
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, 2022

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 001-38485

Amneal Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

32-0546926

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

400 Crossing Boulevard, Bridgewater, NJ

08807

(Address of principal executive offices)

(Zip Code)

(908) 947-3120

(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
Class A Common Stock, par value \$0.01 per share	AMRX	New York Stock Exchange

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. (Check one):

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

Emerging growth company ☐

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

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

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

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

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

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The aggregate market value of the registrant's outstanding shares of common stock, other than shares held by persons who may be deemed affiliates of the registrant, computed by reference to the price at which the registrant's common stock was last sold on the New York Stock Exchange as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2022), was approximately \$470,754,286.

As of February 14, 2023, there were 151,500,830 shares of Class A common stock outstanding and 152,116,890 shares of Class B common stock outstanding, both with a par value of \$0.01.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be furnished pursuant to Part III of this Form 10-K will be set forth in, and is hereby incorporated by reference herein from, the registrant's definitive proxy statement for its 2023 Annual Meeting of Stockholders, to be filed by the registrant with the Securities and Exchange Commission pursuant to Regulation 14A no later than 120 days after December 31, 2022 (the "2023 Proxy Statement").

Amneal Pharmaceuticals, Inc.

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Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K and Amneal Pharmaceuticals, Inc.'s other publicly available documents contain "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Management and representatives of Amneal Pharmaceuticals, Inc. and its subsidiaries ("the Company", "we", "us" or "our") also may from time to time make forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and reflect management's assumptions, views, plans, objectives and projections about the future. Forward-looking statements may be identified by the use of words such as "plans," "expects," "will," "anticipates," "estimates" and other words of similar meaning in conjunction with, among other things: discussions of future operations; expected operating results and financial performance; impact of planned acquisitions and dispositions; our strategy for growth; product development; regulatory approvals; market position and expenditures.

Because forward-looking statements are based on current beliefs, expectations and assumptions regarding future events, they are subject to uncertainties, risks and changes that are difficult to predict and many of which are outside of our control. Investors should realize that if underlying assumptions prove inaccurate, known or unknown risks or uncertainties materialize, or other factors or circumstances change, our actual results and financial condition could vary materially from expectations and projections expressed or implied in its forward-looking statements. Investors are therefore cautioned not to rely on these forward-looking statements.

Summary of Material Risks

Risks and uncertainties that make an investment in the Company speculative or risky or that could cause our actual results to differ materially from the forward-looking statements contained in this Annual Report on Form 10-K, include, but are not limited to:

- our ability to successfully develop, license, acquire and commercialize new products on a timely basis;
- the competition we face in the pharmaceutical industry from brand and generic drug product companies, and the impact of that competition on our ability to set prices;
- our ability to obtain exclusive marketing rights for our products;
- our ability to manage our growth through acquisitions and otherwise;
- our revenues derived from the sales of a limited number of products, a substantial portion of which are through a limited number of customers;
- the continuing trend of consolidation of certain customer groups;
- our dependence on third-party suppliers and distributors for raw materials for our products and certain finished goods;
- our substantial amount of indebtedness and our ability to generate sufficient cash to service our indebtedness in the future, and the impact of interest rate fluctuations on such indebtedness;
- our ability to secure satisfactory terms when negotiating a refinancing or other new indebtedness;
- our dependence on third-party agreements for a portion of our product offerings;
- legal, regulatory and legislative efforts by our brand competitors to deter competition from our generic alternatives;
- risks related to federal regulation of arrangements between manufacturers of branded and generic products;
- our reliance on certain licenses to proprietary technologies from time to time;
- the significant amount of resources we expend on research and development ("R&D");
- the risk of product liability and other claims against us by consumers and other third parties;
- risks related to changes in the regulatory environment, including U.S. federal and state laws related to healthcare fraud abuse and health information privacy and security and changes in such laws;
- changes to Food and Drug Administration ("FDA") product approval requirements;
- the impact of healthcare reform and changes in coverage and reimbursement levels by governmental authorities and other third-party payers;
- our potential expansion into additional international markets subjecting us to increased regulatory, economic, social and political uncertainties;
- our ability to identify, make and integrate acquisitions or investments in complementary businesses and products on advantageous terms;
- the impact of global economic, political or other catastrophic events;
- our ability to attract, hire and retain highly skilled personnel;
- our obligations under a tax receivable agreement may be significant;
- the high concentration of ownership of our Class A Common Stock and the fact that we are controlled by the Amneal Group; and

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- such other factors as may be set forth elsewhere in this Annual Report on Form 10-K, particularly in the section entitled *1A. Risk Factors* and our public filings with the SEC.

Investors also should carefully read the Risk Factors described in *Item 1A. Risk Factors* for a description of certain risks that could, among other things, cause our actual results to differ materially from those expressed in our forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and in *Item 1A. Risk Factors* to be a complete statement of all potential risks and uncertainties. The Company does not undertake to publicly update any forward-looking statement that may be made from time to time, whether as a result of new information or future events or developments.

PART I.

Item 1. Business

Overview

Amneal Pharmaceuticals, Inc. (the “Company”, “we,” “us,” or “our”) is a global pharmaceutical company that develops, manufactures, markets, and distributes a diverse portfolio of essential medicines, including complex generics, injectables, biosimilars and specialty branded pharmaceuticals. We operate principally in the United States, India, and Ireland, and sell to wholesalers, distributors, hospitals, chain pharmacies and individual pharmacies, either directly or indirectly. We are a holding company, whose principal assets are common units (“Amneal Common Units”) of Amneal Pharmaceuticals, LLC (“Amneal”).

The group, together with their affiliates and certain assignees, who owned Amneal when it was a private company (the “Amneal Group”) held 50.1% of Amneal Common Units and the Company held the remaining 49.9% as of December 31, 2022. Although the Company has a minority economic interest in Amneal, it is Amneal’s sole managing member, having the sole voting power to make all of Amneal’s business decisions and control its management. Therefore, the Company consolidates the financial statements of Amneal and its subsidiaries. The Company records non-controlling interests for the portion of Amneal’s economic interests that it does not hold.

Acquisitions

Baclofen Franchise

On December 30, 2021, we entered into an asset purchase agreement with certain entities affiliated with Saol International Limited (collectively, “Saol”), a private specialty pharmaceutical company, pursuant to which we agreed to acquire Saol’s baclofen franchise, including Lioresal®, LYVISPAH™, and a pipeline product under development (the “Saol Acquisition”). The Saol Acquisition expanded our commercial institutional and specialty portfolio in neurology and added commercial infrastructure in advance of our entry into the biosimilar institutional market during October 2022. Consideration for the Saol Acquisition included approximately \$84.7 million, paid at closing with cash on hand, and contingent royalty payments based on annual net sales for certain acquired assets, beginning in 2023. The transaction closed on February 9, 2022.

Puniska Healthcare Pvt. Ltd.

On November 2, 2021, we entered into a definitive agreement to acquire Puniska Healthcare Pvt. Ltd. (“Puniska”), a privately held manufacturer of parenteral and injectable drugs in India. Upon execution of the agreement, we acquired a 74% controlling interest in the equity of Puniska and acquired the remaining 26% of the equity upon approval of the transaction by the government of India in March 2022.

Kashiv Specialty Pharmaceuticals, LLC

On April 2, 2021, the Company and Kashiv Biosciences, LLC (a related party, refer to *Note 24. Related Party Transactions*) (“Kashiv”) closed on a transaction for Amneal to acquire a 98% controlling interest in Kashiv Specialty Pharmaceuticals, LLC (“KSP”), a subsidiary of Kashiv focused on the development of innovative drug delivery platforms, novel 505(b)(2) drugs, and complex generics.

AvKARE, LLC and R&S Northeast LLC

On January 31, 2020, we acquired a 65.1% controlling interest in both AvKARE Inc., a Tennessee corporation, now a limited liability company (“AvKARE, LLC”), and Dixon-Shane, LLC d/b/a R&S Northeast LLC, a Kentucky limited liability company (“R&S”) (collectively, the “Rondo Acquisitions”). AvKARE, LLC is one of the largest private label providers of generic pharmaceuticals in the U.S. federal agency sector, primarily focused on serving the Department of Defense and the Department of Veterans Affairs. R&S is a national pharmaceutical wholesaler focused primarily on offering products to 340b-qualified entities to provide consistency in care and pricing.

For additional information about our acquisitions, refer to *Note 3. Acquisitions* in our consolidated financial statements.

Segments of the Business

We have three reportable segments: Generics, Specialty, and AvKARE.

Generics

Prescription pharmaceutical products are sold either as branded or generic products. Generic pharmaceutical products have the same active pharmaceutical ingredient (“API”), dosage form, strength, route of administration, and conditions of use as patented branded pharmaceutical products, are bioequivalent to the brand it copies, and are usually marketed under their chemical (generic) names rather than brand names. However, generic pharmaceutical products are intended to provide a cost-effective alternative for consumers while maintaining the safety, efficacy, quality and stability of the branded product, and as such are generally sold at prices below their branded equivalents. Typically, a generic pharmaceutical may not be marketed until the expiration of applicable patent(s) on the corresponding branded product, unless the resolution of patent litigation results in an earlier opportunity to enter the market. Generic manufacturers are required to file and receive approval for an Abbreviated New Drug Application (“ANDA”) to market a generic pharmaceutical product.

Our Generics segment includes over 250 product families covering an extensive range of dosage forms and delivery systems, including both immediate and extended release oral solids, powders, liquids, sterile injectables, nasal sprays, inhalation and respiratory products, biosimilar products, ophthalmics, films, transdermal patches and topicals. We focus on developing products that have substantial barriers-to-entry due to complex drug formulations or manufacturing, or legal or regulatory challenges. Focusing on these products allows us the opportunity to offer first-to-file (“FTF”), first-to-market (“FTM”) and other high-value products to customers. A generic pharmaceutical product is considered a FTF product if the ANDA filed with respect to such product is the first to be filed for such product. Pursuant to the Hatch-Waxman Amendments, FTF products may receive a statutory 180-day exclusivity period, subject to certain conditions. A generic product that does not qualify as a FTF may still be a FTM product. A generic product is considered an FTM product if it is the first marketed generic version of a branded pharmaceutical. We define high-value products as products with three or fewer generic competitors at the time of launch. FTF, FTM and high-value products tend to be more profitable and often have longer life cycles than other generic pharmaceuticals. As such, the timing of new product introductions can have a significant impact on our financial results. Market entry by additional competitors generally has a negative impact on the volume and pricing of the affected products. Additionally, pricing is often affected by factors outside of our control. Refer to “Pharmaceutical Approval Process in the United States,” below, for more information.

As of December 31, 2022, our Generics segment had 105 products with a pending ANDA and another 94 products in various stages of development in our pipeline, 61% of which are non-oral solid products. Over half of our generic pipeline consists of what we believe to be potential FTF, FTM and high-value products. We have an integrated, team-based approach to product development that combines our formulation, regulatory, legal, manufacturing and commercial capabilities.

Our Generics segment has a growing portfolio of institutional injectable products primarily for the United States hospital market. Our R&D pipeline has prioritized new product innovations in injectables, such as drug/device combinations, peptides, long-acting injectables and large volume parenteral bags. We have expanded our manufacturing capabilities and infrastructure to support the needs of this expanding business with a focus on development, commercialization and scaling a differentiated injectables portfolio. In December 2022, the FDA approved our first ready-to-use large volume bag, an esmolol hydrochloride in sodium chloride injection, which is indicated for tachycardia.

Additionally, in 2022 we began to commercialize an initial portfolio of oncology biosimilars in the United States. Alymsys®, a biosimilar referencing Avastin®, launched in October 2022, followed by Releuko®, a biosimilar referencing Neupogen®, in November 2022. We plan to launch Flynetra™, a biosimilar referencing Neulasta®, in the first half of 2023. To grow our oncology biosimilars sales, we are focused on serving oncology clinics, integrated health systems and specialty pharmacies. We are focused on expanding our biosimilars portfolio with additional molecules, and we seek to vertically integrate by expanding our biosimilar capabilities.

Our Generics segment had net revenue of \$1.43 billion, \$1.37 billion and \$1.34 billion and operating income of \$224.2 million, \$281.5 million and \$189.4 million, for the years ended December 31, 2022, 2021 and 2020, respectively.

Specialty

Our Specialty segment is engaged in the development, promotion, sale and distribution of proprietary branded pharmaceutical products, with a focus on products addressing central nervous system (“CNS”) disorders, including Parkinson’s disease, and endocrine disorders. Our portfolio of products includes Rytary®, an extended release oral capsule formulation of carbidopa-levodopa for the treatment of Parkinson’s disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication. In addition to Rytary®, our promoted Specialty portfolio also includes Unithroid® (levothyroxine sodium), for the treatment of hypothyroidism, which is sold under a license and distribution

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agreement with Jerome Stevens Pharmaceuticals, Inc., and Lyvispah® (baclofen), a unique dissolvable granule formulation used to treat muscle stiffness, spasms and pain from multiple sclerosis.

Additionally, we are advancing a pipeline of potential Specialty products, most notably IPX203, a novel, oral formulation of carbidopa/levodopa extended-release capsules for the treatment of Parkinson's disease. The FDA accepted our IPX203 NDA and assigned a Prescription Drug User Fee Act date of June 30, 2023 to complete its evaluation of our IPX203 NDA. Beyond IPX203, we have a pipeline of R&D programs at various stages of development, including 505(b)(2) programs that utilize our propriety drug delivery technology platforms, GRANDE® and KRONOTEC®. GRANDE® is an advanced gastric retention system that enables sustained 12 to 24 hour delivery for drugs with site-specific absorption in the upper gastrointestinal tract. KRONOTEC® is an advanced osmotic oral drug delivery technology that provides timed, customized and pulsatile drug release to match timing of disease symptoms.

For Specialty products, the majority of such products' commercial value is usually realized during the period in which the product has market exclusivity. In the United States ("U.S."), when market exclusivity expires and generic versions of a product are approved and marketed, there can often be substantial and rapid declines in the branded product's sales.

Our Specialty segment had net sales of \$374.1 million, \$378.3 million and \$355.6 million and operating income of \$72.6 million, \$56.4 million and \$56.5 million, for the years ended December 31, 2022, 2021 and 2020, respectively.

