Plan to provide that at least 95% of the shares awarded under the plan will be subject to a minimum vesting requirement of at least one year.

The Company initially reserved 5,000,000 shares of common stock for issuance under the Original 2015 Plan and also contained an "evergreen provision" that allowed for an annual increase in the number of shares available for issuance on January 1 of each year during the 10-year term of the 2015 Plan.

In February 2024, the Board of Directors approved the Company's Amended 2015 Plan, which was subsequently approved by the Company's stockholders, and accordingly, adopted by the Company in June 2024. The Amended 2015 Plan, among other things, extended the term of the Original 2015 Plan, increased the number of shares available for issuance under the Original 2015 Plan, and removed the evergreen provision. The term of the Amended 2015 Plan will be extended indefinitely, however, the Company's ability to grant incentive stock options thereunder will continue through February 2034.

As of December 31, 2025, the Company reserved an aggregate of 6,625,746 shares of common stock for future issuance under the Amended 2015 Plan.

2014 Employee Stock Purchase Plan

In June 2014, the Company adopted the ESPP in connection with its initial public offering. A total of 2,000,000 shares of common stock are reserved for issuance under this plan. The Company's ESPP permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. Under the ESPP, the Company may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of its common stock will be purchased for employees participating in the offering. An offering may be terminated under certain circumstances. The price at which

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the stock is purchased is equal to 85% of the lower of the fair market value of the common stock at the beginning of an offering period or on the date of purchase.

As of December 31, 2025, the Company has issued 1,443,046 shares of common stock under the ESPP and 556,954 shares of its common stock remains available for issuance under the ESPP.

For the years ended December 31, 2025, 2024, and 2023, the Company recorded ESPP expense of $1.2 million, $1.2 million, and $1.1 million, respectively.

Share Buyback Program

As of December 31, 2025, the Company's Board of Directors have authorized a total of $435.0 million in the share buyback program. The primary goal of the program is to offset dilution created by the Company's equity compensation programs. The Company's share buyback program is expected to continue for an indefinite period of time.

Purchases are made through open market and private block transactions pursuant to Rule 10b5-1 plans, privately negotiated transactions or other means as determined by the Company's management and in accordance with the requirements of the SEC and applicable laws. The timing and actual number of treasury share purchases will depend on a variety of factors including price, corporate and regulatory requirements, and other conditions. These treasury share purchases are accounted for under the cost method and are included as a component of treasury stock in the Company's consolidated balance sheets.

Pursuant to the Company's existing share buyback program, the Company purchased 2,915,580 shares, 1,919,670 shares, and 1,338,757 shares of its common stock during the years ended December 31, 2025, 2024, and 2023, for total consideration of $75.6 million, $85.5 million, and $58.1 million, respectively.

Share-Based Award Activity and Balances

The Company accounts for share-based compensation payments in accordance with ASC 718, which requires measurement and recognition of compensation expense at fair value for all share-based payment awards made to employees and directors. Under these standards, the fair value of option awards and the option components of the ESPP awards are estimated at the grant date using the Black-Scholes option-pricing model. The fair value of RSUs is estimated at the grant date using the Company's common share price. The Company records share-based compensation expense net of expected forfeitures. Compensation cost for all share-based payments granted with service-based graded vesting schedules is recognized using the straight-line method over the requisite service period.

Options issued under the Company's Amended 2015 Plan, and Original 2015 Plan are granted at exercise prices equal to or greater than the fair value of the underlying common shares on the date of grant and vest based on continuous service. There have been no awards with performance conditions and no awards with market conditions. The options have a contractual term of five to ten years and generally vest over a one- to five-year period. The Black-Scholes option pricing model has various inputs such as the common share price on the date of grant, exercise price, the risk-free interest rate, volatility, expected term and dividend yield, all of which are estimates. The Company records share-based compensation expense net of expected forfeitures. The change of any of these inputs could significantly impact the determination of the fair value of the Company's options as well as significantly impact its results of operations.

The significant assumptions used in the Black-Scholes option-pricing are as follows:

- *Determination of Fair Value of the Underlying Common Stock.* For options and ESPP awards granted, the fair value for its underlying common stock is determined using the closing price on the date of grant as reported on the Nasdaq Global Select Market, or Nasdaq, with consideration of whether there is material nonpublic information that could impact that estimated fair value when it is released.

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- *Expected Volatility.* The Company estimates its volatility based on the historical volatility of its stock price.

- *Expected Term.* The expected term represents the period of time in which the options granted are expected to be outstanding. The Company estimates the expected term of options with consideration of vesting date, contractual term, and historical experience for exercise and post-vesting employment or contractual termination behavior after its common stock has been publicly traded. The expected term of "plain vanilla" options is estimated (using the simplified method as outlined in SAB Topic 14 because historical exercise data does not provide a reasonable basis upon which to estimate the expected term) based on the midpoint between the vesting date and the end of the contractual term under the simplified method permitted by the SEC implementation guidance.

- *Risk-Free Rate.* The risk-free interest rate is selected based upon the implied yields in effect at the time of the option grant on U.S. Treasury zero-coupon issues with a term approximately equal to the expected life of the option being valued.

- *Dividends.* The Company does not anticipate paying cash dividends in the foreseeable future. Consequently, the Company uses an expected dividend yield rate of zero.

The Company estimates forfeitures at the time of grant and revises those estimates in subsequent periods if actual experience differs from those estimates. For each of the years ended December 31, 2025, 2024, and 2023, the Company estimated an average overall forfeiture rate of approximately 7% based on historical experience. Forfeiture rates are separately estimated for its (1) directors and officers, (2) management personnel and (3) other employees. The Company periodically assesses the forfeiture rate and the amount of expense recognized based on estimated historical forfeitures as compared to actual forfeitures. Changes in estimates are recorded in the period they are identified.

Tax benefits resulting from tax deductions in excess of the share-based compensation cost recognized (excess tax benefits) are recorded in the statements of cash flows as financing activities.

The weighted-averages for key assumptions used in determining the fair value of options granted are as follows:

	Year Ended December 31,		
	2025	2024	2023
Average volatility	40.9 %	41.3 %	41.4 %
Average risk-free interest rate	4.2 %	4.2 %	4.1 %
Weighted-average expected life in years	6.2	6.2	6.2
Dividend yield rate	— %	— %	— %

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Stock Options

A summary of option activity under all plans for the year ended December 31, 2025, is presented below:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value[1] (in thousands)
Outstanding as of December 31, 2024	6,655,225	$ 23.75		
Options granted	1,206,844	28.16		
Options exercised	(946,221)	14.53		
Options forfeited	(24,036)	33.74		
Options expired	(7,422)	24.66		
Outstanding as of December 31, 2025	6,884,390	$ 25.75	5.30	$ 33,365
Exercisable as of December 31, 2025	4,731,181	22.20	3.86	$ 33,172
Vested and expected to vest as of December 31, 2025	6,714,992	25.58	5.21	$ 33,365

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the estimated fair value of the Company's stock for those awards that have an exercise price below the estimated fair value at December 31, 2025.

During the years ended December 31, 2025, 2024, and 2023, the Company recorded expense of $13.1 million, $11.6 million, and $9.6 million, respectively, related to stock options granted under all plans.

Information relating to option grants and exercises is as follows:

	Year Ended December 31,		
	2025	2024	2023
	(in thousands, except per share data)		
Weighted-average grant date fair value per share	$ 13.22	$ 21.89	$ 16.76
Intrinsic value of options exercised	11,559	52,068	29,918
Cash received from options exercised	6,388	12,239	14,172
Total fair value of the options vested during the period	11,917	9,818	8,890

A summary of the status of the Company's non-vested options as of December 31, 2025, and changes during the year ended December 31, 2025, are presented below:

	Options	Weighted-Average Grant Date Fair Value
Non-vested as of December 31, 2024	1,803,684	$ 16.76
Options granted	1,206,844	13.22
Options vested	(833,283)	14.30
Options forfeited	(24,036)	15.76
Non-vested as of December 31, 2025	2,153,209	15.73

As of December 31, 2025, there was $21.4 million of total unrecognized compensation cost, net of forfeitures, related to non-vested stock option based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 2.4 years and will be adjusted for future changes in estimated forfeitures.

Restricted Stock Units

The Company grants restricted stock units, or RSUs, to certain employees and members of the Board of Directors with a vesting period of up to four years. The grantee receives one share of common stock at a specified future date for each RSU awarded. The RSUs may not be sold or otherwise transferred until vested. The RSUs do not have any voting or

AMPHASTAR PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

dividend rights prior to the issuance of the underlying common stock. The share-based expense associated with these grants was based on the Company's common stock fair value at the time of grant and is amortized over the requisite service period, which generally is the vesting period, using the straight-line method. During the years ended December 31, 2025, 2024, and 2023, the Company recorded expenses of $13.0 million, $11.5 million, and $9.5 million, respectively, related to RSU awards granted under all plans.

As of December 31, 2025, there was $22.7 million of total unrecognized compensation cost, net of forfeitures, related to non-vested RSU-based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 2.4 years and will be adjusted for future changes in estimated forfeitures.

Information relating to RSU grants and deliveries is as follows:

	Total RSUs Issued	Total Fair Market Value of RSUs Issued[1]
		(in thousands)
RSUs outstanding at December 31, 2024	825,421	
RSUs granted	565,770	$ 15,939
RSUs forfeited	(11,156)	
RSUs vested[2]	(372,602)	
RSUs outstanding at December 31, 2025	1,007,433	

(1) The total FMV is derived from the number of RSUs granted times the current stock price on the date of grant.
(2) Of the vested RSUs, 140,443 shares of common stock were surrendered to fulfill tax withholding obligations.

Share-based Compensation Expense

The Company recorded share-based compensation expense, which is included in the Company's consolidated statement of operations as follows:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Cost of revenues	$ 6,205	$ 5,742	$ 4,891
Operating expenses:			
Selling, distribution, and marketing	1,215	1,063	870
General and administrative	16,919	14,921	12,269
Research and development	2,938	2,642	2,212
Total share-based compensation	$ 27,277	$ 24,368	$ 20,242

Note 16. Employee Benefits

401(k) Plan

The Company has a defined contribution 401(k) plan, or the Plan, whereby eligible employees voluntarily contribute up to a defined percentage of their annual compensation. The Company matches contributions at a rate of 50% on the first 6% of employee contributions, and pays the administrative costs of the Plan. Total employer contributions for the years ended December 31, 2025, 2024, and 2023 were approximately $2.6 million, $2.6 million, and $2.3 million, respectively.

Defined Benefit Pension Plan

The Company's subsidiary, AFP, has an obligation associated with a defined-benefit plan for its eligible employees. This

plan provides benefits to the employees from the date of retirement and is based on the employee's length of time employed by the Company. The calculation is based on a statistical calculation combining a number of factors that include the employee's age, length of service, and AFP employee turnover rate.

The liability under the plan is based on a discount rate of 3.95% and 3.40% as of December 31, 2025 and 2024, respectively. The liability is included in other long-term liabilities in the accompanying consolidated balance sheets. The plan is currently unfunded, and the benefit obligation under the plan was $2.7 million and $2.6 million at December 31, 2025 and 2024, respectively. The Company recorded an immaterial amount of expense under the plan for each of the years ended December 31, 2025, 2024, and 2023. Gain or loss due to change in actuarial valuation of the Company's defined benefit pension plan was not material.

Non-qualified Deferred Compensation Plan

In December 2019, the Company established a non-qualified deferred compensation plan. The plan allows certain eligible participants to defer a portion of their cash compensation and provides a matching contribution at the discretion of the Company. The plan obligations are payable upon retirement, termination of employment and/or certain other times in a lump-sum distribution or in installments, as elected by the participant in accordance with the plan. Participants can allocate their deferred compensation amongst various investment options with earnings accruing to the participant. The Company has established a Rabbi Trust to fund the plan obligations and to hold the plan assets. Eligible participants began contributing to the plan in January 2020. The plan assets were valued at approximately $14.5 million and $10.3 million as of December 31, 2025 and 2024, respectively. The plan liabilities were valued at approximately $15.0 million and $10.7 million as of December 31, 2025 and 2024, respectively. The plan assets and liabilities are included in other long-term assets and other long-term liabilities, respectively, on the Company's consolidated balance sheets.

Note 17. Commitments and Contingencies

Lease Liabilities

Right-of-Use, or ROU, assets represent the Company's right to control an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. Lease terms are generally based on their initial non-cancelable terms, unless there is a renewal option that is reasonably certain to be exercised. Various factors, including economic incentives, intent, past history, and business needs are considered to determine if a renewal option is reasonably certain to be exercised. As most of its leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the discount rate used to present value the lease payments. The Company has lease agreements with both lease and non-lease components, which are accounted for as a single component for all asset classes. The Company leases real and personal property, in the normal course of business, under various non-cancelable operating leases. The Company, at its option, can renew a substantial portion of its leases, at the market rate, for various renewal periods ranging from one to six years.

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The components of lease costs were as follows:

	Year Ended December 31,		
	2025	2024	2023
	(in thousands)		
Operating lease costs	$ 9,446	$ 6,135	$ 5,267
Short-term lease costs	544	400	332
Finance lease costs			
Amortization of right-of-use assets	155	181	189
Interest on lease liabilities	23	34	45
Total finance lease costs	$ 178	$ 215	$ 234
Total lease costs	$ 10,168	$ 6,750	$ 5,833

Other information pertaining to leases is as follows:

	Year Ended December 31,		
	2025	2024	2023
	(in thousands, except lease term and discount rate)		
Cash paid for amounts included in the measurement of lease liabilities			
Operating cash flows paid for operating leases	$ 8,273	$ 5,647	$ 5,106
Operating cash flows paid for finance leases	21	32	40
Financing cash flows paid for finance leases	151	161	154
Right-of use assets obtained in exchange for lease liabilities			
Operating leases	2,537	18,804	10,521
Finance leases	—	—	—
Weighted-average remaining lease term (years)			
Operating leases	6.0	6.6	7.7
Finance leases	1.7	2.5	3.4
Weighted-average discount rate			
Operating leases	6.7 %	6.3 %	5.5 %
Finance leases	6.9 %	6.7 %	6.7 %

AMPHASTAR PHARMACEUTICALS, INC.
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Future minimum rental payments under leases that have initial or remaining non-cancelable lease terms in excess of 12 months as of December 31, 2025, are as follows:

	Operating Leases	Finance Leases	Total
		(in thousands)	
2026	$ 10,642	$ 174	$ 10,816
2027	9,400	104	9,504
2028	8,738	—	8,738
2029	8,595	—	8,595
2030	8,582	—	8,582
Thereafter	9,287	—	9,287
Total lease payments	$ 55,244	$ 278	$ 55,522
Less: interest	9,632	14	9,646
Total	$ 45,612	$ 264	$ 45,876

New Real Estate Lease Agreement

In July 2025, the Company entered into an agreement to lease approximately 225,167 square feet of building space in Rancho Cucamonga, California. The non-cancelable lease term is approximately 10 years with a renewal option to extend the lease for two additional five-year periods. The monthly lease payments are $0.3 million subject to an annual increase of 3.25%. The Company did not recognize any lease expense and has no ROU assets or lease liability recognized as of December 31, 2025, given that the lease commenced on January 1, 2026.

BAQSIMI®

In connection with the BAQSIMI® acquisition from Lilly, the Company may also be required to pay additional contingent consideration of up to $450.0 million to Lilly based on the achievement of certain milestones. The Purchase Agreement provides that the contingent consideration that may become payable to Lilly would be achieved as follows: (i) a one-time payment of $100.0 million if the Company achieves annual net sales of $175.0 million or more of BAQSIMI® and certain related products, or the Milestone Products, in any one contract year during the first five years after the Closing; (ii) up to two payments of $100.0 million each if the Company achieves annual net sales of $200.0 million or more of Milestone Products in any one contract year during the first five years after the Closing; and (iii) a one-time payment of $150.0 million if the Company achieves total cumulative net sales of $950.0 million or more of the Milestone Products for the first five years after the Closing.

In addition, the Company assumed certain contingent consideration of Lilly, which would require the Company to pay up to an aggregate of $125.0 million based on the achievement of annual net sales milestones of $350.0 million, $400.0 million and $600.0 million. Through December 31, 2025, the Company has not triggered any milestones and therefore no amounts have been recognized or paid.

Licensing Agreement with Nanjing Anji Biotechnology Co., Ltd.

In August 2025, the Company and Nanjing Anji Biotechnology Co., Ltd., or Anji, entered into a License Agreement, or License Agreement, pursuant to which Anji has granted the Company an exclusive license to certain intellectual property to develop, make, use and commercialize products incorporating or comprising certain compounds, including three identified products, or Licensed Products, in the United States and Canada, or the Territory. Anji has also been granted a non-exclusive license under certain intellectual property controlled by the Company to develop, make, use and commercialize Licensed Products outside the Territory. For the year ended December 31, 2025, the Company made earnest money and upfront payments for a total of $6.0 million, which were recorded as a research and development

expense in the Company's consolidated statement of operations.

The Company is also obligated to make cash payments to Anji of up to $42.0 million in development-based milestone payments and up to $225.0 million in sales-based milestone payments, subject to the achievement of the applicable development and sales milestone events respectively, and royalty payments of 5% on net sales, not to exceed a maximum annual amount of $22.5 million each calendar year for each Licensed Product and a maximum accumulated amount of $60.0 million for each Licensed Products. The Company is also required to pay Anji a certain percentage of sublicense income received from the sublicense transactions. The term of this License Agreement will expire, on a Licensed Product-by-Licensed Product and region-by-region basis, on the tenth anniversary of the first commercial sale of such Licensed Product in the applicable region in the Territory, with the Company having the right to extend the License Agreement until the earlier of ten additional years or the expiration, lapse, or invalidation of the last remaining valid claim of the patents licensed by Anji to the Company that covers the Licensed Products in the Territory.

Purchase Commitments

As of December 31, 2025, the Company has entered into commitments to purchase inventory and raw materials for an aggregate amount of approximately $37.5 million.

Note 18. Related-Party Transactions

Hanxin Pharmaceutical Technology, Co., Ltd.

The Company has an 11.5% ownership in Hanxin that is accounted for as an equity method investment. The Company maintains a seat on Hanxin's board of directors, and Henry Zhang, the son of Dr. Jack Zhang, is an equity holder, the general manager, and the chairman of the board of directors of Hanxin. Additionally, Dr. Mary Luo and Dr. Jack Zhang, have an ownership interest in Hanxin through an affiliated entity. As a result, Hanxin is a related party.

Contract Manufacturing Agreements with Hanxin

The Company has various contract manufacturing agreements with Hanxin and its subsidiaries, whereby Hanxin will develop several active pharmaceutical ingredients and finished products for the Chinese market and will engage the Company to manufacture the products on a cost-plus basis.

In January 2026, the Company amended the contract manufacturing agreement with Hanxin, whereby, the amendment now expands the territory of the Manufacturing Agreement with the addition of a global territory, with the exception of the United States and Canada for Lidocaine and Cotricotropin, as well as a global territory for API of Semaglutide, and a global territory for Finished Product of Semaglutide tablet with dose 3, 7 and 14 milligrams. Additionally, the amendment clarifies the intellectual property rights and adds indemnification and limitation of liability terms.

During the years ended December 31, 2025, 2024, and 2023, the Company recognized $1.1 million, $0.5 million and $0.1 million of revenue from manufacturing services provided to Hanxin, respectively. As of December 31, 2025, the Company had an immaterial amount of receivables from Hanxin under these agreements.

Contract Research Agreement with Hanxin

The Company entered into various contract research agreements with Hanxin, a related party, whereby Hanxin will develop Recombinant Human Insulin Research Cell Banks and Recombinant Peptide Research Cell Banks, or RCBs, for the Company and license the RCBs to the Company subject to a fully paid, exclusive, perpetual, transferable, sub-licensable worldwide license. Hanxin will also perform scale-up manufacturing process development using the RCBs for the Company.

During the years ended December 31, 2025, 2024, and 2023, the Company paid $0.4 million, $0.2 million and $1.6 million, respectively, under this agreement. As of December 31, 2025, the Company had an immaterial amount of

payable to Hanxin under this agreement.

Supply Agreement with Letop

In November 2022, the Company entered into a supply agreement with Nanjing Letop Biotechnology Co., Ltd., or Letop, which is considered a related-party due to an ownership stake of Henry Zhang. Under the terms of the supply agreement, Letop will manufacture and deliver chemical intermediates to the Company on a cost-plus basis. The agreement is effective for three years and the total cost of the agreement shall not exceed $1.5 million, with payments adjusted based on the then current exchange rates.

During the years ended December 31, 2025 and 2024, the Company paid an immaterial amount under this agreement. During the year ended December 31, 2023, the Company paid $0.7 million under this agreement. As of December 31, 2025, the Company did not have any additional accruals payable to Letop.

Primatene MIST® Distribution Agreement with Hong Kong Genreach Limited

In August 2024, the Company entered into a distribution agreement with Hong Kong Genreach Limited, or Genreach, a wholly owned subsidiary of Hanxin, a related party. Per the terms of the agreement, the Company has appointed Genreach as the exclusive distributor to market and sell Primatene MIST® in Mainland China, Taiwan, Hong Kong, and Macau in the Greater China region. Genreach will be responsible for obtaining any and all regulatory approvals in the region for Primatene MIST®.

In January 2026, Armstrong and Genreach amended the distribution agreement to expand the region of the distribution agreement to include the Middle East countries and Southeast Asia, as well as amending the annual minimum purchase amount.

The term of the agreement is for ten years, with both parties having termination rights without cause after the completion of the second contract year.

During the year ended December 31, 2025, the Company did not recognize any revenue from the distribution agreement. During the year ended December 31, 2024, the Company recognized $1.1 million of revenue from the distribution agreement with Genreach. As of December 31, 2025, the Company did not have any receivables from Genreach.

BAQSIMI® Distribution Agreement with Nanjing Chengong Pharmaceutical Co., Limited.

In October 2025, the Company entered into a distribution agreement with Nanjing Chengong Pharmaceutical Co., Limited, or Chengong, a wholly-owned subsidiary of Hanxin, a related party. Per the terms of the agreement, the Company will collaborate with Chengong to expand distribution of BAQSIMI®, in Mainland China, Taiwan, Hong Kong, and Macau in the Greater China region, and appoint Chengong as the exclusive distributor to market and sell BAQSIMI® in the Greater China Region. Chengong is responsible for obtaining any and all regulatory approvals in the Region, and performing the required post marketing clinical trials for BAQSIMI®.

The term of the agreement is for ten years, with both parties having termination rights without cause after the completion of the fourth contract year.

During the year ended December 31, 2025, the Company did not recognize any revenue from the distribution agreement. As of December 31, 2025, the Company did not have any receivables from Chengong.

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Note 19. Litigation

Employee Litigation Matters

On April 15, 2024, a former employee initiated an employment litigation against Amphastar and IMS by filing a complaint, as amended, having individual and class action claims for alleged violations of the California Labor Code pertaining to California's Private Attorneys General Act, or PAGA, wage and hour, and other state laws. This complaint was filed in the Superior Court of California for the County of Los Angeles. In the complaint, the plaintiff is seeking damages and related remedies under California law, as well as various penalty payments under the California Labor Code. In November 2024, the court ordered the plaintiff to dismiss the individual and class claims, with only the PAGA claim remaining. The Company intends to vigorously defend itself against the complaint.

On June 20, 2024, a former employee initiated an employment litigation against Amphastar, IMS and Roth Staffing Companies L.P. by filing a complaint having individual and class action claims for alleged violations of the California Labor Code pertaining to wage and hour, and other state laws. This complaint was filed in the Superior Court of California for the County of Los Angeles. In the complaint, the plaintiff is seeking damages and related remedies under California law, as well as various penalty payments under the California Labor Code. The Company intends to vigorously defend itself against the complaint.

On October 30, 2025, a former employee initiated a class action litigation against Amphastar and IMS by filing a complaint for alleged violations of the California Labor Code pertaining to California's PAGA, wage and hour, and other state laws. This complaint was filed in the Superior Court of California for the County of Los Angeles. In the complaint, the plaintiff is seeking damages and related remedies under California law, as well as various penalty payments under the California Labor Code. The Company intends to vigorously defend itself against the complaint.

Other Litigation Matters

On August 23, 2023, the Company was subject to a personal injury lawsuit. A jury trial was held in the Superior Court of California, for the County of San Bernardino from September 2025 to October 2025. On October 22, 2025, the jury returned a verdict awarding the plaintiff $34.1 million, of which $11.0 million was covered by the Company's insurance policies. The remaining $23.1 million was recorded within general and administrative expenses in the Company's consolidated statement of operations for the year ended December 31, 2025. The Company entered into a settlement agreement with the plaintiff in November 2025 pursuant to which the settlement amount based on the jury verdict was paid by the Company in the fourth quarter of 2025.

The Company is also subject to various other claims, arbitrations, investigations, and lawsuits from time to time arising in the ordinary course of business. In addition, third parties may, from time to time, assert claims against the Company in the forms of letters and other communications.

The Company records a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. In the opinion of management, the ultimate resolution of any such matters is not expected to have a material adverse effect on its financial position, results of operations, or cash flows; however, the results of litigation and claims are inherently unpredictable and the Company's view of these matters may change in the future. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources, and other factors.

AMPHASTAR PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 20. Subsequent Events

Licensing Agreement with Hanxin

In January 2026, the Company and Hanxin, a related party, entered into a license agreement pursuant to which Hanxin has granted the Company an exclusive license to certain intellectual property controlled by Hanxin to develop, make, use and commercialize products incorporating or comprising of corticotropin compound, or corticotropin, in the United States and Canada, or the Territory. Hanxin has also granted a non-exclusive license under certain intellectual property controlled by the Company to develop, make, use and commercialize corticotropin outside the Territory.

As part of the agreement, the Company made an upfront payment of $2.0 million to Hanxin upon signing.

The Company is also obligated to make cash payments to Hanxin of up to $14.0 million in development milestone payments and up to $75.0 million in sales milestone payments, subject to the achievement of the applicable development and sales milestone events respectively, and royalty payments of 5% on net sales, not to exceed a maximum annual amount of $7.5 million each calendar year and a maximum accumulated amount of $60.0 million for corticotropin. Hanxin will pay to the Company a royalty payment of net sales of corticotropin that are based on any patents licensed by the Company to Hanxin under the License Agreement or regulatory exclusivity covering corticotropin. The term of the license agreement will expire, region-by-region basis, on the tenth anniversary of the first commercial sale of corticotropin in the applicable region, with the Company having the right to extend the license agreement until the earlier of ten additional years or the expiration, lapse, or invalidation of the last remaining valid claim of the patents licensed by Hanxin to the Company that covers the product.

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

Our management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, our principal executive and principal financial officers, respectively, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective (a) to ensure that information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and (b) to include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of senior management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. Based on the evaluation under that framework and applicable SEC rules, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Our internal control over financial reporting as of December 31, 2025 has been audited by Ernst & Young, LLP, an independent registered public accounting firm, as stated in their report appearing below.

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 (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act).

Inherent Limitations of Internal Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management overriding of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Amphastar Pharmaceuticals, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Amphastar 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, Amphastar Pharmaceuticals, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive income, stockholders' equity 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 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

Irvine, California

February 26, 2026

Item 9B. Other Information.

Securities Trading Plans of Directors and Executive Officers

During our last fiscal quarter, the following director, as defined in Rule 16a-1(f), terminated a Rule 10b5-1 trading arrangement, as defined in Regulation S-K Item 408, as follows:

On November 7, 2025, Floyd Petersen, a member of our Board of Directors, terminated a Rule 10b5-1 trading plan providing for the sale from time to time of an aggregate of up to 6,000 shares of our common stock, that was adopted on November 26, 2024. The trading arrangement was intended to satisfy the affirmative defense of Rule 10b5-1(c).

No other officers or directors, as defined in Rule 16a-1(f), adopted or terminated a Rule 10b5-1 trading arrangement, or a non-Rule 10b5-1 trading arrangement, each as defined in Regulation S-K Item 408.

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

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item will be included in our Proxy Statement for our 2026 Annual Meeting of Stockholders to be filed within 120 days after our fiscal year end of December 31, 2025, or 2026 Proxy Statement, and is incorporated by reference into this Annual Report on Form 10-K.

Item 11. Executive Compensation.

Information required by this item will be included in our 2026 Proxy Statement and is incorporated by reference into this Annual Report on Form 10-K.

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

Information required by this item will be included in our 2026 Proxy Statement and is incorporated by reference into this Annual Report on Form 10-K.

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

Information required by this item will be included in our 2026 Proxy Statement and is incorporated by reference into this Annual Report on Form 10-K.

Item 14. Principal Accountant Fees and Services.

Information required by this item will be included in our 2026 Proxy Statement and is incorporated by reference into this Annual Report on Form 10-K.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) (1) Financial Statements filed as part of this report are listed in Part II, Item 8 of this report.

(2) No other financial schedules have been included because they are not applicable, not required or because required information is included in the consolidated financial statements or notes thereto.