AvKARE

Our AvKARE segment provides pharmaceuticals, medical and surgical products, and services primarily to governmental agencies, predominantly focused on serving the U.S. Department of Defense and the U.S. Department of Veterans Affairs. AvKARE is also a wholesale distributor of bottle and unit dose pharmaceuticals under the registered names of AvKARE and AvPAK, and medical and surgical products. AvKARE is also a packager and wholesale distributor of pharmaceuticals and vitamins to its retail and institutional customers that are located throughout the U. S. focused primarily on offering 340b-qualified entities products to provide consistency in care and pricing.

Our AvKARE segment had net sales of \$406.1 million, \$349.0 million and \$293.7 million and operating income (loss) of \$3.3 million, \$6.8 million and \$(7.7) million for the years ended December 31, 2022, 2021 and 2020, respectively.

Geographic Areas

We operate in the U.S., India, and Ireland. During December 2022, we signed a long-term license agreement to commercialize a number of our complex generic products to most parts of Europe as well as in Australia and New Zealand (see *Note 5. Alliance and Collaboration* to our consolidated financial statements for additional information). Investments and activities in some countries outside the U.S. are subject to higher risks than comparable U.S. activities because the investment and commercial climate may be influenced by financial instability in international economies, restrictive economic policies and political and legal system uncertainties. See further discussion of this risk in *Item 1A. Risk Factors*.

Sales & Marketing and Customers

In the U.S. and the Commonwealth of Puerto Rico, we market our Generics and Specialty products primarily through wholesalers and distributors, retail pharmacies, mail-order pharmacies and directly into hospitals and institutions. The majority of our generic pharmaceutical products are marketed to large group purchasing organizations ("GPOs") and sold through wholesalers, directly to large chain retailers or to mail order customers. Our sterile injectable products are generally marketed to GPOs and specialty distributors, and sold through wholesalers, and occasionally directly to large hospitals and institutions. All of our wholesalers purchase products and warehouse them for retail drug stores, independent pharmacies and managed care organizations, such as hospitals, nursing homes, health maintenance organizations, clinics, pharmacy benefit management companies and mail-order customers. On December 28, 2022, we signed a long-term license agreement to commercialize a number of our complex generic products to most parts of Europe as well as in Australia and New Zealand (see *Note 5. Alliance and Collaboration* to our consolidated financial statements for additional information). As of December 31, 2022, we have not sold products under this license agreement. Our Specialty segment, which promotes branded pharmaceutical products, employs a team of dedicated field based sales representatives to engage in the direct marketing and promotion of our branded products to physicians and healthcare providers.

In our AvKARE segment, we market our products primarily through wholesalers and distributors, retail pharmacies, mail-order pharmacies and directly into hospitals and institutions. The majority of our generic pharmaceutical products within the AvKARE segment are marketed to large GPOs and government entities (U.S. Department of Defense and U.S. Department of

Veterans Affairs) and sold through wholesalers. The AvKARE segment's distribution channel primarily sells brand products to clinics, institutions and pharmacies generally marketed to GPOs.

For the year ended December 31, 2022, on a consolidated basis, our four largest customers, AmerisourceBergen Corporation, McKesson Drug Co., Cardinal Health, and CVS Health Corporation, accounted for approximately 71% of our net revenue. In total, we currently have approximately 1,200 customers (including over 1,000 customers specific to our AvKARE segment), some of which are part of large purchasing groups.

We have no long-term agreements that guarantee future business with any of our major customers and the loss of or substantial reduction in orders from any one or more of these customers could have a material adverse effect on our operating results, future prospects and financial condition.

Competition

The pharmaceutical industry is highly competitive and is affected by new technologies, new developments, government regulations, health care legislation, availability of financing, and other factors. Many of our competitors have longer operating histories and substantially greater financial, R&D, marketing, and other resources than we do. Competing manufacturers of generic pharmaceutical products create value for our customers by offering substitutes for branded pharmaceutical products at significantly lower prices, and at times we may not be able to differentiate our product offerings from those of our competitors, successfully formulate and bring to market new products that are less expensive than those of our competitors or offer commercial terms as favorable as those of our competitors. We compete with numerous other companies that currently operate, or intend to operate, in the pharmaceutical industry, including companies that are engaged in the development of controlled-release drug delivery technologies and products, and other manufacturers that may decide to undertake development of such products. Our principal competitors in the generic/biosimilar pharmaceutical products market include Teva Pharmaceutical Industries Ltd., Viatris Inc., Endo International plc, Sandoz International GmbH, Pfizer Inc., Fresenius Kabi KGaA, Sun Pharmaceutical Industries Ltd., Lupin Pharmaceuticals, Inc., Hikma Pharmaceuticals PLC, Dr. Reddy's Laboratories Ltd., Coherus Biosciences, Inc., Amphastar Pharmaceuticals, Inc., and Aurobindo Pharma Limited. Our principal competitors in the specialty pharmaceutical products market include Supernus Pharmaceuticals, Inc., Jazz Pharmaceuticals PLC, and Alkermes PLC.

Our AvKARE segment is also highly competitive, with new smaller competitors entering the space regularly. Our competitors are other wholesalers, including Cardinal Health, Inc., AmerisourceBergen Corporation, and Golden State Medical Supply.

By focusing on our high-value products with complex dosage forms and high barriers-to-entry, as well as taking advantage of our vertically integrated supply chain and selective use of internal API, we aim to manufacture more profitable products relative to our competition. However, this or any future strategy may not enable us to compete successfully in the generic pharmaceutical industry.

The Hatch-Waxman Amendments amended the Federal Food, Drug and Cosmetic Act ("FDCA") and provided for a period of 180 days of generic marketing exclusivity for each applicant that is FTF an ANDA with a Paragraph IV certification, which signifies a challenge to at least one brand patent. The holder of an approved FTF ANDA that successfully challenges the relevant innovator drug patent(s) usually enjoys higher market share and sales during the 180-day period of exclusivity. When the exclusivity period concludes, other generic competitors may launch their versions of the product, which may cause significant price erosion and loss of market share. In cases where we are the holder of an ANDA for a FTF product, upon the expiration of the 180-day exclusivity period, we may adjust the price of such product and provide price adjustments to our customers for the difference between the lower price and the price at which we previously sold the product then held in inventory by our customers. These adjustments are commonly known as shelf stock adjustments. In certain circumstances, we may decide not to provide price adjustments to certain customers and, as a result, we may receive returns of unsold product from these customers and forego future sales volume as opposed to reducing pricing.

Authorized generic pharmaceutical products, which are generic labeled versions of pharmaceutical products introduced by brand companies (directly or through a third-party) under the brand's NDA, have also increased competition in the generic pharmaceutical industry. Authorized generic pharmaceutical products may be sold prior to, during and subsequent to the 180-day exclusivity period and are a significant source of competition, because brand companies do not face any regulatory barriers to rapidly introducing generic versions of their pharmaceutical products.

Additionally, consolidation among wholesalers and retailers and the formation of GPOs has caused increased price competition in the generic pharmaceutical market. The downward price adjustments demanded by distributors of generic pharmaceutical products have reduced revenue and average product gross margin across the industry. Should these price reductions continue or

even increase, it could have a material adverse effect on our revenue and gross margin. Further, even if we reduce the prices we charge our customers, that does not ensure that the prices consumers pay for those drugs will be similarly reduced.

The main competitive factors in the generic pharmaceutical market include:

- a generic pharmaceutical products manufacturer's ability to rapidly develop and obtain regulatory approval for and supply commercial quantities of generic pharmaceutical products;
- the introduction of other generic pharmaceutical manufacturers' products in direct competition with our products;
- the introduction of authorized generic pharmaceutical products in direct competition with our products;
- consolidation among our customers and the formation of buyer consortia;
- pricing pressures by competitors and customers, even if similar price savings are not passed on to consumers;
- product quality of our generic pharmaceutical competitors;
- our and our competitors' breadth of product offerings across its portfolio;
- our ability and the ability of our generic pharmaceutical competitors to quickly enter the market after the expiration of patents or statutory exclusivity periods, limiting the extent and duration of profitability for our products;
- the willingness of our customers to switch their source of supply of products among various generic pharmaceutical competitors;
- the ability of our generic pharmaceutical competitors to identify and market niche products;
- our and our competitors' level of service (including maintenance of inventories for timely delivery) and reputation as a reliable developer and manufacturer of generic pharmaceutical products; and
- product appearance and labeling for our products and those of our competitors.

In the brand-name pharmaceutical market, our principal competitors are pharmaceutical companies that are focused on Parkinson's disease and other CNS disorders. In addition, with respect to products that we are developing internally and/or any additional products we may in-license from third parties, we expect that we will face increased competition from large pharmaceutical companies, drug delivery companies and other specialty pharmaceutical companies that have focused on the same disorders as our branded products.

Research and Development

R&D activities represent a significant part of our business. R&D expenditures relate to the processes of discovering, testing and developing new products, upfront payments and milestones, improving existing products, as well as demonstrating product efficacy, if applicable, and regulatory compliance prior to launch. We are committed to investing in R&D with the aim of delivering high quality and innovative products. For the years ended December 31, 2022, 2021 and 2020, our R&D expense was \$195.7 million, \$201.8 million and \$179.9 million, respectively.

Raw Materials

Raw materials, including APIs, essential to our business are generally readily available from multiple sources. We purchase raw materials from distributors of bulk pharmaceutical chemicals and we also manufacture certain APIs at our facilities in India. In some cases, however, the raw materials used to manufacture our products are available only from a single supplier. Further, even if more than one supplier exists, we may choose, and have done so in the case of our API suppliers for a majority of our products, to list only one supplier in our product applications submitted to the FDA. Generally, we would need as long as 18 months to find and qualify a new sole-source supplier. If we receive less than one year's termination notice from a sole-source supplier that it intends to cease supplying raw materials, it could result in disruption of our ability to produce the drug involved. Although to date we have only experienced occasional interruptions in supplies, no assurance can be given that we will continue to receive uninterrupted or adequate supplies of such raw materials. Any inability to obtain raw materials on a timely basis, or any significant price increases not passed on to customers, could have a material adverse effect on our business.

Because legal and regulatory requirements mandate that our product marketing authorizations specify API and raw material suppliers, if a specified supplier were for any reason unable to continue to supply us, we would need to seek FDA approval of a new supplier. The resulting delay in the manufacture and marketing of the impacted pharmaceutical product during the FDA process to qualify and approve the new supplier could, depending on the product, have a material adverse effect on our results of operations and financial condition. We protect against the risk of such an event by generally providing for, where feasible, two or more suppliers of raw materials for the pharmaceutical products we manufacture, including those for which we manufacture API in-house. Additionally, we may enter into a contract with a raw material distributor in order to secure adequate supply for specific products.

Manufacturing and Distribution

We have a network of manufacturing sites and co-located R&D centers within the U.S., India and Ireland, with broad dosage capabilities. We also have a distribution center for our Generics and Specialty products in Glasgow, Kentucky and a packaging center in East Hanover, New Jersey. We manufacture the majority of our Generics products internally; of these products, for the year ended December 31, 2022, those manufactured in our U.S. facilities contributed 43% of Generics product net revenue compared to 32% for those manufactured in India. We rely on third-party manufacturers to supply products in our Generics portfolio representing approximately 25% of our Generics net revenue for the year ended December 31, 2022. Most of our Specialty products are manufactured by third-party manufacturers. In addition, we selectively manufacture API for a subset of our products, which helps to reduce the overall cost of manufacturing for our products and gives us greater control over our supply chain.

Our AvKARE segment's distribution centers are located in Fountain Run, Kentucky and Philadelphia, Pennsylvania.

Government Regulation

The business of developing, manufacturing, selling, distributing, and marketing generic and branded products is subject to significant health, safety, and environmental laws and regulations, including those governing the approval and pricing of products, clinical trials, laboratory procedures, privacy and security of health and other sensitive information and the handling, use, storage, treatment and disposal of hazardous materials and wastes. These regulatory regimes are overseen by governmental bodies, principally the FDA and, as applicable, the Drug Enforcement Administration (the "DEA"), the Department of Health and Human Services, the Federal Trade Commission (the "FTC") and several state and local government or other agencies, including individual data protection authorities, in the U.S. and abroad. Failure to comply with the laws and regulations of these governmental agencies may result in legal or other enforcement actions, including suspension of regulatory approval, delays in regulatory approval, clinical holds, orders to cease non-compliant activities and potential civil and criminal actions against us. The regulatory environment, particularly enforcement positions, statutes and legal interpretations applicable to the pharmaceutical industry are constantly in flux and not always clear. Significant changes in this environment could have a material adverse effect on our financial condition and results of operations.

The FDCA, the Public Health Service Act (the "PHSA"), the Controlled Substances Act, the regulations that implement these laws and other statutes and regulations govern the development, testing, manufacture, packaging, use, distribution, safety, effectiveness, labeling, storage, record keeping, approval, marketing, sale, and promotion of our products, as well as post-marketing requirements for safety surveillance and reporting. Failure to comply with these laws and regulations can result in judicial and/or administrative sanctions, such as warning letters, recalls, product seizures, injunctions, fines, total or partial suspension of distribution or production, exclusion or debarment from government programs and contracts, restitution, disgorgement and criminal prosecutions. The FDA has the authority to withdraw its approval of pharmaceuticals at any time, in accordance with its regulatory due process procedures, and can enforce the recall of products.

Pharmaceutical Approval Process in the United States

In the U.S., the FDA regulates pharmaceuticals and biologics under the FDCA and the PHSA, and their implementing regulations. To market a new drug or biologic, considerable data must be submitted to the FDA for review and approval. In addition to approval, the FDA also regulates research, development, preclinical and clinical testing, manufacturing, packaging, storage, distribution, recordkeeping, labeling, advertising, promotion, marketing, post-approval monitoring and reporting, and import and export of drugs and biologics. If we fail to comply with the applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval, we may be subject to a variety of administrative or judicial sanctions, which could include, among other actions, the FDA's refusal to approve pending applications, delays in approval, suspension or withdrawal of an approval, imposition of a clinical hold, orders to cease non-compliant activities, criminal charges, issuance of warning letters and other types of enforcement-related letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, exclusion from participation in government programs and contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA, the U.S. Department of Justice ("DOJ") or other governmental entities.

Generally, the following types of applications are used to obtain FDA approval.

New Drug Application and Biologics License Application

For a drug product containing an active ingredient not previously approved by the FDA, a prospective manufacturer must submit a complete NDA containing the results of clinical studies supporting the drug product's safety and efficacy in addition to data and information related to drug product quality and manufacturing. An NDA is also required for a drug with a previously approved active ingredient if the drug will be used to treat an indication for which the drug was not previously approved or if the dosage form, strength or method of delivery is changed and requires clinical studies to support the change. A Biologics License Application ("BLA") is required to introduce, or deliver for introduction, a biologic product into interstate commerce and market the product for one or more indications. The process required by the FDA before a new pharmaceutical or biological product may be approved for marketing in the U.S. generally involves the steps listed below.

- Laboratory and clinical tests;
- Submission to the FDA of an Investigational New Drug ("IND") application;
- Adequate and well-controlled human clinical studies conducted according to the FDA's requirements for good clinical practice ("GCP") and additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed product for its proposed conditions of use;
- For pharmaceutical products, submission of an NDA containing the results of the preclinical tests and clinical studies establishing the safety and efficacy of the proposed product for its proposed conditions of use, proposed labeling and extensive data addressing such matters such as drug product quality and manufacturing;
- For biological products, submission of a BLA that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical studies, as well as information on the chemistry, manufacturing and controls to ensure product identity and quality, and proposed labeling;
- For certain products, development and implementation of a Risk Evaluation and Mitigation Strategy;
- Scale-up to commercial manufacturing;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced to assess compliance with current good manufacturing practices ("cGMP"), and, if applicable, the FDA's current good tissue practice;
- Potential FDA inspection of the nonclinical and clinical study sites and the clinical study sponsor that generated the data in support of the NDA or BLA; and
- FDA review and approval or licensure of an NDA or of the BLA.

Prior to beginning the first clinical trial with a product candidate, the sponsor must submit an IND to the FDA and the IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises safety concerns or questions about the proposed clinical trial and places the IND on clinical hold within that 30-day time period. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, studies may not recommence without FDA authorization and then only under terms authorized by the FDA.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds. Similarly, an independent institutional review board ("IRB") can suspend or terminate approval of a clinical trial at its site if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Human clinical studies are typically conducted in three sequential phases that may overlap or be combined. Phase 1 studies are designed to assess safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. If favorable, Phase 2 studies are initiated to evaluate the efficacy of the product for specific targeted diseases or conditions and to determine dosage tolerance, optimal dosage and dosing schedule, as well as identify any adverse effects that could limit the product's usefulness. If data from the Phase 2 trials are favorable, large-scale Phase 3 trials are undertaken to confirm the product's efficacy and safety.

During all phases of clinical development, FDA and others require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators, and certain progress and safety reports must be submitted to the FDA. Phase 1, Phase 2 and Phase 3 clinical studies may not be completed successfully within any specified period, if at all.

Assuming successful completion of all required testing in accordance with regulatory requirements, the submission of an NDA or BLA requesting approval to market the product is subject to a substantial application user fee, which may be reduced or waived if the FDA finds that certain criteria are met, and there are certain exemptions for products designated for rare diseases or conditions. The submission of an NDA or BLA is not a guarantee that the FDA will find it complete and accept it for filing.

After the application is deemed filed by the FDA, FDA staff will review an NDA or BLA to determine, among other things, whether a product is safe and efficacious for its proposed conditions of use. There can be no assurance that a product will obtain the regulatory approvals necessary for it to be marketed.

If, after reviewing the NDA or BLA, the FDA determines that the application cannot be approved in its current form, the FDA sends the applicant a Complete Response Letter identifying all outstanding deficiencies that preclude final approval. The FDA then halts its review until the applicant resubmits the NDA or BLA with new information designed to address the deficiencies. An applicant receiving a Complete Response Letter may resubmit the application with data and information addressing the FDA's concerns or requirements, withdraw the application without prejudice to a subsequent submission of a related application or request a hearing on whether there are grounds for denying approval of the application. If a product receives regulatory approval, the approval is limited to specific diseases and dosages or the indications for use for which approval had been sought. In addition, the FDA may require an applicant to conduct Phase 4 testing which involves clinical trials designed to further assess a drug's safety and effectiveness after approval, and may require surveillance programs to monitor the safety of approved products which have been commercialized. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety or efficacy questions are raised after the product reaches the market. The agency may also impose requirements that the NDA or BLA holder conduct new studies, make labeling changes, implement Risk Evaluation and Mitigation Strategies, and take other corrective measures.

The FDA has a number of programs, including fast track, breakthrough therapy, priority review and accelerated approval, intended to expedite the development or review of products that meet certain criteria, and applicants may explore some of these opportunities for their product candidates, if appropriate. These programs do not change the standards for approval, but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Additionally, in the context of public health emergencies, applicants may seek an Emergency Use Authorization ("EUA") from the FDA, which if granted, allows for the distribution and use of products during the declared public health emergency, in accordance with the conditions set forth in the EUA, unless the EUA is otherwise terminated.

NDA User Fee Program

On September 30, 2022, the President signed into law the FDA User Fee Reauthorization Act of 2022, which includes the reauthorization of the Prescription Drug User Fee Act ("PDUFA VII") from fiscal year 2023 through 2027. The program provides for the continued timely review of new NDAs and BLAs. The PDUFA VII enhancements include modernizing the user fee structure, a focus on human resource and financial management improvement including a significant increase in staff capacity and capabilities to support the review of cell and gene therapy products; the creation of capacity planning capability; enhancing use of regulatory tools via benefit-risk, patient-focused drug development, complex innovative trial designs, and model informed drug development; enhancing staffing for breakthrough therapy reviews; focusing on communication with industry; and exploring real world evidence in regulatory decision-making.

Biosimilar User Fee Program

The Biosimilar User Fee Act was reauthorized for the second time on September 30, 2022 ("BsUFA III"). In the reauthorization of BsUFA III, enhancements include new supplement types and expedited review timelines; enhancing communication and feedback during the biosimilar biological development process; enhancing pre-licensure inspection communication; introducing a new pilot program to enhance regulatory decision-making and facilitate science-based recommendation; and enhancing financial management, transparency, and strategic hiring.

Abbreviated New Drug Application

For a generic version of an approved drug, an ANDA relies on the FDA's previous finding of safety and effectiveness for a reference listed drug ("RLD") and, as a result, may be approved without submission of the same type and extent of information that is requested for a stand-alone new drug application to establish the safety and effectiveness of the proposed product. Instead, an ANDA must submit data and information demonstrating the proposed product has the same active ingredient, dosage form, route of administration, and strength, and is bioequivalent to the previously approved RLD indicating that the rate of absorption and levels of concentration of the generic drug in the body do not show a significant difference from those of the reference listed drug. For most orally administered pharmaceutical products, bioequivalence between brand and generic is established when there is no statistically significant difference in the rate and extent to which the API in the product is absorbed into the bloodstream. For certain pharmaceutical products, such as topical, locally acting pharmaceutical products, other means

of establishing bioequivalence may be required by the FDA. The proposed product also must have the same labeling as the RLD with certain limited exceptions, include certain information regarding patents for the RLD, and must meet the same legal and regulatory standards for drug product quality and manufacturing as NDA products.

ANDA User Fee Program

In July 2012, the Generic Drug User Fee Amendments (“GDUFA”) were enacted into law. The GDUFA legislation implemented fees for new ANDA applications, Drug Master Files, product and establishment fees and a one-time fee for backlogged ANDA applications pending approval as of October 1, 2012. In return, the program was intended to provide faster and more predictable ANDA reviews by the FDA and increased inspections of drug facilities. On September 30, 2022, it was reauthorized for a second time with provisions that are in effect through September 30, 2027 (“GDUFA III”). The FDA’s commitment letter for GDUFA III, which sets forth performance goals and program enhancements for the reauthorization of GDUFA for fiscal years 2023-2027, sets goals for FDA’s assessment and review of different ANDA submissions and includes enhancements designed to increase pre-submission assessment activities, reduce the number of assessment cycles for ANDAs and facilitate access to generic drugs, in particular for complex products such as those with complex active ingredients or dosage forms that generally are more difficult to genericize and have increased numbers of assessment cycles. The reauthorization also established capacity planning capability.

The Hatch-Waxman Amendments established the modern regulatory system for generic pharmaceutical products by creating a standardized approach for generic pharmaceutical makers to file ANDAs and receive FDA approval for generic pharmaceutical products. In order to gain FDA approval, there are various regulatory hurdles that a prospective generic manufacturer must clear:

Current Good Manufacturing Practices

In order to obtain FDA approval for its products, a pharmaceutical manufacturer must demonstrate that its facilities comply with cGMP regulations. The manufacturer is required to comply with cGMP standards at all times during the production and processing of pharmaceuticals, and the FDA may inspect the manufacturer’s sites at any time to ensure compliance.

Patent Provisions

A branded pharmaceutical product is usually protected under patents granted by the U.S. Patent and Trademark Office that allow only the pharmaceutical company that developed the pharmaceutical product to market and sell such product. The sponsor of a branded product must “list” certain patents with the FDA, which in turn publishes that patent information publicly. For a generic pharmaceutical manufacturer to introduce a generic version of a referenced branded pharmaceutical product (its RLD), it must submit to the FDA an ANDA with a certification for each patent listed by the branded product sponsor stating one of the following:

- Paragraph I: That the required patent information relating to the patent for the referenced branded pharmaceutical product has not been filed;
- Paragraph II: That the patent for the referenced branded pharmaceutical product has expired;
- Paragraph III: That the patent for the referenced branded pharmaceutical product will expire on a particular date; or
- Paragraph IV: That the patent for the referenced branded pharmaceutical product is invalid, unenforceable and/or will not be infringed by the pharmaceutical product for which approval is being sought.

Filing an ANDA with certifications under Paragraph I or II, referenced above, permits the ANDA to be approved immediately, if it is otherwise eligible. Filing an ANDA with certifications under Paragraph III, referenced above, indicates that the applicant agrees to wait until the relevant patent has expired before seeking final approval of its ANDA. Under Paragraph IV, referenced above, a generic pharmaceutical manufacturer can challenge the patent of the branded referenced pharmaceutical product.

If the ANDA for a generic pharmaceutical product has a Paragraph IV certification, the filer must also notify the NDA and patent holders upon acceptance of the ANDA filing by the FDA (the “PIV Notice”). If in response to notice of a paragraph IV certification, the NDA holder or patent owner initiates a patent infringement action against the ANDA applicant within 45 days of receiving the required notice, approval of the ANDA generally will be stayed for 30 months following receipt of the notice or such shorter or longer time as the court might order.

Generic Pharmaceutical Pricing

The pricing of a generic pharmaceutical product generally correlates to the number of companies manufacturing generic versions of such pharmaceutical product. A generic pharmaceutical product is usually at its highest price immediately after the first generic launch of the product, either because a single manufacturer has been granted 180-day exclusivity or because only a few manufacturers have entered the market due to other technical or operational obstacles to bringing such product to market, such as raw materials shortages or complex formulation. As additional generic manufacturers enter the market, the price of a generic pharmaceutical product typically falls as manufacturers compete on price to capture market share. Even if we reduce the prices we charge our customers, the prices consumers pay for those drugs may not be similarly reduced. Additionally, consolidation among wholesalers and retailers and the formation of GPOs has caused increased price competition in the generic pharmaceutical market.

Healthcare Reform

Pricing and reimbursement for our products depend in part on government regulation. In the U.S., there have recently been multiple federal and state proposals, laws and actions related to the pricing of pharmaceuticals and other changes to the healthcare system, including the enactment of the Inflation Reduction Act (“IRA”). The IRA will permit the Centers for Medicare and Medicaid Services (“CMS”) to negotiate maximum fair prices on up to 60 drugs by 2029, starting with 10 drugs in 2026. The drugs must be approved by the FDA for at least seven years (small molecule drugs) or at least eleven years (biologics). The federal government must consider manufacturer-submitted data including R&D costs, production and distribution costs, market data, and revenue and sales volume data. The government must also consider evidence regarding alternative treatments, including whether a drug represents a therapeutic advance compared to existing therapies and the comparative effectiveness of the drug and therapeutic alternatives, including effects on specific populations (e.g., children, elderly, terminally ill). The IRA also requires Medicare Part D plans to limit beneficiaries’ cost-sharing for insulin products, but does not include an insulin cost-sharing cap for commercial plans.

Any significant efforts at the federal or state level to reform the healthcare system by changing the way healthcare is provided or funded or by more directly imposing controls on drug pricing, government reimbursement, and access to products could have a material impact on us. Efforts by states and the federal government to regulate prices or payment for pharmaceutical products, including proposed actions to facilitate drug importation, limit reimbursement to lower international reference prices, and require deep discounts, could adversely affect our business if implemented. States may also advance drug-pricing initiatives with a focus on affordability review boards, financial penalties related to pricing practices, manufacturer pricing and reporting requirements, as well as regulation of prescription drug assistance or copay accumulator programs in the commercial market. In addition, changes to the Medicaid program or the federal 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities, could have a material impact on our business. It is unclear what, if any, legislative proposals may be adopted or how governmental bodies and private payors will respond to such healthcare reform. As such, we cannot predict the impact of potential legislation on our business and cannot guarantee that such legislation will not have a material adverse effect on our financial condition and results of operations.

Pharmaceutical Pedigree Laws

Various pharmaceutical pedigree laws, such as the Drug Supply Chain Security Act enacted in 2014, require the tracking of all transactions involving prescription pharmaceutical products from the manufacturer to the dispensary (e.g., pharmacy). Compliance with such laws requires extensive tracking systems and tight coordination with customers and manufacturers. While we believe that we comply with these laws and we intend to do so in the future, such legislation and government enforcement regarding these laws is constantly evolving. Failure to comply could result in fines, penalties or loss of business that could have a material adverse effect on our financial results.

Sales and Marketing Regulations

Our marketing practices are subject to state laws, as well as federal laws, such as the Anti-Kickback Statute and False Claims Act, intended to prevent fraud and abuse in the healthcare industry. The Anti-Kickback Statute generally prohibits corruptly soliciting, offering, receiving, or paying anything of value to generate business. The False Claims Act generally prohibits anyone from knowingly and willingly presenting, or causing to be presented, any claims for payment for goods or services, including to government payers, such as Medicare and Medicaid, that are false or fraudulent and generally treat claims generated through kickbacks as false or fraudulent. The federal government and states also regulate sales and marketing activities and financial interactions between manufacturers and healthcare providers, requiring disclosure to government authorities and the public of such interactions, disclosure of transfers of value from pharmaceutical companies to healthcare

providers and healthcare organizations, such as academic teaching hospitals, and the adoption of compliance standards or programs. State attorneys general have also taken action to regulate the marketing of prescription drugs under state consumer protection and false advertising laws.