(b) The following exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K, in each case as indicated below.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of Amphastar Pharmaceuticals, Inc., as amended (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 10-Q filed with the SEC on August 7, 2025)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed with the SEC on June 4, 2025)
4.1	Specimen common stock certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
4.2	Description of Securities Registered Under Section 12 of the Exchange Act (incorporated by reference to Exhibit 4.2 to the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2021)
4.3	Indenture, dated September 15, 2023, between Amphastar Pharmaceuticals, Inc. and U.S. Bank Trust Company, National Association, as trustee (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on September 15, 2023)
4.4	Form of 2.00% Convertible Notes due 2029 (incorporated by reference to Exhibit 4.2 (included in Exhibit 4.1) of the Company's Current Report on Form 8-K filed with the SEC on September 15, 2023)
10.1◊	Transfer Contract for the Right to the Use of State-owned Land, dated December 29, 2009, between Amphastar Nanjing Pharmaceuticals Co., Ltd. and Nanjing Xingang Hi-Tech Company Limited (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.2◊	Investment Agreement, dated July 5, 2010, between Amphastar Nanjing Pharmaceuticals Co., Ltd. and the Management Committee of the Nanjing Economic and Technological Development Zone (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.3◊	Transfer Contract for the Right to the Use of State-owned Land, dated December 31, 2010, between Amphastar Nanjing Pharmaceuticals Co., Ltd. and Nanjing Xingang Hi-Tech Company Limited. (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.4+	2014 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.5+	Employment Agreement, dated May 19, 2014, between Amphastar Pharmaceuticals, Inc. and Jack Zhang (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.6+	Employment Agreement, dated May 19, 2014, between Amphastar Pharmaceuticals, Inc. and Mary Luo (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.7+	Employment Agreement, dated March 11, 2014, between Amphastar Pharmaceuticals, Inc. and William Peters (incorporated by reference to Exhibit 10.25 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.8†	Supply Agreement, dated July 31, 2014, between MannKind Corporation and Amphastar France Pharmaceuticals, S.A.S. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2014)

10.9	First Amendment to Supply Agreement, dated October 31, 2014, by and between MannKind Corporation, Amphastar France Pharmaceuticals, S.A.S., and Amphastar Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2014)
10.10†	Second Amendment to Supply Agreement, dated November 9, 2016, by and between MannKind Corporation, Amphastar France Pharmaceuticals, S.A.S., and Amphastar Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2017)
10.11	Partnership Agreement by and between Zhang Chongqing, Bill Zhang and Applied Physics & Chemistry Laboratories, Inc. dated July 27, 2018 (incorporated by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2018)
10.12	Fourth Amendment to Supply Agreement, dated December 24, 2018, by and between MannKind Corporation and Amphastar Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.45 to the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2018)
10.13*	Fifth Amendment to the Supply Agreement by and between MannKind Corporation and Amphastar Pharmaceuticals, Inc., dated August 2, 2019 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2019)
10.14	Amphastar Pharmaceuticals, Inc. Employee Deferred Compensation Plan, effective December 1, 2019 (incorporated by reference to Exhibit 10.39 to the Company's Annual Report on Form 10-K filed with the SEC on March 16, 2020)
10.15+	Amphastar Pharmaceuticals, Inc. 2015 Equity Incentive Plan, as amended and restated effective as of November 3, 2020 (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed with the SEC on November 6, 2020)
10.16*	Sixth Amendment to the Supply Agreement by and between MannKind Corporation and Amphastar Pharmaceuticals, Inc., dated May 24, 2021 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2021)
10.17*	Contract Manufacturing Agreement by and between Amphastar Nanjing Pharmaceutical, Co. Ltd. and Nanjing Hanxin Pharmaceutical Technology Co., Ltd, dated April 19, 2022 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2022)
10.18*	Contract Research Agreement by and between Amphastar Pharmaceuticals, Inc. and Nanjing Hanxin Pharmaceutical Technology Co., Ltd., dated July 5, 2022 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 8, 2022)
10.19*	Supply Agreement by and between Amphastar Nanjing Pharmaceuticals, Inc. and Nanjing Letop Biotechnology Co. Ltd. dated November 15, 2022 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on November 18, 2022)
10.20*	Amendment to Contract Research Agreement by and between Amphastar Pharmaceuticals, Inc. and Nanjing Hanxin Pharmaceutical Technology Co., Ltd., dated March 8, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 9, 2023)
10.21*	Asset Purchase Agreement by and among Amphastar Pharmaceuticals, Inc., Amphastar Medication Co., LLC, and Eli Lilly and Company, dated April 21, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2023)
10.22*	Manufacturing Service Agreement by and between Amphastar Pharmaceuticals, Inc., and Eli Lilly and Company, dated June 30, 2023 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2023)
10.23*	Transition Service Agreement by and between Amphastar Pharmaceuticals, Inc., and Eli Lilly and Company, dated June 30, 2023 (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2023)
10.24	Credit Agreement dated June 30, 2023, by and between Amphastar Pharmaceuticals, Inc. and Wells Fargo Bank, National Association in the original sum of $700,000,000 (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2023)

10.25	Purchase Agreement, dated September 12, 2023, among Amphastar Pharmaceuticals, Inc. and Jefferies LLC, J.P. Morgan Securities LLC, Wells Fargo Securities LLC and BofA Securities Inc. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on September 15, 2023)
10.26*	Seventh Amendment to the Supply Agreement by and between MannKind Corporation and Amphastar Pharmaceuticals, Inc., dated December 22, 2023 (incorporated by reference to Exhibit 10.33 to the Company's Annual Report on Form 10-K filed with the SEC on February 29, 2024)
10.27*	Syndicated Loan Agreement dated January 17, 2024, by and between Amphastar Nanjing Pharmaceuticals, Co., Ltd. and Commercial Bank of China Limited in the original sum of approximately $40,000,000 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 10, 2024)
10.28	2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc. (as amended and restated) (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on June 4, 2024)
10.29*	Distribution Agreement by and between Armstrong Pharmaceuticals, Inc. and Hong Kong Genreach Limited, dated August 28, 2024 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 7, 2024)
10.30*	Second Amendment to the Contract Manufacturing Agreement by and between Amphastar Nanjing Pharmaceutical, Inc., and Nanjing Hanxin Pharmaceutical Technology Co., Ltd, dated May 13, 2025 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 7, 2025)
10.31*	First Amendment to the Contract Research Agreement by and between Amphastar Pharmaceuticals, Inc., and Nanjing Hanxin Pharmaceutical Technology Co., Ltd., dated May 7, 2025 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 7, 2025)
10.32*	License Agreement by and between Amphastar Pharmaceuticals, Inc., and Nanjing Anji Biotechnology Co., Ltd., dated August 8, 2025 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 6, 2025)
10.33*	Contract Research Agreement by and between Amphastar Pharmaceuticals, Inc., and Nanjing Hanxin Pharmaceutical Technology Co., Ltd., dated September 15, 2025 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 6, 2025)
10.34*	Distribution Agreement by and between Amphastar Pharmaceuticals, Inc., and Nanjing Chengong Pharmaceutical Co., Ltd., dated October 21, 2025 (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 6, 2025)
10.35*	License Agreement by and between Amphastar Pharmaceuticals, Inc., and Nanjing Hanxin Pharmaceutical Technology Co., Ltd., dated January 6, 2026
10.36*	Third Amendment to the Contract Manufacturing Agreement by and between Amphastar Nanjing Pharmaceutical, Inc., and Nanjing Hanxin Pharmaceutical Technology Co., Ltd, dated January 6, 2026
10.37*	First Amendment to the Distribution Agreement by and between Armstrong Pharmaceuticals, Inc. and Hong Kong Genreach Limited, dated January 6, 2026
19.1	Amphastar Pharmaceuticals, Inc. Insider Trading Policy, adopted on June 2, 2025
21.1	Subsidiaries of the Company
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (included in signature pages hereto)
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14a of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14a of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1#	Certification of Principal 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 Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1	Compensation Recovery Policy of the Company (incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K filed with the SEC on February 29, 2024)
101.INS	XBRL Instance Document –The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definitions Linkbase Document
104	Cover Page Interactive File (formatted as Inline XBRL and contained in Exhibit 101)

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

* Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10).

\+ Indicates a management contract or compensatory plan or arrangement.

◊ English translation of original Chinese document.

† Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and file separately with the SEC.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements 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.

AMPHASTAR PHARMACEUTICALS, INC.
(Registrant)
By: **/s/ JACK Y. ZHANG**
Jack Y. Zhang
Chief Executive Officer
(Principal Executive Officer)

Date: February 26, 2026

AMPHASTAR PHARMACEUTICALS, INC.
(Registrant)
By: **/s/ WILLIAM J. PETERS**
William J. Peters
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: February 26, 2026

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Jack Y. Zhang and William J. Peters, and each of them, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

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

Signature	Title	Date
/s/ JACK Y. ZHANG Jack Yongfeng Zhang	Chief Executive Officer, President, and Director (Principal Executive Officer)	February 26, 2026
/s/ MARY Z. LUO Mary Z. Luo	Chairman, Chief Operating Officer and Director	February 26, 2026
/s/ WILLIAM J. PETERS William J. Peters	Chief Financial Officer and Director (Principal Financial and Accounting Officer)	February 26, 2026
/s/ JACOB LIAWATIDEWI Jacob Liawatidewi	Executive Vice President of Sales and Marketing, Corporate Administration Center, and Director	February 26, 2026
/s/ GAYLE M. DEFLIN Gayle M. Deflin	Director	February 26, 2026
/s/ DIANE G. GERST Diane G. Gerst	Director	February 26, 2026
/s/ HOWARD LEE Howard Lee	Director	February 26, 2026
/s/ FLOYD PETERSEN Floyd Petersen	Director	February 26, 2026
/s/ RICHARD PRINS Richard Prins	Director	February 26, 2026
/s/ MICHAEL A. ZASLOFF Michael A. Zasloff	Director	February 26, 2026
/s/ DAVID GAUGH David Gaugh	Director	February 26, 2026

Exhibit 10.35

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS ([***]), HAS BEEN OMITTED PURSUANT TO ITEM 601(B)(10)(IV) OF REGULATION S-K, BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) IS THE TYPE THAT THE COMPANY TREATS AS PRIVATE OR CONFIDENTIAL. IN ADDITION, CERTAIN SCHEDULES (OR SIMILAR ATTACHMENTS) HAVE BEEN OMITTED FROM THIS EXHIBIT PURSUANT TO ITEM 601(A)(5) OF REGULATION S-K.

Privileged and Confidential
严格保密

DATED Jan 6, 2026

2026年 1 月 6 日

Nanjing Han Xin Pharmaceutical Technology Co., Ltd.

南京汉欣医药科技有限公司

-and-

与

Amphastar Pharmaceuticals, Inc.

Amphastar Pharmaceuticals, Inc.

LICENSE AGREEMENT

许可协议

LICENSE AGREEMENT

许可协议

This License Agreement ("Agreement") is entered into as of __ Jan 6 ____, 2026 (the "Effective Date") by and between Nanjing Han Xin Pharmaceutical Technology Co., Ltd., a limited liability company duly incorporated and validly existing under the laws of the PRC, with the unified social credit code: [***] ("Licensor") and Amphastar Pharmaceuticals, Inc., a company duly incorporated and validly existing under the laws of United States (hereinafter referred to as "Amphastar" or "Licensee"). Licensor and Licensee are each referred to individually as a "Party" and together as the "Parties."

本许可协议（"本协议"）于2026年_1__月__6_日（"生效日"）南京汉欣医药科技有限公司，一家根据中国法律合法成立并有效存续的有限责任公司，统一社会信用代码为 [***]（"许可方"），与Amphastar Pharmaceuticals, Inc.，一家根据美国法律合法成立并有效存续的公司（下称"Amphastar"或"被许可方"）签订。许可方和被许可方单称"一方"，合称"双方"。

Background

背景

Licensor Controls (as defined below) the Licensed IP (as defined below) relating to the Licensed Compound (as defined below) and Licensed Products (as defined below). Licensee wishes to obtain, and Licensor wishes to grant, rights under the Licensed IP to develop, make, use and sell Licensed Products incorporating the Licensed Compound.

许可方控制（定义见下文）与许可化合物（定义见下文）和许可产品（定义见下文）相关的许可知识产权（定义见下文）。被许可方希望获得且许可方希望授予许可知识产权项下的权利，以开发、生产、使用及销售含有许可化合物的许可产品。

Therefore, the Parties agree as follows:

因此，双方达成协议如下：

1. DEFINITIONS AND INTERPRETATION

定义和释义

1.1 **Definitions**. Unless the context otherwise requires, the terms in this Agreement with initial letters capitalized will have the meanings set forth below, or the meaning as designated in the indicated places throughout this Agreement.

定义。除非上下文另有要求，本协议中的术语具有下文规定的含义或所示的本协议条款所指定的含义。

"**Accounting Standards**" means, U.S. GAAP (US Generally Accepted Accounting Principles), in each case as generally and consistently applied throughout the Party's organization.

"**会计准则**"系指在一方机构内普遍和一贯适用的美国通用会计准则。

"**Affiliate**" means, with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, "control" will mean, direct or indirect ownership of 50% or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or 50% or more of the equity interest in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby the entity or Person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity, or the ability to cause the direction of the management or policies of a corporation or other entity. In the case of entities organized under the laws of certain countries, the maximum percentage ownership permitted by law for a foreign investor may be less than 50%, and in such case such lower percentage will be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity.

"**关联方**"就一方而言，系指控制该方、受该方控制或与该方共同受他方控制的任何主体。为本定义之目的，"控制"系指直接或间接拥有一家公司50%或以上有权投票选举董事的股份或任何其他类型的法律实体50%或以上的股权，或者作为任何合伙企业的普通合伙人，或者可使实体或主体控制或有权控制一家公司或其他实体的董事会或同等管理机构的任何其他安排，或者能够促成主导一家公司或其他实体的管理或政策。对于根据某些国家法律组建的实体，法律允许的外国投资者持股比例上限可能低于50%，在该等情况下，该较低比例将替代前句中规定的比例，但前提是该外国投资者有权主导该实体的管理和政策。

"**Licensor Material**" means the material identified on ***Exhibit C***.

"**许可方材料**"系指***附件C***列明的材料。

"**Applicable Law**" means any national, provincial, federal, state, local or foreign law (including, common law), statute or ordinance, executive order, or any rule, regulation, judgment, order, writ or decree of or from any court, or other Regulatory Authority having jurisdiction over or related to the subject item that may be in effect from time to time, including, as applicable, GCP, GLP, and GMP.

"**适用法律**"系指可能不时有效的任何国家、省、联邦、州、地方或外国法律（包括普通法）、成文法或条例，行政命令，或对主题事项有管辖权的任何法院或其他监管机构的任何规则、法规、判决、命令、令状或法令，包括（按适用情形）药物临床试验质量管理规范、药物非临床研究质量管理规范和药品生产质量管理规范。

"**Calendar Year**" means a period of twelve (12) consecutive calendar months ending on December 31; *provided, that* the first Calendar Year of this Agreement shall commence on the Effective Date and end on December 31, 2026, and the last Calendar Year of this Agreement shall end on the date of expiration or termination of this Agreement in its entirety.

"**日历年**"系指截止于12月31日的连续十二（12）个日历月的期间；但是，本协议的第一个日历年应于生效日开始并于2026年12月31日结束，本协议的最后一个日历年应于本协议整体到期或终止之日结束。

"Change of Control" means, with respect to a Party, (a) a merger, reorganization, consolidation or other transaction involving such Party and any entity that is not an Affiliate of such Party as of the Effective Date, which results in the voting securities of such Party outstanding immediately prior thereto ceasing to represent at least fifty

percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization, consolidation or other transaction, or (b) any entity that is not an Affiliate of such Party as of the Effective Date becoming the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, or (c) any entity that is not an Affiliate of such Party as of the Effective Date acquiring the power (whether through ownership interest, contractual right, or otherwise, including the result of any government action) to direct or cause the direction of the management and policies of such Party.

"**控制权变更**"指，针对一方而言，发生以下任一情形：(a) 该方与在本协议生效日时并非其关联方的任何实体发生合并、重组、并入或其他交易，且在该等交易完成后，原由该方股东持有的有表决权股权不再代表合并后存续实体至少百分之五十（50%）的投票权（经合并计算）；或 (b) 在生效日并非该方关联方的任何实体成为该方已发行股份或权益中拥有合并投票权百分之五十（50%）或以上的实际受益人；或 (c) 在生效日并非该方关联方的任何实体通过股权、合同或其他方式（包括政府行为的结果）取得控制或导致控制该方经营管理和政策方向的权力。

"**Claims**" means all Third Party demands, claims, actions, proceedings and liability (whether criminal or civil, in contract, tort or otherwise) for losses, damages, reasonable legal costs, and other reasonable expenses of any nature whatsoever.

"**权利主张**"系指有关任何性质的损失、损害、合理法律费用及其他合理费用的所有第三方要求、权利主张、诉讼、程序和责任（无论是刑事或民事、合同、侵权或其他方面的）。

"**Commercialize**" means to manufacture for commercial use, market, promote, distribute, import, export, offer to sell or sell Licensed Products, engage with patient advocates, conduct pre-launch activities to prepare a market for potential sale, as well as conducting all associated post-launch regulatory activities, including medical affairs oversight and post-approval studies, and any activities directed to obtaining pricing or reimbursement approvals, and "**Commercialization**" means commercialization activities relating to Licensed Products.

"**商业化**"系指为商业用途而生产、营销、促销、分销、进口、出口、要约出售或销售许可产品，也包括与患者倡导者的互动、为潜在销售做市场准备的上市前活动，以及开展所有相关的上市后监管活动（包括医疗事务监督和批准后研究），以及旨在获得定价或医保审批的任何活动。"**商业化活动**"系指与许可产品相关的商业化活动。

"**Commercially Reasonable Efforts**" means, with respect to a Party, the carrying out of such activities with respect to the Licensed Products or the Licensed Compound with such measure of efforts that is consistent with the efforts that are typically expended or used by a pharmaceutical company operating in the respective territory with similar resources and of comparable size in a program of a similar value, stage of development, life cycle and commercial potential, based on conditions then prevailing and taking into account issues of safety and efficacy, approved labelling, product, competitiveness of alternative Third Party products in the marketplace, the patent or other proprietary position of such Licensed Product, and the regulatory structure involved, as applicable, and other relevant scientific, technical, legal, operational and commercial factors, as determined on a jurisdiction-by-jurisdiction and indication-by-indication basis.

“**商业上合理的努力**”指就一方而言，就开展与许可产品或许可化合物相关的活动，其付出的努力程度应当与一家在对应区域内运营具有相似资源水平和可比规模的医药公司在具有相似价值、开发阶段、生命周期及商业潜力的项目中所通常投入或使用的努力相一致，基于当时实际情况，并综合考虑以下因素：安全性及有效性、获批的适应症标签、产品、第三方竞品的市场竞争力、许可产品的专利或其他专有权状态、相关监管框架（如适用），以及其他科学、技术、法律、运营和商业相关因素，且需按不同司法管辖区和适应症分别评估。

“**Confidential Information**” means all Know-How and other confidential or proprietary information and data of a financial, commercial or technical nature, including information comprising or relating to concepts, discoveries, inventions, data, designs or formulae, which the disclosing Party, its Affiliates, or its or their licensors has supplied or otherwise made available to the other Party or its Affiliates, prior to or during the Agreement Term, whether made available orally, in writing or in electronic form, pursuant to this Agreement.

“**保密信息**”系指在本协议期限之前或期间，披露方、其关联方或其各自的许可方根据本协议的规定已向另一方或其关联方提供的或以其他方式给予的（无论以口头、书面或电子形式提供）所有专有技术及其他保密或专有的财务、商业或技术性质的信息和资料，包括构成或涉及概念、发现、发明、数据、设计或配方的信息。

“**Control**” or “**Controlled**” means, with respect to any Know-How, Patent Rights, other intellectual property rights, or any proprietary or trade secret information, the legal authority or right (whether by ownership, license or otherwise, other than by a license granted under this Agreement) of a Party or its Affiliates, to grant a license or a sublicense of or under such Know- How, Patent Rights, or intellectual property rights to another Person, or to otherwise disclose such proprietary or trade secret information to another Person, without breaching the terms of any agreement with a Third Party or misappropriating the proprietary or trade secret information of a Third Party.

“**控制**”或“**受控制**”就任何专有技术、专利权、其他知识产权或任何专有或商业秘密信息而言，系指一方或其关联方具有法定权限或权利（无论通过所有权、许可或其他方式，但通过本协议项下授予的许可除外），在不违反与第三方的任何协议条款或盗用第三方的专有或商业秘密信息的情况下，向另一主体授予该等专有技术、专利权或知识产权的或其项下的许可或再许可，或以其他方式向另一主体披露该等专有或商业秘密信息。

“**Cover**”, “**Covered**” or “**Covering**” means, with respect to a Valid Claim of a Patent Right and a product or other subject matter, that, in the absence of ownership of, or a license under such Patent Right (i) with respect to a Valid Claim that is issued or granted, the manufacture, use, offer for sale, sale or importation of such product or other subject matter would infringe such Valid Claim of such Patent Right, or (ii) in the case of a Valid Claim that is pending, the manufacture, use, offer for sale, sale or importation of such product or other subject matter would infringe such Valid Claim if such Valid Claim were actually issued.

“**涵盖**”就专利权的有效权利要求和产品或其他标的而言，系指在不存在该专利权的所有权或许可的情况下，(i)就已颁发或授予的有效权利要求而言，该产品或其他标的的生产、使用、要约出售、销售或进口会侵犯该专利权的有效权利要求，或(ii)就申请中的有效权利要求而言，如果该有效权利要求已实际颁发，

该产品或其他标的的生产、使用、要约出售、销售或进口会侵犯该有效权利要求。

"**Develop**" or "**Development**" means drug development activities, including, non-commercial manufacture of the Licensed Compound or Licensed Products, analytical test method development and stability testing, audit development, pharmacology, pharmacokinetics, toxicology, formulation, manufacturing, quality assurance/quality control development, statistical analysis, pre-clinical studies, clinical studies, packaging development, regulatory affairs, and the preparation, filing, and prosecution of Regulatory Filings as necessary to obtain Regulatory Approval to market or sell a Licensed Product.

"**开发**"系指药物开发活动，包括许可化合物或许可产品的非商业化生产、分析测试方法开发和稳定性测试、稽查开发、药理学、药代动力学、毒物学、配方、生产、质量保证/质量控制开发、统计分析、临床前研究、临床研究、包装开发、监管事务，以及为获得许可产品营销或销售的监管批准所需的监管申报的准备、提交和推进。

"**Encumbrance**" means any claim, charge, equitable interest, hypothecation, lien, mortgage, pledge, option, license, assignment, power of sale, retention of title, right of pre-emption, right of first refusal or security interest of any kind.

"**权利负担**"系指任何权利主张、押记、衡平法权益、不转移占有的抵押、留置、抵押、质押、期权、许可、转让、销售权、所有权保留、优先权、优先购买权或任何种类的担保权益。

"**FDA**" means the United States Food and Drug Administration or any successor entity thereto.

"**美国食药监局**"系指美国食品药品监督管理局或其任何继任机构。

"Field" means any and all uses, including all prophylactic, therapeutic, palliative and diagnostic uses for all current and future indications in humans.

"**适用范围**"系指任何及所有用途，包括对于所有当前和将来的人类适应症的所有预防、治疗、缓解和诊断用途。

"**First Commercial Sale**" means, on a Region-by-Region basis, the first sale or transfer, in all cases through a bona fide arm's-length transaction, or commercial use, of a Licensed Product by Licensee or its Affiliates or its sublicensees to a Third Party (including a governmental authority) in a Region after receipt of Regulatory Approval (to the extent applicable for Commercialization and Applicable Laws) of such Licensed Product in such Region, excluding Non-Commercial Sales as any Licensed Product transferred or disposed of as samples or for clinical trials or at or below costs of goods therefor for any so-called treatment investigational new drug sales, named patient sales, expanded access program, compassionate or emergency use sales or pre-license sales made for non-commercial, compassionate purposes, or any indigent program or promotional or educational purposes.

"**首次商业销售**"系指在逐一地区的基础上，被许可方及其关联方或分许可方在获得该地区相关监管批准（如适用于商业化及适用法律的范围内）后，向第三方（包括政府机构）以真实独立交易方式进行的以下任一首次行为：销售、转让许可产品，或将许可产品用于商业用途。但以下非商业销售不应视为首次商

业销售：用于临床试验的转让或处置、样品提供、以不高于成本价进行的销售、治疗用试验新药（IND）相关销售、指定患者计划销售、扩大用药计划（EAP）销售、同情用药或紧急使用销售、获得上市许可前出于非商业目的或人道主义考虑的销售、针对贫困患者的援助计划销售，以及用于推广或教育目的的销售。

"**FTE Rate**" means, an hourly rate for Licensor's employee providing technical assistance or other support to Licensee under this Agreement, which shall be: [***] RMB (RMB [***]) per hour.

"**FTE费率**"指许可方的员工向被许可方提供本协议项下技术协助或其他支持的小时费率，为每小时[***]元人民币(RMB[***])。

"**GCP**" means the ethical, scientific, and quality standards required by the FDA for designing, conducting, recording, and reporting trials that involve the participation of human subjects, as set forth in FDA regulations in 21 C.F.R. Parts 11, 50, 54, 56, and 312 and related FDA guidance documents, and by the International Conference on Harmonization E6: Good Clinical Practices Consolidated Guideline, any similar regulations or guidelines as promulgated by Health Canada, or its predecessor, or as otherwise required by Applicable Laws in the Territory, each as may be amended and applicable from time to time.

"**药物临床试验质量管理规范**"系指美国食药监局对设计、实施、记录和报告有人类受试者参与的试验所要求的伦理、科学和质量标准，具体包括《美国联邦法规汇编》第21编第11、50、54、56和312部分及相关的美国食药监局指导性文件中的美国食药监局法规，国际人用药品注册技术协调会《E6：药物临床试验质量管理规范综合指南》，以及加拿大卫生部或其前身发布的或区域内适用法律另行规定的任何类似法规或指引，以及前述各项不时修订和适用的版本。

"**GLP**" means good laboratory practice as required by the FDA under 21 C.F.R. part 58 and all applicable FDA rules, regulations, orders and guidances, and the requirements with respect to current good laboratory practices prescribed by the ICH Guidelines, any similar regulations or guidelines as promulgated by Health Canada, or its predecessor, or as otherwise required by Applicable Laws in the Territory, each as may be amended and applicable from time to time.

"**药物非临床研究质量管理规范**"系指美国食药监局在《美国联邦法规汇编》第21编第58部分及所有适用的美国食药监局规则、法规、命令和指引项下所要求的良好实验室规范，国际人用药品注册技术协调会指南规定的关于现行良好实验室规范的要求，以及加拿大卫生部或其前身发布的或区域内适用法律另行规定的任何类似法规或指引，以及前述各项不时修订和适用的版本。

"**GMP**" means good manufacturing practices and regulations as required by the FDA under provisions of 21 C.F.R. parts 210 and 211 and all applicable FDA rules, regulations, orders and guidances, and the requirements with respect to current good manufacturing practices prescribed by Health Canada, or its predecessor, or as otherwise required by Applicable Laws in the Territory, each as may be amended and applicable from time to time.

"**药品生产质量管理规范**"系指美国食药监局在《美国联邦法规汇编》第21编第210和211部分及所有适用的美国食药监局规则、法规、命令和指引项下所要求的良好生产规范和法规，加拿大卫生部或其前身发布的关于现行良好生产

规范的要求，以及区域内适用法律另行规定的任何类似法规或指引，以及前述各项不时修订和适用的版本。

"**IND**" means an application or submission filed with or submitted to a Regulatory Authority for approval to initiate human clinical trials in conformance with the requirements of such Regulatory Authority, including (a) for the United States, an Investigational New Drug application or any successor application or procedure filed with the FDA pursuant to 21 C.F.R. part 312, (b) any equivalent to the application or procedure referenced in clause (a) in other jurisdictions within the Territory outside the United States, and (c) all supplements and amendments that may be filed with respect to (a) or (b).

"**新药研究申请**"系指向监管机构提交的、旨在获准开展人类临床试验的申请或程序，该申请须符合相关监管机构的要求，包括(a)就美国而言，根据《美国联邦法规汇编》第21编第312部分的规定向美国食药监局提交的新药研究申请或任何后继替代申请或程序，(b)在美国境外但属于区域内的其他国家或地区，与第(a)项提及的申请或程序等同效力的申请或程序，及(c)可能就第(a)项或第(b)项提交的所有补充和修订。

"**IND Acceptance**" means with respect to an IND, (a) for an IND for a Licensed Product filed with the FDA, the earlier of (i) receipt by a Party or its Affiliate of a "may proceed" letter from a Regulatory Authority; or (ii) expiration of thirty (30) days from the IND submission date without the FDA issuing a clinical hold notice within that period or (b) for an IND filed with any Regulatory Authority outside the United States but within the Territory, an equivalent authorization to proceed with human clinical trials.

"**新药临床研究申请受理**"系指就一项新药研究申请而言，(a) 对于向美国食药监局提交的关于许可产品的新药研究申请，系指下列情况中较早发生者：(i)一方或其关联方从监管机构收到关于可进行该等新药研究申请项下的临床研究的"可开始临床研究"通知函；(ii) 自新药研究申请提交之日起三十(30)天期限届满且未收到美国食药监局关于该新药研究申请被临床搁置的通知；或(b) 对于在美国境外但属于区域内的监管机构提交的新药研究申请，系指获得开展临床试验的同等效力的批准。

"**Insolvency Event**" means, with respect to a Party,

"**破产事件**"就一方而言，系指以下事件：

(a) such Party ceases to function as a going concern by suspending or discontinuing its business;
该方通过中止或终止业务的方式停止作为持续经营实体的运作；

(b) such Party is the subject of voluntary or involuntary bankruptcy proceedings instituted on behalf of or against such Party (except for involuntary bankruptcy proceedings that are dismissed within ninety (90) days);
该方进入代表该方或针对该方提起的自愿或非自愿破产程序（在九十（90）日内被驳回的非自愿破产程序除外）；

(c) an administrative receiver, receiver and manager, interim receiver, custodian, sequestrator, or similar officer is appointed for such Party;

为该方指定行政接管人、接管人与管理人、临时接管人、保管人、查封人或类似人员；

(d) a resolution to wind up such Party is passed at a meeting of the directors or shareholders of such Party;
在该方的董事或股东会议上通过对该方进行清算的决议；

(e) a resolution shall have been passed by such Party or its directors to make an application for an administration order or to appoint an administrator for all of such Party's assets; or
该方或其董事通过决议，就该方的所有资产申请破产管理令或指定管理人；或

(f) such Party makes any general assignment for the benefit of all of its creditors.
该方为其所有债权人的利益进行任何概括转让。

"**Invoice**" means an invoice in a form requesting payment for goods delivered or services rendered.

"**发票**"系指以请求已交付货物或已提供服务的付款为目的所开具的票据形式。

"**Know-How**" means all proprietary or confidential technical information, know-how and data, including inventions (whether patentable or not), discoveries, trade secrets, specifications, instructions, processes, formulae, materials, expertise and other technology for a compound or product or to its or their manufacture, regulatory approval, pricing and reimbursement approval, development, or commercialization, or methods of assaying or testing a compound or product, and including all biological, chemical, pharmacological, biochemical, toxicological, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data, instructions, processes, formulae, expertise and information, regulatory filings and copies thereof.

"**专有技术**"系指所有专有或保密的技术信息、专有技术和资料，包括化合物或产品或其生产、监管批准、定价和医保审批、开发或商业化活动或者化合物或产品的化验或测试方法的发明（无论是否可获得专利）、发现、商业秘密、规格、说明、工艺、配方、材料、专长及其他技术，包括所有生物、化学、药理、生化、毒理、物理及分析、安全、质量控制、生产、临床前及临床数据、说明、工艺、配方、专长及信息、监管申报及其副本。

"**Licensed Compound**" means coded as "AC02" ("**AC02**") (to be specified in ***Exhibit D***), chemical structure thereof, and including all indications, any formulation, any dose amount, any dosage forms, any product presentation, any type of combination product.

"**许可化合物**"系指编号为"AC02"（"**AC02**"）（具体详见***附件D***），其化学结构，包括所有适应症、任何配方、剂量规格、剂型、产品包装形式、任何类型的组合产品。

"**Licensed IP**" means the Licensed Know-How and the Licensed Patents.

"**许可知识产权**"系指许可专有技术及许可专利。

"**Licensed Know-How**" means all Know-How Controlled by Licensor or its Affiliates as of the Effective Date or at any time during the Agreement Term that is

reasonably necessary or useful for the Development of the Licensed Compound or the Licensed Products in the Field in the Territory. The Licensed Know-How existing as of the Effective Date are set forth on ***Exhibit B***.

"**许可专有技术**"系指许可方或其关联方截至生效日或在本协议期限内的任何时间控制的、对于许可化合物或许可产品在区域的适用范围内的开发活动合理必要或有用的所有专有技术。截至生效日存在的许可专有技术列于***附件 B***。

"**Licensed Patents**" means all Patents Rights Controlled by Licensor or its Affiliates as of the Effective Date or at any time during the Agreement Term that Cover the composition of matter, formulation, method of manufacture, use, sale or otherwise exploitation of the Licensed Compound or the Licensed Products in the Field in the Territory. The Licensed Patents existing as of the Effective Date are set forth onset forth on ***Exhibit A***.

"**许可专利**"系指许可方或其关联方截至生效日或在本协议期限内的任何时间控制的、涵盖许可化合物或许可产品在区域的适用范围内的物质组成、配方、生产、使用、销售或其他利用方法的所有专利权。截至生效日存在的许可专利列于***附件A***。

"**Licensed Product(s)**" means prophylactic, therapeutic, palliative or diagnostic products in any form incorporating or comprising a Licensed Compound, alone or in combination with other active ingredients, in any and all indications, any formulation, any dose amount, any dosage forms, any product presentation, any type of combination product, specifically including AC02 Product. "**AC02 Product**" shall mean such product incorporating or comprising AC02.

"**许可产品**"系指任何及所有含有或包含许可化合物（单独或与其他活性成分结合）的预防、治疗、缓解或诊断产品，包括所有适应症、任何配方、剂量规格、剂型、产品包装形式、任何类型的组合产品，且包括AC02产品。"**AC02产品**"系指含有或包含AC02的产品。

"**Licensing Term**" means both the Initial Licensing Term and Extended Licensing Term (if applicable). For the purpose of this Agreement, the "**Initial Licensing Term**" means, on a Region-by-Region basis, the period commencing on the Effective Date and ending on the ten (10) year anniversary of the First Commercial Sale of a Licensed Product in such Region. The "**Extended Licensing Term**" means, if elected by Licensee to extend the Initial Licensing Term (Licensee has the right (but not the obligation) to extend the Initial Licensing Term at its sole discretion), the period commencing on the next day of the expiration date of the Initial Licensing Term and ending on the earlier of the following: (x) additional ten (10) years after the Initial Licensing Term, or (y) the expiration, lapse, or invalidation of the last remaining Valid Claim of the Licensed Patents that Covers the Licensed Products in the Territory.

"**许可期限**"是指初始许可期限和展期许可期限（如使用）。就本协议而言，"**初始许可期限**"是指，在逐个地区的基础上，自生效日起至许可产品在该地区首次商业销售满十（10）周年止的期间。"**展期许可期限**"是指，如果被许可方选择延长初始许可期限（被许可方有权（但无义务）自行决定延长初始许可期限），从初始许可期限到期日的次日起至下列较早日期止的期限：(x) 初始许可期限届满后延期十（10）年，或 (y) 涵盖许可产品的许可专利的最后剩余的有效权利要求在区域内到期、失效或无效。

"**MAA**" means an application for the authorization to market Licensed Product in any country or group of countries outside the United States, as defined in the Applicable Laws and filed with the Regulatory Authority of a given country or group of countries.

"**药品上市许可申请**" 系指根据适用法律的规定向一个或多个国家的监管机构提交的许可产品在美国以外的一个或多个国家的上市许可申请。

"**NDA**" means a New Drug Application, as described in the FDA regulations, 21 C.F.R. § 314.50, submitted to the FDA.