Federal Regulation of Patent Litigation Settlements and Authorized Generic Arrangements

Pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003, generic and brand pharmaceutical companies must file with the DOJ and FTC certain agreements entered into between other brand and/or generic pharmaceutical companies in regards to the settlement of patent litigation and/or the manufacture and marketing of generic versions of branded pharmaceutical products. This requirement impacts the ways in which generic pharmaceutical companies resolve intellectual property litigation and may result in an increase in private-party litigation against pharmaceutical companies and/or additional investigations by the FTC or other governmental organizations.

Other Regulatory Requirements

We are subject to the Maximum Allowable Cost Regulations, which limit reimbursements for certain generic prescription drugs under Medicare, Medicaid, and other programs to the lowest price at which these drugs are generally available. In many instances, only generic prescription drugs fall within the regulations' limits. Generally, the pricing and promotion of, method of reimbursement and fixing of reimbursement levels for, and the reporting to federal and state agencies relating to drug products is under active review by federal, state and local governmental entities, as well as by private third-party reimbursors and individuals under whistleblower statutes. At present, the DOJ and U.S. Attorneys Offices and State Attorneys General have initiated investigations, reviews, and litigation into industry-wide pharmaceutical pricing and promotional practices, and whistleblowers have filed qui tam suits. We cannot predict the results of those reviews, investigations, and litigation, or their impact on our business. For further detail, see *Note 21. Commitments and Contingencies* to our consolidated financial statements.

Virtually every state, as well as the District of Columbia, has enacted legislation permitting the substitution of equivalent generic prescription drugs for brand-name drugs where authorized or not prohibited by the prescribing physician, and some states mandate generic substitution in Medicaid programs.

In addition, numerous state and federal requirements exist for a variety of controlled substances, such as narcotics, that may be part of our product formulations. We must meet the requirements of controlled substances laws, such as the Controlled Substances Act, as amended, DEA regulations for certain of our products and activities, and related state requirements. These laws and regulations relate to the manufacture, shipment, storage, security, inventory, recordkeeping, distribution, sale, dispensing, and use of controlled substances. The DEA and other regulatory agencies limit the availability of the controlled substances used in certain of our current products and products in development. We must annually apply to the DEA and similar governmental and regulatory authorities for procurement quotas in order to obtain these substances. The DEA has authority similar to the FDA's and may also pursue monetary penalties, administrative penalties such as revocation of a registration to manufacture controlled substances and criminal penalties for controlled substances violations.

Other federal and state regulatory agencies have far reaching authority. For example, the State of California requires that any manufacturer, wholesaler, retailer or other entity in California that sells, transfers, or otherwise furnishes certain so called precursor substances must have a permit issued by the California Department of Justice, Bureau of Narcotic Enforcement. The substances covered by this requirement include ephedrine, pseudoephedrine, norpseudoephedrine, and phenylpropanolamine, among others. The Bureau has authority to issue, suspend and revoke precursor permits, and a permit may be denied, revoked or suspended for various reasons, including (i) failure to maintain effective controls against diversion of precursors to unauthorized persons or entities; (ii) failure to comply with the Health and Safety Code provisions relating to precursor substances, or any regulations adopted thereunder; (iii) commission of any act which would demonstrate actual or potential unfitness to hold a permit in light of the public safety and welfare, which act is substantially related to the qualifications, functions or duties of the permit holder; or (iv) if any individual owner, manager, agent, representative or employee of the permit applicant/permit holder willfully violates any federal, state or local criminal statute, rule, or ordinance relating to the manufacture, maintenance, disposal, sale, transfer or furnishing of any precursor substances.

Privacy, Security and Data Standards Regulations

Numerous federal, state, and foreign laws and regulations govern the creation, collection, dissemination, receipt, maintenance, protection, use, transmission, disclosure, privacy, confidentiality, security, availability, integrity, creation, processing, and disposal (collectively, "Processing") of protected health information ("PHI") and other personal, sensitive, regulated or

confidential data, including personally identifiable information (“PII”). Many of our activities involve the Processing of PHI and PII.

On the federal level we are subject to a number of sector specific regulations. The federal Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, the 21st Century Cures Act, Public Law 116-321, and the regulations that implement these laws (collectively “HIPAA”) impose requirements on covered entities and business associates that address the privacy and security of PHI. In the conduct of our business, we may be either a covered entity or business associate, and we may also be held liable for HIPAA violations by our vendors that are business associates. HIPAA imposes contracting requirements, requires breach notifications, and establishes rules that standardize the format and content of certain electronic transactions, including eligibility and claims. Violations of HIPAA may result in enforcement actions, civil and criminal penalties, and settlement, resolution, and monitoring agreements. Further, state attorneys general may bring civil actions seeking either injunctions or damages in response to violations of HIPAA that threaten the privacy of state residents and may negotiate settlements for related cases on behalf of their respective residents. There can be no assurance that we will not be the subject of an investigation, audit or compliance review regarding our compliance with HIPAA. While HIPAA does not create a private right of action, its standards have been used as a basis for the duty of care in state civil suits, such as those for negligence or recklessness in the handling, misuse or breach of PHI. HIPAA does not preempt more stringent state health privacy laws and regulations, which may protect the health information of certain individuals, such as minors, and certain types of sensitive health information, such as transgender care, HIV/AIDS status, reproductive health information, genetic information, and mental and behavioral health.

Additionally, under Section 5 of the Federal Trade Commission Act (“FTC Act”), the FTC has jurisdiction over certain privacy and security practices that are deemed unfair and deceptive acts and practices in or affecting commerce. The FTC has charged companies with violating this act based on failures to appropriately and transparently safeguard personal information, respect consumers’ privacy rights, based on disclosures of health and personal information to third parties, the failure to limit third-party use of health information, the failure to implement policies and procedures to prevent the improper or unauthorized disclosure of health information, and the failure to provide notice and obtain consent before the use and disclosure of health information for advertising. In addition to the FTC Act, the FTC also enforces other federal laws and regulations relating to consumers’ privacy and security.

The SEC has proposed additional cybersecurity disclosure obligations on reporting companies, with final rulemaking expected this year.

Over the past several years, the federal government has increasingly focused on the cybersecurity requirements applicable to government contractors, including enhanced guidance and regulation. These include compliance with the Privacy Act of 1974, the Defense Federal Acquisition Regulation Supplement cybersecurity requirements, the Cybersecurity Maturity Model Certification (going into effect over the next four years and based on NIST standards), the Federal Information Security Modernization Act, and the White House’s 2021 Executive Order on Improving the Nation’s Cybersecurity.

State and local authorities are increasingly focused on protecting individuals from identity theft and a number of states have adopted comprehensive data security laws and regulations requiring, among other things, certain minimum data security standards and security breach notifications that may apply to us in certain circumstances, as well as certain limitations on access to and use of PII. These laws and regulations include state general data breach laws, which exist in all fifty states and protect PII generally. Many states also have their own sector-specific laws regarding the Processing of PII which may apply to us as well.

In the past few years, five states have adopted their own comprehensive consumer privacy statutes and many more states are considering doing so. Generally, these statutes exempt data and/or entities regulated by HIPAA but are, in varying respects, applicable to other data we collect, such as PII provided by website visitors, and in California, employees and business partners. Additionally, we anticipate federal and state legislators and regulators will continue to enact legislation related to privacy and cybersecurity, including with respect to ransomware incidents.

In addition, international laws, rules and regulations governing the use and disclosure of PII can be more stringent than those in the United States, and they vary from jurisdiction to jurisdiction. The European Union’s General Data Protection Regulation (“GDPR”), which became effective May 2018, enhanced or created obligations regarding the handling of PII relating to European residents (such as regarding notices, data protection impact assessments and individual rights) and provides for greater penalties for noncompliance than the previous European Directive or laws. Under GDPR, fines of up to 20 million Euros or up to 4% of the annual global revenues, whichever is greater, can be imposed for violations. In addition, many countries outside of Europe where we conduct business have implemented or may implement data protection laws and regulations, some of which include requirements modeled after those in the GDPR. Some non-U.S. jurisdictions are also

instituting data residency regulations requiring that data be maintained within the respective jurisdiction or otherwise restricting transfer of personal data across borders unless specified regulatory requirements are met.

Data privacy laws and regulations are constantly evolving and can be subject to significant change or interpretive application. Varying jurisdictional requirements could increase the costs and complexity of our compliance efforts and violations of applicable data privacy laws can result in significant penalties. Any failure, or perceived failure, by us to comply with applicable data protection laws could result in proceedings or actions against us by governmental entities or others, subject us to significant fines, penalties, judgments and negative publicity, require us to change our business practices, increase the costs and complexity of compliance and adversely affect our business.

Environmental Laws

We are subject to comprehensive federal, state and local environmental laws and regulations that govern, among other things, air polluting emissions, waste water discharges, solid and hazardous waste disposal, and the remediation of contamination associated with current or past generation handling and disposal activities. We are subject periodically to environmental compliance reviews by various environmental regulatory agencies. While it is impossible to predict accurately the future costs associated with environmental compliance and potential remediation activities, compliance with environmental laws is not expected to require significant capital expenditures and has not had, and is not expected to have, a material adverse effect on our business, operations or financial condition.

Patents, Trademarks and Licenses

We own or license a number of patents in the U.S. and other countries covering certain products and product candidates and have also developed brand names and trademarks for other products and product candidates.

Generally, the branded pharmaceutical business relies upon patent protection to ensure market exclusivity for the life of the patent. We consider the overall protection of our patents, trademarks and license rights to be of material value and act to protect these rights from infringement. However, our business is not dependent upon any single patent, trademark or license.

In the branded pharmaceutical industry, the majority of an innovative product's commercial value is usually realized during the period in which the product has market exclusivity. In the U.S. and some other countries, when market exclusivity expires and generic or biosimilar versions of a product are approved and marketed, there can often be very substantial and rapid declines in the branded product's sales, more so for introduction of a generic product as compared to a biosimilar. The rate of this decline also varies by country and by therapeutic category; however, following patent expiration, branded products often continue to have market viability based upon the goodwill of the product name, which typically benefits from trademark protection.

An innovator product's market exclusivity is generally determined by two forms of intellectual property: patent rights held by the innovator company and any regulatory forms of exclusivity to which the innovator is entitled.

Patents are a key determinant of market exclusivity for most branded pharmaceuticals. Patents provide the innovator with the right to exclude others from practicing an invention related to the medicine. Patents may cover, among other things, the active ingredient(s), various uses of a drug product, pharmaceutical formulations, drug delivery mechanisms and processes for (or intermediates useful in) the manufacture of products. Protection for individual products extends for varying periods in accordance with the expiration dates of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent, its scope of coverage and the availability of meaningful legal remedies in the country.

Market exclusivity is also sometimes influenced by regulatory exclusivity rights. Many developed countries provide certain non-patent incentives for the development of medicines. For example, the U.S., the European Union and Japan each provide for a minimum period of time after the approval of a new drug during which the regulatory agency may not rely upon the innovator's data to approve a competitor's generic copy or biosimilar. Regulatory exclusivity rights are also available in certain markets as incentives for research on new indications, on orphan drugs and on medicines useful in treating pediatric patients. Regulatory exclusivity rights are independent of any patent rights and can be particularly important when a drug lacks broad patent protection. However, most regulatory forms of exclusivity do not prevent a competitor from gaining regulatory approval prior to the expiration of regulatory data exclusivity on the basis of the competitor's own safety and efficacy data on its drug, even when that drug is identical to that marketed by the innovator.

We estimate the likely market exclusivity period for each of our branded products on a case-by-case basis. It is not possible to predict the length of market exclusivity for any of our branded products with certainty because of the complex interaction

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between patent and regulatory forms of exclusivity, and inherent uncertainties concerning patent litigation. We cannot assure that a particular product will enjoy market exclusivity for the full period of time that we currently estimate or that the exclusivity will be limited to the estimate.

In addition to patents and regulatory forms of exclusivity, we also market products with trademarks. Trademarks have no effect on market exclusivity for a product, but are considered to have marketing value. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registration is for fixed terms and may be renewed indefinitely.

Seasonality

Consistent with the U.S. pharmaceutical industry trends, the first quarter of each year, excluding the impact of the COVID-19 pandemic, is typically our lowest revenue quarter in the year. Certain products within our portfolio are specifically affected by seasonality. For example, sales of oseltamivir correlate with flu seasonality and sales of Adrenaclick® (epinephrine injection, USP auto-injector) correlate with allergy seasonality. The seasonal impact of these particular products may affect a quarterly comparison within any fiscal year.

Human Capital

We lead the Company from a people-first mindset, recognizing that it is our people who generate ideas, operate machinery and deliver success. Since our founding in 2002, we have focused on recruiting, empowering, incentivizing and rewarding employees who are passionately engaged in our mission to “make healthy possible”. In 2022, we elevated our steadfast commitment to these areas in the various ways highlighted below.

Workforce Demographics and Commitment to Diversity and Inclusion

As of December 31, 2022, we had approximately 7,600 employees (“Amneal Employees”), excluding approximately 150 employees in our AvKARE segment. Of the Amneal Employees, approximately 2,400 employees were in the U.S. and approximately 5,200 employees were located outside of the U.S., primarily in India and Ireland. As a global employer, we hired approximately 2,000 Amneal Employees in 2022, and global turnover of those employees was approximately 19%. We regularly monitor our turnover rate and continuously evolve our human capital management strategies to meet Amneal’s needs while also considering the dynamic labor market and increased competition for talent over the past year.

Diversity, Equity, Inclusion and Belonging (“DEIB”)

Diversity is essential to our success and is an important element of our human capital management strategy. It starts at the top, with the recent expansion of our Board of Directors diversity via the nomination of an additional, highly qualified, diverse Director in 2022. Further, six out of ten of our executives identified as diverse by race, ethnicity, or gender. More broadly, approximately 72% of our U.S. workforce of Amneal Employees identified as diverse by race or ethnicity and women represented 18% of our global workforce of Amneal Employees. In the U.S., women represented 40% of our workforce and held 31% of leadership roles at the level of Director and above for Amneal Employees. In 2022, we deepened our commitment to equity with the launch of DEIB training to approximately 100 global people leaders and introduced Amneal Women - an Employee Resource Group U.S. pilot program supporting the development of women within the Company.