"**新药上市申请**"系指根据《美国联邦法规汇编》第21编第314.50部分的美国食药监局法规向美国食药监局提交的新药上市申请。

"**Net Sales**" means, with respect to a Licensed Product, the gross amount invoiced for sales, in an arm's length transaction, by Licensee, its Affiliates, and its sublicensees, to a Third Party, commencing with the First Commercial Sale of such Licensed Product, less the following deductions from such gross amounts which are actually incurred, allowed, accrued or specifically allocated, in accordance with the Accounting Standards of the applicable selling party, and not otherwise deducted in computing other amounts hereunder (without duplication):

"**净销售额**"就许可产品而言，系指被许可方及其关联方及其分许可方自该许可产品首次商业销售之时起在公平交易中向第三方进行的销售开具发票的总金额减去从该等总金额中扣除的按照适用销售方的会计准则实际发生的、允许的、累计的或专门分摊的以下金额后所得的金额，并且扣除金额属于在计算本协议项下其他金额时未被另行扣除（不得重复扣除）的部分：

(a) credits, price adjustments or allowances for damaged products, returns or rejections of Licensed Products;
针对损坏产品或退回或拒收的许可产品的赊销、价格调整或折让；

(b) normal and customary trade, cash and quantity discounts, allowances and credits (other than price discounts granted at the time of invoicing which have already been included in the gross amount invoiced);
常规的贸易、现金及数量折扣、折让及赊销（在发票开具时已包含在发票总金额中的价格折扣除外）；

(d) discounts, refunds, rebates, chargebacks, retroactive price adjustments, and any other allowances which effectively reduce the net selling price granted to any Third Party;
折扣、退款、回扣、退货款、有追溯效力的价格调整及任何其他给予第三方的实际降低净售价的折让；

(c) any invoiced freight, postage, shipping, distribution fee, insurance and other transportation charges;
任何已开具发票的运费、邮费、装运费、分销费、保险费及其他运输费用；

(e) sales, value-added, and excise taxes, tariffs and duties, and other taxes directly related to the sale (but not including taxes assessed against the income derived from such sale);

销售税、增值税、消费税、关税及其他与销售直接相关的税项（但不包括对来源于该销售的收入征收的税款）；

(f) actual sales write-offs for uncollectible amounts consistently applied under Accounting Standards, provided that if the amount is thereafter paid, the corresponding amount shall be added to the Net Sales of the period during which it is paid and
会计准则项下对不可收回金额一贯采用的实际销售冲销，前提是如果该等款项随后被收回，则相应金额应计入收回当期的净销售额。；及

(g) any other customary adjustments in accordance with U.S. GAAP as generally and consistently applied by Amphastar in the preparation of its financial statements filed with the SEC to determine "Net Sales".
Amphastar在准备其向美国证券交易委员会提交的财务报表时为确定"净销售额"而普遍及一贯采用的根据美国通用会计准则进行的任何其他惯常调整。

Such amounts shall be determined from the books and records of the Licensee or its Affiliates or its sublicensees. For purposes of determining Net Sales, (i) sales of a Licensed Product shall not include transfers, uses or dispositions for charitable, promotional, pre-clinical, clinical, regulatory or governmental purposes, in each case, at or below cost, and (ii) sales between or among the Licensee and its Affiliates for re-sale shall be excluded from the computation of Net Sales, but subsequent sales by the Licensee or its Affiliates to third parties shall be included in the computation of Net Sales, and (iii) if a Licensed Product is delivered to the Third Party before being invoiced (or is not invoiced), Net Sales will be calculated at the time all the revenue recognition criteria under Licensee's Accounting Standards are met.

上述金额应根据被许可方或其关联方或其分许可方的账簿及记录确定。为确定净销售额之目的，(i)许可产品的销售不包括为慈善、推广、临床前、临床、监管或政府目的进行的转让、使用或处置，且均不高于成本价；(ii)被许可方及其关联方之间为转售目的的销售不得包括在净销售额的计算中，但被许可方或其关联方对第三方的后续销售应包括在净销售额的计算中；及(iii)如果许可产品在开具发票前已交付第三方（或未开具发票），净销售额应在被许可方会计准则项下的所有收入确认条件均被满足之时计算。

"**Party**" or "**Parties**" has the meaning set forth in the preamble.

"一方"或"双方"具有前言中规定的含义。

"**Patent Rights**" means

"专利权"系指

(a) all patent applications, including any provisional patent applications, in any country;
在任何国家的所有专利申请，包括临时专利申请；

(b) any patent application claiming priority from such patent application in (a) or provisional application, including all divisionals, continuations, substitutions, continuations-in-part, provisionals, converted provisionals and continued prosecution applications, or any foreign equivalents;

就第(a)项的该等专利申请或临时申请主张优先权的任何专利申请，包括所有的分案、接续、替代、部分接续、临时申请、转换临时申请及继续审查申请，或任何其他国家对应申请；

(c) any patent that has issued or in the future issues from any of the foregoing patent applications, ((a) and (b)), including any utility patent, utility model patent, petty patent, design patent, certificate of invention, or any foreign equivalents;
在任何上述专利申请（第(a)项和第(b)项）中已经颁发或未来颁发的任何专利，包括任何发明专利、实用新型专利、小专利、外观设计专利、发明证书，或任何其他国家对应权利；

(d) any re-examinations, reissues, additions, renewals, extensions, registrations, supplemental protection certificates of any of the foregoing patents or patent applications ((a), (b), and (c)), or any foreign equivalents; and
任何上述专利或专利申请（第(a)项、第(b)项和第(c)项）的任何复审、再颁、增补、续期、延期、登记、补充保护证书，或任何其他国家对应程序；及

(e) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent application or patent.
任何类似的权利，包括所谓的临时保护，或任何针对前述任一专利申请或专利的进口、恢复、确认或引进专利或注册专利，或任何上述专利申请或专利的增补专利。

"**Person**" means any individual, partnership, limited liability company, firm, corporation, association, trust, unincorporated organization or other entity.

"**主体**"系指任何个人、合伙、有限责任公司、商号、公司、协会、信托、非法人组织或其他实体。

"**PRC"** means People's Republic of China, for the purpose of this Agreement, excluding the Hong Kong Special Administrative Region, the Macau Special Administrative Region and the islands of Taiwan.

"中国"系指中华人民共和国，为本协议之目的，不包括香港特别行政区、澳门特别行政区和台湾岛。

"**Pricing and Reimbursement Approval**" means the authorization or approval of reimbursement for a pharmaceutical product in a country or jurisdiction by the relevant Regulatory Authority, government agency, or other body responsible for such activities in such country or jurisdiction under Applicable Law.

"**定价和医保审批**" 系指在任何国家或司法管辖区的相关监管机构、政府部门或其他根据适用法律负责相关活动的机构授权或批准在该等国家或司法管辖区的药品报销。

"**Region**" means any individual country within the Territory.

"**地区**"系指区域内的任何单个国家。

"**Regulatory Approval**" means, with respect to a Licensed Product in any country or jurisdiction, any approval, registration, license or authorization from a Regulatory Authority in a country or other jurisdiction that is reasonably necessary to market and sell a Licensed Product in such country or jurisdiction.

"**监管批准**"就任何国家或司法管辖区的许可产品而言，系指从一个国家或其他司法管辖区的监管机构获得的、许可产品在该国或司法管辖区上市和销售而合理所需的任何批准、注册、许可或授权。

"**Regulatory Authority**" means any governmental authority or agency responsible for authorizing or approving the marketing or sale of pharmaceutical products in a jurisdiction (*e.g.*, the FDA, European Commission, the NMPA, and corresponding national or regional regulatory agencies or organizations).

"**监管机构**"系指负责授权或批准药品在任何司法管辖区上市或销售的任何政府机构或部门（例如美国食药监局、欧盟委员会、中国药监局，以及相应的国家或地区监管机构或组织）。

"**Regulatory Exclusivity**" means, with respect to a Licensed Product in any country or jurisdiction, any one or more of data, market or other regulatory exclusivity (other than Patent exclusivity) granted or afforded by Applicable Law or by a Regulatory Authority in such country or jurisdiction that confers exclusive marketing rights with respect to such Licensed Product in such country or jurisdiction, including without limitation orphan drug exclusivity, new chemical entity exclusivity, data exclusivity, pediatric exclusivity, rights conferred in the U.S. under the Hatch-Waxman Act or the FDA Modernization Act of 1997, in European Union member states under national implementations of Article 10 of Directive 2001/83/EC, and rights similar thereto in other country or jurisdiction.

"**监管独占权**"是指，就任何国家或司法管辖区中的一个许可产品而言，依据适用法律或该国或司法管辖区的监管机构授予或提供的任何一种或多种数据、市场或其他监管独占权（不包括专利独占权），该等独占权在该国或司法管辖区赋予该许可产品专属的市场销售权利，包括但不限于孤儿药独占权、新化学实体独占权、数据独占权、儿科独占权、美国根据《哈奇-瓦克斯曼法案》或《1997年食品药物管理局现代化法案》赋予的权利、欧盟成员国根据《2001/83/EC号指令》第10条的国家实施办法赋予的权利，以及其他国家或司法管辖区赋予的类似权利。

"**Regulatory Filings**" means, with respect to a Licensed Compound or Licensed Product, any submission to a Regulatory Authority of any appropriate regulatory application, and includes any submission to a regulatory advisory board, marketing authorization application, and any supplement or amendment thereto. For the avoidance of doubt, Regulatory Filings will include any IND, CTA, NDA, MAA or the corresponding application in any other country or group of countries.

"**监管申报**"就许可化合物或许可产品而言，系指向监管机构提交的任何适当的监管申请，包括向监管咨询委员会提交的任何资料、上市许可申请及其任何补充或修改。为避免疑义，监管申报将包括任何新药研究申请、临床试验申请、新药上市申请、药品上市许可申请或在任何其他一个或多个国家的相应申请。

"**Royalty Term**" means, on a Region-by-Region basis, the period commencing on the First Commercial Sale of a Licensed Product upon the later of (i) [***], (ii) [***], or (iii) [***].

“**许可费期限**”系指在逐个地区的基础上，自许可产品首次商业销售开始至以下时间孰晚的期间：(i) [***]，(ii) [***]，或(iii) [***]。

“**Sales & Royalty Report**” means a written report or reports on the Region-by-Region basis showing each of:

“**销售与许可费报告**”系指显示以下各项分地区分别计算的书面报告：

(a) the Net Sales of the Licensed Product during the reporting period by Licensee , its Affiliates and its sublicensees (in all cases itemizing by category the various deductions taken from gross to compute Net Sales as set forth in the definition of Net Sales, above); and
报告期内被许可方、其关联方及其分许可方许可产品的净销售额（在所有情况下，按类别分项列明上文净销售额定义所述的为计算净销售额而从总金额中扣除的各项金额）； 以及

(b) the royalties payable (in USD), and the rate of exchange with supporting calculations if the currency of sale was not U.S. dollars), which will have accrued hereunder with respect to such Net Sales, with supporting calculations showing the applicable royalty rate applied.
在本协议项下就该等净销售额累计的应付许可费（以美元计算，如销售货币非美元，则附带换算汇率及计算依据），并附有适用许可使用费率的计算明细。

“**Senior Officers**” means, for Licensor, its General Manager or his or her designee, and for Amphastar, its Executive Vice President, or his or her designee as appointed by the Executive Vice President.

“**高级管理人员**”就许可方而言，系指其总经理或其指定人；就Amphastar而言，系指其执行副总裁或执行副总裁指定的其他人。

“**Territory**” means the United States and Canada.

“**区域**”系指美国和加拿大。

“**Third Party**” means any Person other than a Party or an Affiliate of a Party.

“**第三方**”系指除任何一方或其关联方以外的任何主体。

“**United States**” or “**US**” means the United States of America, its territories and possessions.

“**美国**”系指美国、其领土及属地。

“**USD**” or “$” means US Dollars.

“**美元**”或“$” 系指美元。

“**US Data Security Program**” means US Executive Order 14117 and rules issued thereunder, including 28 C.F.R. Part 202, as amended from time to time.

“**美国数据安全计划**” 指美国第14117号行政命令及其颁布的相关规则，包括但不限于《联邦法规汇编》第28编第202部分及其不时修订的版本。

"**Valid Claim**" means

"有效权利要求"系指

(a) a claim of an issued and unexpired patent of a granted Licensed Patent (as may be extended through supplementary protection certificate or patent term extension or the like) that, in each case:
已授权且未到期的许可专利（包括可通过补充保护证书、专利期限延长或类似方式延展的专利）的、符合下列情况的权利要求：

(i) Covers the Development, manufacture, use, offer for sale, sale or import of the relevant Licensed Compound or Licensed Product in the relevant jurisdiction;
涵盖在相关司法管辖区内相关许可化合物或许可产品的开发、生产、使用、要约出售、销售或进口；

(ii) has not been irrevocably or unappealable disclaimed, cancelled, withdrawn, or abandoned, or been held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency or tribunal of competent jurisdiction; and
未被具有管辖权的法院或其他政府或裁判机构决定放弃、注销、撤回或废止（且该等否认或放弃不可撤销或不可上诉）或者认定为不可强制执行、不可授予专利或无效；及

(iii) has not been admitted to be invalid or unenforceable through reissue, disclaimer, or otherwise by Regulatory Authority; or
未被监管机构通过重新公告、否认或其他方式被承认无效或不可强制执行；或

(b) a claim included in a pending patent application within the Licensed Patents that:
许可专利中包含的未决专利申请中的、符合下列情况的权利要求：

(i) would Cover the Development, manufacture, use, offer for sale, sale or import of the relevant Licensed Compound or Licensed Product in the relevant jurisdiction if such claim were part of a pending patent application; and
若该权利要求属于在申请中专利的一部分，则将涵盖相关许可化合物或许可产品在相关司法管辖区的开发、生产、使用、要约出售、销售或进口；及

(ii) has not been cancelled, withdrawn or abandoned, nor been pending for more than seven (7) years since its official filing date in the Region in which such patent application was filed.
未被取消、撤回或放弃，且自提出该专利申请的正式申请日起未处于申请中状态超过七（7）年。

1.2 **Interpretation**. In this agreement unless otherwise specified:

解释。在本协议中，除非另有说明：

(a) "includes" and "including" mean, respectively, includes without limitation and including without limitation;
"包括"系指包括但不限于；

(b) a Party includes its permitted assignees and the respective successors in title to substantially the whole of its undertaking;
一方包括其经允许的受让人及其各自实质上全部业务的所有权继承人；

(c) a statute or statutory instrument or any of their provisions is to be construed as a reference to that statute or statutory instrument or such provision as the same may have been or may from time to time hereafter be amended or re-enacted;
法令或法定文书或其任何条款应解释为可能已经或此后可能不时修订或重新颁布的该等法令或法定文书或该等条款；

(d) words denoting the singular will include the plural and vice versa and words denoting any gender will include all genders;
单数形式的词语包括复数形式，反之亦然，任何性别的词语包括所有性别；

(e) the Exhibits and other attachments form part of the operative provision of this Agreement and references to this Agreement shall, unless the context otherwise requires, include references to the Exhibits and attachments;
附件及其他附录构成本协议执行条款的一部分，且除非上下文另有要求，提及本协议应包括附件和附录；

(f) the headings in this Agreement are for information only and will not be considered in the interpretation of this Agreement;
本协议中的标题仅为参考而设，在解释本协议时不予考虑；

(g) general words will not be given a restrictive interpretation by reason of their being preceded or followed by words indicating a particular class of acts, matters or things;
概括性的词语不会由于其前后为表明特定类别的行为、事项或事物的词语而被赋予限制性解释；

(h) references to days means calendar days unless otherwise indicated; and
除非另行指明，提及的日系指日历日；及

(i) the terms of this Agreement are the result of negotiations between the Parties, and this Agreement will not be construed in favor of or against any Party by reason of the extent to which any Party participated in the preparation of this Agreement.
本协议的条款系双方协商的结果，本协议不会因任何一方参与准备本协议的程度而以对任何一方有利或不利的方式进行解释。

2. INTELLECTUAL PROPERTY LICENSE

知识产权许可

2.1 **License Grant**. Subject to the terms of this Agreement, Licensor and its Affiliates hereby grant to Licensee an exclusive (even as to Licensor and its Affiliates), royalty-

bearing license, sublicensable within the Licensing Term (with the right to sublicense in accordance with Section 2.2) in, to and under the Licensed IP in the Field and in the Territory, to (i) research, Develop, make and have made, use Licensed Compound and Licensed Products; and (ii) to Commercialize Licensed Products. For clarity, Licensee's rights to Licensed Compound and Licensed Products shall include all indications, any formulation, any dose amount, any dosage forms, any product presentation, any type of combination product.
许可授予。受限于本协议的条款，许可方及其关联方特此授予被许可方一项在许可期限内有关许可知识产权的独占的（即使对许可方及其关联方而言）、需支付许可费的、可分许可的（根据第2.2款的规定享有分许可权利）的许可，以在区域的适用范围内进行：(1) 许可化合物和许可产品的研究、开发、生产和委托生产、使用；以及(2) 就许可产品进行商业化。为免疑义，被许可方对许可化合物及许可产品的权利应包括所有适应症、任何配方、剂量规格、剂型、产品包装形式、任何类型的组合产品。

2.2 **Sublicense and Subcontract Rights**.

分许可和分包权。

(a) Subject to the terms and conditions of this Agreement, Licensee may sublicense (through multiple tiers) the license set forth in Section 2.1 at any time at its sole discretion to any Person.
在遵守本协议的条款和条件的前提下，被许可方可以（通过多层）随时自行决定将第2.1款中规定的许可分许可给任何主体。

(b) Each sublicense shall be subject to a written agreement that is consistent with the terms of this Agreement. Each sublicense of the Licensed IP shall be consistent with the terms of this Agreement. A copy of any sublicense agreement (or any supplements or amendments thereto) executed by Licensee shall be provided to Licensor within thirty (30) business days after the execution, provided that Licensee may redact any terms that are commercially sensitive which are unnecessary for Licensor to confirm compliance with this Agreement, notwithstanding of the foregoing, Licensee shall not redact or obscure any terms related to financial consideration (e.g., upfront payments, royalties, milestone payments, or pricing structure), sublicense scope, field of use limitations, or termination rights, which are necessary for Licensor to confirm compliance with this Agreement.
每项分许可均应受限于一份与本协议的条款保持一致的书面协议。许可知识产权的每次分许可均应符合本协议的条款。被许可方应在签署任何分许可协议（或其任何补充或修订）后三十(30)个工作日内向许可方提供一份该协议的副本，但被许可方有权对涉及商业敏感信息且许可方无需用于确认合规性的条款进行删节处理，尽管有前述规定，被许可方不得对任何涉及财务对价的条款（如预付款、特许权使用费、里程碑付款或价格结构）、分许可范围、使用领域限制或终止权利的内容（为许可方确认本协议合规性所必需的条款）进行删减或遮蔽。

(c) Licensee may engage subcontractors, including but not limited to Third Party contract research organization ("CRO"), Third Party contract manufacturing organization ("CMO") and Third Party contract sales organization ("CSO") (such subcontractor(s) individually and collectively, "Subcontractor(s)") to exercise its rights or perform its obligations under this Agreement; provided that such subcontracting will be pursuant to a written and executed subcontracting agreement that does not conflict with and is subject to the terms

of this Agreement, and shall not relieve Licensee of its obligations hereunder, and Licensee shall be directly responsible for any act or omission of its Subcontractor.
被许可方有权聘请分包商，包括但不限于第三方合同研发组织(CRO)、第三方合同生产公司(CMO)以及第三方合同销售组织(CSO)（此类分包商单独及合称为"分包商"）行使其在本协议项下的权利或履行其在本协议项下的义务，但该等分包应依据已签署的书面分包协议进行，该协议不得与本协议条款冲突且应受本协议条款约束，且不免除被许可方在本协议项下的义务，且被许可方应对其分包商的任何作为或不作为直接负责。

(d) Licensee shall remain directly responsible for all of its obligations under this Agreement that have been delegated or sublicensed to any sublicensee or other Subcontractor. Any sublicensee or Subcontractor conduct, act, omission or state of affairs that would have constituted a breach of this Agreement shall be imputed to Licensee and deemed a breach of this Agreement as if such conduct, act, omission or state of affairs had been directly attributable to Licensee. Licensee shall not grant a sublicense to any sublicensee or engage the services of any Subcontractor that has been debarred or disqualified by a Regulatory Authority.
被许可方应继续直接对其在本协议下的所有义务负责，即便这些义务已委托或分包给任何分许可方或其他分包商。任何分许可方或分包商的行为、作为、不作为或事务状态，如构成对本协议的违反，应归咎于被许可方，并视为对本协议的违反，如同该行为、作为、不作为或事务状态直接归咎于被许可方一样。被许可方不得向任何被监管机构禁止或取消资格的分许可方或分包商授予分许可或聘用其提供服务。

2.3 **Cross-license**. Amphastar and its Affiliates grant to Licensor a non-exclusive, non-transferable, sublicensable (subject to second paragraph in this Section 2.3), royalty-bearing license under the Patent Rights that Amphastar owns from Development, manufacture, use of Licensed Compound and Licensed Products and Commercialization of Licensed Products under this Agreement (the "Cross-license Patents") to research, Develop, make and have made, use Licensed Compound and Licensed Products and Commercialize Licensed Products in the Field outside the Territory.
交叉许可。 Amphastar及其关联方向许可方授予Amphastar根据本协议因开发、生产、使用许可化合物和许可产品以及商业化许可产品而拥有的专利权项下的非独占性的、不可转让的、可分许可的（受限于本第2.3条第二段）且支付许可费的许可，以在除区域以外的其他地区在适用范围内进行许可化合物和许可产品的研究、开发、生产和委托生产、使用以及许可产品的商业化（"交叉许可专利"）。

For clarity, Licensor shall not, and shall not permit any of its Affiliates or sublicensees or any Third Party to, Commercialize Licensed Compound and Licensed Products utilizing Cross-license Patents in the Field in the Territory.
为避免歧义，许可方不得，且不得允许其任何关联方、分许可方或任何第三方，就使用了交叉许可专利的许可化合物和许可产品在区域内、在适用范围内进行商业化活动。

2.4 **Retained Rights; No Implied Licenses.** Except for the licenses expressly granted to the other Party pursuant to this Agreement, the Parties on behalf of itself and its Affiliates (and on behalf of its sublicensees) and contractors) grant no other rights or

licenses, including any other rights or licenses under the Licensed IP and Cross-License Patents, whether by implication, estoppel or otherwise. For clarity, on behalf of itself and its Affiliates (and on behalf of its sublicensees and contractors), Licensor retains (a) exclusive rights to research, Develop, make and have made, use, seek Regulatory Approval for and Commercialize each Licensed Product and Licensed Compound, as well as the Licensed IP outside the Territory, and (b) rights under Licensed IP to the extent necessary for the performance of its obligations under this Agreement.

保留权利；无默示许可。除根据本协议明确授予另一方的许可外，双方（代表其自身及其关联方，并代表各自分许可方及分包商）不授予任何其他权利或许可（无论是通过默示、禁止反言或其他方式），包括许可知识产权和交叉许可专利项下的任何其他权利或许可。为避免歧义，许可方特此声明，其代表自身及其关联方（以及其分许可方和分包商）保留以下权利：(a) 在区域外，对每一个许可产品、许可化合物以及许可知识产权进行研究、开发、制造和委托制造、使用、申请监管批准和商业化的专属权利；和(b) 利用许可知识产权，为履行本协议项下义务开展活动所必须的权利。

3. GOVERNANCE.

治理。

3.1 **Alliance Managers**. Within thirty (30) days after the Effective Date, each Party shall appoint (and notify the other Party of the identity of) a senior representative having a general understanding of pharmaceutical development to act as its alliance manager under this Agreement ("Alliance Manager"). The Alliance Managers will (a) serve as the contact point between the Parties for the purpose of providing Licensor with information on the progress of Licensee's Development of Licensed Compound and Licensed Products; and (b) subject to Section 13.3(c), be primarily responsible for facilitating the flow of information and otherwise promoting communication, coordination, and the transfer of Licensed Know-How from Licensor to Licensee as described in Article 4; (c) facilitate the prompt resolution of any disputes. Each Party may replace its Alliance Manager on written notice to the other Party.

合作项目管理人。在生效日后的三十（30）日内，每一方应任命一名对医药开发有全面了解的资深代表担任其在本协议项下的合作项目管理人（"合作项目管理人"）（并向另一方通知其具体身份）。合作项目管理人将(a) 担任双方之间的联络人，向许可方提供被许可方许可化合物和许可产品的开发进度信息；及(b) 受限于第13.3(c)款的规定，主要负责促进信息交流及以其他方式促进沟通、协调，以及许可方根据第4条的规定向被许可方进行的许可专有技术转移；(c) 促进任何争议的及时解决。每一方可经书面通知另一方更换其合作项目管理人。

3.2 **Final decision**. Licensee will be solely responsible for and, subject to compliance with the terms of this Agreement, will have the final decision-making authority with respect to the Development, manufacture and otherwise exploitation of the Licensed Products and Licensed Compound and Commercialization Licensed Products in the Field in the Territory, provided that Licensee shall not use such final decision making authority in a manner that would violate Applicable Laws or create material financial burden upon Licensor.

最终决定。对于许可产品和许可化合物在区域的适用范围内的开发、制造、以其他方式利用以及许可产品在区域的适用范围内的商业化，被许可方将全权负责，并在遵守本协议的条款的前提下拥有最终决策权，但条件是被许可方行使该最终决策权时，不得违反适用法律或对许可方增加重大的财务责任。

4. DISCLOSURE OF LICENSED IP & COOPERATION

许可知识产权的披露与合作

4.1 **Disclosure of Licensed IP, transfer of Licensor Materials and other documents.**
许可知识产权的披露，许可方材料及其他文件的转移。

(a) Within fifteen (15) days after each quarter during the Agreement Term, Licensor shall provide to Licensee a complete list of Licensed Patents that is not specified in ***Exhibit A*** (i.e. the Licensed Patents Controlled by Licensor after the Effective Date). For avoidance of doubt, such Licensed Patents shall also be licensed to Licensee in accordance with the terms herein.
在本协议期限内每个季度结束后十五（15）日内，许可方应向被许可方提供一份完整的许可专利清单，该清单包含所有未在***附件A***中列明的许可专利（即许可方在生效日后控制的许可专利）。为避免疑义，此类许可专利同样应根据本协议条款授予被许可方许可。

(b) Within fifteen (15) days (or the timeline otherwise specified in ***Exhibit B***) after execution of this Agreement, Licensor shall provide to Licensee a copy (in electronic format if it is available in electronic format or a hard copy upon written request if it is not available in electronic format) of the documentation listed on ***Exhibit B***. All documentation and information within the Licensed Know-How will be provided in the language such documentation was generated and will not be translated.
在签署本协议后的十五（15）日内（或根据***附件B***所列明的时间），许可方应向被许可方提供***附件B***所列文件的一份副本（如有电子格式，应提供电子格式，如无电子格式，应按书面要求提供纸质副本）。许可专有技术中的所有文件和信息将以生成该等文件的语言提供，且不进行翻译。

(c) If any Party reasonably identifies specific documents that constitute Licensed Know-How Controlled by Licensor that were used for or arose from the Development of any Licensed Compound or Licensed Product which is not included on ***Exhibit B***, Licensor shall locate and provide such documents to Licensee within fifteen (15) days thereafter, and the content of such documents shall be deemed to be Licensed Know-How and licensed for Licensee's use under this Agreement, subject to Article 2. Without prejudice to the foregoing provisions, during the Agreement Term and upon reasonable request by Licensee, Licensor shall promptly and continuously provide the Licensee with documents, data, or materials related to the Licensed Know-How and Licensed Patents that are acquired by Licensor and have not been previously disclosed to Licensee.
如果任何一方合理发现构成用于或源于任何许可化合物或许可产品开发的由许可方控制的、但未列入***附件B***的许可专有技术的特定文件，则许可方应在其后的十五（15）日内找到并向被许可方提供该等文件，该等文件的内容应被视为许可专有技术，并根据第2条许可被许可方在本协议项下使用。在不影响前述条款效力的前提下，在本协议期限内，经被许可方合理要求，许可方应及时持续地向被许可方提供其获得且此前未向被许可方披露的、与许可专有技术及许可专利相关的文件、数据或资料。

(d) Within fifteen (15) days after execution of this Agreement, Licensor shall provide to Licensee the Licensor Material specifically identified on each of ***Exhibit C***, at no cost to Licensee, in the form and quantities set forth on each of ***Exhibit C***.
在签署本协议后的十五（15）日内，许可方应以***附件 C***所列明的相关格式和数量，向被许可方无偿提供***附件 C***所列明的许可方材料。

(e) In addition to the Licensed Know-How and Licensor Materials, Licensor will provide reasonably necessary assistance to Licensee, which are reasonably required for the proper use and understanding of the aforementioned Licensed Know-How and Licensor Material or the Development and Manufacture of Licensed Compound and Licensed Products.
除许可专有技术及许可方材料外，为正确使用和理解上述许可专有技术及许可方材料或开发和生产许可化合物和许可产品，许可方还将为被许可方提供合理必要的协助。

4.2 **Assistance and FTE Rate**. At the request of Licensee, Licensor shall provide Licensee with reasonable technical assistance to help Licensee to understand and use Licensed Know-How and Licensed Compound in connection with the Development of the Licensed Products in the Field in the Territory, for avoidance of any doubts, excluding any assistance relating to knowledge innovation, derivative improvements, or the research and development of new products (whether or not based on the Licensed Know-How). Licensee shall reimburse Licensor for the amount that has been previously agreed by both Parties, including documented, reasonable out-of-pocket costs and internal costs at the applicable FTE Rate incurred to provide such technical assistance.
协助与人力成本。根据被许可方的请求，许可方应向被许可方提供合理的技术协助，以帮助其理解和使用许可方的许可专有技术及许可化合物，用于本协议适用范围内在区域内开发许可产品，为避免疑问，此类协助不包括任何涉及知识成果创新、改进或新产品研发的协助（无论是否基于现有许可技术）。被许可方应向许可方报销双方事先同意的金额，包括其为提供该等技术协助所产生的有据可查的、合理的外部支出以及按适用FTE费率计算的内部成本。

5. REGULATORY; DEVELOPMENT

监管；开发

Development and Regulatory. Licensor confirms that, as of the Effective Date, neither Licensor nor its Affiliates have filed any IND, Clinical Trial Applications ("CTA") (*i.e.*, sponsorship of the Regulatory Filings themselves) or equivalent Regulatory Filings for any Licensed Compound or Licensed Product in the Field within the Territory. Subject to the terms and conditions of this Agreement, Licensee shall have the exclusive right (but not the obligation) to prepare, submit, and control all such Regulatory Filings in the Territory. From and after the Effective Date, Licensee will be solely responsible for the Development of Licensed Compound and Licensed Products in the Field in the Territory, and all regulatory matters arising in connection therewith in the Field and in the Territory at its sole cost and expense (which Licensee will retain ownership of any NDA, MAA and other Regulatory Filings and Regulatory Approvals related to Licensed Products within the Field in the Territory).
开发和监管。许可方确认，截至生效日，许可方及其关联方均未在区域内就适用范围内的任何许可化合物或许可产品提交任何新药研究申请、临床试验申

请（“临床试验申请”）（即作为监管申报文件的申办方）或同等的监管申报。受限于本协议的条款与条件，被许可方有排他性的权利（但无义务）准备、提交和控制区域内的所有该等监管申报。自生效日起，被许可方将独自负责区域内的适用范围内的许可化合物和许可产品的开发，以及与之相关在区域的适用范围内产生的所有监管事项，并自行承担相关费用和支出（被许可方将保留对任何新药上市申请、药品上市许可申请及其他监管申报和监管批准的所有权）。

6. MANUFACTURING

生产

Manufacturing. From and after the Effective Date, Licensee will be solely responsible for and will, subject to the terms of this Agreement, have final decision-making authority with respect to the manufacturing of Licensed Compound and Licensed Products (including drug substance and drug product) in the Territory, at its sole cost and expense. For clarity, Licensee, and/or its affiliates and/or its sublicensee, is allowed to manufacture the Licensed Compounds and Licensed Product outside the Territory as long as the Licensed Products are only commercialized in the Territory.

生产。自生效日起，被许可方将自行负责在区域内生产许可化合物和许可产品（包括原料药和制剂）并将在符合本协议规定的情况下拥有与之相关的最终决策权，并自行承担相关费用和支出。为明确起见，只要许可产品仅在区域内进行商业化，则允许被许可方和/或其关联方和/或分许可方在区域外生产许可化合物及许可产品。

7. COMMERCIALIZATION

商业化活动

Commercialization. Subject to the terms and conditions of this Agreement, from and after the Effective Date, Licensee will be solely responsible and shall exercise sole discretion for all aspects of Commercialization of Licensed Products in the Field and in the Territory, including planning and implementation, distribution, marketing, booking of sales, pricing, and reimbursement.

商业化活动。受限于本协议的条款与条件，自生效日起，被许可方将自行负责并自主决定许可产品在区域的适用范围内的商业化活动的所有方面，包括规划和实施、分销、营销、销售确认、定价和医保报销。

8. FINANCIAL PROVISIONS

财务条款

8.1 **Development Milestone Payments.**

开发里程碑付款.