Programs for Amneal Employees

Workplace Safety and Employee Well-being

To ensure the health and safety of our employees and patients, we maintained a strategic task force of top leaders to guide our ongoing COVID-19 response. In 2022, we continued to prioritize employee health, safety, and well-being through the appropriate updates to our health and safety protocols aligned with the Centers for Disease Control and Prevention and World Health Organization guidelines, employee benefits, and continued with hybrid work arrangements where possible.

The Company’s focus on employee wellness was further amplified in 2022 with the continued expansion of our AmWell Program, powered by Virgin Pulse in the U.S., encompassing free access to four applications offering digital financial wellness, nutrition, fitness, and mental well-being content along with an incentive program to inspire wellness engagement.

Culture

Our “Rise, Lead, Succeed” culture is central to uniting our global team and serves as a dynamic framework for driving, celebrating and rewarding individual and team performance. Every day, we foster an environment that encourages colleagues to bring their best selves to work and be actively engaged, offer new ideas, and deliver real results. Permeating our culture and day-to-day business operations is a steadfast commitment to ethics and compliance, which is guided by our Code of Conduct and Supplier Code of Conduct, both championed by our executive management team and employees across the Company.

Total Rewards

Our Total Rewards program includes industry competitive benefit, compensation and recognition offerings designed to attract and retain the best and brightest talent. At the heart of our Total Rewards commitment is a broad, flexible and competitive benefits program that enables employees to choose the plans and coverage that meet their personal needs.

These robust programs, which vary by country, include basic and supplemental health and insurance benefits, health savings and flexible spending accounts, access to a personal health advocate, paid parental leave for birth, adoption or foster placement, family leave, employee assistance programs, travel assistance, tuition reimbursement assistance and retirement savings plans. In addition to our health, wellness and financial benefits, we offer a remote work policy that enables eligible U.S.-based employees the flexibility of a hybrid work schedule of three days onsite and two days remote.

We strongly believe that encouragement and recognition of employee achievement is pivotal to inspiring an engaged and high-performing culture. In 2022, over 3,500 colleagues were recognized by their peers via Amneal Applause, our company’s online and on-the-spot rewards and recognition program. We also continued our global CEO Awards program, which recognized a select group of employees for rising well above and beyond their regular job duties to advance Amneal’s success. Over 75 nominations were submitted, and 12 winners were selected by the executive leadership team and selection committee.

Our compensation program includes competitive base salaries, annual cash performance-based incentives and each of equity-based long-term incentive awards and cash-based long term incentive awards for eligible employees. Together, these programs play a key role in attracting and retaining key talent as well as rewarding performance and achievement.

Talent Development and Engagement

We groom employees to continuously elevate their careers by offering opportunities to expand skills through robust experiences, organizational mentoring and a continuously evolving learning and development platform. In 2022, we continued the rollout of the Amneal Leadership Lab program by internalizing instruction via our growing Leaders as Teachers network and introducing 80 additional senior and mid-level leaders to content that bolsters social awareness and better prepares them to navigate the modern challenges and opportunities of our time. The Amneal Leadership Lab curricula included sessions on the following topics: growth mindset, psychological safety, building trust, effective decisions, winning collaborations, communicating with presence, direct conversation and feedback and leading and embracing change. We recognize that taking Amneal to the next level can be accelerated by upskilling all employees to think and act as leaders and requires investment in our people. To help cascade Amneal Leadership Lab principles to all colleagues, we offer access to LinkedIn Learning which also hosts Amneal’s growing library of custom-curated learning paths supporting individual and organization-wide leadership growth.

Employee Engagement

In 2022, we launched Amneal Listens, an employee listening strategy powered by a reputable third-party tool focused on strengthening engagement. We released our first employee engagement pulse survey to approximately 3,500 of our global employee base. We also leveraged the survey tool to poll our top 200 leaders to assess the strength of our human capital strategies and identify areas for improvement. Going forward, we will continue to expand our Amneal Listens strategy via an annual employee engagement survey as well as various strategically focused ad hoc surveys throughout the year.

Driving Impact through Corporate Responsibility

Prioritizing corporate responsibility and environmental sustainability is essential to keeping Amneal resilient and able to meet future challenges and opportunities effectively. These commitments have been embedded in Amneal’s mission to make healthy possible by delivering affordable essential medicines since its founding. Twenty years later, we remain focused on elevating responsibility, prioritizing patients, and considering our impacts on the environment, as well as the environment’s impact on our physical assets, in our decision making.

In 2021, we built a formal environmental, social and governance (“ESG”) framework and throughout 2022 that framework was elevated through partnership with leaders and teams across the Company, ranging from Employee Health and Safety and Corporate Compliance to Human Resources. Our ESG function continues to guide our environmental, social and governance-related programs as well as ongoing reporting, including the publishing of our annual Corporate Social Responsibility report. Among other highlights, the report details our philanthropic partnerships and the many ways we encourage employees to actively support the vitality of our communities through company-sponsored social and environmental impact opportunities including advocacy, employee volunteerism, fundraising and product donations. Key company commitments have included product donations to longstanding partners including AmeriCares, Dispensary of Hope, and Kingsway Charities.

In 2022, Amneal became an AmeriCares Emergency Response Partner to help provide the reliable funding base necessary for AmeriCares to respond to disaster events around the globe. To celebrate 20 years of supporting our communities, we also hosted our first global employee give-back day offering hygiene and nutrition kit-building activities for employees in India, Ireland and the U.S. Thanks to our employees’ efforts, we were able to assist nearly 7,000 neighbors in need.

These are just some of our many human capital initiatives. Every year, we aim to review and enhance these and other programs to ensure that we are improving, staying competitive and putting our people at the center of our success.

Further information on our Responsibility program is available at <https://www.amneal.com/about/responsibility>. The information on our website is not, and will not be deemed, a part of this Annual Report on Form 10-K or incorporated into any other filings we make with the SEC.

For discussion of the risks relating to the attraction and retention of management and executive management employees, refer to *Part I. Item 1A. Risk Factors*.

Available Information

Our main corporate website address is www.amneal.com. Copies of our Quarterly Reports on Form 10-Q, Annual Reports on Form 10-K, Current Reports on Form 8-K, proxy statements and any amendments to such reports filed with or furnished to the U.S. Securities and Exchange Commission (“SEC”), are available free of charge on our website as soon as reasonably practicable after having been filed with or furnished to the SEC. All SEC filings are also available at the SEC’s website at www.sec.gov. In addition, the written charters of our Audit Committee, Compensation Committee, Nominating and Governance Committee, and Conflicts Committee of the Board of Directors and our Code of Business Conduct, Corporate Governance Guidelines and other corporate governance materials are available on our website. We may use our website as a distribution channel of material company information. Financial and other important information regarding the Company is routinely posted on and accessible through the Company’s website at <https://investors.amneal.com>. In addition, you may automatically receive email alerts and other information about the Company when you enroll your email address by visiting <https://investors.amneal.com/investor-resources/email-alerts/default.aspx>. The information on our website is not, and will not be deemed, a part of this Report or incorporated into any other filings we make with the SEC.

Item 1A. Risk Factors

An investment in our common stock involves a high degree of risk. In deciding whether to invest in our common stock, you should consider carefully the following risk factors, as well as the other information included in this Annual Report on Form 10-K. The materialization of any of these risks could have a material adverse effect on our business, results of operations and financial condition.

Operational and Competitive Risks

If we are unable to successfully develop or commercialize new products, our operating results will suffer.

Developing and commercializing a new product is time consuming, costly and subject to numerous factors that may delay or prevent such development and commercialization. Our future results of operations will depend to a significant extent upon our ability to successfully commercialize new products in a timely manner. We face several challenges when developing and commercializing new products, including:

- our ability to develop products in a timely and cost-efficient manner and in compliance with regulatory requirements, including delays associated with the FDA listing and approval process and our ability to obtain required regulatory approvals in a timely manner, or at all, and maintain such approvals if obtained;
- the success of our clinical testing process to ensure that new products are safe and effective or bioequivalent to the reference listed drug;

- the risk that legal action may be brought against our generic drug products by our branded drug product competitors, including patent infringement claims among others;
- the availability, on commercially reasonable terms, of raw materials, including APIs and other key ingredients necessary to the development of our drug products; and
- Our ability to scale-up manufacturing methods to successfully manufacture commercial quantities of drug product in compliance with regulatory requirements.

As a result of these and other difficulties, our products in development may or may not receive necessary regulatory approvals on a timely basis or at all, which may result in unsuccessful development or commercialization of new products. Separately, product licensing involves inherent risks including uncertainties due to matters that may affect the achievement of milestones, as well as the possibility of contractual disagreements with regard to terms such as license scope or termination rights. If any of our products, when acquired or developed and approved, cannot be successfully or timely commercialized, our operating results could be adversely affected. We cannot guarantee that any investment we make in developing, marketing or licensing products will be recouped, even if we are successful in commercializing those products.

We face intense competition in the pharmaceutical industry from both brand and generic drug product companies, which could significantly limit our growth and materially adversely affect our financial results.

The pharmaceutical industry is highly competitive. The principal competitive factors in the pharmaceutical market include:

- introduction of other generic drug manufacturers' products in direct competition with our generic drug products;
- introduction of authorized generic drug products in direct competition with our products, particularly during exclusivity periods;
- the ability of generic drug product competitors to quickly enter the market after the expiration of patents or exclusivity periods, diminishing the amount and duration of significant profits;
- consolidation among distribution outlets through mergers and acquisitions and the formation of buying groups;
- the willingness of generic drug customers, including wholesale and retail customers, to switch among products of different pharmaceutical manufacturers;
- pricing pressures by competitors and customers, even if similar price savings are not passed on to consumers;
- a company's reputation as a manufacturer and distributor of quality products;
- a company's level of service (including maintaining sufficient inventory levels for timely deliveries);
- product appearance and labeling; and
- a company's breadth of product offerings.

Many of our competitors have longer operating histories and greater financial, R&D, marketing and other resources than we do. Consequently, some of our competitors may be able to develop products and/or processes competitive with, or superior to, our products and/or processes. Furthermore, we may not be able to (i) differentiate our products from those of our competitors, (ii) successfully develop or introduce new products, on a timely basis or at all, that are less costly than those of our competitors, or (iii) offer customers payment and other commercial terms as favorable as those offered by our competitors. The markets in which we compete and intend to compete are undergoing, and are expected to continue to undergo, rapid and significant change. We expect competition to intensify as technology advances and consolidation continues. New developments by other manufacturers and distributors could render our products uncompetitive or obsolete.

We believe our principal competitors in the U.S. generic/biosimilar pharmaceutical products market, where we primarily compete, are Teva Pharmaceutical Industries Ltd., Viatris Inc., Endo International plc, Sandoz International GmbH, Pfizer Inc., Fresenius Kabi KGaA, Sun Pharmaceutical Industries Ltd., Lupin Pharmaceuticals, Inc., Hikma Pharmaceuticals PLC, Dr. Reddy's Laboratories Ltd., Coherus Biosciences, Inc., Amphastar Pharmaceuticals, Inc., and Aurobindo Pharma Limited. Our principal competitors in the specialty pharmaceutical products market include Supernus Pharmaceuticals, Inc., Jazz Pharmaceuticals PLC, and Alkermes PLC. Our competitors in the AvKARE segment are other wholesalers, including Cardinal Health, Inc., AmerisourceBergen Corporation, and Golden State Medical Supply.

The products produced by these companies, among others, collectively compete with the majority of our products. We also face price competition generally as other generic manufacturers enter the market. Any such price competition may be especially pronounced where our competitors source their products from jurisdictions where production costs may be lower (sometimes significantly) than our production costs, especially lower-cost foreign jurisdictions. Any of these factors could result in reductions in our sales prices and gross margin. This price competition has led to an increase in demands for downward price

adjustments by generic pharmaceutical distributors. Our principal strategy in addressing our competition is to offer customers a consistent supply of our generic drug products, as well as to pursue product opportunities with the potential for limited competition, such as high-barrier-to-entry FTF or FTM products. We cannot provide assurance, however, that this strategy will enable us to compete successfully in the generic drug product industry or that we will be able to develop and implement any new or additional viable strategies.

Competition in the generic drug industry has also increased due to the proliferation of authorized generic pharmaceutical products. Authorized generic drug products are generic drug products that are introduced by brand companies, either directly or through third parties, under the brand's NDA approval. Authorized generics do not face any regulatory barriers to introduction and are not prohibited from sale during the 180-day marketing exclusivity period granted to the FTF ANDA applicant. The sale of authorized generics adversely impacts the market share of a generic drug product that has been granted 180 days of marketing exclusivity. This is a significant source of competition for us, because an authorized generic drug product can materially decrease the profits that we could receive as an otherwise exclusive marketer of a generic drug product. Such actions have the effect of reducing the potential market share and profitability of our generic drug products and may inhibit us from developing and introducing generic pharmaceutical drug products corresponding to certain branded drugs.

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

The Hatch-Waxman amendments to the FDCA 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 branded drug (commonly referred to as a "Paragraph IV certification"). "First filers" are often able to price the applicable generic drug to yield relatively high gross margins during this 180-day marketing exclusivity period.

With respect to our generic products, ANDAs containing Paragraph IV certifications generally become the subject of patent litigation that can be both lengthy and costly. There is no certainty that we will prevail in any such litigation, that we will be the first to file and thus 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. Even where we are awarded marketing exclusivity, we may be required to share our exclusivity period with other first filers. In addition, branded drug product companies often authorize a generic version of the corresponding branded drug product to be sold during any period of marketing exclusivity that is awarded, which reduces gross margins during the marketing exclusivity period. Branded drug product companies may also reduce the price of their branded drug product to compete directly with generic drug products entering the market, which would similarly have the effect of reducing gross margins. Furthermore, timely commencement of the 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 decision is adverse to the ANDA applicant, the ANDA approval will be delayed until the challenged patent expires, and the applicant forfeits the 180-day marketing exclusivity.

Our future profitability depends, to a significant extent, upon our ability to introduce, on a timely basis, new generic drug products that are either the first-to-market (or among the first-to-market) or that otherwise can gain significant market share. The timeliness of our product introductions is dependent upon, among other things, the timing of regulatory approval of our products, which to a large extent is outside of our control, as well as the timing of the introduction of competing products. As additional distributors introduce comparable generic pharmaceutical products, price competition intensifies, market access narrows, and product sales prices and gross margins decline, often significantly and rapidly, regardless of whether consumers ultimately pay less for the drug. 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 in a timely and effective manner or, alternatively, to enter into contractual relationships with other parties that have obtained marketing exclusivity. We cannot provide any assurance that we will 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.

With respect to our branded products, generic equivalents for branded pharmaceutical products are typically sold at lower prices than the branded products. The regulatory approval process in the U.S. and European Union exempts generic products from costly and time-consuming clinical trials to demonstrate their safety and efficacy and relies instead on the safety and efficacy of prior products. After the introduction of a competing generic product, a significant percentage of the prescriptions previously written for the branded product are often written for the generic version. In addition, legislation enacted in most U.S. states allows, or in some instances mandates, a pharmacist to dispense an available generic equivalent when filling a prescription for a branded product, in the absence of specific instructions from the prescribing physician. Pursuant to the provisions of the Hatch-

Waxman Act, manufacturers of branded products often bring lawsuits to enforce their patent rights against generic products released prior to the expiration of branded products' patents, but it is possible for generic manufacturers to offer generic products while such litigation is pending. As a result, branded products typically experience a significant loss in revenues following the introduction of a competing generic product, even if subject to an existing patent. Our branded pharmaceutical products are or may become subject to competition from generic equivalents because there is no proprietary protection for some of the branded pharmaceutical products we sell, because our patent protection expired or because our patent protection is not sufficiently broad or enforceable.

If we are unable to execute acquisitions or other strategic transactions, or manage our growth therefrom, it could have a material adverse effect on our business.

We may seek to expand our business through complementary or strategic acquisitions of other businesses, products or assets, or through joint ventures, strategic agreements or other arrangements. Any such acquisitions, joint ventures or other business combinations may involve significant integration challenges, operational complexities and time consumption, adversely affect liquidity and require substantial resources and effort. It may also disrupt our ongoing businesses, which may adversely affect our relationships with customers, employees, regulators and others with whom we conduct business or other dealings. Further, if we are unable to realize synergies or other benefits expected to result from any acquisitions, joint ventures or other business combinations, or to generate additional revenue to offset any unanticipated inability to realize these expected synergies or benefits, our growth and ability to compete may be impaired, which would require us to focus additional resources on the integration of operations rather than other profitable areas of our business, and may otherwise cause a material adverse effect on our business, results of operations and financial condition. Acquisitions may also have hidden costs, including unforeseen pre-acquisition liabilities or the impairment of customer relationships or certain acquired assets such as goodwill. We may also incur costs and inefficiencies to the extent an acquisition expands the industries, markets or geographies in which we operate due to our limited exposure to and experience in a given industry, market or region. Finally, acquisitions can also involve litigation and/or post-transaction disputes, including with the counterparty regarding purchase price or other working capital adjustment or liabilities for which we believe we were indemnified under the relevant transaction agreements, among other matters.

As our competitors introduce their own generic equivalents of our generic drug products, our revenues and gross margin from such products generally decline, often rapidly.

Revenues and gross margin derived from generic pharmaceutical products often follow a pattern based on regulatory and competitive factors that we believe are unique to the generic pharmaceutical industry. As the patent(s) for a brand name product or the statutory marketing exclusivity period (if any) expires, the first generic manufacturer to receive regulatory approval for a generic equivalent of the product is often able to capture a substantial share of the market. However, as other generic manufacturers receive regulatory approvals for their own generic versions, that market share, and the price of that product, will typically decline depending on several factors, including the number of competitors, the price of the branded product and the pricing strategy of the new competitors. During the year ended December 31, 2022, we experienced significant competition with many of our generic products, and as a result, our revenue and gross margin from such products declined significantly. We cannot provide assurance that we will be able to continue to develop such products or that the number of our competitors for any given product will not increase to such an extent that we may stop marketing a generic drug product for which we previously obtained approval, which may have a material adverse impact on our revenues and gross margin.

The illegal distribution and sale by third parties of counterfeit versions of our products or of stolen products could have a negative impact on our reputation and a material adverse effect on our business, results of operations and financial condition.

Third parties could illegally distribute and sell counterfeit versions of our products, which do not meet the rigorous manufacturing and testing standards that our products undergo. Counterfeit products are frequently unsafe or ineffective and can be life-threatening. Counterfeit medicines may contain harmful substances, the wrong dose of the API or no API at all. However, to distributors and users, 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. It is possible that adverse events caused by unsafe counterfeit products will mistakenly be attributed to the authentic product. In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

Public loss of confidence in the integrity of pharmaceutical products as a result of counterfeiting or theft could have a material adverse effect on our business, results of operations and financial condition.

Our business is highly dependent on market perceptions of us and the safety and quality of our products. Our business, products or product pricing could be subject to negative publicity, which could have a material adverse effect on our business, results of operations and financial condition.

Market perceptions of our business are very important to us, especially market perceptions of the safety and quality of our products. If any of our products or similar products that other companies distribute are subject to market withdrawal or recall or are proven to be, or are claimed to be, harmful to consumers, then this could have a material adverse effect on our business, results of operations and financial condition. Also, because our business is dependent on market perceptions, negative publicity associated with product quality, illness or other adverse effects resulting from, or perceived to be resulting from, our products could have a material adverse impact on our business, results of operations and financial condition.

The generic pharmaceutical industry has also in recent years been the subject of significant publicity regarding the pricing of pharmaceutical products more generally, including publicity and pressure resulting from prices charged by competitors and peer companies for new products as well as price increases by competitors and peer companies on older products that the public has deemed excessive. Even if we may have reduced the prices we charge our customers for certain products, often consumers do not see similar reductions in the prices they paid. Any downward pricing pressure on the price of certain of our products arising from social or political pressure to lower the cost of pharmaceutical products could have a material adverse impact on our business, results of operations and financial condition.

Accompanying the press and media coverage of pharmaceutical pricing practices and public complaints about the same, has been increasing U.S. federal and state legislative and enforcement interest with respect to drug pricing. For instance, the DOJ issued subpoenas to pharmaceutical companies, including to the Company, seeking information about the sales, marketing and pricing of certain generic drugs. See *Note 21. Commitments and Contingencies* for additional information on the DOJ investigation. In addition to the effects of any investigations or claims brought against us, our business, results of operations and financial condition could also be adversely affected if any such inquiries, of us or of other pharmaceutical companies or the industry more generally, were to result in legislative or regulatory proposals that limit our ability to increase the prices of our products.

A substantial portion of our total revenues is expected to be derived from sales of a limited number of products.

We expect that we will continue to derive a substantial portion of our revenue from sales of a limited number of products. For the year ended December 31, 2022, our significant product families accounted for 24% of our consolidated net revenue. The sale of our products may be significantly influenced by market conditions, as well as regulatory actions. We may experience decreases in the sale of our products in the future as a result of actions taken by our competitors, such as price reductions, or as a result of regulatory actions related to our products or to competing products, which could have a material impact on our results of operations. Actions which could be taken by our competitors, which may materially and adversely affect our business, results of operations and financial condition, may include, without limitation, pricing changes and entering or exiting the market for specific products.

Our approved products may not achieve expected levels of market acceptance.

Even if we are able to obtain regulatory approvals for our new products, the success of those products is dependent upon market acceptance. Levels of market acceptance for our new products could be affected by several factors, including:

- the availability of alternative products from our competitors;
- the prices of our products relative to those of our competitors;
- the timing of our market entry;
- the ability to market our products effectively at the retail level;
- the perception of patients and the healthcare community, including third-party payers, regarding the safety, efficacy and benefits of our drug products compared to those of competing products; and
- the acceptance of our products by government and private formularies.

Some of these factors will not be in our control, and our products may not achieve expected levels of market acceptance. Additionally, continuing and increasingly sophisticated studies of the proper utilization, safety and efficacy of pharmaceutical

products are being conducted by the industry, government agencies and others which can call into question the utilization, safety and efficacy of products currently or previously marketed by us. In some cases, studies have resulted, and may in the future result, in the discontinuance of product marketing or other risk management programs such as the need for a patient registry.

We may discontinue the manufacture and distribution of certain existing products, which may adversely impact our business, results of operations and financial condition.

We continually evaluate the performance of our products and may determine that it is in our best interest to discontinue the manufacture and distribution of certain of our products. We cannot guarantee that we have correctly forecasted, or will correctly forecast in the future, the appropriate products to discontinue or that our decision to discontinue various products is prudent if market conditions change. In addition, we cannot assure you that the discontinuance of products will reduce our operating expenses or will not cause us to incur material charges associated with such a decision. Furthermore, the discontinuance of existing products entails various risks, including, in the event that we decide to sell the discontinued product, the risk that we will not be able to find a purchaser for such products or that the purchase price obtained will not be equal to at least the book value of the net assets for such products. Other risks include managing the expectations of, and maintaining good relations with, our customers who previously purchased products from among our discontinued products, which could prevent us from selling other products to them in the future. Moreover, we may incur other significant liabilities and costs associated with our discontinuance of products, which could have a material adverse effect on our business, results of operations and financial condition.

Manufacturing or quality control problems may damage our reputation for quality production, demand costly remedial activities and negatively impact our business, results of operations and financial condition.

As a pharmaceutical company, we are subject to substantial regulation by various governmental authorities. For instance, we must comply with requirements of the FDA, DEA and other healthcare regulators with respect to the manufacture, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. We must register our facilities, whether located in the U.S. or elsewhere, with the FDA as well as regulators outside the U.S., and our products must be made in a manner consistent with cGMP, or similar standards in each territory in which we manufacture. The failure of one of our facilities, or a facility of one of our third-party suppliers, to comply with applicable laws and regulations may lead to breach of representations made to our customers or to regulatory or government action against us related to products made in that facility.

In addition, the FDA, DEA and other agencies periodically inspect our manufacturing facilities. Following an inspection, agencies have in the past issued, and may in the future issue a notice listing conditions that are believed to violate cGMP or other regulations, or a warning letter for violations of “regulatory significance” that may result in enforcement action if not promptly and adequately corrected. We remain committed to continuing to improve our quality control and manufacturing practices; however, we cannot be assured that the FDA will continue to be satisfied with our corrective actions and with our quality control and manufacturing systems and standards. Failure to comply strictly with these regulations and requirements, or our failure to remedy any deficiencies, may damage our reputation and lead to financial penalties, compliance expenditures, the recall or seizure of products, total or partial suspension of production and/or distribution, withdrawal or suspension of the applicable regulator’s review of our submissions, enforcement actions, injunctions and criminal prosecution. Further, other federal agencies, our customers and partners in our alliance, development, collaboration and other partnership agreements with respect to our products and services may take any such FDA observations or warning letters into account when considering the award of contracts or the continuation or extension of such partnership agreements. Because regulatory approval to manufacture a drug is site-specific, the delay and cost of remedial actions, or obtaining approval to manufacture at a different facility, could negatively impact our business. Any failure by us to comply with applicable laws and regulations and/or any actions by the FDA and other agencies as described above could have a material adverse effect on our business, financial position and results of operations.

The majority of our products are produced at a few locations, and a business interruption at one or more of these locations or within our supply chain could have a material adverse effect on our business, financial position and results of operations.

We produce the majority of the products that we manufacture at our manufacturing facilities in New York, New Jersey and India, as well as at certain third-party suppliers, one of which is located in Taiwan. Disruptions at these facilities or within our supply chain can occur for many reasons, including events unrelated to us or beyond our control, such as fires and other industrial accidents, floods and other severe weather events, natural disasters, environmental incidents or other catastrophes, utility and transportation infrastructure disruptions, shortages of raw materials, pandemic diseases or viral contagions such as

COVID-19, and acts of war or terrorism. Natural disasters and adverse weather conditions can be caused or exacerbated by climate change, and the spate of extreme weather events experienced during 2021 presents an alarming trend. During 2021, for example, Tropical Storm Ida brought extreme rainfall and flash flooding to New Jersey that caused damage to two of the Company's facilities, compromising the Company's inventory and equipment and resulting in significant costs to repair both facilities. Furthermore, work stoppages, whether union-organized or not, can also disrupt operations. Business interruption could also be caused by compliance failures. A significant disruption at any of these facilities or otherwise within our supply chain, even on a short-term basis, could impair our ability to produce and ship products to the market on a timely basis or at all, which could have a material adverse effect on our business, financial position and results of operations.

Our profitability depends on our major customers. If these relationships do not continue as expected, our business, condition (financial and otherwise), prospects and results of operations could materially suffer.

Our four largest customers, AmerisourceBergen Corporation, McKesson Drug Co., Cardinal Health, Inc. and CVS Health Corporation, accounted for approximately 71%, 75% and 74% of total net sales of products for the years ended December 31, 2022, 2021 and 2020, respectively. The loss of any one or more of these or any other major customer or the substantial reduction in orders from any one or more of our major customers could have a material impact on our future operating results and financial condition. In total, we currently have over 1,200 customers (including over 1,000 customers specific to our AvKARE segment), some of which are part of large purchasing groups.

We may experience declines in the sales volume and prices of our products as a result of the continuing trend of consolidation of certain customer groups, which could have a material adverse effect on our business, financial position and results of operations.

Our ability to successfully commercialize any generic or branded pharmaceutical product depends in large part upon the acceptance of the product by third parties, including pharmacies, government formularies, other retailers, physicians and patients. Therefore, our success will depend in large part on market acceptance of our products. We make a significant amount of our sales to a relatively small number of drug wholesalers and retail drug chains. These customers represent an essential part of the distribution chain of our pharmaceutical products. Drug wholesalers and retail drug chains have undergone, and are continuing to undergo, significant consolidation. This consolidation may result in these groups gaining additional purchasing leverage and, consequently, increasing the product pricing pressures facing our business. Additionally, the emergence of large buying groups representing independent retail pharmacies and other drug distributors, and the prevalence and influence of managed care organizations and similar institutions, potentially enable such groups to demand larger price discounts on our products. For example, there has been a recent trend of large wholesalers and retailer customers forming partnerships, such as the alliance between Walgreens and AmerisourceBergen Corporation, the alliance between Rite Aid and McKesson Drug Company, and the alliance between CVS Caremark and Cardinal Health. The result of these developments may have a material adverse effect on our business, financial position and results of operations.