(a) During the Initial Licensing Term, upon achievement of each of the Milestones corresponding to the AC02 Product (each a “Development Milestone”) by or on behalf of Licensee or its Affiliates or its sublicensees, the corresponding Milestone Payment (a “Development Milestone Payment”) will be payable to Licensor in USD:

在初始许可期限内，在以下针对AC02产品的每一对应的里程碑（均称为“开发里程碑”）由或代表被许可方或其关联方或分许可方实现之时，相应的里程碑付款（“开发里程碑付款”）将以美元支付给许可方：

No. 序号	Development Milestone 开发里程碑	Development Milestone Payment (US $ Million) 开发里程碑付款 （百万美元） AC02 Product AC02产品
1	Execution of this Agreement 签署本协议	[***]
2	IND Acceptance for such Licensed Product, and approval (or implied approval) issued to commence clinical trial by the FDA or Health Canada 就该许可产品，获得新药临床研究申请受理，并且美国食药监局或加拿大卫生部签发启动临床试验的批文（或者默示许可）	[***]
3	3.1 For such Licensed Product, the first dosing in human in the phase I trial in the Territory 就该许可产品，在授权区域内I期试验中实现首个病人给药	[***]
	3.2 For such Licensed Product, successful completion of phase I trial in the Territory, and FDA (or Health Canada) has no objection to start phase II trial in the United States (or Canada) 就该许可产品，在授权区域内成功完成I期试验，且美国食药监局（或加拿大卫生部）未拒绝在美国（或加拿大）开启II期试验	[***]
	3.3 For such Licensed Product, the first dosing in human in the phase II trial in the Territory 就该许可产品，在授权区域内II期试验中实现首个病人给药	[***]
	3.4 For such Licensed Product, successful completion of phase II trial (if applicable, IIa and IIb) in the Territory, and FDA (or Health Canada) has no objection to start phase III trial in the United States (or Canada) 就该许可产品，在授权区域内成功完成II期试验（如适用，IIa期和IIb期）且美国食药监局（或加拿大卫生部）未拒绝在美国（或加拿大）开启III期试验	[***]
4	4.1 For such Licensed Product, the first dosing in human in the phase III trial in the Territory 就该许可产品，在授权区域内III期试验中实现首个病人给药	[***]
	4.2 For such Licensed Product, successful completion of phase III trial (i.e. FDA or Health Canada agrees for a Pre-NDA meeting) in the Territory 就该许可产品，在授权区域内成功完成III期试验（即美国食药监局或加拿大卫生部同意召开新药上市申请前会议）	[***]

5	For such Licensed Product, NDA filing accepted for review by FDA or Health Canada 就该许可产品，新药上市申请被美国食药监局或加拿大卫生部受理审查	[***]
6	For such Licensed Product, NDA Approval by FDA or Health Canada 就该许可产品，美国食药监局或加拿大卫生部批准新药上市申请	[***]
Maximum Development Milestone Payment 开发里程碑付款上限		[***]

(b) Each Development Milestone Payment in the table above will be paid not more than once; for further clarity, if a Development Milestone is firstly triggered in Canada, the corresponding Development Milestone Payment shall become due and payable, and Licensee will not make any payment for the same Development Milestone again which is later triggered in the United States. Accordingly, unless otherwise agreed in this Agreement, in no event shall the Licensee or its Affiliates pay the Licensor more than [***] in the aggregate pursuant to Section 8.1(a). Licensee will provide Licensor with written notice of the achievement of each Development Milestone within ten (10) days after such Milestone is achieved by or on behalf of Licensee or its Affiliates or its sublicensees. Licensor shall following receipt of such notice issue an Invoice to Licensee in respect of the relevant Development Milestone Payment. Licensee shall pay such invoice to Licensor within thirty (30) days after the date of its receipt of such invoice, with the exception of Development Milestone No.1, which shall be within ten (10) business days after receipt of such invoice.
上表中每项开发里程碑付款的支付次数不得超过一次。为进一步澄清起见，如果一个开发里程碑首次在加拿大被触发，该开发里程碑款付款应当被支付，但被许可方无需为了同样的开发里程碑之后在美国触发而再次支付任何款项。因此，除非本协议另有约定，被许可方或其关联方根据第8.1(a)款向许可方支付的总额在任何情况下不得超过 [***]。在每一开发里程碑由或代表被许可方或其关联方或其分许可方实现后的十（10）日内，被许可方将向许可方书面通知该等里程碑的实现。在收到该等通知后，许可方应就相关开发里程碑付款向被许可方出具发票。被许可方应在收到该等发票之日起三十(30)日内向许可方支付该等发票金额（第一个开发里程碑除外，该笔款项应在收到该等发票之日起十(10)个工作日内支付）。

(c) For each Development Milestone 2# to 6#, if any Development Milestone event is bypassed and a later Development Milestone event is achieved, the payment corresponding to any such bypassed Development Milestone event shall be due at the same time that payment is due for the achievement of such later Development Milestone event.
对于开发里程碑事件2#至6#，如某一开发里程碑事件被跳过，且后续的某一开发里程碑事件已达成，则被跳过的开发里程碑事件所对应的付款应与该后续开发里程碑事件应付款项的时间同时支付。

8.2 **Sales Milestone Payments.**
销售里程碑付款.

(a) During the Licensing Term, upon achievement of the Net Sales amount of the AC02 Product in any one (1) Calendar Year period in the Territory set forth below (each a "Sales Milestone", collectively with the Development

Milestones, the "Milestones") by or on behalf of Licensee and its Affiliates and its sublicensees, the following corresponding Milestone Payment (a "Sales Milestone Payment", collectively with the Development Milestone Payment, the "Milestone Payments") will be payable to Licensor in USD:
在许可期限内，在AC02产品于任何一（1）个日历年在区域内的下述净销售额（均称为"销售里程碑"，与开发里程碑合称"里程碑"）由或代表被许可方和其关联方和其分许可方实现之时，以下相应的里程碑付款（"销售里程碑付款"，与开发里程碑付款合称"里程碑付款"）将以美元支付给许可方：

No. 序号	**Sales Milestone** 销售里程碑	**Sales Milestone Payment (US $ Million)** 销售里程碑付款（百万美元） **AC02 Product** **AC02产品**
1	Annual Net Sales amount throughout the Territory reaching [***] 整个区域的年度净销售额达到 [***]	[***]
2	Annual Net Sales amount throughout the Territory reaching [***] 整个区域的年度净销售额达到 [***]	[***]
3	Annual Net Sales amount throughout the Territory reaching [***] 整个区域的年度净销售额达到 [***]	[***]
4	Annual Net Sales amount throughout the Territory reaching [***] 整个区域的年度净销售额达到 [***]	[***]
5	Annual Net Sales amount throughout the Territory reaching [***] 整个区域的年度净销售额达到 [***]	[***]
Maximum Sales Milestone Payment 销售里程碑付款上限		[***]

(b) Each Sales Milestone Payment in the table above will be paid not more than once. Accordingly, unless otherwise agreed in this Agreement, in no event shall the Licensee or its Affiliates pay the Licensor more than [***] in the aggregate pursuant to Section 8.2(a). Licensee will provide Licensor with written notice of the achievement of each Sales Milestone and the corresponding Sales & Royalty Report before March 31st of the next Calendar Year after such Milestone is achieved by or on behalf of Licensee and its Affiliates and its sublicensees. Licensor shall following receipt of such notice issue an Invoice to Licensee in respect of the relevant Sales Milestone Payment. Licensee shall pay such invoice to Licensor within thirty (30) days after the date of its receipt of such invoice. For clarity, if multiple Sales Milestone Events are achieved in the same Calendar Year, then each applicable Sales Milestone Payment associated with such Sales Milestone events would nonetheless be owed to Licensor in full after the end of such Calendar Year in accordance with this Section 8.2(b).
上表中每项销售里程碑付款的支付次数不得超过一次。因此，除非本协议另有约定，被许可方或其关联方根据第8.2(a)款向许可方支付的总

额在任何情况下不得超过 [***]。在每一销售里程碑由或代表被许可方和其关联方和其分许可方实现后的下一日历年的3月31日前，被许可方将向许可方书面通知该等里程碑的实现以及对应的销售与许可费报告。在收到该等通知后，许可方应就相关销售里程碑付款向被许可方出具发票。被许可方应在收到该等发票之日起三十（30）日内向许可方支付该等发票金额。为避免歧义，如在同一日历年度内达成多个销售里程碑事件，则与该等销售里程碑事件相关的每一项应付款项，均应在该日历年度结束后根据本第8.2(b)款全额支付给许可方。

8.3 **Royalty Payments.**
许可费付款.

(a) In further consideration of the licenses and rights granted to Licensee hereunder, each Calendar Year during the Royalty Term, Licensee will make royalty payments ("Royalty Payment") to Licensor on annual Net Sales in the Territory by Licensee and its Affiliates and its sublicensees at the rates set forth below.
作为本协议项下授予被许可方的许可和权利的进一步对价，在许可费 期限内的每一日历年，被许可方将就被许可方及其关联方和分许可方在区域内实现的年度净销售额按下述费率向许可方支付许可费（"许可费付款"）。

No. **序号**	**Royalty Payment based on annual Net Sales in the Territory** **基于区域内年度净销售额的许可费付款**	**Royalty Payment** **许可费付款**
		AC02 Product **AC02产品**
1	Royalty rate 许可费费率	[***]

(b) The Royalty Payment (excluding any Milestone Payment) shall be subject to a maximum annual amount of [***] each Calendar year for AC02 Product (the "Maximum Annual Royalty Payment") and a maximum accumulated amount of [***] for AC02 Product (the "Maximum Accumulated Royalty Payment"). Once the Maximum Accumulated Royalty Payment has been paid, the Royalty Payment obligation shall be deemed to be terminated.
AC02产品的许可费付款（不包括任何里程碑付款）[***]（"年度许可费付款上限"），AC02产品的许可费付款累计上限为 [***]（"累计许可费付款上限"）。一旦已支付的金额达到累计许可费付款上限，则被许可方许可费付款义务应终止。

(c) Before March 31st of the next Calendar Year, Licensee shall provide a Sales & Royalty Report of the previous Calendar Year to Licensor. Licensor shall submit an Invoice to Licensee with respect to the royalty amount shown therein. Licensee shall pay such royalty amount to Licensor within thirty (30) days after the date of receipt of the Invoice.
在下一日历年的3月31日前，被许可方应向许可方提供上一日历年的销售与许可费报告。许可方应就该报告显示的许可费金额向被许可方提交发票。被许可方应在收到发票之日起三十(30)日内向许可方支付该许可费金额。

8.4 **Payments.**
付款.

(a) All payments from Licensee to Licensor will be made by wire transfer in USD to the credit of such bank account as may be designated by Licensor in this Agreement or in writing to Licensee. Any payment which falls due on a date which is not a business day in the location from which the payment may be made shall occur on the next succeeding business day in such location. Licensor shall be solely responsible for obtaining all applicable permits necessary for receiving all payments required to be made under this Agreement. Licensee shall not be responsible nor required to reissue any amounts, whether whole or partial, for any payments issued by Licensee pursuant to Licensor's written instruction(s).
被许可方向许可方支付的所有款项应以美元电汇至许可方在本协议中指定的或向被许可方书面指定的银行账户。任何款项的到期日如为付款来源地的非工作日，则应在该地的下一个工作日到期。许可方应自行负责取得收取本协议项下要求支付的所有款项所需的所有适用许可。被许可方对于根据许可方书面指令支付的所有款项（无论全额或部分）均不承担任何责任，且无义务进行任何形式的重新支付。

(b) In case that Licensee fails to provide Licensor with such notice of any Milestones within such time period as set forth under Section 8.1(b) and Section 8.2(b), while Licensor believes that any Milestone has been achieved, it shall have the right to notify Licensee in writing of the same and issue an invoice for the Milestone Payments to Licensee, and in the case the Milestone was actually achieved, Licensee shall make the corresponding Milestone Payments to Licensor within thirty (30) days thereafter for the relevant Milestone Payments. If Licensee disputes this matter, Licensee will notify Licensor within thirty (30) days from receipt of Licensor's notice, and both Parties shall resolve the dispute in accordance with Section 15.5.
若被许可方未能在第8.1(b)条和第8.2(b)条规定的期限内向许可方提供任一里程碑通知，但许可方认为任何里程碑已达成，许可方有权书面通知被许可方该事实并向被许可方开具里程碑付款的发票；若该里程碑确已达成，被许可方应在收到发票后三十(30)日内向许可方支付相应的里程碑付款。如被许可方对此事项存在异议，应自收到许可方通知之日起三十（30）日内告知许可方，双方应按照第15.5款规定解决争议。

(c) All payments under this Agreement shall be made in U.S. dollars. Payments shall be made by electronic wire transfer of immediately available funds to the account of Licensor. Licensee will record all Net Sales in accordance with the Accounting Standards.
本协议项下的所有付款均应以美元支付。付款应通过电子电汇方式将可即刻使用的资金汇入许可方书面指定的账户。被许可方应按照会计准则记录所有净销售额。

(d) During the Licensing Term, once the Maximum Accumulated Royalty Payment and the Maximum Sales Milestone Payment (as listed in Section 8.2) have been paid, the licenses granted to Licensee pursuant to this Agreement shall be considered as fully paid-up by Licensee and such license will continue in effect, but will become fully paid-up, royalty-free, transferable, perpetual and irrevocable regardless of whether the Agreement Term has expired or terminated. For avoidance of doubt, the Maximum Accumulated Royalty Payment (as listed in Section 8.3) and the Maximum

Sales Milestone Payment (as listed in Section 8.2), aggregate to a total payment from Licensee to Licensor of [***] (before deducting any withholding tax or other deductible amounts).
在许可期限内，一旦支付的金额已分别达到其累计许可费付款上限和销售里程碑付款上限（如第8.2款所列），则根据本协议授予被许可方的许可应被视为已由被许可方全额付清，且该许可将持续有效，但将成为已全额支付对价的、免许可费的、可转让的、无期限的及不可撤销的许可，而无论本协议期限是否届满或终止。为免疑义，被许可方应支付许可方的累计许可费付款上限（如第8.3条款列）及销售里程碑付款上限（如第8.2条款列）总额为 [***]（扣除任何预提税或其他可抵扣金额前的金额）。

(e) For avoidance of doubt, if Licensee extends the Initial Licensing Term to the Extended Licensing Term, during the Extended Licensing Term, the only applicable payment obligation of Licensee is Sales Milestone Payment and Royalty Payment as long as the Maximum Sales Milestone Payment (as listed in Section 8.2) and Maximum Accumulated Royalty Payment (as listed in Section 8.3) have not been paid during the Initial Licensing Term.
为避免疑义，如果被许可方延长初始许可期限至展期许可期限的，则在展期许可期限内，如在初始许可期限内支付的金额未达到其销售里程碑付款上限（如第8.2款所列）和其累计许可费付款上限（如第8.3款所列），则被许可方唯一适用付款义务为销售里程碑付款和许可费付款。

(f) Each Party shall each bear any and all taxes levied against such Party on account of any payment received by such Party under this Agreement. All amounts payable by the Licensee to Licensor under this Agreement shall be deemed to be inclusive of all applicable taxes, levies, duties, or similar governmental charges, including without limitation any income tax, gross receipts tax, value-added tax, sales tax, use tax, or other tax of a similar nature that may be imposed by any governmental authority in connection with or arising out of the receipt of such payments by the Licensor. The Licensee shall have no obligation to gross up or otherwise pay any additional amount to Licensor to account for or compensate Licensor for any tax, deduction or withholding assessed or imposed on such payments, except to the extent otherwise expressly provided in this Agreement.
双方应各自承担因其根据本协议收到的任何付款而对其征收的任何及所有税款。被许可方根据本协议应向许可方支付的所有金额，均应被视为包含任何适用的税款、规费、关税或类似政府性收费，包括但不限于任何政府机关就许可方收取该等款项可能征收的所得税、营业税、增值税、销售税、使用税或其他类似的税费。除非本协议另有明确约定，对于就该等付款所征收或施加的任何税负、扣减或预提税，被许可方无义务通过补足或其他方式向许可方支付任何额外税额补偿，以弥补或补偿许可方。

(g) If any withholding tax is required to be withheld by Licensee under the Applicable Law of any jurisdiction, including extra-territorial taxation and is paid over to the applicable tax authority, Licensee will deduct the withholding tax from the payment made to Licensor and such payment shall be treated as having been paid to Licensor for all purposes under this Agreement. Licensee will reasonably assist Licensor in lawfully claiming exemption from or minimizing such withholding tax under double taxation laws including but not limited to the submission or issuance of requisite forms.

如果根据任何司法管辖区的适用法律（包括域外征税）应由被许可方预扣任何预提税且该等预提税已缴纳给相关税务机构，被许可方将从支付给许可方的款项中扣除该等预提税，且在本协议项下，该等款项就各方面而言应被视为已支付给许可方。被许可方将合理协助许可方根据避免双重征税法律合法主张免除或尽可能减少该等预提税，包括但不限于提交或出具必要的表格。

(h) Other than as provided in Section 8.4(g), each Party shall be responsible for its own taxes, including any tax, fee, assessment or other charge based on or measured by the capital or net income, or any other tax imposed by any jurisdiction and neither Party shall have any obligation towards the other Party for the taxes of the other Party.
除第8.4(g)款规定的以外，每一方应自行负责缴纳其税额，包括任何税项、费用、核定税额或其他基于资本或净收入或以资本或净收入计量的费用，或任何司法管辖区征收的任何其他税项，且任何一方均不对另一方的税项负有任何义务。

(i) With respect to any amounts owed under this Agreement by a Party to the other Party for which no other invoicing and payment procedure is specified herein, the Party owing such payment obligation will provide to the other Party an invoice, together with reasonable supporting documentation, for such amounts owed and such other Party will pay any undisputed amounts within thirty (30) days after receipt of the invoice.
对于本协议项下一方应向另一方支付的、且本协议中未另行规定开票和付款程序的任何款项，负有付款义务的一方应向另一方提供发票及合理的支持性文件，另一方应在收到发票后三十（30）日内支付无争议的款项。

(j) Licensee shall be solely responsible for obtaining all applicable permits necessary for making all payments required to be made under Sections 8.1 to 8.3 and will bear all costs associated with such payments.
被许可方应自行负责取得支付第8.1款至第8.3款项下要求支付的所有款项所需的所有适用许可，并承担与该等付款有关的所有费用。

8.5 **Records.**
记录。

(a) Licensee will keep, and will require its Affiliates to keep, complete, true and accurate books and records in accordance with its Accounting Standards in relation to Milestones, Net Sales and Royalty Payments payable to Licensor hereunder with respect to Licensed Compound and Licensed Products.
被许可方将根据其会计准则就里程碑、净销售额和本协议项下就许可化合物和许可产品应向许可方支付的许可费保存并要求其关联方保存完整、真实和准确的账簿和记录。

(b) Subject to Section 13.3(c), Licensee will, and will require its Affiliates and its sublicensees to, make their records available for inspection by Licensor's designated third-party auditor (the "**Auditor**") (subject to confidentiality obligations and shall only disclose the results to Licensor), during regular business hours at such place or places where such records are customarily kept, upon receipt of notice at least thirty (30) days in advance from Licensor. The records will be reviewed to solely verify the accuracy of the Sales & Royalty

Reports, the statement or other reports provided by Licensee and to verify the accuracy of the payments due hereunder accounted for in accordance with applicable Accounting Standards for any Calendar Year(s). Such inspection right will not be exercised more than once in any Calendar Year and not more frequently than once with respect to records covering any specific period of time. Licensor is entitled to inspect Licensee's records dating back at least for two (2) years (or such longer period as required by Applicable Law) from the date of Licensor's request for inspection. In the event Licensor requests to inspect records beyond the aforementioned period, Licensor may only do so upon mutual agreement between the Parties. Licensor shall be responsible for the auditor's costs, unless the auditor certifies that an underpayment by Licensee that resulted from a discrepancy in a report that Licensee provided to Licensor during the applicable audit period, which underpayment was more than five percent (5%) of the amount set forth in such report, in which case Licensee shall bear the full cost of such audit. If such accounting firm correctly identifies a discrepancy made during such period, any unpaid amounts or overpaid amounts that are discovered shall be paid/refunded promptly but in any event within thirty (30) days of the date of delivery of such accounting firm's written report so correctly concluding, or as otherwise agreed upon by the Parties. Licensor and any auditor engaged by it will hold in confidence all Confidential Information received and all Confidential Information learned in the course of inspection, except to the extent necessary to enforce its rights under this Agreement or if disclosure is required by Applicable Law.

根据本协议第13.3(c)款，被许可方将且将要求其关联方和分许可方在收到许可方至少提前三十（30）日发出的通知后，在通常保存该等记录的一个或多个地点的正常工作时间内提供该等记录，以供许可方指定的第三方审计师（"审计方"）（受限于保密义务，且应仅向许可方披露结果）检查。检查该等记录的目的仅为核实销售与许可费报告、被许可方提供的报表或其他报告，以及核实本协议项下所应支付款项在任何一个或多个日历年度内依据适用会计准则进行核算的准确性。该等检查权的行使次数在任何日历年内不得超过一次，且对涉及任何特定期间的记录的行使次数不得超过一次。许可方有权检查被许可方自检查要求提出之日向前追溯至少两(2)年（或适用法律要求的更长期限）内的记录。若许可方要求检查超过前述期限的记录，则须经双方协商一致方可进行。许可方应承担审计费用，除非审计师确认，在相关审计期间内，由于被许可方向许可方提供的报告存在差异，导致被许可方少付的金额超过该报告所列金额的百分之五(5%)。在此情形下，被许可方应承担该次审计的全部费用。许可方及其聘请的审计师将对收到的所有保密信息和在检查过程中获悉的所有保密信息保密，但为强制执行其在本协议项下的权利或适用法律要求进行披露的除外。

8.6 **No Projections**. Licensor and Licensee acknowledge that nothing in this Agreement will be construed as representing an estimate or projection of anticipated sales of any Licensed Product, and that the Milestones and Net Sales levels set forth above or elsewhere in this Agreement or that have otherwise been discussed by the Parties are merely intended to define the Milestone Payments and Royalty Payments obligations to Licensor if the applicable Milestones or Net Sales levels are achieved. LICENSEE MAKES NO REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY COMMERCIALIZE ANY LICENSED PRODUCT OR, IF COMMERCIALIZED, THAT ANY PARTICULAR NET SALES LEVEL OF SUCH LICENSED PRODUCT WILL BE ACHIEVED.

无预测.。许可方和被许可方确认，本协议的任何内容不应被解释为代表对任何许可产品预期销售额的估计或预测，且本协议上文或其他条款规定的或双方另行协商的里程碑和净销售额水平仅旨在确定在相关里程碑或净销售额水平实现之时对许可方的里程碑付款和许可费义务。被许可方未作出任何明示或默示的陈述或保证，表明其将能够成功实现任何许可产品的商业化，或者在实现商业化的情况下，该许可产品将实现任何特定的净销售额水平。

8.7 **Royalty for Amphastar**.

Amphastar许可费.

(a) Each Calendar Year during the Amphastar Royalty Term, for the license of Cross-license Patents, Licensor will pay [***] royalty to Amphastar from the Net Sales (calculated in the same principle as the "Net Sale" of the AC02 Product) of the commercial sales of products that are based on such Cross-license Patents (the "Royalty for Amphastar").
在Amphastar许可费期限内的每一个日历年，对于交叉许可专利的许可，许可方将向Amphastar支付基于该等交叉许可专利的产品的商业销售净销售额（根据AC02产品"净销售额"的相同原则计算）[***]的许可费（"Amphastar许可费"）。

"**Amphastar Royalty Term**" means, on a region-by-region basis, the period commencing on the First Commercial Sale of a product upon the latest of (i) [***], (ii) [***], and (iii) [***].
"Amphastar许可费期限"是指，在逐个地区的基础上，自产品首次商业销售开始至以下时间孰晚的期间：(i) [***]，(ii) [***]，及(iii) [***]。

(b) The Royalty for Amphastar shall be subject to a maximum annual amount of [***] each Calendar year and a maximum accumulated amount of [***] (the "Maximum Accumulated Royalty Payment for Amphastar"). Once the Maximum Accumulated Royalty Payment for Amphastar has been paid, the payment obligation of Royalty for Amphastar shall be deemed to be terminated.
Amphastar许可费年度上限均为每个日历年 [***]，累计上限为 [***]（"Amphastar累计许可费付款上限"）。一旦已支付的金额达到Amphastar累计许可费付款上限，则许可方支付Amphastar许可费的付款义务应终止。

(c) During the Amphastar Royalty Term, before March 31st of every Calendar Year, Licensor shall provide a sales & royalty report (prepared in the same principle as the "Sales & Royalty Report" of the AC02 Product) of the previous Calendar Year to Amphastar. Amphastar shall submit an Invoice to Licensor with respect to the royalty amount shown therein. Licensor shall pay such royalty amount to Amphastar within thirty (30) calendar days after the date of receipt of the Invoice by wire transfer in RMB to the credit of such bank account as may be designated by Amphastar.
在Amphastar许可费期限内，在每一日历年的3月31日前，许可方应向Amphastar提供上一日历年的销售与许可费报告（根据AC02产品"销售与许可费报告"的相同原则编制）。Amphastar应就其中所示许可费金额向许可方提交发票。许可方应在收到发票之日起三十（30）日内向Amphastar支付该许可费金额，具体支付方式为以人民币电汇至Amphastar指定的银行账户。

(d) Licensor shall be solely responsible for obtaining all applicable permits necessary for making all payments required to be made under this Section 8.7 and will bear all costs associated with such payments.
许可方应自行负责取得支付本第8.7款项下要求支付的所有款项所需的所有适用许可，并承担与该等付款有关的所有费用。

(e) Section 8.4 and 8.5 shall apply to Licensor *mutatis mutandis* with respect to the payment of Royalty for Amphastar.
就支付Amphastar的许可费而言，第8.4及8.5款在细节上作必要修改后应适用于许可方。

9. INTELLECTUAL PROPERTY.

知识产权。

9.1 **Ownership of Background Intellectual Property**. As between the Parties, (a) Licensor shall solely own and retain all right, title and interest in and to any and all Licensed IPs, including any improvements made by Licensor thereto; and (b) each Party shall solely own and retain all right, title and interest in and to any and all Know-How, inventions, Patent Rights and other intellectual property rights that are owned or otherwise Controlled by such Party or its Affiliates or its or their sublicensees (as applicable) outside of this Agreement.
背景知识产权的所有权。就双方之间而言，(a) 许可方应单独拥有并保留对任何及所有许可知识产权及基于该等许可知识产权由许可方作出的改进的全部权利、所有权和权益；且 (b) 每一方应单独拥有并保留其自身或其关联方、或其分许可方（如适用）在本协议之外所拥有或以其他方式控制的所有专有技术、发明、专利及其他知识产权的全部权利、所有权和权益。

9.2 **Arising Product IP.** All intellectual properties (including but not limited to inventions, whether or not patentable or reduced to practice, trademarks, copyrights and Know-How) arising from Licensee's activities under this Agreement, including activities conducted by or on behalf of Licensee or its Affiliates, including any Patent Rights claiming such inventions that arise from such activities after the Effective Date (collectively, the "Arising Product IP"), will be owned by Licensee.
衍生产品知识产权。被许可方在本协议项下的活动（包括由或代表被许可方或其关联方开展的活动）所产生的所有知识产权（包括但不限于发明（无论是否可获得专利或已完成实施）、商标、著作权和专有技术），包括在生效日后该等活动产生的主张该等发明的任何专利权（合称"衍生产品知识产权"），将归被许可方所有。

9.3 **Ownership of Results and Data.** All data and results arising from Licensee's activities under this Agreement, including activities conducted by or on behalf of Licensee or its Affiliates, including Development, clinical and regulatory data and information generated for regulatory purposes relating to Licensed Compound or Licensed Product will be solely owned by Licensee.
成果和数据的所有权。被许可方在本协议项下的活动（包括由或代表被许可方或其关联方开展的活动）所产生的所有数据和成果，包括为与许可化合物或许可产品相关的监管目的而产生的开发、临床及监管数据和信息，将归被许可方单独所有。

9.4 **Patent Prosecution and Maintenance After the Effective Date**.
生效日后的专利申请和维护。

(a) Licensor will control prosecution and maintenance of the Licensed Patents outside the Territory at Licensor's sole cost and expense and in the Territory at Licensee's sole cost and expense. Licensor will use Commercially Reasonable Efforts to keep Licensee informed of matters relating to the prosecution and maintenance of the Licensed Patents in the Territory, and will provide Licensee with copies of documents relevant to such prosecution and maintenance in sufficient time. With respect to communications issued by competent patent offices within the Territory concerning the Licensed Patents, Licensor will use Commercially Reasonable Efforts to notify Licensee of said communications but no later than forty-five (45) days after their issuance. With respect to documents to be filed at competent patent offices within the Territory concerning Licensed Patents, Licensor will use Commercially Reasonable Efforts to notify Licensee but no later than thirty (30) days prior to the filing of such documents to allow for review and comment by Licensee, and Licensor will reasonably consider Licensee's comments in good faith. Licensor will notify Licensee of any decision not to continue to pay the expenses of prosecution and maintenance of any Licensed Patent within the Territory, which notice must be delivered at least ninety (90) days prior to any payment due date or the relevant action's due date. Licensee will provide Licensor, at Licensee's expense, with all reasonable assistance and cooperation in relation to Licensor's prosecution and maintenance of Licensed Patents in the Territory, including providing any necessary powers of attorney and any other documents or instruments required therefor. Licensor shall have no obligation to continue to prosecute any Licensed Patents in the Territory. If Licensor elects not to prosecute any Licensed Patent in the Territory, Licensor shall notify Licensee of any decision to cease prosecution of any Licensed Patents in the Territory. Licensee shall have the right to continue the prosecution and maintenance of such Licensed Patent in such Region at its own cost. If Licensee undertakes such prosecution and maintenance, (i) Licensor will provide Licensee, with all reasonable assistance and cooperation in relation thereto, including providing any necessary powers of attorney and any other documents or instruments required therefor, and (ii) the expenses of such prosecution and maintenance necessary to preserve the validity of the Licensed Patents in relevant Region shall be borne by Licensee. Such assistance and cooperation by Licensor shall not be unreasonably withheld, delayed or conditioned upon.

许可方应负责在全球范围（除区域外）对许可专利的申请和维护，并承担全部费用；在区域内，则由被许可方承担全部费用。许可方将尽商业上合理的努力告知被许可方许可专利在区域内的申请和维护的相关事项，并提前充足时间向被许可方提供该等申请和维护相关文件的副本。对于区域内主管专利局发布的有关许可专利的信息，许可方将尽商业上合理的努力但不迟于发布后的四十五（45）天通知被许可方。对于向区域内主管专利局提交的有关许可专利的文件，许可方将尽商业上合理的努力但不迟于提交前三十（30）天通知被许可方，以便被许可方审阅并提出意见，且许可方将基于善意合理考虑被许可方的意见。许可方将通知被许可方关于不再继续支付任何区域内许可专利的申请和维护费用的任何决定，该通知必须在任何付款到期日或相关行动到期日前至少九十（90）天送达被许可方。被许可方在区域内将向许可方提供与许可方申请和维护许可专利有关的所有合理协助和配合，

包括提供任何必要的委托书及任何其他所需的文件或文书，相关费用由被许可方承担。许可方没有义务继续申请或推进任何区域内的许可专利的审查程序。如果许可方选择不再推进区域内任何许可专利的申请，许可方应通知被许可方其决定在区域内停止推进该许可专利的申请程序。被许可方有权自行决定在该地区继续申请和维护该许可专利。如果被许可方进行该等申请和维护，(a)许可方将向被许可方提供与之相关的所有合理协助和配合，包括提供任何必要的委托书及任何其他所需的文件或文书，(b)该等为维持相关地区许可专利的有效性所必需的申请和维护的费用应由被许可方承担，许可方不得无理拒绝、拖延或附加条件地提供此类协助与配合。

(b) Licensee shall be solely responsible for the prosecution, maintenance, defense, and enforcement against infringement of Arising Product IP in the Territory.
被许可方应自行负责衍生产品知识产权在区域内的申请、维护、抗辩和侵权执行。

9.5 **Third Party Infringement**.
第三方侵权。

(a) Each Party will promptly notify the other of any infringement by a Third Party of any of the Licensed Patents or misappropriation of any Licensed Know-How in the Territory of which it becomes aware, including any filing of an Abbreviated New Drug Application ("ANDA") in the United States or such similar filing under Applicable Law in jurisdictions in the Territory other than the United States. Each Party shall provide the other Party with all available evidence supporting such infringement, suspected infringement, unauthorized use or misappropriation or suspected unauthorized use or misappropriation (collectively, "Third Party Infringement").
一方将立即通知另一方其获悉的第三方在区域内侵犯任何许可专利或盗用任何许可专有技术的任何行为，包括在美国境内提交简化新药上市申请（"简化新药上市申请"）或根据适用法律在美国以外的区域内的司法辖区提交该等类似申请。一方应向另一方提供所有可获得的支持该等侵权、涉嫌侵权、未经授权的使用或盗用或涉嫌未经授权的使用或盗用（合称"第三方侵权"）的证据。

(b) As between the Parties, Licensee shall have the right to bring and control any legal action in connection with the Third Party Infringement in the Territory relating to any Licensed Patent at its own expense as it reasonably determines appropriate, and Licensor will have the right (but not the obligation), at its own expense, to be represented in any such action by counsel of its own choice. If Licensee does not bring such legal action within sixty (60) days after its aware of such Third Party Infringement, Licensor shall have the right to bring and control any legal action in connection with such Third Party Infringement in the Territory at its own expense as it reasonably determines appropriate.
在双方之间，被许可方有权在其合理认为适当的情况下就与任何许可专利相关的区域内的第三方侵权自费提起并控制任何法律诉讼，许可方有权（但无义务）自费由自己选择的律师代理任何该等诉讼。如果被许可方未在知悉该等第三方侵权后的六十(60)日内提起此类法律诉讼，则许可方应有权在其合理认为适当的情况下，自费提起并控制与该第三方侵权有关的区域内的任何法律诉讼。

(c) At the request of the Party controlling the Third Party Infringement claim, the other Party will provide assistance in connection therewith, including by executing reasonably appropriate documents, access to such Party's employees, cooperating reasonably in discovery and joining as a party to the action if required.
经控制第三方侵权权利主张的一方要求，另一方将提供相关协助，包括签署合理适当的文件，接触该方的员工，合理配合调查取证，以及在必要时作为一方加入诉讼。

(d) In connection with any such proceeding, neither Party will enter into any settlement admitting the invalidity of, or otherwise impairing any Party's rights in, the Licensed IP without the prior written consent of the other Party, which will not be unreasonably withheld or delayed.
就任何该等程序而言，未经另一方事先书面同意（该等同意不得无理拒给或延迟），一方不得达成承认许可知识产权无效或以其他方式损害任何一方拥有的许可知识产权权利的任何和解。

(e) Any recoveries resulting from such an action relating to a Third Party Infringement shall be first applied against payment of each Party's costs and expenses in connection therewith, and any recoveries in excess of such costs and expenses shall be retain by the enforcing Party.
因该等第三方侵权诉讼而获得的任何赔偿，应首先用于支付双方在该等诉讼中产生的各自费用和支出，超过该等费用和支出的部分由执行方留存全部赔偿款项。

9.6 **Third Party Patent Invalidity Claim**. If a Third Party at any time asserts a claim that any Licensed Patent is invalid or otherwise unenforceable in the Territory (an "Invalidity Claim"), whether as a defense in an infringement action brought by a Party pursuant to Section 9.5, in a declaratory judgment action or any patent office proceeding anywhere in the world (*e.g.*, inter-partes review), the provisions of Section 9.5 will apply to such Invalidity Claim, *mutatis mutandis* as they apply to Third Party Infringement suits.
第三方专利无效权利主张。如果第三方在任何时间提出一项任何许可专利在区域内无效或以其他方式不可强制执行的权利主张（"无效权利主张"），无论是作为一方根据第9.5款提起的侵权诉讼中的抗辩，还是作为宣告式判决诉讼或世界上任何地方的任何专利局程序（例如多方复审）中的抗辩，第9.5款的规定在细节上作适当修正后将适用于该无效权利主张，如同适用于第三方侵权诉讼。

9.7 **Defense of Infringement Claims of Licensed IP**. Subject to Section 14.1, if any Third Party asserts a claim, demand, action, suit or proceeding against a Party (or any of its Affiliates), alleging that any Licensed Product manufactured or sold, or the use or practice of the Licensed IP, by or on behalf of Licensee or any of its Affiliates infringes, misappropriates or violates the intellectual property rights of any Person in the Territory (any such claim, demand, action, suit or proceeding being referred to as an "Infringement Claim"), the Party first having notice of the Infringement Claim shall promptly notify the other Party thereof in writing specifying the facts, to the extent known, in reasonable detail and the following shall apply:
许可知识产权侵权权利主张的抗辩。受限于第14.1款，如果任何第三方针对一方（或其任何关联方）提出权利主张、要求、诉求、诉讼或程序，声称由或代表被许可方或其任何关联方生产或销售的任何许可产品或者使用或实施许可知识产权侵犯、盗用或违反任何主体在区域内的知识产权（任何该等权

利主张、要求、诉求、诉讼或程序称为“侵权权利主张”），首先收到侵权权利主张通知的一方应立即书面通知另一方，在已知的范围内以合理的细节说明事实，并且以下条款应适用：

(a) In the case of any such Infringement Claim being asserted against either Party individually or against both Licensor and Licensee, in each case, with respect to the Licensed Product, Licensee shall assume control of the defense of such Infringement Claim. Both Parties shall share equally the defense costs. Licensor, upon request of Licensee and if required by Applicable Law, will join in any such litigation, and in any event will reasonably cooperate with Licensee. Licensor will have the right to consult with Licensee concerning such Infringement Claim and to participate in and be represented by independent counsel in any litigation in which Licensee is a party, at its own expense. If Licensee elects not to defend or control the defense of or otherwise fails to initiate and maintain the defense of any such Infringement Claim within such time periods so that either Party is not prejudiced by any delays, Licensor may conduct and control the defense of such Infringement Claim, at its own cost and expense.
如果任何该等侵权权利主张单独针对任何一方或共同针对许可方和被许可方，在每种情况下，就许可产品而言，被许可方应控制对该等侵权权利主张的抗辩。双方应平均分担抗辩费用。经被许可方要求，如果适用法律规定，许可方将参加任何该等诉讼，在任何情况下许可方将与被许可方合理地合作。许可方有权就该等侵权权利主张与被许可方进行协商，自费参加被许可方作为一方的任何诉讼，并由独立律师代理该等诉讼。如果被许可方选择不进行抗辩或控制抗辩，或未能在上述期限内启动和维持任何此类侵权索赔的抗辩，以使许可方不因任何延迟而受到损害，许可方可进行和控制此类侵权索赔的抗辩，费用和开支由许可方自行承担。

(b) Licensee shall not have the right to settle any Infringement Claim without the written consent of Licensor (*provided*, *however*, that Licensee may settle such suit without such consent if such settlement involves only the payment of money and Licensee makes all such payments, and such settlement would not adversely impact or diminish the rights and benefits of Licensor under this Agreement, and would not impose any new obligations or adversely impact any obligations of Licensor under this Agreement).
未经许可方书面同意，被许可方无权就任何侵权权利主张达成和解（但前提是，如果和解仅涉及款项支付，且被许可方支付所有该等款项，且该解决不会对许可方在本协议项下的权利和利益造成不利影响或减少，也不会对许可方在本协议项下的任何义务造成任何新的义务或不利影响，则被许可方无需该等同意即可就该诉讼达成和解）。

(c) During the period in which such Infringement Claim is pending and following the resolution thereof, both Parties shall bear equally, all costs incurred in connection therewith (including litigation costs, attorneys' fees, costs of settlement) including damage awards, and any other payment resulting therefrom, provided that to the extent such Infringement Claim is attributable to the Licensed IP, then Licensor shall compensate Licensee for any losses incurred by Licensee and its Affiliates.
在该等侵权权利主张未决期间以及在该等侵权权利主张得到解决后，双方应平均分担与该等侵权权利主张相关发生的所有费用（包括诉讼费用、律师费、和解费用），包括损害赔偿，以及由此产生的任何其他款项，

但前提是，如果该等侵权权利主张可归于许可知识产权，则许可方应就被许可方及其关联方遭受的任何损失补偿被许可方。

(d) Any recoveries awarded to Licensee in connection with any Infringement Claim defended under this Section 9.7 shall be applied first to reimburse the Parties for their reasonable costs and expenses and then be retained by such Party controlling the defense.
根据第9.7条的规定，被许可方在侵权权利主张中获得的任何赔偿金应首先用于补偿双方的合理成本和费用，然后由控制抗辩的一方保留。

(e) Licensor shall have the exclusive right to control the defense of such Infringement Claim outside the Territory, at its own expense and as it reasonably determines appropriate.
许可方有权自费并在其合理认为适当的情况下，控制任何区域外的侵权权利主张的抗辩。

9.8 **Trademarks**. Licensee will have the right to brand the Licensed Products using Licensee related trademarks and any other trademarks and trade names it Controls and determines appropriate for Licensed Products in the Territory, which may vary by country or within a country ("Product Marks"). Licensee will own all rights in the Product Marks within the Territory and register and maintain the Product Marks in the countries and regions it determines reasonably necessary within the Territory.
商标。 被许可方有权使用被许可方的相关商标以及被许可方控制并确定在区域内适合许可产品的任何其他商标和商号（"产品标志"）来建立许可产品的品牌，产品标志可能因国家而异或在一国内也有所不同。被许可方将在区域内拥有产品标志的所有权利，并将在被许可方确定合理必要的区域内国家和地区注册和维持产品标志。

9.9 **Inventor Remuneration Obligations**. As between the Parties, Licensor shall be solely responsible for the payment of any rewards and remuneration for inventions as required by Applicable Law, to named inventors of the Licensed Patents.
发明人报酬义务。 在双方之间，许可方应自行负责向许可专利的具名发明人支付适用法律规定的任何发明奖励和报酬。

10. CONFIDENTIALITY

保密

10.1 **Duty of Confidence**. Subject to the other provisions of this Article 10 and during the Term and for a period of seven (7) years thereafter, all Confidential Information disclosed by a Party or its Affiliates under this Agreement will be maintained in confidence and otherwise safeguarded by the recipient Party. The recipient Party may only use the Confidential Information for the purposes of this Agreement and pursuant to the rights granted to the recipient Party under this Agreement. Subject to the other provisions of this Article 10, each Party will hold as confidential such Confidential Information of the other Party or its Affiliates in the same manner and with the same protection as such recipient Party maintains its own confidential information. Subject to the other provisions of this Article 10, a recipient Party may only disclose Confidential Information of the other Party to employees, agents, contractors, consultants and advisers of the Party and its Affiliates and to Third Parties to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; *provided* that such Persons are bound to maintain the

confidentiality of the Confidential Information in a manner consistent with the confidentiality provisions of this Agreement.
保密义务. 受限于本第10条的其他规定，在本协议期限内至协议期限届至后七(7)年，接收方将对一方或其关联方在本协议项下披露的所有保密信息进行保密并以其他方式加以保护。接收方仅可根据本协议项下授予接收方的权利为本协议之目的使用保密信息。受限于本第10条的其他规定，每一方将采用与该接收方保护自己的保密信息相同的方式和措施，对另一方或其关联方的保密信息保密。受限于本第10条的其他规定，接收方仅可为本协议之目的以及为根据本协议承办的事项合理必要的范围内，将另一方的保密信息披露给该方及其关联方的员工、代理人、承包商、顾问和咨询人员以及第三方；但前提是，该等主体有义务以符合本协议的保密规定的方式对保密信息进行保密。

10.2 **Exceptions**. The obligations under this Article 10 will not apply to any information to the extent the recipient Party can demonstrate by competent evidence that such information:
例外情形. 本第10条项下的义务不适用于接收方能够以有效证据证明的任何信息，该等信息：

(a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the recipient Party or its Affiliates;
非因接收方或其关联方违反本协议而在披露时为公众所知或在披露后成为公共领域的一部分；

(b) was known to, or was otherwise in the possession of, the recipient Party or its Affiliates prior to the time of disclosure by the disclosing Party or any of its Affiliates;
在披露方或其任何关联方披露前为接收方或其关联方所知或以其他方式掌握；

(c) is disclosed to the recipient Party or its Affiliate on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the disclosing Party or any of its Affiliates; or
由有权披露该等信息的第三方在非保密基础上向接收方或其关联方披露，且该第三方未违反向披露方或其任何关联方承担的任何保密义务；或

(d) is independently developed by or on behalf of the recipient Party or its Affiliates, as evidenced by its written records, without use, reliance or reference to the Confidential Information disclosed by the disclosing Party or its Affiliates under this Agreement.
由或代表接收方或其关联方独立开发（以书面记录为证），且接收方或其关联方未使用、依赖或参考由披露方或其关联方在本协议项下披露的保密信息。

Specific aspects or details of Confidential Information will not be deemed to be within the public domain or in the possession of the recipient Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the recipient Party. Further, any combination of Confidential Information will not be considered in the public domain or in the possession of the recipient Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the recipient

Party unless the combination and its principles are in the public domain or in the possession of the recipient Party.

保密信息的具体方面或细节不会仅仅因为保密信息包含在处于公共领域或被接收方掌握的更广泛信息中而被视为处于公共领域或被接收方掌握。此外，保密信息的任何组合不会仅仅因为该等保密信息的个别要素处于公共领域或被接收方掌握而被视为处于公共领域或被接收方掌握，除非该组合及其原理已处于公共领域或被接收方掌握。

10.3 **Authorized Disclosures**.
授权披露。

(a) Except as otherwise required by Applicable Law and/or Regulatory Authorities, neither Party shall issue any press release, trade announcement or make any other public announcement or statement with regard to the transactions contemplated by this Agreement without the other Party's prior written consent, which shall not be unreasonably withheld or delayed. If either Party is required to disclose this Agreement or other Confidential Information related to this Agreement as required by Applicable Law and/or Regulatory Authorities, the Party obligated to make the disclosure shall provide the other Party a copy of the proposed disclosure. The other Party shall provide comments and proposed redactions within two (2) business days of receiving the proposed disclosure. The Party obligated to make the disclosure shall consider all comments in good faith; make reasonable efforts to minimize such disclosure; and make reasonable efforts to obtain confidential treatment for any Confidential Information it is required to disclose. No press release can be made before the payment of the Development Milestone No.1 under Section 8.1(a) of this Agreement.
除适用法律和/或监管机构另有要求外，未经另一方事先书面同意（该等同意不得无理拒给或延迟），任何一方不得就本协议拟议的交易发布任何新闻稿、交易公告或作出任何其他公告或声明。如果根据适用法律或监管机构的要求，任何一方必须披露本协议或与本协议相关的其他保密信息，则有义务披露的一方应向另一方提供一份拟议披露的副本。另一方应在收到拟披露内容后二（2）个工作日内提出意见和编辑建议。有义务披露信息的一方应善意考虑所有意见，做出合理努力尽量减少此类披露，并做出合理努力为其必须披露的任何保密信息获得保密处理。在本协议第8.1(a)款规定的第一个开发里程碑被支付之前，不得发布任何新闻稿。

(b) In addition to disclosures permitted pursuant to Sections 10.1 and 10.2, either Party may disclose Confidential Information without notice to or consent from the other Party, belonging to the other Party or its Affiliates, to the extent such disclosure is necessary in the following instances: (i) filing or prosecuting Patent Rights Covering Licensed Products to a patent authority as may be reasonably necessary or useful for purposes of obtaining or enforcing a Patent as permitted by this Agreement, provided that reasonable measures shall be taken to assure confidential treatment of such information; (ii) in connection with Regulatory Filings with Regulatory Authority for Licensed Products; (iii) prosecuting or defending litigation as permitted by this Agreement (in which case, notice and/or consent shall be required as otherwise contemplated in this Agreement); (iv) complying with applicable court orders, governmental regulations, or the inquiries of Regulatory Authorities; (v) in connection with an offering of securities or securities law disclosure requirements if counsel

determines that such disclosure is required; (vi) to the extent otherwise necessary or appropriate in connection with exercising the license and other rights granted to it hereunder; (vii) to bona fide potential investors, licensees, licensors, collaborators, lenders and acquirors/acquirees, and to such Party's consultants and advisors, in connection with a proposed equity or debt financing of such Party, an actual or proposed license, collaboration or similar arrangement, or a proposed acquisition or business combination, so long as such recipients are bound in writing to maintain the confidentiality of such information in accordance with the terms of this Agreement; or (viii) to distributors, so long as such recipients are bound in writing to maintain the confidentiality of such information in accordance with the terms of this Agreement.
除根据第10.1款和第10.2款允许进行的披露之外，一方可以在下列情况下未经通知另一方或另一方书面同意在必要的范围内披露属于另一方或其关联方的保密信息：(i)在本协议允许的情况下，有权为获得或执行专利之目的，向专利主管机关提交或提起涵盖许可产品的专利权申请（如合理必要或有益），但前提是应采取合理措施确保此类信息的保密处理；(ii)就许可产品的监管申报向监管机构进行披露；(iii)在本协议允许的情况下提起诉讼或进行抗辩（在此情况下，应按照本协议其他相关规定发出通知和/或取得同意）；(iv)遵守适用的法院命令、政府法规或监管机构的质询；(v)如果法律顾问决定需要披露，就证券发行或证券法披露要求进行披露；(vi)在另行需要或适当的范围内，就行使本协议项下授予该方的许可和其他权利进行披露；(vii)就任一方的拟议股权或债务融资、实际或拟议的许可、合作或类似安排或拟议的收购或业务合并，向善意的潜在投资者、被许可方、许可方、合作者、贷款人及收购方/被收购方以及向该方的顾问和咨询人员进行披露，但前提是，该等接收方以书面形式受到约束，根据本协议的条款对该等信息保密；或(viii)向经销商进行披露，但前提是，该等接收方以书面形式受到约束，根据本协议的条款对该等信息保密。

(c) If the recipient Party is required to disclose Confidential Information of the disclosing Party by law or in connection with a *bona fide* legal process, such disclosure will not be a breach of this Agreement; *provided* that the recipient Party (i) informs the disclosing Party as soon as reasonably practicable of the required disclosure; (ii) limits the disclosure to the required purpose; and (iii) at the disclosing Party's request and expense, assists in an attempt to object to or limit the required disclosure or to otherwise receive "confidential" or "trade secret" treatment with respect to relevant portions of such disclosure. The disclosing Party shall not be required to complete the requirements outlined in this paragraph if the disclosing Party's use of the Confidential Information is pursuant to the disclosing Party's performance obligation(s) contemplated herein.
如果根据法律或就善意的法律程序而言，接收方被要求对披露方的保密信息进行披露，该等披露不违反本协议；但前提是，接收方(i)在合理可行的情况下尽快通知披露方要求进行的披露；(ii)将披露限制于要求之目的；及(iii)在披露方提出要求和承担费用时，协助尝试反对或限制要求进行的披露或就该等披露的相关部分以其他方式获得"保密"或"商业秘密"处理。披露方依据本协议履行其合同义务而使用机密信息的，无需履行本款规定的相关要求。

10.4 **Scientific Publications**. Licensor shall not publish or give other forms of public disclosure, such as by public oral presentation, manuscript or abstract, of the plan, progress or results of Development activities, including clinical trials, with respect to the Licensed Product without Amphastar's prior written approval. Licensee shall not publish or give other forms of public disclosure, such as by public oral presentation, manuscript or abstract, of any Licensor's Confidential Information without Licensor's prior written approval. Any such proposed publication or disclosure shall be subject to the prior review and written consent of the other party, and the parties shall cooperate in good faith to resolve any concerns regarding authorship, confidentiality prior to publication.
学术发表。 未经Amphastar事先书面批准，许可方不得公布或以其他形式公开披露许可产品的开发活动（包括临床试验）计划、进展或成果，如公开口头介绍、原稿或摘要。未经许可方事先书面批准，Amphastar不得公布或以其他形式公开披露许可方的保密信息，如公开口头介绍、原稿或摘要。任何拟进行的该等发表或公开披露均须事先提交另一方审查并获得其书面同意，且双方应本着诚信原则协商解决与作者署名、保密相关的任何问题，之后方可发表。

10.5 **Ongoing Obligation of Confidentiality**. Upon early termination of this Agreement for any reason, each Party and its Affiliates will immediately return to the other Party or destroy any Confidential Information disclosed by the other Party, except for one copy which may be retained in its confidential files for archive purposes.
持续性保密义务。 在本协议由于任何原因提前终止时，每一方及其关联方将向另一方立即归还或销毁由另一方披露的任何保密信息，但为存档之目的在保密文档中可能保留的副本除外。

11. TERM AND TERMINATION

期限和终止

11.1 **Agreement Term**.
本协议期限.

(a) The term of this Agreement will commence on the Effective Date and unless earlier terminated pursuant to this Article 11, shall expire on the last expiration date of the Licensing Term for the Licensed Product in the Territory. The period commencing on the Effective Date and ending on the expiration date or early termination date of this Agreement in its entirety shall be referred to herein as the "**Agreement Term**".

Upon expiration (but not early termination) of the Royalty Term in a particular Region, the licenses granted under Section 2.1 (License) shall convert to an exclusive, perpetual, irrevocable, sublicensable (through multiple tiers) and fully-paid up license to Licensee.

本协议的期限将在生效日开始，除非根据本第11条提前终止，本协议的期限应在区域内许可产品的许可期限届满时到期。自生效日起至本协议全部届满之日或提前终止之日止的期限在本协议中称为"本协议期限"。

在特定地区内的许可费期限到期（而非提前终止）的情况下，第2.1条项下授予的许可应转换为一个对被许可方而言排他的、永久的、不可撤销的、可分许可（通过多层分许可）和许可费充分付讫的许可。

(b) Subject to the requirement as set forth in Section 12.1(b), if this Agreement is expired or terminated by either Party pursuant to this Article 11, and a clinical trial of a Licensed Compound or Licensed Product is ongoing as of the effective date of termination, the Parties shall discuss in good faith the appropriate steps to take regarding the closure or handover of such clinical trial, and in no event will the Party sponsoring the clinical trial be required to breach any Applicable Law or ethical requirement concerning treatment of study subjects.
受限于本协议第12.1款(b)项的要求，如果本协议到期或任何一方根据本第11条的约定终止本协议，且截至终止的生效日许可化合物或许可产品的临床试验仍在进行，双方应善意协商就该临床试验的结束或移交采取的适当措施，且在任何情况下均不得要求发起临床试验的一方违反任何适用法律或关于研究对象治疗的伦理要求。

11.2 **Termination by Licensor**. In the event Licensee fails to pay undisputed amount due and payable hereunder for a period of ninety (90) days from the due date, Licensor shall have the right to terminate this Agreement
许可方终止权。若被许可方未支付本协议项下到期应付的无争议的款项，且该等逾期超过九十（90）日的，许可方有权终止本协议。

11.3 **Termination by Licensee**. Licensee may terminate this Agreement in whole or in part, by providing written notice to Licensor, due to any one of the following reasons:
被许可方终止权。被许可方可向许可方发出书面通知后，基于以下任一原因全部或部分终止本协议：

(a) Licensor is in material breach of this Agreement, and such material breach is not cured within ninety (90) days after written notice by the Licensee specifying the claimed particulars of such breach;
许可方发生对本协议的重大违约，且在被许可方发出说明该等违约细节的书面通知后九十（90）日内未纠正该违约；

(b) Efficacy or safety do not meet the regulatory requirement and rejected by FDA;
疗效或安全性不符合监管要求，并且被FDA拒绝；

(c) In the event the stability (i.e. product shelf life) of the Licensed Products(s) cannot meet the Regulatory Authority requirements after intensive efforts by Licensee, and 6-month after Licensor's efforts to provide Licensee with formulation that will meet the Regulatory Authority requirements;
经被许可方努力改进后，许可产品的稳定性（即药品货架期）仍无法达到监管机构要求，且在许可方努力向被许可方提供符合监管要求的配方改进方案后的6个月未能解决该问题；

(d) In the event the United States market for Licensed Product has changed that Licensee decided not to pursue the Licensed Product any longer;
美国市场就许可产品发生重大变化，导致被授权方决定不再继续开发许可产品；

(e) Any other force majeure causes.
其他不可抗力原因。

11.4 **Termination by Licensee Without Cause**. Licensee may terminate this Agreement, in whole or in part, without cause at any time, by providing at least ninety (90) days' prior written notice to Licensor.
被许可方无理由终止。被许可方有权在任何时间，通过至少提前九十（90）天向许可方发出书面通知，无理由全部或部分终止本协议。

11.5 **Insolvency**. If an Insolvency Event occurs, (a) the Party subject to the Insolvency Event will give immediate (not longer than three (3) business days') notice to the other Party of such occurrence, and (b) the other Party will have the right to immediately terminate this Agreement by giving written notice to the Party that is subject to the Insolvency Event. In the event that Licensor is the insolvent Party, and Licensee does not elect to terminate this Agreement pursuant to this Section 11.5, Licensee is entitled to, (i) request Licensor to continue to perform this Agreement, and (ii) if Licensor is unable to perform this Agreement or this Agreement is otherwise terminated, Licensee shall have the right to purchase the Licensed IP in its entirety at the fair market value appraised by a Third Party appraisal agency. The Parties hereby acknowledge and agree that, to the extent permitted by Applicable Laws, Licensee shall have the right of first refusal to purchase the Licensed IP under same terms and conditions in the event of any bona fide offers from third parties. To the extent permitted under Applicable Law, Licensor will provide any and all assistance to facilitate Licensee's achievement of the foregoing objectives.

破产。如果发生破产事件，(a)发生破产事件的一方将立即（不超过三（3）个工作日）向另一方发出该事件的通知，及(b)另一方有权向发生破产事件的一方发出书面通知立即终止本协议。如果许可方是破产一方，且被许可方未根据本第11.5款选择终止本协议的，则被许可方有权：(i) 要求许可方继续履行本协议；及(ii) 如果许可方无法履行本协议或者本协议被终止的，被许可方有权以第三方评估机构评定的公允市场价值购买许可知识产权。双方特此确认和同意，在适用法律允许的前提下，若存在任何善意第三方要约，被许可方对许可知识产权享有同等条款下的优先购买权。在适用法律允许的范围内，许可方将提供一切必要协助以促成被许可方实现上述目标。

11.6 **Termination for Sanctions**. Licensee may terminate this Agreement immediately or upon such other date as may be designated by the Licensee in its written notice, if: (a) Licensor is added to any US or non-US sanctions- or export-related restricted party list, including without limitation the US Department of the Treasure Office of Foreign Assets Control's List of Specially Designated Nationals and Blocked Persons and the US Commerce Department Bureau of Industry and Security's Entity List or Denied Persons List; or (c) the purpose of this Agreement is prohibited or materially limited by any Applicable Laws (including the US BIOSECURE Act and similar legislation, if passed). This Agreement will automatically and immediately terminate without action by either Party if the performance of the Agreement would be in violation of Applicable Laws because of the Licensor's status under US sanctions laws. Notwithstanding anything to the contrary in this Agreement, neither Party shall have any liability to the other whatsoever for termination of the Agreement pursuant to this Section 11.6 (Termination for Sanctions).

因制裁终止。出现以下情形时，被许可方有权立即终止本协议，或在书面通知中指定其他终止日期：(a)许可方被列入任何美国或非美国制裁或出口相关的限制方名单，包括但不限于美国财政部外国资产控制办公室特别指定国民与被封锁人员名单、美国商务部工业与安全局实体清单或拒绝交易人员名单；或(b)本协议目的被任何适用法律（包括美国《生物安全法案》及类似立法，如获通过）禁止或受到重大限制。若因许可方受美国制裁法律约束导致履行本协议将违反适用法律，则本协议自动立即终止，无需任何一方采取行动。即使本协议有任何相反约定，任一方均无需就根据第11.6款（因制裁终止）终止协议向另一方承担任何责任。

11.7 **Remedy-in-lieu-of-termination.** If Licensee has the right to terminate this Agreement pursuant to Section 11.3 or Section 11.5, then as the monetary remedy

available to Licensee (in addition to any other available remedies), in lieu of terminating this Agreement, Licensee may, in its sole discretion, retain all of its licenses and other rights granted under this Agreement, except that the then-unearned Milestone Payments and Royalty Payments thereafter under this Agreement, in each case, will be reduced by [***].
终止的替代补救措施。如果被许可方有权根据第11.3条或第11.5条终止本协议，作为被许可方可获得的金钱补救措施（除其他可用补救措施外），被许可方有权自行选择不终止本协议，而保留其在本协议项下获得的所有许可及其他权利，但届时未支付的里程碑付款和许可费付款均应减少 [***]。

12. EFFECT OF TERMINATION

终止的效力

12.1 **Effect of Termination**. Upon termination of this Agreement:
终止的效力. 本协议终止后：

(a) **Licenses**. The licenses and other rights granted by a Party to the other Party under the Licensed IP or Cross-license Patents will terminate;
许可。一方在许可知识产权或交叉许可专利项下授予另一方的许可和其他权利将终止；

(b) **Clinical Trials.** Licensee will responsibly wind-down, in accordance with accepted pharmaceutical industry norms and ethical practices and all legal and regulatory requirements, any on-going clinical trials for which it has responsibility hereunder in which patient dosing has commenced
临床试验。被许可方应根据公认的制药行业规范与伦理实践，以及所有法律和监管要求，负责、有序地终止其在本协议项下负责的所有已开始给药的正在进行的临床试验；

(c) **Return of Confidential Information.** At the disclosing Party's election, the receiving Party shall return or destroy all tangible materials to the extent comprising or containing any Confidential Information of the disclosing Party that are in receiving Party's or its Affiliates' possession or control and provide written certification of such destruction, provided that the receiving Party may retain one (1) copy of such Confidential Information for its archives solely to monitor compliance with its obligations herein;
保密信息归还。根据披露方的选择，接收方应将其本人或其关联方拥有或控制的、构成或包含披露方任何保密信息的所有有形材料予以归还或销毁，并提供书面销毁证明。但前提是：接收方可保留一(1)份该等保密信息用于档案存档，仅用于监督其在本协议项下义务的履行情况；

(d) Except as set forth in this Section 12.1 and in Section 12.2, the rights and obligations of the Parties hereunder will terminate as of the date of such termination.
除本第12.1款和第12.2款规定的之外，双方在本协议项下的权利和义务将于该等终止日终止。

12.2 **Survival**. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, Articles 1, 8, 9, 12, 14 and 15will survive the expiration or termination of this Agreement for any reason. Article 10 (Confidentiality) of this Agreement

will survive the termination or expiration of this Agreement for a period of seven (7) years after the effective date of termination or expiration (as the case may be).
继续有效。本协议到期或终止不得免除双方在该等到期或终止前产生的任何义务。在不限制上述规定的情况下，第1条、第8条、第9条、第12条、第14条、第15条将在本协议到期或由于任何原因终止后继续有效。本协议第10条（保密）将在本协议终止的生效日或到期（视情况而定）后的七(7)年期内继续有效。

12.3 **Termination Not Sole Remedy**. Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies will remain available except as agreed to otherwise herein. For the avoidance of doubt, nothing in this Agreement shall obligate a Party to terminate this Agreement if the other Party breaches any obligation under this Agreement, and failure to terminate this Agreement shall not prohibit or modify the recovery of damages available to it pursuant to Section 15.5 or at law.
终止非唯一救济。终止并非本协议项下的唯一救济，无论终止是否发生，尽管本协议有任何相反的规定，所有其他救济仍可获得，但本协议另行约定的除外。为避免疑义，本协议的任何规定不得使一方有义务在另一方违反本协议项下的任何义务的情况下终止本协议，且未能终止本协议的行为不得禁止或修改该方根据第15.5款或法律可获得的损害赔偿金。

13. REPRESENTATIONS, WARRANTIES AND COVENANTS

陈述、保证和承诺

13.1 **Representations and Warranties by Each Party**. Each Party represents and warrants to the other as of the Effective Date that:
每一方的陈述和保证. 在生效日，一方向另一方陈述并保证：

(a) it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;
该方是一家根据成立所在司法辖区的法律正式组建、有效存续且声誉良好的公司；

(b) it has full corporate power and authority to execute, deliver, and perform this Agreement, and has taken all corporate action required by law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;
该方拥有充分的公司权力和权限以签署、交付和履行本协议，并已采取法律和其组织文件规定的所有公司行动以授权本协议的签署和交付以及完成本协议拟议的交易；

(c) this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles and public policy constraints (including those pertaining to limitations or exclusions of liability, competition laws, penalties and jurisdictional issues including conflicts of laws);

本协议构成一份有效且具有约束力的协议，可根据其条款针对该方强制执行，但可强制执行性可能受到对债权人的权利具有一般相关性或影响的破产、欺诈性转让、资不抵债、重组、延期偿还和其他法律以及受到一般衡平法原则和公共政策约束（包括责任限制或免除、竞争法律、处罚和管辖权问题，包括法律冲突）限制的除外；

(d) all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained;
该方就本协议需要取得的所有政府机构或其他第三方的所有同意、批准和授权均已取得；

(e) the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and will not (i) conflict with or result in a breach of any provision of its organizational documents; (ii) result in a breach of any agreement to which it is a party; or (iii) violate any Applicable Laws;
签署和交付本协议以及根据本协议需要签署的所有其他文书和文件以及完成本协议拟议的交易目前和将来均不(i)抵触或导致违反该方组织文件的任何规定；(ii)导致违反该方作为一方的任何协议；或(iii)违反任何适用法律；

(f) it is not aware of any action, suit, inquiry or investigation instituted by any Person or governmental agency that questions or threatens the validity of this Agreement;
该方不知悉由任何主体或政府机构提起的质疑或可能质疑本协议有效性的任何诉求、诉讼、质询或调查；

(g) neither such Party nor, to the actual knowledge of such Party, any employee, agent or subcontractor of such Party involved or to be involved in the Development or manufacture of any Licensed Compound or Licensed Product has been debarred under Subsection (a) or (b) of Section 306 of the Federal Food, Drug and Cosmetic Act (21 USC §§ 335a) or any equivalent or similar provision under Applicable Law in the People's Republic of China or elsewhere; and
该方以及（据该方实际所知）目前或将来参与开发或生产任何许可化合物或许可产品的该方的任何员工、代理人或分包商均未在《联邦食品、药品和化妆品法案》（《美国法典》第21编第335a章）第306条第(a)款或第(b)款或者中华人民共和国或其他地方的适用法律项下的任何同等或类似规定项下被禁止从业；及

(h) neither such Party or its Affiliates, nor any of its current and former directors, officers, employees, or agents have provided, offered, or promised the provision of anything of value (regardless of monetary value), directly or indirectly, to any governmental official or agent, for the purpose of securing any improper or illegal advantage in violation of relevant and applicable anti-bribery and anti-corruption laws, regulations, and international conventions, including, but not limited to, the US Foreign Corrupt Practices Act of 1977 and the Criminal Law and Anti-Unfair Competition Law in China.