We depend to a large extent on third-party suppliers and distributors for the raw materials for our products, particularly the chemical compounds comprising the APIs that we use to manufacture our products, as well as for certain finished goods. A prolonged interruption in the supply of such products could have a material adverse effect on our business, financial position and results of operations.

We purchase the bulk of the raw materials essential to our manufacturing business from third parties. If we experience supply interruptions or delays, or if a supplier discontinues the sale of certain products, we may have to obtain substitute materials or products, which in turn would require us to obtain amended or additional regulatory approvals, subjecting us to additional expenditures of significant time and resources. In addition, changes in our raw material suppliers could result in significant delays in production, higher raw material costs and loss of sales and customers, because regulatory authorities must generally approve raw material sources for pharmaceutical products, which may be time consuming. For example, we may need as long as 18 months to find and qualify a new sole-source supplier. If we receive less than one year's termination notice from a sole-source supplier that intends to cease supplying raw materials, it could result in disruption of our ability to produce the drug involved. Any significant supply interruption could have a material adverse effect on our business, condition (financial and otherwise), prospects and results of operations. To date, although we have experienced occasional interruptions in supplies, we have experienced no significant difficulties in obtaining raw materials. However, because the federal drug application process requires specification of raw material suppliers, if raw materials from a specified supplier were to become unavailable, FDA approval of a new supplier would be required. The amount of time required for the FDA to qualify a new supplier and confirm that our manufacturing processes meet the necessary standards could cause delays in the manufacturing and marketing of one or more of our products and could, depending on the particular product, have a material adverse effect on our results of operations and financial condition.

The time necessary to develop generic drugs may adversely affect whether, and the extent to which, we receive a return on our capital.

We generally begin our development activities for a new generic drug product several years in advance of the patent expiration date of the brand-name drug equivalent. The development process, including drug formulation, testing, and FDA review and approval, often takes three or more years. This process requires that we expend considerable capital to pursue activities that do not yield an immediate or near-term return. Also, because of the significant time necessary to develop a product, the actual market for a product at the time it is available for sale may be significantly less than the originally projected market for the product. If this were to occur, our potential return on our investment in developing the product, if approved for marketing by the FDA, would be adversely affected and we may never receive a return on our investment in the product. It is also possible for the manufacturer of the brand-name product for which we are developing a generic drug to obtain approvals from the FDA to switch the brand-name drug from the prescription market to the OTC market. If this were to occur, we would be prohibited from marketing our product other than as an OTC drug, in which case revenues could be substantially less than we anticipated.

The use of legal, regulatory and legislative strategies by brand competitors, including authorized generics and citizen's petitions, as well as the potential impact of proposed legislation, may have an adverse effect on our business.

Brand drug companies often pursue strategies that may serve to prevent or delay competition from our generic alternatives to their branded products. These strategies include, but are not limited to:

- marketing an authorized generic version of a branded product, directly or through agreement with a generic competitor, at the same time that we introduce a generic equivalent of that product;
- filing "citizen's petitions" with the FDA to thwart generic competition by causing delays of our product approvals;
- using risk evaluation and mitigation strategies ("REMS"), related distribution restrictions or other means of limiting access to their branded products, to prevent us from obtaining product samples needed to conduct bioequivalence testing required for ANDA approval, thereby delaying or preventing us from obtaining FDA approval of a generic version of such branded products;
- seeking to secure patent protection of certain "Elements to Assure Safe Use" of a REMS program, which are required medical interventions or other actions healthcare professionals need to execute prior to prescribing or dispensing the drug to the patient, in an attempt to thwart our ability to avoid infringement of the patents in question or secure approval;
- seeking to establish regulatory and legal obstacles that would make it more difficult for us to demonstrate a generic product's bioequivalence or "sameness" to the related branded product;
- initiating legislative and administrative efforts in various states to limit the substitution of generic versions of branded pharmaceutical products for the corresponding branded products;
- filing suits for patent infringement that automatically delay FDA approval of our generic products;
- introducing "next-generation" products prior to the expiration of market exclusivity for their branded product, which often materially reduces the demand for the generic product for which we may be seeking FDA approval;
- obtaining extensions of market exclusivity by conducting clinical trials of branded drugs in pediatric populations or by other methods as discussed below;
- persuading the FDA to withdraw the approval of branded drugs for which the associated patents are about to expire, thus allowing the brand company to develop and launch new patented products serving as substitutes for the withdrawn products;
- seeking to obtain new patents on drugs for which patent protection is about to expire;
- filing patent applications that are more complex and costly to challenge;
- seeking temporary restraining orders and injunctions against selling a generic equivalent of their branded product based on alleged misappropriation of trade secrets or breach of confidentiality obligations;
- seeking temporary restraining orders and injunctions against us after we have received final FDA approval for a product for which we are attempting to launch at-risk prior to resolution of related patent litigation;
- reducing the marketing of the branded product to healthcare providers, thereby reducing the branded drug's commercial exposure and market size, which in turn adversely affects the market potential of the equivalent generic product; and

- converting branded prescription drugs that are facing potential generic competition to over-the-counter products, thereby significantly impeding the growth of the generic prescription market for such drugs.

These and other strategies by brand competitors, as well as the potential impact of proposed legislation, may increase our costs associated with the introduction or marketing of our generic products, delay or prevent such introduction and/or significantly reduce the profit potential of our products.

The risks and uncertainties inherent in conducting clinical trials could delay or prevent the development and commercialization of our own branded products, which could have a material adverse effect on our business, results of operations and financial condition.

With respect to our branded products which do not qualify for the FDA's abbreviated application procedures, we must demonstrate through clinical trials that these products are safe and effective for use. We have only limited experience in conducting and supervising clinical trials. The process of completing clinical trials and preparing a NDA may take several years and requires substantial resources. Our studies and filings may not result in FDA approval to market our new drug products and, if the FDA grants approval, we cannot predict the timing of any approval. There are substantial filing fees for NDAs that are not refundable if FDA approval is not obtained.

There are a number of risks and uncertainties associated with clinical trials. The results of clinical trials may not be indicative of results that would be obtained from large scale testing. Clinical trials are often conducted with patients having advanced stages of disease and, as a result, during the course of treatment these patients can die or suffer adverse medical effects for reasons that may not be related to the pharmaceutical agents being tested, but which nevertheless affect the clinical trial results. In addition, side effects experienced by the patients may cause delay of approval or limit the profile of an approved product. Moreover, our clinical trials may not demonstrate sufficient safety and efficacy to obtain approval from the FDA or foreign regulatory authorities. The FDA or foreign regulatory authorities may not agree with our assessment of the clinical data or they may interpret it differently. Such regulatory authorities may require additional or expanded clinical trials. Even if the FDA or foreign regulatory authorities approve certain products developed by us, we cannot provide assurance that such regulatory authorities will not subject marketing of such products to certain limits on indicated use.

Developing and commercializing branded pharmaceutical products is generally more costly than developing and commercializing generic products. In order to grow and achieve success in our branded product business, we must continually identify, develop, acquire and license new products that we can ultimately market. There are many difficulties and uncertainties inherent in pharmaceutical R&D, and there is a high rate of failure inherent in new drug discovery and development. Failure can occur at any point in the process, including late in the process after substantial investment. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain necessary regulatory approvals and payer reimbursement, limited scope of approved uses, difficulty or excessive costs to manufacture, or infringement of the patents or intellectual property rights of others. Products that do reach the market may ultimately be subject to recalls or other suspensions in sales. Delays and uncertainties in the FDA approval process and the approval processes in other countries can result in delays in product launches and lost market opportunity. Because there is a high rate of failure inherent in the R&D process of new products, there is a significant risk that funds invested in R&D will not generate financial returns. We cannot be certain when or whether any of our products currently under development will be approved or launched or whether, once launched, such products will be commercially successful. We may be required to spend several years and incur substantial expense in completing certain clinical trials. The length of time, number of trial sites and patients required for clinical trials vary substantially, and we may have difficulty finding a sufficient number of sites and subjects to participate in our trials. Delays in planned clinical trials can result in increased development costs, delays in regulatory approvals and delays in product candidates reaching the market. We rely on independent third-party clinical investigators to recruit subjects and conduct clinical trials in accordance with applicable study protocols and laws and regulations. If regulatory authorities determine that we have not complied with regulations in the development of a product candidate, they may refuse to accept trial data from the site and/or not approve the product candidate, and we would not be able to market and sell that product. If we are not able to market and sell our products after significant expenditures to develop and test them, our business and results of operations could be materially and adversely affected.

Failure can occur at any time during the clinical trial process; in addition, the results from early clinical trials may not be predictive of results obtained in later and larger clinical trials, and product candidates in later clinical trials may fail to show the desired safety or efficacy despite having progressed successfully through earlier clinical testing. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even in advanced clinical trials after

showing positive results in earlier clinical trials. The completion of clinical trials for our product candidates may be delayed or halted for the reasons noted above in addition to many other reasons, including:

- delays in patient enrollment, and variability in the number and types of patients available for clinical trials;
- regulators or institutional review boards may not allow us to commence or continue a clinical trial;
- our inability, or the inability of our partners, to manufacture or obtain from third parties materials sufficient to complete our clinical trials;
- delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective clinical trial sites;
- risks associated with trial design, which may result in a failure of the trial to show statistically significant results even if the product candidate is effective;
- difficulty in maintaining contact with patients after treatment commences, resulting in incomplete data;
- poor effectiveness of product candidates during clinical trials;
- safety issues, including adverse events associated with product candidates;
- the failure of patients to complete clinical trials due to adverse side effects, dissatisfaction with the product candidate, or other reasons;
- governmental or regulatory delays or changes in regulatory requirements, policy and guidelines; and
- varying interpretation of data by the FDA or foreign regulatory authorities.

In addition, our product candidates could be subject to competition for clinical study sites and patients from other therapies under development which may delay the enrollment in or initiation of our clinical trials.

The FDA or foreign regulatory authorities may require us to conduct unanticipated additional clinical trials, which could result in additional expense and delays in bringing our product candidates to market. Any failure or delay in completing clinical trials for our product candidates would prevent or delay the commercialization of our product candidates. We cannot assure you that our expenses related to clinical trials will lead to the development of brand-name drugs that will generate revenues in the near future. Delays or failure in the development and commercialization of our own branded products could have a material adverse effect on our business, results of operations and financial condition.

We are increasingly dependent on information technology, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks.

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information. Additionally, our information technology systems are critical to our ability to store electronic and financial information and to manage a variety of business processes and activities, including manufacturing, financial, logistics, sales, marketing and administrative functions. We depend on our information technology infrastructure to communicate internally and externally with employees, customers, suppliers and others. We also use information technology networks and systems to comply with regulatory, legal and tax requirements. We have outsourced significant elements of our information technology infrastructure; as a result we manage independent vendor relationships with third-parties who are responsible for maintaining significant elements of our information technology systems and infrastructure and who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of our third-party vendors, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners or vendors. These systems are also vulnerable to attacks by malicious third parties, such as phishing or ransomware attacks, and may be susceptible to intentional or accidental physical damage to the infrastructure maintained by us or by third parties, including as a result of extreme weather events, such as fires, floods, hurricanes, or tornadoes. For example, from mid-December 2021 to late January 2022, our operations were affected by the shutdown of the UKG, Inc.'s Kronos cloud-based employee work time keeping system, which certain of our operations and corporate functions use to record employee hours worked and manage paid time off. Our human resources and operations management teams quickly implemented alternate procedures until the Kronos system was restored. We do not believe that we have incurred a material loss due to the outage. UKG, Inc. reported their forensic investigation found no evidence that Amneal employee data was compromised.

Maintaining the secrecy of confidential, proprietary, and/or trade secret information is important to our competitive business position. We continually assess these threats and make investments to increase internal protection, detection, and response capabilities, as well as ensure our third-party providers have required capabilities and controls, to address these risks. Like other

public companies, our computer systems and those of our third-party vendors and service providers are regularly subject to, and will continue to be the target of, computer viruses, malware or other malicious codes (including ransomware), unauthorized access, cyber-attacks or other computer-related penetrations, which have caused, and may continue to cause, disruptions to our operations. For example, we have been the victim of phishing attempts, some of which have been successful. While we have experienced threats to our data and systems, to date, we are not aware that we have experienced a material cyber-security breach. Over time, however, the sophistication of these threats continues to increase. The preventative actions we take to reduce the risk of cyber incidents and protect our information may be insufficient. Our efforts may not prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology or information, and/or adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, financial position, results of operations and/or cash flow.

Our future success depends on our ability to attract and retain talented employees and consultants.

Our future success depends, to a substantial degree, upon the continued service of the members of our management team. The loss of the services of members of our management team, or their inability to perform services on our behalf, could have a material adverse effect on our business, condition (financial and otherwise), prospects and results of operations. Our success also depends, to a large extent, upon the contributions of our sales, marketing, scientific and quality assurance staff. We compete with brand and generic pharmaceutical manufacturers for qualified personnel, and our competitors may offer more favorable employment opportunities than we do. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we could experience constraints that would adversely affect our ability to sell and market our products effectively, to meet the demands of our strategic partners in a timely fashion, and to support our R&D programs. In particular, our sales and marketing efforts depend on the ability to attract and retain skilled and experienced sales, marketing and quality assurance representatives. Although we believe that we have been successful in attracting and retaining skilled personnel in all areas of our business, we cannot provide assurance that we can continue to attract, train and retain such personnel. Any failure in this regard could limit the rates at which we generate sales and develop or acquire new products.

Catastrophic events, including severe weather events and global pandemics such as the COVID-19 pandemic, may negatively affect our business and results of operations.