该方或其关联方以及各方的任何现任和前任董事、管理人员、员工和代理人均未违反相关和适用的反贿赂和反腐败法律、法规和国际公约（包括但不限于美国《1977年反海外腐败法》以及中国《中华人民共和国刑法》和《中华人民共和国反不正当竞争法》），为获得任何不当或非法利益之目的，直接或间接地向任何政府官员或代理人提供、给予或承诺提供任何有价馈赠（与金钱价值无关）。

13.2 **Additional Representations and Warranties by Licensor**. Licensor represents and warrants to Licensee as of the Effective Date that:
许可方的额外陈述和保证。截至本协议生效日，许可方向被许可方陈述并保证：

(a) ***Exhibit A*** and ***Exhibit B*** set forth a true, complete and correct list of all intellectual properties Controlled by Licensor or its Affiliates as of the Effective Date that claim the composition or method of use of Licensed Compound;
附件A和***附件B***真实、完整且正确地列出了许可方或其关联方截至生效日控制的所有说明许可化合物的构成或使用方法的知识产权；

(b) each Person who has or has had any rights in or to any Licensed IP has assigned by virtue of employment or written assignment its entire right, title and interest in and to such Licensed IP to Licensor or its Affiliates;
过去或现在拥有任何许可知识产权权利的每一主体已经通过雇用或书面转让方式向许可方或其关联方转让该主体拥有的该等许可知识产权的全部权利、权属和权益；

(c) Licensor and its Affiliates are the sole and exclusive owners of the entire right, title and interest in, to and under the Licensed IP, free and clear of all liens, encumbrances, security interests, claims, restrictions, licenses, options, or any other third-party rights that would interfere with Licensee's rights, and have not granted any license or other right under the Licensed IP that is in conflict with the license hereunder or prejudices Amphastar's rights granted hereunder; Licensor has procured all of its Affiliates to have exclusively licensed or assigned to Licensor all of their right, title, and interest in and to the Licensed IP as of the Effective Date hereof (if necessary);
许可方及其关联方是许可知识产权的全部权利、权属和权益的唯一和独家所有人，不附带所有留置权、权利负担、担保权益、权利主张、限制、许可、选择权或会妨碍被许可方权利的任何其他第三方权利，并且未授予与本协议项下的许可相冲突或损害在本协议项下授予的Amphastar权利的许可知识产权项下的任何许可或其他权利；许可方已促使其所有关联方向许可方排他性地许可或转让其关联方截至本协议的生效日拥有的许可知识产权的全部权利、权属和权益（如有必要）；

(d) each of the Licensed Patents properly identifies each and every inventor of the claims thereof as determined in accordance with the Applicable Laws of the jurisdiction in which such Licensed Patent is issued or patent application is pending; provided, however, that if a Licensed Patent does not properly identify each and every inventor in accordance with the foregoing, Licensor shall be responsible for correcting the inventorship of such Licensed Patent at its sole cost and expense;

每项许可专利均适当标明根据颁发该许可专利或专利申请待批的司法辖区的适用法律确定的该许可专利的权利要求的每一发明人；但前提是，如果一项许可专利并未根据上述规定适当标明每一发明人，许可方应负责自费纠正该许可专利的发明人身份；

(e) Licensor has filed and prosecuted patent applications within the Licensed Patents in good faith and complied with all duties of disclosure with respect thereto;
许可方已善意地提交并提起许可专利内的专利申请，并已遵守与之相关的披露义务；

(f) to the knowledge of Licensor, there are no facts that could form the basis for the invalidation or unenforceability of the Licensed Patents;
据许可方所知，不存在可能构成许可专利无效或不可强制执行依据的任何事实；

(g) Licensor has not initiated or been involved in any proceedings or Claims in which it alleges that any Third Party is or was infringing or misappropriating any Licensed IP relating to Licensed Compound or Licensed Products, or any other proceedings or Claims that resulted in or would reasonably be expected to result in monetary damages or changes in intellectual property rights to the Licensed IP or impairing Amphastar's ability to use and commercialize the Licensed Compound or Licensed Products;
许可方并未提起或参与其声称任何第三方现在或过去侵犯或盗用与许可化合物或许可产品相关的任何许可知识产权的任何程序或权利主张，也未提起或参与已经导致或经合理预期会导致金钱赔偿或许可知识产权的知识产权变更或损害Amphastar对许可化合物或许可产品进行使用和商业化能力的任何其他程序或权利主张；

(h) to the knowledge of Licensor, there are no activities by Third Parties that would constitute infringement or misappropriation of the Licensed Patents (in the case of pending claims, evaluating them as if issued);
据许可方所知，不存在由第三方开展的会构成侵犯或盗用许可专利的任何活动（就待批的专利申请，按已获授权的标准进行评估）；

(i) to the knowledge of Licensor, the development and practice of the Licensed IP do not and will not infringe or otherwise conflict with any intellectual property rights or other rights of any Third Party;
据许可方所知，许可知识产权的开发和实施目前和将来均不侵犯或以其他方式抵触任何第三方的任何知识产权或其他权利；

(j) Licensor has not entered into any agreement with a Third Party that is in conflict with the rights granted to Licensee under this Agreement, and has not taken any action that would prevent it from granting the rights granted to Licensee under this Agreement, or that would otherwise materially conflict with or materially adversely affect the rights granted to Licensee under this Agreement;
许可方并未与第三方签订与在本协议项下授予被许可方的权利相冲突的任何协议，也未采取会阻止许可方授予在本协议项下授予被许可方的权利的任何行动，或会以其他方式与在本协议项下授予被许可方的权利发生重大冲突或对在本协议项下授予被许可方的权利产生重大不利影响的任何行动；

(k) Licensor and its Affiliates have taken reasonable precautions to preserve the confidentiality of the Licensed Know-How, including securing binding, written confidentiality agreements with respect thereto from all employees, consultants, agents and independent contractors of Licensor and its Affiliates No employee, consultant, agent or independent contractor of Licensor and its Affiliates is in violation of the terms of any such agreement or has otherwise made unauthorized use of or misappropriated any Licensed IP. No employee or consultant of Licensor and its Affiliates, of whom are subject to such non-compete obligations, is in violation of the terms of any such agreement or has otherwise carried out any actions that would adversely affect Licensor's right to grant any license of Licensed IP hereunder or Licensee's right to use any Licensed IP hereunder; and
许可方及其关联方已采取合理的预防措施保护许可专有技术的保密性，包括确保许可方及其关联方的所有员工、顾问、代理人和独立承包商就许可专有技术签订具有约束力的书面保密协议。许可方及其关联方的任何员工、顾问、代理人和独立承包商均未违反任何该等协议的条款，也未以其他方式擅自使用或盗用任何许可知识产权。负有竞业禁止义务的许可方及其关联方的任何员工和顾问均未违反任何该等协议的条款，也未以其他方式实施会对许可方在本协议项下授予许可知识产权的任何许可的权利或会对被许可方在本协议项下使用任何许可知识产权的权利产生不利影响的任何行动；及

(l) To Licensor's knowledge, all core information and core data that Licensor and/or its Affiliates provide to Licensee in relation to this Agreement are true, complete, accurate, unadulterated and not misleading in material respect, and further, Licensor and its Affiliates have not retained, deleted or otherwise withheld any material information regarding the Licensed IP from Licensee that is necessary to perform the license hereunder;
据许可方所知，许可方及/或其关联方根据本协议向被许可方提供的所有核心信息与核心数据在重大方面均真实、完整、准确、未篡改且不具误导性；且许可方及其关联方未保留、删除或以其他方式隐瞒被许可方实施本协议项下许可所必需的有关许可知识产权的任何重大信息。

13.3 **Covenants of Licensor**. Licensor covenants that:
许可方的承诺。许可方承诺：

(a) it will not grant any interest in the Licensed IP that is inconsistent or otherwise conflicting with the terms of this Agreement;
许可方不会授予与本协议的条款不一致或以其他方式相冲突的许可知识产权的任何权益；

(b) if, at any time after execution of this Agreement, it becomes aware that it or any employee, agent or subcontractor of Licensor who participated in the Development or manufacture of a Licensed Compound or Licensed Product is on, or is being added to the FDA Debarment List or to any of the FDA clinical investigator enforcement lists, it will provide written notice of this to Licensee within ten (10) business days after becoming aware of this fact.
如果在本协议签署后的任何时间，许可方获悉其或参与开发或生产许可化合物或许可产品的许可方的任何员工、代理人或分包商被列入或加入美国食药监局排除清单或美国食药监局的任何临床研究人员执行

名单，许可方将在获悉该事实后的十（10）个工作日内书面通知被许可方。

(c) Licensor understands and agrees that, notwithstanding any other provision of this Agreement, neither Licensor nor any entity acting on behalf of Licensor, including the Auditor and Licensor's Alliance Manager, shall request or accept from Amphastar, its affiliates or its sublicensees, and Amphastar, its affiliates or its sublicensees is not obligated to provide, "access" to any "government-related data" or "bulk U.S. sensitive personal data," within the meaning ascribed to each such term under the US Data Security Program. Licensor agrees to not evade or avoid, cause a violation of, or attempt to violate any of the prohibitions set forth in the US Data Security Program in connection with this Agreement.
许可方理解并同意，即使本协议存在任何其他条款规定，许可方或代表许可方行事的任何实体（包括审计方及许可方合作项目管理人）均不得向Amphastar、其关联方或分许可方要求或接收，且Amphastar、其关联方或分许可方亦无义务提供美国数据安全计划所定义的任何"政府相关数据"或"美国敏感个人数据批量信息"的"访问权限"。许可方同意，在本协议履行过程中不会规避、违反或试图违反美国数据安全计划规定的任何禁令。

13.4 **Covenants of Licensee**. Licensee covenants that:
被许可方的承诺。被许可方承诺：

(a) Licensee understands and agrees that, notwithstanding any other provision of this Agreement, neither Licensee nor any entity acting on behalf of Licensee, including the Auditor and Licensee's Alliance Manager, shall request or accept from Licensor, its affiliates or its sublicensees, and Licensor, its affiliates or its sublicensees is not obligated to provide any data in violation of Chinese data security laws and regulations. Licensee agrees to not evade or avoid, cause a violation of, or attempt to violate any of the prohibitions set forth in Chinese data security laws and regulations in connection with this Agreement.
被许可方理解并同意，即使本协议存在任何其他条款规定，被许可方或代表被许可方行事的任何实体（包括审计方及被许可方合作项目管理人）均不得向许可方、其关联方或分许可方要求或接收，且许可方、其关联方或分许可方亦无义务提供任何违反中国数据安全法律法规的数据。被许可方同意，在本协议履行过程中不会规避、违反或试图违反中国数据安全法律法规。

14. INDEMNIFICATION; LIABILITY

赔偿；责任

14.1 **Indemnification by Licensor**. Licensor will indemnify and hold Licensee, its Affiliates, and their respective officers, directors and employees ("Licensee Indemnitees") harmless from and against any Claims against them to the extent arising or resulting from:
许可方的赔偿。 许可方将赔偿被许可方、其关联方及其各自的管理人员、董事和员工（"被许可方受偿方"）由下列事项引起或导致的针对被许可方受偿方提出的任何权利主张，并使其免受损害：

(a) the breach of any of the obligations, covenants, warranties or representations made by Licensor to Licensee under this Agreement; or
违反许可方在本协议项下向被许可方作出的任何义务、承诺、保证或陈述；或

(b) any activities conducted by Licensor or its Affiliates in the Territory with respect to the Licensed Compound or Licensed Products prior to the Effective Date;
许可方或其关联方在生效日前在区域内就许可化合物或许可产品开展的任何活动；

provided, however, that Licensor will not be obliged to so indemnify, defend and hold harmless the Licensee Indemnitees for any Claims to the extent Licensee has an obligation to indemnify the Licensor Indemnitees pursuant to Section 14.2 or to the extent that such Claims arise from the breach, negligence or wilful misconduct of Licensee or the Licensee Indemnitees.

但前提是，如果被许可方根据第14.2款有义务赔偿许可方受偿方，或如果任何权利主张是由被许可方或被许可方受偿方的违约、过失或故意不当行为引起，则许可方无义务就该等权利主张赔偿被许可方受偿方，为其抗辩，并使其免受损害。

14.2 **Indemnification by Licensee**. Licensee will indemnify and hold Licensor, its Affiliates, and their respective officers, directors and employees ("Licensor Indemnitees") harmless from and against any Claims against them to the extent arising or resulting from:
被许可方的赔偿。被许可方将赔偿许可方、其关联方及其各自的管理人员、董事和员工（"许可方受偿方"）由下列事项引起或导致的针对许可方受偿方提出的任何权利主张，并使其免受损害：

(a) actions by Licensee, its Affiliates, its sublicensees, and their respective employees, agents and Subcontractors, in connection with the Development, manufacture or Commercialization of any Licensed Compound or Licensed Products by Licensee in the Territory after the Effective Date; or
被许可方、其关联方、其分许可方及其各自的员工、代理人和分包商就被许可方在生效日后在区域内进行的任何许可化合物或许可产品的开发、生产或商业化活动采取的行动；或

(b) the breach of any of the obligations, covenants, warranties or representations made by Licensee to Licensor under this Agreement;
违反被许可方在本协议项下向许可方作出的任何义务、承诺、保证或陈述；

provided, however, that Licensee will not be obliged to so indemnify, defend and hold harmless the Licensor Indemnitees for any Claims to the extent Licensor has an obligation to indemnify the Licensee Indemnitees pursuant to Section 14.1 or to the extent that such Claims arise from the breach, negligence or wilful misconduct of Licensor or the Licensor Indemnitees.

但前提是，如果许可方根据第14.1款有义务赔偿被许可方受偿方，或如果任何权利主张是由许可方或许可方受偿方的违约、过失或故意不当行为引起，

则被许可方无义务就该等权利主张赔偿许可方受偿方，为其抗辩，并使其免受损害。

14.3 **Indemnification Procedure**.
赔偿程序。

(a) For the avoidance of doubt, all indemnification claims in respect of a Licensee Indemnitee or Licensor Indemnitee will be made solely by Licensee or Licensor, respectively.
为避免疑义，与被许可方受偿方或许可方受偿方相关的所有赔偿权利主张将由被许可方或许可方单独提出。

(b) A Party seeking indemnification hereunder ("Indemnified Party") will notify the other Party ("Indemnifying Party") in writing reasonably promptly after the assertion against the Indemnified Party of any Claim or fact in respect of which the Indemnified Party intends to base a claim for indemnification hereunder ("Indemnification Claim Notice"), but the failure or delay to so notify the Indemnifying Party will not relieve the Indemnifying Party of any obligation or liability that it may have to the Indemnified Party, except to the extent that the Indemnifying Party demonstrates that its ability to defend or resolve such Claim is adversely affected thereby. The Indemnification Claim Notice will contain a description of the Claim and the nature and amount of the Claim (to the extent that the nature and amount of such Claim is known at such time). Upon the request of the Indemnifying Party, the Indemnified Party will furnish promptly to the Indemnifying Party copies of all correspondence, communications and official documents (including court documents) received or sent in respect of such Claim.
寻求本协议项下赔偿的一方（"受偿方"）将在针对受偿方提出任何权利主张或事实（受偿方拟议就该权利主张或事实提出本协议项下的赔偿权利主张）后，合理迅速地书面通知（"赔偿权利主张通知"）另一方（"赔偿方"），但未能或迟延通知赔偿方不会免除赔偿方对受偿方可能承担的任何义务或责任，除非赔偿方证明其抗辩或解决该权利主张的能力因此受到不利影响。赔偿权利主张通知将包含对权利主张的描述以及权利主张的性质和金额（在该权利主张的性质和金额届时已知的范围内）。经赔偿方要求，受偿方将立即向赔偿方提供就该权利主张收到或发送的所有通信、通讯和官方文件（包括法院文件）的副本。

(c) Subject to the provisions of Sections 14.3(d) and 14.3(e), the Indemnifying Party will have the right, upon written notice given to the Indemnified Party within thirty (30) days after receipt of the Indemnification Claim Notice, to assume the defense and handling of such Claim, at the Indemnifying Party's sole expense, in which case the provisions of Section 14.3(d) will govern. The assumption of the defense of a Claim by the Indemnifying Party will not be construed as acknowledgement that the Indemnifying Party is liable to indemnify any indemnitee in respect of the Claim, nor will it constitute a waiver by the Indemnifying Party of any defenses it may assert against any Indemnified Party's claim for indemnification. If it is ultimately decided that the Indemnifying Party is not obligated to indemnify or hold an indemnitee harmless from and against the Claim, the Indemnified Party will reimburse the Indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any losses incurred by the Indemnifying Party in its defense of the Claim. If the Indemnifying Party does not give

written notice to the Indemnified Party, within thirty (30) days after receipt of the Indemnification Claim Notice, of the Indemnifying Party's election to assume the defense and handling of such Claim, the provisions of Section 14.3(e) will govern.
受限于第14.3(d)款和第14.3(e)款的规定，赔偿方有权在收到赔偿权利主张通知后的三十（30）天内，通过向受偿方发出书面通知，承担该权利主张的抗辩和处理，费用由赔偿方自行承担，在该等情况下，第14.3(d)款的规定将适用。赔偿方承担一项权利主张的抗辩不得被解释为确认赔偿方有责任就该权利主张赔偿任何受偿方，也不得构成赔偿方放弃其针对任何受偿方的赔偿权利主张可能提出的任何抗辩。如果最终判决赔偿方无义务就该权利主张赔偿受偿方或使其免受损害，受偿方将偿付赔偿方在对该权利主张进行抗辩的过程中发生的任何和所有费用和支出（包括律师费和诉讼费）以及任何损失。如果赔偿方未在收到赔偿权利主张通知后的三十（30）天内向受偿方发出书面通知，说明赔偿方选择承担该权利主张的抗辩和处理，第14.3(e)款的规定将适用。

(d) Upon assumption of the defense of a Claim by the Indemnifying Party: (i) the Indemnifying Party will have the right to and will assume sole control and responsibility for dealing with the Claim; (ii) the Indemnifying Party may, at its own cost, appoint as counsel in connection with conducting the defense and handling of such Claim any law firm or counsel reasonably selected by the Indemnifying Party; (iii) the Indemnifying Party will keep the Indemnified Party informed of the status of such Claim; and (iv) the Indemnifying Party will have the right to settle the Claim on any terms the Indemnifying Party chooses; *provided, however*, that it will not, without the prior written consent of the Indemnified Party, agree to a settlement of any Claim which will admit any liability or fault by the Indemnified Party, could harm the Indemnified Party's reputation or goodwill, could lead to liability or create any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to indemnification hereunder or which admits any wrongdoing or responsibility for the claim on behalf of the Indemnified Party. The Indemnified Party will cooperate with the Indemnifying Party and will be entitled to participate in, but not control, the defense of such Claim with its own counsel and at its own expense. In particular, the Indemnified Party will furnish such records, information and testimony, provide witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation will include access during normal business hours by the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Claim, and making the Indemnified Party and its employees and agents available on a mutually convenient basis to provide additional information and explanation of any records or information provided.
在赔偿方承担一项权利主张的抗辩后：(i)赔偿方有权并将独自控制和负责处理该权利主张；(ii)赔偿方可自费聘请赔偿方合理选择的任何律师事务所或法律顾问作为进行该权利主张的抗辩和处理的律师；(iii)赔偿方将随时告知受偿方该权利主张的状况；及(iv)赔偿方有权根据赔偿方选择的任何条款就该权利主张达成和解；但前提是，如果任何权利主张的和解将承认受偿方的责任或过错、可能损害受偿方商誉或声誉、可能导致受偿方承担责任或任何财务或其他义务（而受偿方无权就该等责任或义务获得本协议项下的赔偿），或者该等和解代表受

偿方就该权利主张承认任何不当行为或责任，则未经受偿方事先书面同意，赔偿方不得就该权利主张达成和解。受偿方将与赔偿方合作，并有权通过自己的律师自费参与但不控制对该权利主张的抗辩。特别是，受偿方将提供合理要求的相关记录、信息和证词，提供证人并参加合理要求的相关会议、调查取证程序、听证、审理和上诉。该等合作将包括赔偿方在正常营业时间内查阅与该权利主张合理相关的记录和信息，以及受偿方合理保留与该权利主张合理相关的记录和信息，并使受偿方及其员工和代理人在相互方便的基础上提供额外信息和对已提供的任何记录或信息的解释。

(e) If the Indemnifying Party does not give written notice to the Indemnified Party as set forth in Section 14.3(c) or fails to conduct the defense and handling of any Claim in good faith after having assumed such, the Indemnified Party may, at the Indemnifying Party's expense, select counsel reasonably acceptable to the Indemnifying Party in connection with conducting the defense and handling of such Claim and defend or handle such Claim in such manner as it may deem appropriate. In such event, the Indemnified Party will keep the Indemnifying Party timely apprised of the status of such Claim and will not settle such Claim without the prior written consent of the Indemnifying Party, which consent will not be unreasonably withheld. If the Indemnified Party defends or handles such Claim, the Indemnifying Party will cooperate with the Indemnified Party, at the Indemnified Party's request but at no expense to the Indemnified Party, and will be entitled to participate in the defense and handling of such Claim with its own counsel and at its own expense.
如果赔偿方未根据第14.3(c)款的规定向受偿方发出书面通知，或未能在承担后善意地进行任何权利主张的抗辩和处理，受偿方可以在赔偿方承担费用的情况下就进行该权利主张的抗辩和处理选择赔偿方可合理接受的律师，并以其认为适当的方式对该权利主张进行抗辩或处理。在该等情况下，受偿方将及时告知赔偿方该权利主张的状况，未经赔偿方事先书面同意（该等同意不得无理拒绝），受偿方不得就该权利主张达成和解。如果受偿方对该权利主张进行抗辩或处理，经受偿方要求，赔偿方将与受偿方合作，但不向受偿方收取任何费用，并且赔偿方有权通过自己的律师自费参与对该权利主张的抗辩和处理。

14.4 **Mitigation of Loss**. Each Indemnified Party will take and will procure that its Affiliates take all such reasonable steps and action as are necessary or as the Indemnifying Party may reasonably require in order to mitigate any Claims (or potential losses or damages) under this Article 14. Nothing in this Agreement will or will be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.
减轻损失。每一受偿方将采取并将促使其关联方采取需要的或赔偿方可能合理要求的所有合理措施和行动，以减轻本第14条项下的任何权利主张（或潜在的损失或损害）。本协议的任何规定不得也不得被视为免除任何一方减轻该方遭受的任何损失的任何普通法或其他责任。

14.5 **Special, Indirect and Other Losses**. NO PARTY NOR ANY OF SUCH PARTY'S AFFILIATES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR FOR ANY ECONOMIC LOSS OR LOSS OF PROFITS SUFFERED BY THE OTHER PARTY, EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE

REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 14 OR FOR A BREACH OF SECTION 2.1, ARTICLE 9 OR ARTICLE 10.

特殊、间接和其他损失。任何一方以及该方的任何关联方均不对另一方遭受的任何特殊、间接、附带、惩罚性或后果性损害或者任何经济损失或利润损失承担合同、侵权、过失、违反法定义务或其他方面的责任，除非该等损害属于根据本第14条项下由一方进行赔偿的第三方索赔的一部分，或源于对第2.1条、第9条或第10条的违反。

15. GENERAL PROVISIONS

一般规定

15.1 **Assignment**. This Agreement may not be assigned or otherwise transferred (however structured, whether by merger, acquisition, sale of all or substantially all of its assets to which this Agreement relates or otherwise), in whole or in part, nor, except as expressly provided hereunder, may any right or obligation hereunder be assigned or transferred, by either Party without the prior written consent of the other Party; provided, however, that (i) either Party may, without such consent, assign this Agreement and its rights and obligations hereunder, in whole or in part, to any of its Affiliates; provided that the assigning Party shall continue to remain fully responsible for the actions or inactions of such Affiliate, and (ii) either Party may, without such consent, assign this Agreement and its rights and obligations hereunder, to its successor in interest in connection with (x) a Change of Control or (y) a sale of all or substantially all of its assets to which this Agreement relates, or in connection with a merger, acquisition or similar transaction. Written notice of any permitted assignment of this Agreement shall be promptly provided to the non-assigning Party promptly following consummation and any permitted assignee shall assume all rights and obligations of its assignor under this Agreement. Any permitted assignee will assume all obligations of its assignor under this Agreement. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors, heirs and permitted assigns.

转让。本协议不得被全部或部分转让或以其他方式转移（无论以何种形式，包括通过合并、收购、出售本协议所涉及的全部或实质性资产或其他方式），任何一方亦不得转让或转移本协议项下的任何权利或义务，除非事先获得另一方的书面同意；但前提是：(i) 任一方可在无需获得对方同意的情况下，将本协议及其在本协议项下的权利和义务全部或部分转让给其任何关联方；但该转让方应继续对该关联方的作为或不作为承担全部责任；并且 (ii) 任一方可在无需获得对方同意的情况下，在以下情形中将本协议及其项下的权利和义务转让给其权益继承人： (x) 控制权变更，或 (y) 出售本协议相关的全部或实质性全部资产，或是基于兼并、收购或类似交易。在完成任何被允许的转让后，转让方应及时向非转让方提供书面通知，且任何被允许的受让方应承担其转让方在本协议项下的所有权利与义务。受限于本协议的条款，本协议将对双方及其各自的继承人、继受人和获准受让人具有约束力，并及于其利益。

15.2 **Extension to Affiliates**. Each Party will have the right to extend the rights, immunities and obligations granted in this Agreement to one or more of its Affiliates. All applicable terms of this Agreement will apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms apply to

Licensee. Licensor and Licensee will remain primarily liable for any acts or omissions of its Affiliates.
延伸至关联方。 每一方有权将本协议中授予的权利、豁免和义务延伸至其一个或多个关联方。本协议的所有适用条款将适用于本协议已延伸至的任何该等关联方，与该等条款适用于被许可方的范围相同。许可方和被许可方将对其关联方的任何作为或不作为持续承担主要责任。

15.3 **Severability**. Should one or more provisions of this Agreement become void or unenforceable as a matter of law, then this Agreement will be construed as if such provision were not contained herein and the remainder of this Agreement will be in full force and effect, and the Parties will use their commercially reasonable efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the Parties.
可分割性。 如果本协议的一项或多项规定作为法律问题无效或不可强制执行，则对本协议进行解释，如同该规定不包含在本协议中，本协议的其余规定将完全有效，且双方将尽其商业上的合理努力以尽可能符合双方最初意图的有效且可强制执行的规定替代该无效或不可强制执行的规定。

15.4 **Governing Law and Jurisdiction**. This Agreement will be governed by and construed under the laws of Singapore, without giving effect to the conflicts of laws provision thereof.
适用法律和管辖权. 本协议将受新加坡法律管辖并依其解释，但其法律冲突规定不予实行。

15.5 **Dispute Resolution**.
争议解决。

(a) In the event of a dispute relating to, arising out of or in any way connected with this Agreement or any term hereof, or the performance by either Party of its obligations hereunder (a "Dispute"), the Parties will refer the Dispute to the Alliance Managers for discussion and resolution. If the Alliance Managers are unable to resolve the Dispute within thirty (30) days after the Dispute is referred to them, either Party may require that the Parties forward the Dispute to the Senior Officers (or designees with similar authority to resolve such Dispute), who will attempt in good faith to resolve the Dispute. If the Senior Officers cannot resolve the Dispute within thirty (30) days after the Dispute is referred to them, either Party will be free to initiate the arbitration proceeding set forth in Section 15.5(b) to resolve the Dispute.
如果发生由本协议或本协议的任何条款或任何一方对其在本协议项下义务的履行引起或与之相关或以任何方式相关连的争议（"争议"），双方应将该争议提交合作项目管理人讨论解决。如果合作项目管理人无法在该争议提交后的三十（30）天内解决该争议，任何一方可要求双方将该争议提交高级管理人员（或拥有解决该争议类似权限的指定人），高级管理人员将善意地尝试解决该争议。如果高级管理人员无法在该争议提交后的三十（30）天内解决该争议，任何一方将自由启动第15.5(b)款规定的仲裁程序解决该争议。

(b) Any unresolved Disputes between the Parties, whether arising before or after termination of this Agreement, will be resolved by final and binding arbitration. Whenever a Party decides to institute arbitration proceedings, it will give written notice to that effect to the other Party. Arbitration will be held by the International Chamber of Commerce ("ICC") in accordance with

the ICC Rules in force when the notice of arbitration is submitted, as may be amended by this Article 15. The seat of arbitration shall be Singapore. The arbitration will be conducted by a panel of three (3) arbitrators appointed in accordance with ICC Rules; *provided that* each Party will, within fifteen (15) days after the institution of the arbitration proceedings, appoint an arbitrator, and such arbitrators will together, within thirty (30) days, select a third arbitrator as the chair of the arbitration panel, and each arbitrator will have significant experience in the biopharmaceutical industry. If the two initial arbitrators are unable to select a third arbitrator with in such thirty (30) day period, the third arbitrator will be appointed in accordance with the ICC Rules. Decisions of the panel of arbitrators will be final and binding on the Parties.
双方之间未解决的任何争议，无论是在本协议终止之前还是之后产生，将通过具有约束力的终局仲裁解决。只要一方决定启动仲裁程序，该方将向另一方发出书面通知。仲裁将由国际商会（“国际商会”）根据提交仲裁通知时有效的国际商会规则（以及根据本第15条可能作出的修订）进行。仲裁地点应为新加坡。仲裁将由根据国际商会规则指定的三（3）名仲裁员组成的仲裁庭进行；但前提是，每一方将在仲裁程序启动后的十五（15）天内指定一名仲裁员，该等仲裁员将在三十（30）天内共同选择第三名仲裁员担任仲裁庭主席，且每名仲裁员将具有丰富的生物制药行业经验。如果最初的两名仲裁员无法在该三十（30）天期间内选择第三名仲裁员，第三名仲裁员将根据国际商会规则指定。仲裁庭的决定将是终局的并对双方具有约束力。

Notwithstanding Section 15.4 and Section 15.5(b) and without prejudice to the Parties' agreement to submit Disputes to arbitration, (a) either Party has the right to submit any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent Right Covering the manufacture, use, importation, offer for sale or sale of any Licensed Compound or Licensed Product or of any trademark rights relating to any Licensed Product to a court of competent jurisdiction in the country in which such Patent Right or trademark rights were granted or arose, and (b) either Party whose rights in Confidential Information have been infringed shall have the right to seek from a court of competent jurisdiction an injunction or other similar forms of relief necessary to protect its such rights to the extent permitted by applicable laws in the jurisdiction in question.
尽管有第15.4款和第15.5(b)款的规定，在不影响双方将争议提交仲裁的约定的情况下，(a)任何一方有权将与涵盖任何许可化合物或许可产品的生产、使用、进口、要约销售或销售的任何专利权或与任何许可产品相关的任何商标权的范围、有效性、可强制执行性或侵权相关的任何争议、纠纷或权利主张提交授予或产生该等专利权或商标权所在国家的有管辖权的法院，及(b)保密信息权利已被侵犯的任何一方有权在相关司法辖区的适用法律允许的范围内，向有管辖权的法院寻求保护该等权利需要的禁令或其他类似形式的救济。

15.6 **Force Majeure**. If either Party is prevented from performing its obligations under this Agreement as a result of any contingency beyond its reasonable control ("Force Majeure"), including any actions of governmental authorities or agencies, war, hostilities between nations, civil commotions, riots, sabotage, energy shortages, fire, floods and acts of nature such as typhoons, hurricanes, earthquakes, or tsunamis, the Party so affected will not be responsible to the other Party for any delay or failure of performance of its obligations hereunder, for so long as Force Majeure prevents such

performance. In the event of Force Majeure, the Party immediately affected thereby will give prompt written notice to the other Party specifying the Force Majeure event complained of, and will use diligent efforts to cure such failure or omission as soon as is practicable after the occurrence of the Force Majeure event. Notwithstanding the foregoing, if such Force Majeure induced delay or failure of performance continues for more than ninety (90) days, either Party may terminate this Agreement upon written notice to the other Party without penalty, liability, liquidated damages, termination fees or any other costs incurred as a result of the early termination of this Agreement.
不可抗力。 如果任何一方由于超出其合理控制的任何意外事件（“不可抗力”）而被阻止履行其在本协议项下的义务，包括政府机构或部门的任何行动、战争、国家之间的敌对行为、民变、暴动、蓄意破坏、能源短缺、火灾、水灾以及台风、飓风、地震或海啸等自然灾害，只要不可抗力阻止受影响的一方延迟履行或未履行其在本协议项下义务，则受影响的一方不会就该等延迟履行或未履行行为对另一方承担责任。如果发生不可抗力，立即受影响的一方将及时向另一方发出书面通知说明不可抗力事件，并将尽勤勉努力在不可抗力事件发生后尽快纠正该等未履行或不履行行为。尽管有上述规定，如果该不可抗力导致的延迟履行或未履行行为的持续期限超过九十（90）天，任何一方可以向另一方发出书面通知终止本协议，且无需承担任何违约金、赔偿责任、损害赔偿、终止费用或因本协议提前终止而产生的其他任何费用。

15.7 **Waivers and Amendments**. The failure of any Party to assert a right hereunder or to insist upon compliance with any particular term of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term by the other Party. No waiver will be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.
放弃和修订。 任何一方未主张本协议项下的权利或未坚持对本协议的任何特定条款的遵守不得构成对该权利的放弃或对另一方以后类似未履行任何该等条款的免责。任何放弃除非以书面形式作出并由放弃一方签署方可生效。本协议的任何规定不得进行修订或修改，但由每一方的授权代表签署书面文件的除外。

15.8 **Relationship of the Parties**. Nothing contained in this Agreement will be deemed to constitute a partnership, joint venture, or legal entity of any type between Licensor and Licensee, or to constitute one as the agent of the other. Moreover, each Party will not construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party will act solely as an independent contractor, and nothing in this Agreement will be construed to give any Party the power or authority to act for, bind, or commit the other.
双方的关系。 本协议的任何规定不得被视为构成许可方和被许可方之间的合伙、合资或任何类型的法律实体，也不得被视为构成一方作为另一方的代理人。此外，每一方不得为任何税务目的将本协议或本协议拟议的任何交易解释为合伙关系。每一方将仅作为独立的承包商行事，本协议的任何规定不得被解释为授予任何一方代表另一方行事、约束另一方或使另一方作出承诺的权力或权限。

15.9 **Non-Solicitation**. Each Party agrees that during the Licensing Term and for twelve (12) months thereafter, each Party will not, either directly or through others, solicit or encourage or attempt to solicit or encourage any employee or consultant of the other Party to terminate his or her relationship with such Party in order to become

an employee, consultant or independent contractor to or for any other person or entity.
不招揽。双方同意，在许可期限内及其后十二 (12) 个月内，一方不得直接或通过他人招揽或鼓励或试图招揽或鼓励另一方的任何雇员或顾问终止与该方的关系，以成为任何其他个人或实体的雇员、顾问或独立承包商。

15.10 **Notices**. All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when: (a) delivered by hand (with written confirmation of receipt); (b) received by the addressee, if sent by an internationally recognized overnight delivery service (receipt requested); or (c) immediately upon electronic delivery with receipt for confirmation of delivery, in each case to the appropriate addresses set forth below (or to such other addresses as a Party may designate by notice):
通知。 本协议项下的所有通知、同意、放弃及其他通讯必须以书面形式作出，(a)在专人递送（书面确认收到）时将被视为已正式送达；(b)如果通过国际认可的次日递送服务（索要收据）发送，在收件人收到时将被视为已正式送达；或(c)通过电子方式交付并取得送达回执确认后立即视为送达。在每种情况下，送达至下列适当地址（或一方通过通知可能指定的其他地址）：

If to Licensee:

致被许可方：

Amphastar Pharmaceuticals, Inc.

Address: 11570 Sixth Street
Rancho Cucamonga, CA 91730
U.S.A.
Attn: [***]
Email: [***]
With a copy to:
Legal Department
Email: [***]

Amphastar Pharmaceuticals, Inc.
地址：11570 Sixth Street
Rancho Cucamonga, CA 91730
U.S.A.
收件人：[***]
电子邮件： [***]
抄送：法律部
电子邮件：[***]

If to Licensor:

致许可方：

Nanjing Han Xin Pharmaceutical Technology Co., Ltd.
Address: [***]
Attn: [***]
Email: [***]

南京汉欣医药科技有限公司
地址：[***]
收件人：[***]
电子邮件： [***]

15.11 **Further Assurances**. Licensee and Licensor will execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary to carry out the intent and purposes of this Agreement.
进一步保证。 被许可方和许可方将签署、确认并交付实现本协议意图和目的合理需要的任何及所有其他文件，并采取实现本协议意图和目的合理需要的其他行动。

15.12 **Compliance with Law**. Each Party will perform its obligations under this Agreement in accordance with all Applicable Laws. No Party will, or will be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any Applicable Law, including but not limited to any and all applicable anti-bribery laws such as the United States Foreign Corrupt Practices Act and the Anti-Unfair Competition Law enacted and amended by the People's Republic of China. To the extent that registration or record-filing of this Agreement with a governmental authority is required under the Technology Import and Export Administrative Regulations of the People's Republic of China in respect of any of the licenses granted or envisaged hereunder, Licensor shall take necessary steps to register or record-file a redacted version of this Agreement or a summary thereof, using reasonable efforts to seek confidential treatment for the terms of this Agreement or all other Confidential Information, with the relevant governmental authority in consultation with Licensee.
遵守法律。 每一方将根据所有适用法律履行其在本协议项下的义务。任何一方不得且不得被要求从事本协议项下或与本协议相关的违反或（该方善意认为）可能违反任何适用法律的任何活动，包括但不限于任何及所有适用的反腐败法律，例如美国《反海外腐败法》及中华人民共和国颁布与修订的《反不正当竞争法》。如果《中华人民共和国技术进出口管理条例》就本协议项下授予或拟议的任何许可规定在政府机构对本协议进行登记或备案，许可方应采取必要措施，与被许可方协商后，在相关政府机构登记或备案本协议的编辑版本或摘要，尽合理努力寻求对本协议的条款或所有其他保密信息的保密处理。

15.13 **No Third Party Beneficiary Rights**. The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they will not be construed as conferring any rights to any Third Party (including any third party beneficiary rights).
无第三方受益权。 本协议的规定仅为双方及其承继方和获准受让方之利益，且不得被解释为授予任何第三方任何权利（包括任何第三方受益权）。

15.14 **Cumulative Remedies**. No remedy referred to in this Agreement is intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.
累积救济。 本协议中提及的任何救济均不具有排他性，但每项救济将为累积救济，并作为本协议中提及的或法律项下可另行获得的任何其他救济的补充。

15.15 **Expenses**. Except as otherwise expressly provided in this Agreement, each Party will pay the fees and expenses of its respective lawyers and other experts and all

other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution and delivery of this Agreement.
费用。除非本协议另有明确规定，每一方将支付各自的律师和其他专家的费用和支出，以及该方与本协议的谈判、准备、签署和交付相关发生的所有其他费用和支出。

15.16 **Entire Agreement**. This Agreement, together with its Exhibits and schedules, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter. In the event of any conflict between a substantive provision of this Agreement and any Exhibit or schedule hereto, the substantive provisions of this Agreement will prevail.
完整协议。本协议及其附件和附录构成双方就本协议主题事项达成的完整协议和谅解，并取代双方先前就该等主题事项达成的所有口头或书面建议书和所有其他通讯。如果本协议的实质性条款与本协议的任何附件或附录发生任何冲突，则以本协议的实质性条款为准。

15.17 **Counterparts**. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe Portable Document Format (.pdf) sent by electronic mail shall be deemed to be original signatures.
文本。本协议可签署两份或多份文本，每份文本将被视为原件，但所有文本将共同构成同一份文件。通过传真或以Adobe便携式文档格式（.pdf）通过电子邮件发送的签名应被视为亲笔签名。

15.18 **Language**. This Agreement is written in English and Chinese with both languages equally binding.
语言。本协议以英文和中文书就，且具有相同法律效力。

[SIGNATURE PAGE FOLLOWS]

[下接签字页]

THIS AGREEMENT IS EXECUTED by the authorised representatives of the Parties as of the date first written above.
本协议由双方的授权代表于文首所述日期签署。

Nanjing Han Xin Pharmaceutical Technology Co., Ltd. **南京汉欣医药科技有限公司**	**Amphastar Pharmaceuticals, Inc.** **Amphastar Pharmaceuticals, Inc.**
By/签署: /s/Bao Haitao	By/签署: /s/Jacob Liawatidewi
Name/姓名: Bao Haitao 鲍海涛	Name/姓名: Jacob Liawatidewi
Title/职位: General Manager 总经理	Title/职位: Executive Vice President

[Signature page to the License Agreement]

[许可协议签字页]

EXHIBIT A

附件**A**

LIST OF LICENSED PATENTS

许可专利清单

[***]

EXHIBIT B

附件B

LIST OF LICENSED KNOW-HOW

许可专有技术清单

[***]

EXHIBIT C

LIST OF LICENSOR MATERIALS

许可方材料清单

[***]

EXHIBIT D

附件**D**

LICENSED COMPOUND

许可化合物

[***]

Exhibit 10.36

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS ([***]), HAS BEEN OMITTED PURSUANT TO ITEM 601(B)(10)(IV) OF REGULATION S-K, BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) IS THE TYPE THAT THE COMPANY TREATS AS PRIVATE OR CONFIDENTIAL. IN ADDITION, CERTAIN SCHEDULES (OR SIMILAR ATTACHMENTS) HAVE BEEN OMITTED FROM THIS EXHIBIT PURSUANT TO ITEM 601(A)(5) OF REGULATION S-K.

Amendment No.: 3

AMENDMENT 3 TO CONTRACT MANUFACTURING AGREEMENT

委托生产协议第三次增补协议

This Third Amendment (the "**Third Amendment**") to that certain Contract Manufacturing Agreement by and between Amphastar Nanjing Pharmaceuticals, Inc. ("**ANP**") and Nanjing Han Xin Pharmaceutical Technology Co., Ltd. (the "**Customer**"), originally dated April 19, 2022 (the "**CMA**"), and subsequently amended by Supplement Agreement to Contract Manufacturing Agreement, dated August 22, 2024 (the "**First Amendment**") and Amendment 2 to Contract Manufacturing Agreement, dated May 13, 2025 (the "**Second Amendment**"), is hereby made as of January 5th, 2026 ("**Effective Date**"), by and between ANP and the Customer. For purposes of this Third Amendment, the CMA, First Amendment and Second Amendment shall collectively be referred to as "**Agreement**." Any capitalized terms not defined herein shall maintain the same meaning as prescribed to it in the Agreement.

本修订协议（"**第三次增补协议**"）系对由美药星（南京）制药有限公司（"**ANP**"）和南京汉欣医药科技有限公司（"**委托方**"）于2022年4月19日签订的委托生产协议（"**CMA**"）、于2024年8月22日签订的第一次增补协议（"**第一次增补协议**"）以及于2025年5月13日签订的第二次增补协议（"**第二次增补协议**"）的第三次增补修订，特此于2026年[1]月[5]日（"**生效日期**"）由ANP和委托方签署。为本第三次增补协议之目的，CMA、第一次增补协议及第二次增补协议合称"**原协议**"。本第三次增补协议中未定义的大写术语均保持原协议中规定的相同含义。

WHEREAS, ANP and the Customer have previously entered into the Agreement, pursuant to which the Parties mutually agree that ANP manufactures Product for the Customer, and the Customer purchases Product from ANP;

鉴于，ANP和委托方之前已签订原协议，根据原协议的约定，双方一致同意ANP为委托方生产产品，委托方从ANP采购产品；

WHEREAS, ANP and the Customer have determined it to be mutually beneficial to amend the Agreement subject to the terms set forth herein;

鉴于，ANP与委托方已确定根据本第三次增补协议的条款修订原协议符合双方共同利益；

NOW THEREFORE, in consideration of the mutual covenants set forth herein, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree to amend and/or supplement the Agreement as follows:

因此，鉴于双方已确认收到并认可的本第三次增补协议中所述的相互承诺，双方特此同意对原协议进行如下增补：

1. Amendment to Section 1.3(p) ("Territory"). The Parties mutually agree to amend the definition of "Territory" under Section 1.3(p) on page 6 of the CMA by deleting it in its entirety and replacing it with the following language:

   对第1.3(p)条（"区域"）的修订。双方一致同意修订CMA第6页第1.3(p)条中"区域"的定义，将其整体删除并替换为以下表述：

   "'Territory' means:

   "'区域'指：

   (i) global except for United States and Canada for [***] and [***];

   就[***]和[***]而言，除美国和加拿大之外的全球范围；

   (ii) global for active pharmaceutical ingredient of [***], and global for Finished Product of [***] but limited to tablet with dose [***] milligrams, [***] milligrams and [***] milligrams;

   就[***]的活性药物成分而言，全球范围；就[***]的成品而言，且仅限于[***]毫克、[***]毫克及 [***]毫克剂型的片剂，全球范围；

   (iii) the PRC for other Products. No other territory rights are granted or applicable to such other Products.

   就其他产品而言，中国。其他地区规定的权利不适用于该等其他产品。

   The Customer is specifically prohibited from making any use of the Product outside the designated Territory."

   委托方禁止在指定区域外使用产品。"

2. Amendment to Section 14(Intellectual Property Rights). The Parties mutually agree to amend Section 14 of the CMA by deleting it in its entirety and replacing it with the following language:

   对第14条（知识产权）的修订。双方一致同意修订CMA第14条，将其整体删除并替换为以下表述：

   "14.1 ANP will retain ownership of all ANP Confidential Information that may be shared with the Customer during the Term of this Agreement, including retention of any manufacturing and production process of any Product (and all know-how of such process). The ownership of the manufacturing and production process proposed and requested to ANP by the Customer according to the special requirements for the product in the process of entrusted manufacturing process shall belong to the Customer. ANP shall retain ownership of any intellectual property in ANP's possession prior to the effective date of this Agreement.

   "14.1 ANP将保留在执行本协议的过程中可能与委托方共享的所有ANP保密信息的所有权，包括保留任何产品的生产和制作流程（以及相应的专有技术）。委托方在委托生产过程中，根据产品特殊要求向ANP提出并要求的生产和制作流程的所有权由委托方享有。在本协议生效前ANP享有的任何知识产权的所有权的仍归ANP所有。

14.2 The Customer will retain ownership of all Confidential Information the Customer shares with ANP during the Term of this Agreement, including the exclusive right to retain the patent rights of the Product and all rights attached thereto, the process requirements and the process routes and technologies provided by the Customer. All materials, information and original documents based on the Products under this Agreement shall belong to the Customer and in the custody of ANP.

14.2 委托方将保留在执行本协议过程中与ANP共享的所有委托方保密信息的所有权，包括保留产品的专利权及其附加的全部权益、委托方提供的工艺要求和工艺路线和技术的专有权利。基于本协议下产品的所有资料、信息和原始文件归委托方所有，由ANP保管。

14.3 Background Intellectual Property: A Party shall retain all right, title and interest in and to any Intellectual Property owned or entitled to be used by such Party or its Affiliates prior to the date of this Agreement, or acquired independently of this Agreement, and used in connection with the Product under this Agreement ("**Background Intellectual Property**").

14.3 背景知识产权：对于一方或其关联公司在本协议签订之前已拥有或有权使用的、或是独立于本协议所获取的，并且被用于本协议下产品的任何知识产权（"**背景知识产权**"），该方应保留对其背景知识产权享有的所有权利、所有权和利益。

14.4 Ownership of Project R&D Results: The Customer shall own the technical results created or generated as a result of ANP's provision of Product technical services under this Agreement ("**Project R&D Results**"), including, but not limited to, the Product's 1) manufacturing process and Specifications; 2) indications; 3) formulation; 4) route of administration or dosage range; and 5) uses (including, but not limited to, therapeutic prophylactic use, diagnostic use or in vivo imaging, or veterinary use); and 6) assays, models and other methods used to test or determine biological or medicinal activity, pharmacokinetic properties, toxicology or safety.

14.4 项目研发成果的所有权：对于ANP提供本协议下的产品技术服务而创造的或者产生的技术成果（**"项目研发成果"**）归委托方所有，包括但不限于产品的1)生产工艺和质量标准；2)适应症；3)制剂；4)给药途径或剂量范围；5)用途（包括但不限于治疗预防用途、诊断用途或体内影像，或兽用）；以及6)化验、模型和其他用于测试或决定生物活性或药用活性的、药代动力学特性、毒理或安全性的方法。

14.5 The Customer shall be entitled to the ownership of the Project R&D Results and related rights, including but not limited to any copyrights, technical secrets, patents or other intellectual property rights. ANP shall be requested by the Customer to cooperate in signing relevant documents for the necessary administrative procedures such as registration and application, and ANP may provide the Customer with data related to the completed research content for the purpose of patent application. The Customer shall guarantee ANP's right of authorship of the relevant Project R&D Results, but ANP shall not have any economic rights to the Project R&D Results. If the Project R&D Results cannot be transferred to the Customer for any reason, ANP shall grant the Customer an exclusive, sub-licensable, free, perpetual, irrevocable, worldwide license to ensure that the right to use the aforementioned Project R&D Results is exclusively vested in the Customer, and ANP shall not use the Project R&D Results except for the purposes of this Agreement, and shall transfer the foregoing Project R&D Results to the Customer as soon as the impediment is removed.

14.5 委托方享有项目研发成果的所有权和相关权益，包括但不限于任何著作权、技术秘密、专利或其他知识产权。ANP应受委托方之要求配合签署相关文件用于办理必要之注册、申请等行政手续，如为专利申请目的ANP可向委托方提供已完成研究内容相关的数据。委托方应保证ANP对相关项目研发成果的署名权，但ANP对项目研发成果不享有任何经济权利。如因任何原因导致项目研发成果不能转移至委托方名下，则ANP应给予委托方独家的、可分许可的、免费的、永久的、不可撤销的、在全球范围内的许可，以确保除前述项目研发成果之使用权独家归属委托方，ANP除为实现本协议目的外，不得使用项目研发成果；一旦阻碍原因排除，ANP应当立即将前述项目研发成果转移至委托方名下。

14.6 ANP shall not publish abstracts, papers or make public the Project R&D Results related to this Agreement without the prior written permission of the Customer. If the Customer agrees in writing to publish abstracts, papers or to make public the Project R&D Results related to this Agreement, the Customer shall determine the authors and their authorship and the form, occasion, publication, etc., based on the substantial contribution.

14.6 在未取得委托方事先书面许可之前，ANP不得发表与本协议有关的摘要、论文或对外公开与本协议相关的项目研发成果。如委托方书面同意发表摘要、论文或对外公开与本协议相关的项目研发成果，委托方应根据实质贡献决定作者及其署名方式及发表形式、场合、刊物等。

14.7 Limited License: The Customer hereby grants ANP a license to use the Customer's Background Intellectual Property for the purpose of performing this Agreement and to develop, optimize or improve upon the Customer's Background Intellectual Property for the purposes of this Agreement. ANP shall refrain from embedding its Background Intellectual Property in the Project R&D Results; in the event of such a case, ANP hereby grants the Customer a limited license to use ANP's Background Intellectual Property for the purpose of using the Project R&D Results without compensation.

14.7 有限许可：委托方在此许可ANP为履行本协议之目的使用委托方的背景知识产权，并为本协议之目的开发、优化或改进委托方的背景知识产权。ANP应避免将其背景知识产权嵌入项目研发成果之中；如发生此类情况，则ANP在此有限许可委托方为使用项目研发成果之目的而无偿使用ANP的背景知识产权。

14.8 If the Customer decides to produce the Products on its own or by a third party, upon reasonable request of the Customer or the third party, ANP shall provide the Customer or its designated third party with all information and related supports for such manufacturing processes, including but not limited to transfer programs, documentation, technical support, materials and personnel cooperation, to assist the Customer or its designated third party in completing the technology transfer necessary for the use of qualified products as required by Application Law and quality agreements.

14.8 如果委托方决定自行或委托第三方生产产品，应委托方或第三方的合理要求，ANP应向委托方或其指定的第三方提供该等生产工艺的所有信息和相关支持，包括但不限于转移方案、文件、技术支持，物料和人员合作，以协助委托方或其指定的第三方完成符合适用法律项下及质量协议要求的为使用合格产品所必须的技术转移。

14.9 Upon termination of this Agreement for any reason, ANP shall not use the Customer's Background Intellectual Property and Confidential Information without permission, and shall not redevelop, optimize or improve the Customer's Background Intellectual Property, Project R&D Results and other technical information attributable to the

Customer without permission. Upon termination of this Agreement for any reason, the Customer shall not use ANP's Background Intellectual Property and Confidential Information without permission, and shall not redevelop, optimize or improve ANP's Background Intellectual Property and other technical information attributable to ANP without permission."

14.9 本协议因任何原因终止后，ANP未经许可不得使用委托方的背景知识产权及保密信息，未经许可不得对委托方的背景知识产权、项目研发成果及归属于委托方的其他技术信息进行再次开发、优化或改进。本协议因任何原因终止后，委托方未经许可不得使用ANP的背景知识产权及保密信息，未经许可不得对ANP的背景知识产权及归属于ANP的其他技术信息进行再次开发、优化或改进。"

3. Amendment to Section 16.1. The Parties mutually agree to amend Section 16.1 of the CMA by deleting it in its entirety and replacing it with the following language:

对第16.1条的修订。双方一致同意修订CMA第16.1条，将其整体删除并替换为以下表述：

"16.1 Unless arising from the willful misconduct of ANP, the Customer will defend, indemnify and hold ANP and its Affiliates and each of their respective owners, officers, directors, employees, delegates, servants and agents (collectively, the "**ANP Indemnitees**") harmless against any liability, judgment, demand, action, suit, loss, damage, cost or other expense (including reasonable attorneys' fees and other costs of defense) resulting from: (i) any third party claims made or proceedings brought against ANP or any other ANP Indemnitees, including, without limitation, claims of intellectual property infringement, relating to a Product set forth herein; (ii) the Customer's material breach of this Agreement; and (iii) the Customer's breach of any term, condition, representation, or warranty made under this Agreement."

"16.1 除非因ANP故意不当行为引起，当(i) 任何第三方对ANP或其他ANP被赔偿方提出的与本协议项下产品有关的主张或诉讼，包括但不限于知识产权侵权相关的主张或诉讼；(ii) 委托方实质性违反本协议；或(iii) 委托方违反其在本协议项下的任何条款、条件、陈述或保证时，委托方应为ANP及ANP关联方、ANP及其关联方的所有人、管理人员、董事、雇员、代表、服务人员、代理商（合称"**ANP被赔偿方**"）提供抗辩及赔偿，以使得ANP被赔偿方免受任何责任、判决、要求、行为、诉讼、损失、损害或费用支出（包括合理的律师费及其他辩护费用）。"

4. Amendment to Section 28 (Limitation of Liability). The Parties mutually agree to amend Section 28 of the CMA by deleting it in its entirety and replacing it with the following language:

对第28条（责任限制）的修订。双方一致同意修订CMA第28条，将其整体删除并替换为以下表述：

"28.1 In no event, however, to the extent permitted by the Applicable Law, shall ANP be liable to the Customer or to any third party, under this Agreement, in contract, tort (including negligence), or other-wise howsoever, and whatever the cause thereof, for lost profits, goodwill, the cost of procurement of substitute goods or for any consequential or indirect damages. This limitation shall apply even where ANP has been

advised of the possibility of such damage and notwithstanding the failure of the essential purpose of any limited remedy stated herein.

"28.1 在适用法律允许的范围内，ANP对于委托方或任何第三方就利润损失、商誉、替代商品的采购成本或任何后续或间接损害均不承担赔偿责任，不论是基于合同、侵权（包括过失）或其他方式，且不论是何种原因造成。即使ANP已被告知该等损害的可能性，且本协议规定的任何有限救济的基本目的未能实现，该等限制仍应适用。

28.2 To the extent permitted by Applicable Law and subject to the provisions of Section 28.1 of this Agreement, ANP's total liability under this Agreement shall be limited to an amount of a half million US Dollars (US$500,000.00) in the aggregate, excluding insurance coverage, provided, however that ANP is only liable to the Customer, if the Customer has materially complied with and fulfilled all of its relevant terms, conditions, representations, warranties and obligations under this Agreement at the time of ANP's breach of this Agreement."

28.2 在适用法律允许的范围内，且受限于本协议第28.1条之约定，ANP在本协议项下的合计责任金额应以500,000美元为限（不包括保险赔付的金额），但ANP仅在其违约行为发生时委托方已经实质遵守和履行其在本协议项下全部相关条款、条件、陈述、保证和义务的情况下，对委托方承担违约责任。"

5. Governing Law and Dispute Resolution. Section 21 (Governing Law and Dispute Resolution) of the CMA shall, *mutatis mutandis*, apply to this Third Amendment.

   管辖法律及争议解决。CMA第21条（管辖法律及争议解决）应经必要调整后适用于本第三次增补协议。

6. Effectiveness. This Third Amendment will take effect as of the Effective Date by and between the Parties.

   效力。本第三次增补协议自生效日期起对双方产生效力。

7. Entire Agreement. This Third Amendment, together with the Agreement, constitutes the entire agreement of the Parties hereto with respect to the subject matter of the Agreement and supersedes all prior agreements, understanding, promises and representations, whether written or oral, with respect to the subject matter thereof.

   完整协议。本第三次增补协议连同原协议构成双方之间关于原协议主题事项达成的完整协议，并取代双方此前就该主题事项达成的所有书面或口头的协议、理解、承诺及陈述。

8. No Further Modification. Except as expressly and specifically amended hereby, all other provisions, terms and conditions of the Agreement shall remain unchanged, and in full force and effect.

   无其他修订。除本第三次增补协议明确且具体修订的内容外，原协议中所有其他条款和条件均保持不变，并继续完全有效。

9. Counterparts. This Third Amendment may be executed by facsimile (including a PDF image delivered via e-mail) or electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures. This Third Amendment may be executed in counterparts, each of which shall be deemed to be an original, and which together will constitute one original.

   副本。本第三次增补协议可通过传真（包括通过电子邮件发送的PDF图像）或电子传输签名的方式签署，此类签名应被视为与原始签名一样对各方具有约束力。本第三次增补协议可签署成若干副本，每份副本均应视为正本，且所有副本共同构成一份正本。

[Signature Page Follows]

[以下为签署页]

IN WITNESS WHEREOF, each of ANP and the Customer has caused this Third Amendment to be executed by their duly authorized officers.

特此证明，ANP和委托方各自已由其正式授权的人员签署本第三次增补协议。

Amphastar Nanjing Pharmaceuticals, Inc.	**Nanjing Haxin Pharmaceutical Technology Co., Ltd.**
美药星（南京）制药有限公司	南京汉欣医药科技有限公司
By/签署: /s/Qiu Yinhua	By/签署: /s/Bao Haitao
Name/姓名: Qiu Yinhua邱银华	Name/姓名: Bao Haitao鲍海涛
Title/职位: General Manager总经理	Title/职位: General Manager总经理
Date/日期: 2026-01-06	Date/日期: 2026-01-06

Exhibit 10.37

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS ([***]), HAS BEEN OMITTED PURSUANT TO ITEM 601(B)(10)(IV) OF REGULATION S-K, BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) IS THE TYPE THAT THE COMPANY TREATS AS PRIVATE OR CONFIDENTIAL. IN ADDITION, CERTAIN SCHEDULES (OR SIMILAR ATTACHMENTS) HAVE BEEN OMITTED FROM THIS EXHIBIT PURSUANT TO ITEM 601(A)(5) OF REGULATION S-K.

Amendment No.: 1

AMENDMENT 1 TO DISTRIBUTION AGREEMENT
经销协议第一次增补协议

This Amendment 1 to Distribution Agreement (this "**First Amendment**") is effective as of the last signature date below (the "**Execution Date**") by and between **Armstrong Pharmaceuticals, Inc.**, a company incorporated under the laws of the State of Delaware, with its principal place of business located at 25 John Road, Canton, Massachusetts ("**ARMSTRONG**"), and **Hong Kong Genreach Limited**, a company incorporated under the laws of Hong Kong, with its registered place located at RM 1007B,10/F.,HO KING COMMERCIAL CTR.,NO.2-16 FA YUEN STREET, MONGKOK HONG KONG, China ("**GENREACH**" or "**Distributor**") (each of ARMSTRONG and GENREACH is referred to as a "**Party**" and collectively as the "**Parties**").
本经销协议第一次增补协议（下称"**本第一次增补协议**"）由 **Armstrong Pharmaceuticals, Inc.**（一家根据特拉华州法律注册成立的公司，其主要营业地址位于马萨诸塞州坎顿市约翰路25号，下称"**ARMSTRONG**"）与**香港金瑞驰有限公司**（一家根据香港法律注册成立的公司，其注册地址位于中国香港九龙旺角花园街2- 16号好景商业中心10楼1007B室，下称"**GENREACH**"或"**经销商**"）共同订立，自文末双方孰晚的签署日期（下称"**签署日期**"）起生效（ARMSTRONG与GENREACH下文各称"**一方**"，合称"**双方**"）。

WHEREAS, the Parties entered into that certain Distribution Agreement dated August 28, 2024 (the "**Agreement**"), pursuant to which ARMSTRONG appointed the Distributor as its exclusive distributor to market and sell Product P within the Collaboration Region pursuant to the terms and conditions thereof;
鉴于，双方曾于2024年8月28日签订一份《经销协议》（下称"**原协议**"），根据原协议，ARMSTRONG指定经销商作为其在合作区域内依照协议条款与条件营销和销售产品P的独家经销商；

Whereas, the Parties have determined it to be mutually beneficial to amend the Agreement subject to the terms set forth herein.
鉴于，双方已确定根据本第一次增补协议的条款修订原协议符合双方共同利益。

NOW, THEREFORE, in consideration of the mutual covenants set forth herein, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree to amend and/or supplement the Agreement as follows:
因此，鉴于双方已确认收到并认可的本第一次增补协议中所述的相互承诺，双方特此同意对原协议进行如下增补：

1. Amendment to Section 1.3. The Parties mutually agree to amend Section 1.3 of the Agreement by deleting it in its entirety and replacing it with the following:
对第1.3条的修订。双方一致同意修订原协议第1.3条，将其整体删除并替换为以下内容：

Collaboration Region means Mainland China, Taiwan, Hong Kong, and Macau in the Greater China region, the Middle East countries, Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam.

合作区域指大中华地区的中国大陆、台湾、香港及澳门，以及中东国家、文莱、柬埔寨、印度尼西亚、老挝、马来西亚、缅甸、菲律宾、新加坡、泰国和越南。

2. Amendment to Section 4.1. The Parties mutually agree to amend Section 4.1 by inserting a new section 4.1.3 Step Three after the existing "4.1.2 Step Two" and before the original paragraph "The Distributor shall have exclusive general distribution rights...". The newly inserted Section 4.1.3 shall read as follows:
对第4.1条的修订。双方一致同意修订原协议第4.1条，在现有的"4.1.2 第二步"之后、原"在获得所有必要的监管批准后，经销商在合作区域内拥有产品P的独家总经销权。"段落之前，插入新的第4.1.3条"第三步"。新插入的第4.1.3条内容如下：

"Step Three. The Distributor or its designated Affiliate shall file the drug registration application of Product P as an imported drug with NMPA in Mainland China in the name of GENREACH or its designated Affiliate (to the extent in compliance with applicable laws), and shall be responsible for other import-relevant procedures, including but not limited undergoing recordation of importing medicinal product with competent medicinal product regulatory department. The drug registration certificate of Product P and relevant permits, files and materials in Mainland China shall be solely owned by GENREACH or its designated Affiliate (if mandatorily required by applicable laws, ARMSTRONG will be the Marketing Authorization Holder of Product P, GENREACH or its designated Affiliate will be the designated pharmaceutical domestic agent in Mainland China, and fulfil the obligations on behalf of the Marketing Authorization Holder of Product P and is jointly and severally liable with the Marketing Authorization Holder in accordance with applicable laws), and the Distributor shall have exclusive distribution rights of Product P within the Collaboration Region after the achievement of all necessary Regulatory Approval."

"第三步。经销商或其指定关联方应（在符合适用法律的前提下）以GENREACH或其指定关联方的名义，作为进口药品向中国大陆国家药品监督管理局（NMPA）提交产品P的药品注册申请，并应负责办理其他进口相关程序，包括但不限于在主管药品监管部门办理进口药品备案。产品P在中国大陆的药品注册证及相关许可、文件和资料应由GENREACH或其指定关联方单独所有（若根据适用法律强制要求，ARMSTRONG将作为产品P的药品上市许可持有人，而GENREACH或其指定关联方将作为指定的中国境内代理人，并代表产品P的药品上市许可持有人履行义务，且根据适用法律与药品上市许可持有人承担连带责任），并且，在取得所有必要的监管批准后，经销商应在合作区域内拥有产品P的独家总经销权。"

3. Amendment to Section 5.2. The Parties mutually agree to amend the definition of "Minimum Purchase Amount" defined in Section 5.2 of the Agreement by deleting the phrase "one (1) batch (approximately [***] units) per Contract Year" and replacing it with "[***] units per Contract Year", and add the following sentence: "Each purchase order submitted by Distributor for the purchase of Product P shall, at all times during the Term, be no less than the Minimum Purchase Amount". All other provisions of Section 5.2 shall remain unchanged.
对第5.2条的修订。双方一致同意修订原协议第5.2条中"最低购买量"的定义，删除"每一合同年购买量应不少于一（1）个生产批次（大约[***]支）"的表述，并替换为"每一合同年购买量应不少于[***]支"，同时增加以下句子："在本协议有效期内，经销商提交的每一份采购产品P的采购订单，其数量在任何时候均不得低于最低购买量"。第5.2条的所有其他规定应保持不变。

4. Amendment to Section 13.1. Notices for Armstrong is amended by *including* the following contact information:
对第13.1条的修订。针对ARMSTRONG的通知方式修订如下，*增加*以下联系信息：

ARMSTRONG: Legal Department
ARMSTRONG：法务部
Address: 11570 6th Street, Rancho Cucamonga, CA 91730
地址：加利福尼亚州兰乔库卡蒙加市第六街11570号，邮编91730
Email: [***]
邮箱：[***]

All other contact information for Armstrong remains the same.
Armstrong的所有其他联系信息保持不变。

5. Governing Law and Dispute Resolution. Section 14 (Governing Law and Dispute Resolution) of the Agreement shall, *mutatis mutandis*, apply to this First Amendment.
管辖法律和争议解决。原协议第14条（管辖法律和争议解决）应经必要调整后适用于本第一次增补协议。

6. Effectiveness. This First Amendment will take effect as of the Execution Date by and between the Parties.
生效。本第一次增补协议自双方签署之日起生效。

7. Entire Agreement. This First Amendment, together with the Agreement, constitutes the entire agreement of the Parties hereto with respect to the subject matter of the Agreement and supersedes all prior agreements, understanding, promises and representations, whether written or oral, with respect to the subject matter thereof.
完整协议。本第一次增补协议连同原协议构成双方之间关于原协议主题事项达成的完整协议，并取代双方此前就该主题事项达成的所有书面或口头的协议、理解、承诺及陈述。

8. No Further Modification. Except as expressly and specifically amended hereby, all other provisions, terms and conditions of the Agreement shall remain unchanged, and in full force and effect.
无进一步修改。除本文件明确且具体修订的内容外，原协议中所有其他条款和条件均保持不变，并继续完全有效。

9. Counterparts. This First Amendment may be executed by facsimile (including a PDF image delivered via e-mail) or electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures. This First Amendment may be executed in counterparts, each of which shall be deemed to be an original, and which together will constitute one original.
副本。本第一次增补协议可通过传真（包括通过电子邮件发送的PDF图像）或电子传输签名的方式签署，此类签名应被视为与原始签名一样对各方具有约束力。本第一次增补协议可签署成若干副本，每份副本均应视为正本，且所有副本共同构成一份正本。

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IN WITNESS WHEREOF, each of ARMSTRONG and GENREACH has caused this First Amendment to be executed by their duly authorized officers.
兹此为证， ARMSTRONG和GENREACH双方已促使其正式授权代表签署本第一次增补协议。

Armstrong Pharmaceuticals, Inc.		**HongKong Genreach Limited** (香港金瑞驰有限公司）(seal)	
By/签署:	/s/Tony Marrs	By/签署:	/s/Yang Xuefeng
Name/姓名:	Tony Marrs	Name/姓名:	Yang Xuefeng
Title/职位:	President	Title/职位:	General Manager
Date/日期:	2026-01-06	Date/日期:	2026-01-06

Exhibit 19.1

AMPHASTAR PHARMACEUTICALS, INC.

INSIDER TRADING POLICY

(Adopted on June 2, 2025)

A. POLICY OVERVIEW

Amphastar Pharmaceuticals, Inc. (together with any subsidiaries, collectively the "**Company**") has adopted this Insider Trading Policy (the "**Policy**") to help you comply with the federal and state securities laws and regulations that govern trading in securities and to help the Company minimize its own legal and reputational risk.

It is your responsibility to understand and follow this Policy. Insider trading is illegal and a violation of this Policy. In addition to your own liability for insider trading, the Company, as well as individual directors, officers and other supervisory personnel, could face liability. Even the appearance of insider trading can lead to government investigations or lawsuits that are time-consuming, expensive and can lead to criminal and civil liability, including damages and fines, imprisonment and bars on serving as an officer or director of a public company, not to mention irreparable damage to both your and the Company's reputation.

For purposes of this Policy, the Company's Chief Financial Officer, General Counsel, and EVP Corporate Administration Center collectively referred to as the "**Insider Trading Compliance Officers**" with each serving as the "**Compliance Officer**" for purposes of this Policy. The Compliance Officer may designate others, from time to time, to assist with the execution of his or her duties under this Policy.

B. POLICY STATEMENT

1. No Trading on Material Nonpublic Information. It is illegal for anyone to trade in securities on the basis of material nonpublic information. If you are in possession of material nonpublic information about the Company, you are prohibited from:

   a. using it to transact in securities of the Company;

   b. disclosing it to other directors, officers, employees, consultants, contractors, or advisors whose roles do not require them to have the information;

   c. disclosing it to anyone outside of the Company, including family, friends, business associates, investors or consulting firms, without prior written authorization from the Compliance Officer; or

   d. using it to express an opinion or make a recommendation about trading in the Company's securities.

In addition, if you learn of material nonpublic information through your service with the Company that could be expected to affect the trading price of the securities of another company, you cannot (x) use that information to trade, directly or indirectly through others, or (y) provide that information to another person in order to trade, in the securities of that other company. Any such action will be deemed a violation of this Policy.

2. No Disclosure of Confidential Information. You may not at any time disclose material nonpublic information about the Company or about another company that you obtained in connection with your service with the Company to friends, family members or any other person or entity that the Company has not authorized to know such information. In addition, you must handle the confidential information of others in accordance with any related non-disclosure agreements and other obligations that the Company has with them and limit your use of the confidential information to the purpose for which it was disclosed.

If you receive an inquiry for information from someone outside of the Company, such as a stock analyst, or a request for sensitive information outside the ordinary course of business from someone outside of the Company, such as a business partner, vendor, supplier or salesperson, then you should refer the inquiry to the Chief Financial Officer. Responding to a request yourself may violate this Policy and, in some circumstances, the law. Please consult the Company's External Communications Policy for more details.

3. Definition of Material Nonpublic Information. "**Material information**" means information that a reasonable investor would be substantially likely to consider important in deciding whether to buy, hold or sell securities or would view as significantly altering the total mix of information available in the marketplace about the issuer of the securities. In general, any information that could reasonably be expected to affect the market price of a security is likely to be material. Either positive or negative information may be material.

It is not possible to define all categories of "material" information. However, some examples of information that could be regarded as material include, but are not limited to:

a. financial results, key metrics, financial condition, earnings pre-announcements, guidance, projections or forecasts, particularly if inconsistent with the Company's guidance or the expectations of the investment community;

b. restatements of financial results, or material impairments, write-offs or restructurings;

c. changes in independent auditors, or notification that the Company may no longer rely on an audit report;

d. business plans or budgets;

e. creation of significant financial obligations, or any significant default under or acceleration of any financial obligation;

f. impending bankruptcy or financial liquidity problems;

g. significant developments involving business relationships, including execution, modification or termination of significant agreements or orders with customers, suppliers, distributors, manufacturers or other business partners;

h. significant information relating to the operation of product or service, such as new products or services, major modifications or performance issues, defects or recalls, significant pricing changes or other announcements of a significant nature;

i. significant developments in research and development, relating to the Company's clinical studies, including, without limitation, status, results and communications with regulatory agencies, or relating to intellectual property;

j. significant legal or regulatory developments, whether positive or negative, actual or threatened, including litigation or resolving litigation;

k. major events involving the Company's securities, including calls of securities for redemption, adoption of stock repurchase programs, option repricings, stock splits, changes in dividend policies, public or private securities offerings, modification to the rights of security holders or notice of delisting;

l. significant corporate events, such as a pending or proposed merger, joint venture or tender offer, a significant investment, the acquisition or disposition of a significant business or asset or a change in control of the Company;

m. major personnel changes, such as changes in senior management or employee lay-offs;

n. data breaches or other cybersecurity events;

o. updates regarding any prior material disclosure that has materially changed; and

p. the existence of a special blackout period.

"**Material nonpublic information**" means material information that is not generally known or made available to the public. Even if information is widely known throughout the Company, it may still be nonpublic. Generally, in order for information to be considered public, it must be made generally available through media outlets or SEC filings.

After the release of information, a reasonable period of time must elapse in order to provide the public an opportunity to absorb and evaluate the information provided. As a general rule, at least two full trading days must pass after the dissemination of information before such information is considered public.

As a rule of thumb, if you think something might be material nonpublic information, it probably is. You can always reach out to the Compliance Officer if you have questions.

C. PERSONS COVERED BY THIS POLICY

This Policy applies to you if you are a director, officer, employee, consultant, contractor or advisor of the Company, both inside and outside of the United States. To the extent applicable to you, this Policy also covers your immediate family members, persons with whom you share a household, persons who are your economic dependents and any entity whose transactions in securities you influence, direct or control. You are responsible for making sure that these other individuals and entities comply with this Policy.

This Policy continues to apply even if you leave the Company or are otherwise no longer affiliated with or providing services to the Company, for as long as you remain in possession of material nonpublic information. In addition, if you are subject to a trading blackout under this Policy at the time you leave the Company, you must abide by the applicable trading restrictions until at least the end of the relevant blackout period.

D. TRADING COVERED BY THIS POLICY

Except as discussed in Section H (*Exceptions to Trading Restrictions*), this Policy applies to all transactions involving the Company's securities or other companies' securities for which you possess

material nonpublic information obtained in connection with your service with the Company. This Policy therefore applies to:

1. any purchase, sale, loan or other transfer or disposition of any equity securities (including common stock, options, restricted stock units, warrants and preferred stock) and debt securities (including debentures, bonds and notes) of the Company and such other companies, whether direct or indirect (including transactions made on your behalf by money managers), and any offer to engage in the foregoing transactions;

2. any disposition in the form of a gift of any securities of the Company;

3. any distribution to holders of interests in an entity if the entity is subject to this Policy; and

4. any other arrangement that generates gains or losses from or based on changes in the prices of such securities including derivative securities (for example, exchange-traded put or call options, swaps, caps and collars), hedging and pledging transactions, short sales and certain arrangements regarding participation in benefit plans, and any offer to engage in the foregoing transactions.

There are no exceptions from insider trading laws or this Policy based on the size of the transaction or the type of consideration received.

E. TRADING RESTRICTIONS

Subject to the exceptions set forth below, this Policy restricts trading during certain periods and by certain people as follows:

1. Quarterly Blackout Periods. Except as discussed in Section H (*Exceptions to Trading Restrictions*), all directors and officers of the Company, and those employees identified by the Company, must refrain from conducting transactions involving the Company's securities during quarterly blackout periods. Individuals subject to quarterly blackout periods will be informed by the Compliance Officer that they are listed on the covered persons list maintained by the Compliance Officer (the "**Covered Persons List**"). To the extent applicable to you, quarterly blackout periods also cover your immediate family members, persons with whom you share a household, persons who are your economic dependents, and any entity whose transactions in securities you influence, direct or control. Even if you are not specifically identified as being subject to quarterly blackout periods, you should exercise caution when engaging in transactions during quarterly blackout periods because of the heightened risk of insider trading exposure.

Quarterly blackout periods will begin at the end of the last trading day two (2) calendar weeks prior to the last business day of the quarter and continue up through and including two (2) full trading days following the date of public disclosure of the financial results for that fiscal quarter (i.e., the blackout period ends and is over at the start of the third full trading day following the date of public disclosure of the financial results for that fiscal quarter).

The prohibition against trading during the blackout period also means that brokers cannot fulfill open orders on your behalf or on behalf of your immediate family members, persons with whom you share a household, persons who are your economic dependents, or any entity whose transactions in securities you influence, direct or control, during the blackout period, including "limit orders" to buy or sell stock at a specific price or better and "stop orders" to buy or sell stock once the price of the stock reaches a specified price. If you are subject to blackout periods or pre-clearance requirements, you should so inform any broker with whom such an open order is placed at the time it is placed.

From time to time, the Company may identify other persons who should be subject to quarterly blackout periods, and the Compliance Officer may update and revise the Covered Persons List as appropriate.

2. Special Blackout Periods. The Company always retains the right to impose additional or longer trading blackout periods at any time on any or all of its directors, officers, employees, consultants, contractors and advisors. The Compliance Officer will notify you if you are subject to a special blackout period by providing to you a notice in writing or via email. If you are notified that you are subject to a special blackout period, you may not engage in any transaction involving the Company's securities until the special blackout period has ended other than the transactions that are covered by the exceptions below. You also may not disclose to anyone else that the Company has imposed a special blackout period. To the extent applicable to you, special blackout periods also cover your immediate family members, persons with whom you share a household, persons who are your economic dependents, and any entity whose transactions in securities you influence, direct or control.

3. Regulation BTR Blackouts. Directors and officers may also be subject to trading blackouts pursuant to Regulation Blackout Trading Restriction, or Regulation BTR, under U.S. federal securities laws. In general, Regulation BTR prohibits any director or officer from engaging in certain transactions involving Company securities during periods when 401(k) plan participants are prevented from purchasing, selling or otherwise acquiring or transferring an interest in certain securities held in individual account plans. Any profits realized from a transaction that violates Regulation BTR are recoverable by the Company, regardless of the intentions of the director or officer effecting the transaction. In addition, individuals who engage in such transactions are subject to sanction by the SEC as well as potential criminal liability. The Company will notify directors and officers if they are subject to a blackout trading restriction under Regulation BTR. Failure to comply with an applicable trading blackout in accordance with Regulation BTR is a violation of law and this Policy.

F. PROHIBITED TRANSACTIONS

You may not engage in any of the following types of transactions other than as noted below, regardless of whether you have material nonpublic information or not.

1. Short Sales. You may not engage in short sales (meaning the sale of a security that must be borrowed to make delivery) or "sell short against the box" (meaning the sale of a security with a delayed delivery) if such sales involve the Company's securities.

2. Derivative Securities and Hedging Transactions. You may not, directly or indirectly, (a) trade in publicly-traded options, such as puts and calls, and other derivative securities with respect to the Company's securities (other than stock options, restricted stock units and other compensatory awards issued to you by the Company) or (b) purchase financial instruments (including prepaid variable forward contracts, equity swaps, collars and exchange funds), or otherwise engage in transactions, that hedge or offset, or are designed to hedge or offset, any decrease in the market value of Company equity securities either (i) granted to you by the Company as part of your compensation or (ii) held, directly or indirectly, by you.

3. Pledging Transactions. Executive officers and directors of the Company will not enter into any transaction whereby the executive officer or director, directly or indirectly, pledges, hypothecates, or otherwise encumbers more than 40% of shares held by such individual of the Company's common stock or more than 10% of the total Company's outstanding shares, whichever is lower, as collateral for indebtedness. This restriction extends to any hedging or similar transaction designed to decrease the risks associated with holding Company securities. This restriction includes, but is not limited to, holding such shares in a margin account or any other account that could cause the Company's common stock to be subject

to a margin call or otherwise be available as collateral for a margin loan. This restriction applies to the Company's common stock that (i) an executive officer or director owns directly or indirectly, or (ii) are granted by the Company as part of an executive officer or director's compensation.

Stock options, stock appreciation rights and other securities issued pursuant to Company benefit plans or other compensatory arrangements with the Company are not subject to this prohibition.

4. Margin Accounts. In accordance with Section F.3 above, you may not hold the Company's common stock in margin accounts.

G. PRE-CLEARANCE OF TRADES

The Company's directors and officers and any other persons identified on the Covered Persons List of this Policy as being subject to pre-clearance requirements must obtain pre-clearance prior to trading the Company's securities. If you are subject to pre-clearance requirements, you should submit a pre-clearance request to the Compliance Officer prior to your desired trade date. The pre-clearance request must be made on the form provided by the Compliance Officer. The person requesting pre-clearance will be asked to certify that he or she is not in possession of material nonpublic information about the Company. The Compliance Officer is under no obligation to approve a transaction submitted for pre-clearance and may determine not to permit the transaction.

If the Compliance Officer is the requester, then another Compliance Officer, or their delegate, must pre-clear or deny any trade. All trades must be executed within two business days of any pre-clearance.

Even after preclearance, a person may not trade the Company's securities if they become subject to a blackout period or aware of material nonpublic information prior to the trade being executed.

From time to time, the Company may identify other persons who should be subject to the pre-clearance requirements set forth above, and the Compliance Officer may update and revise the Covered Persons List as appropriate.

H. EXCEPTIONS TO TRADING RESTRICTIONS

There are no unconditional "safe harbors" for trades made at particular times, and all persons subject to this Policy should exercise good judgment at all times. Even when a quarterly blackout period is not in effect, you may be prohibited from engaging in transactions involving the Company's securities because you possess material nonpublic information, are subject to a special blackout period or are otherwise restricted under this Policy.

Other than the limited exceptions set forth below, any other exceptions to this Policy must be approved by the Compliance Officer, in consultation with the Company's board of directors of the Company (the "**Board**") or an independent committee of the Board.

The following are certain limited exceptions to the quarterly and special blackout period restrictions and pre-clearance requirements imposed by the Company under this Policy:

1. stock option exercises where the purchase price of such stock options is paid in cash and there is no other associated market activity;

2. purchases pursuant to the employee stock purchase plan; however, this exception does not apply to subsequent sales of the shares;

3. receipt and vesting of stock options, restricted stock units, restricted stock or other equity compensation awards from the Company;

4. net share withholding with respect to equity awards where shares are withheld by the Company in order to satisfy tax withholding requirements, (*x*) as required by either the Board (or a committee thereof) or the award agreement governing such equity award or (*y*) as you elect, if permitted by the Company, so long as the election is irrevocable and made in writing at a time when a trading blackout is not in place and you are not in possession of material nonpublic information;

5. sell to cover transactions where shares are sold on your behalf upon vesting of equity awards and sold in order to satisfy tax withholding requirements, (*x*) as required by either the Board (or a committee thereof) or the award agreement governing such equity award or (*y*) as you elect, if permitted by the Company, so long as the election is irrevocable and made in writing at a time when a trading blackout is not in place and you are not in possession of material nonpublic information; however, this exception does not apply to any other market sale for the purposes of paying required withholding; upon vesting of equity awards and sold in order to satisfy tax withholding requirements; however, this exception does not apply to any other market sale for the purposes of paying required withholding;

6. transactions made pursuant to a valid 10b5-1 trading plan approved by the Company (see Section I (*10b5-1 Trading Plans*) below);

7. purchases of the Company's stock in the 401(k) plan resulting from periodic contributions to the plan based on your payroll contribution election; *provided, however,* that the blackout period restrictions and pre-clearance requirements do apply to elections you make under the 401(k) plan to (a) increase or decrease the amount of your contributions under the 401(k) plan if such increase or decrease will increase or decrease the amount of your contributions that will be allocated to a Company stock fund, (b) increase or decrease the percentage of your contributions that will be allocated to a Company stock fund, (c) move balances into or out of a Company stock fund, (d) borrow money against your 401(k) plan account if the loan will result in liquidation of some or all of your Company stock fund balance and (e) prepay a plan loan if the pre-payment will result in the allocation of loan proceeds to a Company stock fund;

8. transfers by will or the laws of descent or distribution and, provided that prior written notice is provided to the Compliance Officer, distributions or transfers (such as certain tax planning or estate planning transfers) that effect only a change in the form of beneficial interest without changing your pecuniary interest in the Company's securities; and

9. changes in the number of the Company's securities you hold due to a stock split or a stock dividend that applies equally to all securities of a class, or similar transactions.

If there is a Regulation BTR blackout (and no quarterly or special blackout period), then the limited exceptions set forth in Regulation BTR will apply. Please be aware that even if a transaction is subject to an exception to this Policy, you will need to separately assess whether the transaction complies with applicable law.

I. 10B5-1 TRADING PLANS

The Company permits its directors, officers and employees to adopt written 10b5-1 trading plans in order to mitigate the risk of trading on material nonpublic information. These plans allow for individuals to enter into a prearranged trading plan as long as the plan is not established or modified during a blackout period or when the individual is otherwise in possession of material nonpublic information. To be approved by the Company and qualify for the exception to this Policy, any 10b5-1 trading plan adopted by a director,

officer or employee must be submitted to the Compliance Officer for approval and comply with the requirements set forth in the Requirements for Trading Plans attached as Exhibit A. If the Compliance Officer is the requester, then the other Compliance Officer or their delegate, must approve the written 10b5-1 trading plan.

J. SECTION 16 COMPLIANCE

All of the Company's officers and directors and certain other individuals are required to comply with Section 16 of the Securities and Exchange Act of 1934 and related rules and regulations which set forth reporting obligations, limitations on "short swing" transactions, which are certain matching purchases and sales of the Company's securities within a six-month period, and limitations on short sales.

To ensure transactions subject to Section 16 requirements are reported on time, each person subject to these requirements must provide the Company with detailed information (for example, trade date, number of shares, exact price, *etc.*) about his or her transactions involving the Company's securities.

The Company is available to assist in filing Section 16 reports, but the obligation to comply with Section 16 is personal. If you have any questions, you should check with the Compliance Officer.

K. VIOLATIONS OF THIS POLICY

Company directors, officers, employees, consultants, contractors and advisors who violate this Policy will be subject to disciplinary action by the Company, including ineligibility for future Company equity or incentive programs or termination of employment or an ongoing relationship with the Company. The Company has full discretion to determine whether this Policy has been violated based on the information available.

There are also serious legal consequences for individuals who violate insider trading laws, including large criminal and civil fines, significant imprisonment terms and disgorgement of any profits gained or losses avoided. You may also be liable for improper securities trading by any person (commonly referred to as a "tippee") to whom you have disclosed material nonpublic information that you have learned through your position at the Company or made recommendations or expressed opinions about securities trading on the basis of such information.

Please consult with your personal legal and financial advisors as needed. Note that the Company's legal counsel, both internal and external, represent the Company and not you personally. There may be instances where you suffer financial harm or other hardship or are otherwise required to forego a planned transaction because of the restrictions imposed by this Policy or under securities laws. If you were aware of the material nonpublic information at the time of the trade, it is not a defense that you did not "use" the information for the trade. Personal financial emergency or other personal circumstances are not mitigating factors under securities laws and will not excuse your failure to comply with this Policy. In addition, a blackout or trading-restricted period will not extend the term of your options. As a consequence, you may be prevented from exercising your options by this Policy or as a result of a blackout or other restriction on your trading, and as a result your options may expire by their term. In such instances, the Company cannot extend the term of your options and has no obligation or liability to replace the economic value or lost benefit to you. It is your responsibility to manage your economic interests and to consider potential trading restrictions when determining whether to exercise your options.

L. PROTECTED ACTIVITY NOT PROHIBITED

Nothing in this Policy, or any related guidelines or other documents or information provided in connection with this Policy, shall in any way limit or prohibit you from engaging in any of the protected activities set forth in the Company's Whistleblower Policy, as amended from time to time.

M. REPORTING

If you believe someone is violating this Policy or otherwise using material nonpublic information that they learned through their position at the Company to trade securities, you should report it to the Compliance Officer, or if the Compliance Officer is implicated in your report, then you should report it in accordance with the Company's Whistleblower Policy.

N. AMENDMENTS

The Company reserves the right to amend this Policy at any time, for any reason, subject to applicable laws, rules and regulations, and with or without notice, although it will attempt to provide notice in advance of any change. Unless otherwise permitted by this Policy, any amendments must be approved by the Board.

EXHIBIT A

REQUIREMENTS FOR TRADING PLANS

For transactions under a trading plan to be exempt from (A) the prohibitions in the Company's Insider Trading Policy (the "**Policy**") of Amphastar Pharmaceuticals, Inc. (together with any subsidiaries, collectively the "**Company**") with respect to transactions made while aware of material nonpublic information and (B) the pre-clearance procedures and blackout periods established under the Policy, the trading plan must comply with the affirmative defense set forth in Exchange Act Rule 10b5-1 and must meet the following requirements (collectively, the "**Trading Plan Requirements**"):

1. The trading plan must be in writing and signed by the person adopting the trading plan.

2. The trading plan must be adopted at a time when:

    a. the person adopting the trading plan is not aware of any material nonpublic information; and

    b. there is no quarterly, special or other trading blackout in effect with respect to the person adopting the plan.

3. The trading plan must be entered in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1, and the person adopting the trading plan must act in good faith with respect to the trading plan.

4. The trading plan must include representations that, on the date of adoption of the trading plan, the person adopting the trading plan:

    a. is not aware of material nonpublic information about the securities or the Company; and

    b. is adopting the trading plan in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1

5. The person adopting the trading plan may not have entered into or altered a corresponding or hedging transaction or position with respect to the securities subject to the trading plan and must agree not to enter into any such transaction while the trading plan is in effect.

6. The first trade under the trading plan may not occur until the expiration of a cooling-off period consisting of the later of (a) 90 calendar days after the adoption of the trading plan and (b) two business days after the filing by the Company of its financial results in a Form 10-Q or Form 10-K for the completed fiscal quarter in which the trading plan was adopted (but, in any event, this required cooling-off period is subject to a maximum of 120 days after adoption of the trading plan).

7. The trading plan must have a minimum term of one year (starting from the date of adoption of the trading plan).

8. No transactions may occur during the term of the trading plan (except for the "Exceptions to Trading Restrictions" identified in the Policy and *bona fide* gifts) except for those transactions specified in the trading plan. In addition, the person adopting the trading plan may not have an outstanding (and may not subsequently enter into any additional) trading plan except as permitted by Rule 10b5-1. For example, as contemplated by Rule 10b5-1, a person may adopt a new trading plan before the scheduled termination date of an existing trading plan, so long as the first scheduled trade under the new trading plan does not occur prior to the last scheduled trade(s) of the existing trading plan and otherwise complies with these guidelines. Termination of the existing trading plan prior to its scheduled termination date may impact the timing of the first trade or the availability of the affirmative defense for the new trading plan; therefore,

persons adopting a new trading plan are advised to exercise caution and consult with the Compliance Officer prior to the early termination of an existing trading plan.

9. Any modification or change to the amount, price or timing of transactions under the trading plan is deemed the termination of the trading plan, and the adoption of a new trading plan ("**Modification**"). Therefore, a Modification must be submitted to the Insider Trading Compliance Officers for approval in accordance with Section I of the Policy and is subject to the same conditions as a new trading plan as set forth in Sections 1 through 8 herein.

10. Within the one year preceding the adoption or a Modification of a trading plan, a person may not have otherwise adopted or made a Modification to a plan more than once.

11. A person may adopt a trading plan designed to cover a single trade only once in any consecutive 12-month period except as permitted by Rule 10b5-1.

12. If the person that adopted the trading plan terminates the plan prior to its stated duration, he or she may not trade in the Company's securities until after the expiration of 30 calendar days following termination, and then only in accordance with the Policy.

13. The Company must be promptly notified of any Modification or termination of the trading plan, including any suspension of trading under the trading plan.

14. The Company must have authority to require the suspension of the trading plan if there are legal, regulatory or contractual restrictions applicable to the Company or the person that adopted the trading plan, or to require the cancellation of the trading plan at any time, subject to any reasonable broker notice requirements as may be set forth in the trading plan.

15. If the trading plan grants discretion to a stockbroker or other person with respect to the execution of trades under the trading plan:

a. the person adopting the trading plan may not exercise any subsequent influence over how, when or whether to effect purchases or sales under the plan;

b. the person adopting the trading plan may not confer with the person administering the trading plan regarding the Company or its securities; and

c. the person administering the trading plan must provide prompt notice to the Company of the execution of a transaction pursuant to the plan.

16. All transactions under the trading plan must be in accordance with applicable law.

17. Any exceptions to the Trading Plan Requirements must be approved by the Insider Trading Compliance Officers or, in the case of directors and officers who are subject Section 16 of the Securities Exchange Act of 1934, by the Insider Trading Compliance Officers, in consultation with the Board or an independent committee of the Board.

18. The trading plan (including any Modification) must meet such other requirements as the Insider Trading Compliance Officers may determine.

Exhibit 21.1

SUBSIDIARIES OF THE COMPANY

Company Name	State of Incorporation/ Organization	Country of Incorporation/ Organization
International Medication Systems, Limited	California	United States of America
Armstrong Pharmaceuticals, Inc.	Massachusetts	United States of America
Amphastar Nanjing Pharmaceuticals, Inc.		China
Amphastar France Pharmaceuticals, S.A.S.		France
Amphastar UK Limited		United Kingdom
International Medication Systems (UK) Limited		United Kingdom

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-197054) pertaining to the 1999-2002 Stock Option/Stock Issuance Plans, the Amended and Restated 2005 Equity Incentive Award Plan and the 2014 Employee Stock Purchase Plan of Amphastar Pharmaceuticals, Inc.,
(2) Registration Statement (Form S-8 No. 333-203017) pertaining to the Amended and Restated 2005 Equity Incentive Award Plan of Amphastar Pharmaceuticals, Inc.,
(3) Registration Statement (Form S-8 No. 333-205470) pertaining to the 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.,
(4) Registration Statement (Form S-8 No. 333-210213) pertaining to the 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.,
(5) Registration Statement (Form S-8 No. 333-216700) pertaining to the 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.,
(6) Registration Statement (Form S-8 No. 333-223651) pertaining to the 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.,
(7) Registration Statement (Form S-8 No. 333-230330) pertaining to the 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.,
(8) Registration Statement (Form S-8 No. 333-237223) pertaining to the 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.,
(9) Registration Statement (Form S-8 No. 333-254293) pertaining to the 2015 Amended and Restated Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.,
(10) Registration Statement (Form S-3 No. 333-260916) of Amphastar Pharmaceuticals, Inc.,
(11) Registration Statement (Form S-8 No. 333-263491) pertaining to the Amended and Restated 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.,
(12) Registration Statement (Form S-8 No. 333-270180) pertaining to the Amended and Restated 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc., and
(13) Registration Statement (Form S-8 No. 333-277537) pertaining to the Amended and Restated 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.;

of our reports dated February 26, 2026, with respect to the consolidated financial statements of Amphastar Pharmaceuticals, Inc. and the effectiveness of internal control over financial reporting of Amphastar Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of Amphastar Pharmaceuticals, Inc. for the year ended December 31, 2025.

/s/ Ernst & Young LLP

Irvine, California
February 26, 2026

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14a OF THE SECURITIES EXCHANGE ACT OF 1934 AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, Jack Y. Zhang, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Amphastar Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: February 26, 2026

By: **/s/ JACK Y. ZHANG**
Jack Y. Zhang
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14a OF THE SECURITIES EXCHANGE ACT OF 1934 AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, William J. Peters, certify that:

1. I have reviewed this Annual Report on Form 10-K of Amphastar Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: February 26, 2026

By: **/s/ WILLIAM J. PETERS**
William J. Peters
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

The undersigned officer of Amphastar Pharmaceuticals, Inc. (the "Company"), hereby certifies, to the best of such officer's knowledge, that:

(i) the Annual Report on Form 10-K of the Company for the year ended December 31, 2025 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Date: February 26, 2026

By: **/s/ JACK Y. ZHANG**
Jack Y. Zhang
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

The undersigned officer of Amphastar Pharmaceuticals, Inc. (the "Company"), hereby certifies, to the best of such officer's knowledge, that:

(i) the Annual Report on Form 10-K of the Company for the year ended December 31, 2025 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Date: February 26, 2026

By: **/s/ WILLIAM J. PETERS**
William J. Peters
Chief Financial Officer
(Principal Financial and Accounting Officer)