We rely on our network infrastructure and enterprise applications, internal technology systems and websites to run our business as well as our or our third-party partners' physical facilities, such as our R&D or manufacturing premises. In addition, we rely on third-party hosted services. A disruption, infiltration or failure of these systems, facilities or third-party hosted services in the event of a hurricane, tsunami, tornado, earthquake, wildfire or flooding or other weather event, power loss, telecommunications failure, software or hardware malfunctions, pandemics (including the COVID-19 pandemic), cyber-attack, war, terrorist attack or other catastrophic event that our disaster recovery plans do not adequately address, could cause system interruptions, reputational harm, loss of intellectual property, delays in our product development, lengthy interruptions in our services, breaches of data security and loss of critical data. Any of these events could prevent us from conducting our day-to-day activities and could disrupt the operation of our supply chain. For example, on September 1, 2021, Tropical Storm Ida brought extreme rainfall and flash flooding to New Jersey that caused damage to two of our facilities. Additionally, certain of our products utilize a contract manufacturing company in Taiwan, and an escalation of tensions between China and Taiwan could impair or prevent altogether our ability to source these products. A catastrophic event that results in the destruction or disruption of any of our or our third-party partners' business centers, manufacturing facilities, data centers, R&D or manufacturing facilities, or our critical business or information technology systems could severely affect our ability to conduct normal business operations and, as a result, our future operating results could be adversely affected. The adverse effects of any such catastrophic event would be exacerbated if experienced at the same time as another unexpected and adverse event, such as the COVID-19 pandemic. Additionally, the impacts of the changing weather on water resources may result in water scarcity, limiting our ability to access sufficient high-quality water in certain locations, which may increase operational costs. Our business interruption plans may be insufficient to mitigate these, and any other, catastrophic events.

The occurrence of regional epidemics or a global pandemic, such as the COVID-19 pandemic, have had and may continue to have an adverse effect on how we and our customers are operating our businesses and our operating results. Our operations have also been and may in the future be negatively affected by a range of external factors related to the pandemic that are not

within our control, including the emergence and spread of more transmissible variants. The extent to which global pandemics, such as the COVID-19 pandemic, impact our financial condition or results of operations will depend on factors such as the duration and scope of the pandemic, as well as whether there is a material impact on the businesses or productivity of our customers, partners, employee, suppliers and other partners. To the extent that the pandemic harms our business and results of operations, many of the other risks described in this Part I, Item 1A of this report may be heightened

Our business is subject to evolving corporate governance and public disclosure regulations and expectations, including with respect to environmental, social and governance matters, that could expose us to numerous risks.

We are subject to changing rules and regulations promulgated by a number of governmental and self-regulatory organizations, including the SEC, the New York Stock Exchange and the Financial Accounting Standards Board. These rules and regulations continue to evolve in scope and complexity and many new requirements have been created in response to laws enacted by Congress, making compliance more difficult and uncertain. In addition, increasingly regulators, customers, investors, employees and other stakeholders are focusing on ESG matters and related disclosures. Concern over severe weather may also result in new or additional legal or regulatory requirements designed to mitigate the effects of severe weather on the environment. If such laws or regulations are more stringent than current legal or regulatory obligations, we may experience disruption in, or an increase in the costs associated with sourcing, manufacturing and distribution of our products, which may adversely affect our business, results of operations or financial condition.

These changing rules, regulations and stakeholder expectations have resulted in, and are likely to continue to result in, increased general and administrative expenses and increased management time and attention spent complying with or meeting such regulations and expectations. For example, developing and acting on initiatives within the scope of ESG, and collecting, measuring and reporting ESG related information and metrics can be costly, difficult and time consuming and is subject to evolving reporting standards, including the SEC's recently proposed climate-related reporting requirements, and similar proposals by other international regulatory bodies. We may also communicate certain initiatives and goals, regarding environmental matters, diversity, responsible sourcing and social investments and other ESG related matters, in our SEC filings or in other public disclosures. These initiatives and goals within the scope of ESG could be difficult and expensive to implement, the technologies needed to implement them may not be cost effective and may not advance at a sufficient pace, and we could be criticized for the accuracy, adequacy or completeness of the disclosure. Further, statements about our ESG related initiatives and goals, and progress against those goals, may be based on standards for measuring progress that are still developing, internal controls and processes that continue to evolve, and assumptions that are subject to change in the future. In addition, we could be criticized for the scope or nature of such initiatives or goals, or for any revisions to these goals. If our ESG-related data, processes and reporting are incomplete or inaccurate, or if we fail to achieve progress with respect to our goals within the scope of ESG on a timely basis, or at all, our reputation, business, financial performance and growth could be adversely affected.

Risks Relating to Our Indebtedness

We have a substantial amount of indebtedness, which could adversely affect our financial health.

We have a substantial amount of indebtedness. In order to finance the acquisition of Impax Laboratories, Inc. ("Impax"), during the year ended December 31, 2018, we borrowed an aggregate principal amount of \$2.7 billion under a senior secured term loan (the "Term Loan") due May 2025 and entered into a senior secured asset based revolving credit facility ("Revolving Credit Facility"). On June 2, 2022, we entered into a revolving credit agreement that amended the Revolving Credit Facility and reduced the principal amount of loans and letters of credit to \$350.0 million (the "New Revolving Credit Facility"). The Company may request an incremental increase in New Revolving Credit Facility commitments by up to \$150.0 million. The new credit facility matures on June 2, 2027 (the "New Credit Facility") and had \$60.0 million outstanding as of December 31, 2022. The net proceeds from the Term Loan were used to finance in part the acquisition of Impax, to pay off certain existing indebtedness of Amneal and Impax and to pay fees and expenses related to the foregoing. For additional details of our debt, refer to *Note 16. Debt*.

Our substantial level of indebtedness could have important consequences. For example, it could:

- increase our vulnerability to adverse economic and industry conditions;
- limit our ability to obtain additional financing for future working capital, capital expenditures, raw materials, strategic acquisitions and other general corporate requirements;
- expose us to unhedged interest rate fluctuations (such as recent increases in interest rates during 2022, which are expected to continue into 2023 and potentially beyond) because the interest on certain debt under the credit facilities is imposed at variable rates;

- require us to dedicate a substantial portion of our cash flow from operations to payments on our debt, thereby reducing the availability of cash flow for operations and other purposes;
- make it more difficult for us to satisfy our obligations to our lenders, resulting in possible defaults on and acceleration of such indebtedness;
- limit our ability to refinance indebtedness or increase the associated costs;
- require us to sell assets to reduce debt or influence the decision about whether to do so;
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate or prevent us from carrying out capital spending that is necessary or important to our growth strategy and efforts to improve operating margins or our business; and
- place us at a competitive disadvantage compared to any competitors that have less debt or comparable debt at more favorable interest rates and that, as a result, may be better positioned to withstand economic downturn.

In addition, our borrowings under our Term Loan bear a variable interest rate based on the London Inter-bank Offered Rate (“LIBOR”) as a benchmark for establishing the rate of interest, while borrowings under our Revolving Credit Facility bear a variable interest rate based on the Standard Overnight Financing Rate (“SOFR”). The phase-out of LIBOR is underway and will conclude by July 1, 2023 when LIBOR rates and quotations are scheduled to be discontinued. In response to the phasing out of LIBOR, on March 15, 2022, President Biden signed the Adjustable Interest Rate (LIBOR) Act (the “LIBOR Act”), pursuant to which certain contracts that rely on LIBOR and do not contain procedures for determining an alternative base rate in the event that LIBOR is discontinued will transition from LIBOR to SOFR, effective July 1, 2023. While the LIBOR Act effectively established SOFR as the default replacement rate for LIBOR, there can be no assurances that SOFR will become a widely accepted benchmark, or that SOFR or other alternative base rates will be more or less favorable than LIBOR. The discontinuance of LIBOR and the adoption of SOFR and/or other alternative based rates could create volatility and instability in the financial markets and within banking and financial institutions. Regardless, we will continue to monitor to take steps to assess LIBOR exposure and mitigate potential impacts of the transition. The consequences of these developments cannot be entirely predicted but could include an increase in the cost of our borrowings under the Term Loan or could have a material adverse effect on our ability to refinance our Term Loan on favorable terms.

We may not be able to generate sufficient cash to service all of our indebtedness and may be forced to take other actions to satisfy our obligations under our indebtedness, which may not be successful.

Our ability to make scheduled payments on or refinance our debt obligations depends on our financial condition and operating performance, which are subject to prevailing economic and competitive conditions and to certain financial, business, legislative, regulatory and other factors which may be beyond our control. We may be unable to maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness. As of December 31, 2022, we had approximately \$2.7 billion of total indebtedness. We expect to make \$27.0 million in principal payments and make interest payments totaling \$209.5 million, excluding the impact of our interest rate swap, during 2023 related to our Term Loan. Related to the term loan we entered into in connection with the Rondo Acquisition (the “Rondo Term Loan”), we expect to make \$9.0 million in principal payments and make interest payments totaling \$4.1 million during 2023. Refer to *Note 16. Debt* and “*Commitments and Contractual Obligations*” under *Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations* for additional information.

If our cash flows and capital resources are insufficient to fund our debt service obligations, we could face substantial liquidity problems and could be forced to reduce or delay investments and capital expenditures or to dispose of material assets or operations, seek additional debt or equity capital or restructure or refinance our indebtedness. We may not be able to effect any such alternative measures on commercially reasonable terms or at all and, even if successful, those alternative actions may not allow us to meet our scheduled debt service obligations. Our credit agreements restrict our ability to dispose of assets and use the proceeds from those dispositions and also restrict our ability to raise debt or equity capital to be used to repay other indebtedness when it becomes due. We may not be able to consummate those dispositions or obtain proceeds in an amount sufficient to meet any debt service obligations when due.

Our inability to generate sufficient cash flows to satisfy our debt obligations, or to refinance our indebtedness on commercially reasonable terms or at all, would materially and adversely affect our financial position and results of operations and our ability to satisfy our obligations, including our indebtedness.

If we cannot make scheduled payments on our debt, we will be in default and, as a result:

- our debt holders could declare all outstanding principal and interest to be due and payable;
- the lenders under our credit agreements could terminate their commitments to lend us capital; and
- we could be forced into bankruptcy or liquidation.

The terms of our credit agreements restrict our operations, particularly our ability to respond to changes or to take certain actions.

Our credit agreements contain a number of restrictive covenants that impose operating and financial restrictions on us and may limit our ability to engage in acts that may be in our long-term best interest, including restrictions on the ability to:

- incur additional indebtedness;
- pay dividends or make other distributions or repurchase or redeem capital stock;
- prepay, redeem or repurchase certain debt;
- make loans and investments;
- sell assets;
- incur liens;
- enter into transactions with affiliates;
- alter the businesses conducted by us;
- enter into agreements restricting subsidiaries' ability to pay dividends; and
- consolidate, merge or sell all or substantially all of our assets.

A breach of the covenants under such credit agreements could result in an event of default under the applicable indebtedness. Such a default may allow the creditors to accelerate the related debt and may result in the acceleration of any other debt to which a cross-acceleration or cross-default provision applies which could have a material adverse effect on our business, operations and financial results. Furthermore, if we were unable to repay the amounts due and payable under our credit agreements, those lenders could proceed against the collateral granted to them to secure that indebtedness which could force us into bankruptcy or liquidation. In the event our lenders accelerated the repayment of the borrowings, we and our subsidiaries may not have sufficient assets to repay that indebtedness. Any acceleration of amounts due under the credit agreements would likely have a material adverse effect on us. As a result of these restrictions, we may be:

- limited in how we conduct business;
- unable to raise additional debt or equity financing to operate during general economic or business downturns; or
- unable to compete effectively or to take advantage of new business opportunities.

These restrictions may affect our ability to grow in accordance with our strategy.

Intellectual Property and Licensing Risks

Federal regulation of arrangements between manufacturers of branded and generic products could adversely affect our business.

We are involved in numerous patent litigations in which we challenge the validity or enforceability of innovator companies' listed patents and/or their applicability to our generic and/or biosimilar pharmaceutical products, as well as patent infringement litigation in which other generic/biosimilar companies challenge the validity or enforceability of our patents and/or their applicability to their generic/biosimilar pharmaceutical products, and therefore settling patent litigations has been and is likely to continue to be an important part of our business. As part of the Medicare Prescription Drug and Modernization Act of 2003, companies, including us, are required to file with the FTC and the DOJ agreements entered into between branded and generic and/or biosimilar pharmaceutical companies related to the manufacture, marketing and sale of generic/biosimilar versions of branded drugs for their review. In June 2013, the U.S. Supreme Court in its decision in *FTC v. Actavis* determined that "reverse payment" patent settlement agreements between brand and generic/biosimilar companies could violate the antitrust laws. The Supreme Court held that such settlement agreements are neither immune from antitrust attack nor presumptively illegal but rather should be analyzed under the "Rule of Reason" test to determine whether they violate the federal antitrust laws. This holding has resulted in heightened scrutiny of such settlement agreements by the FTC and state and local authorities, and has increased the risk of liability in pending antitrust litigation brought by private plaintiffs. The FTC has brought actions against parties to such settlement agreements, including us, and we have become subject to increased FTC investigations or enforcement actions arising from such settlement agreements. Further, private plaintiffs, including direct and indirect purchasers of our products, have also become more active in bringing private litigation claims against us and other brand and generic/biosimilar pharmaceutical companies alleging that such settlement agreements violate the antitrust laws. Accordingly, we have in the past received and may receive formal or informal requests from the FTC for information about a particular settlement agreement, and there is a risk that the FTC, state and local authorities, or private plaintiffs, may commence an action against us alleging violations of the antitrust laws. We have been and are currently involved in private antitrust actions involving certain settlement agreements as described in *Note 21. Commitments and Contingencies - Other Litigation Related to the Company's Business*.

Antitrust investigations and claims are generally expensive and time consuming, and we can give no assurance as to the timing or outcome of such investigations or claims or of any future private litigation or government action alleging that one of our settlement agreements violates antitrust laws. The impact of federal regulation of arrangements between manufacturers of brand and generic/biosimilar products, further legislation and the potential for private-party lawsuits associated with such arrangements could adversely affect our business.

From time to time we may need to rely on licenses to proprietary technologies, which may be difficult or expensive to obtain.

We may need to obtain licenses to patents and other proprietary rights held by third parties to develop, manufacture and market products. If we are unable to timely obtain these licenses on commercially reasonable terms, our ability to commercially market our products may be inhibited or prevented, which could have a material adverse effect on our business, results of operations and financial condition.

Our competitors or other third parties may allege that we are infringing upon their intellectual property, forcing us to expend substantial resources in litigation, the outcome of which is uncertain. Any unfavorable outcome of such litigation, including losses related to "at-risk" product launches, could have a material adverse effect on our business, financial position and results of operations.

Companies that produce branded pharmaceutical products routinely bring litigation against ANDA filers or similar applicants that seek regulatory approval to manufacture and market generic forms of their branded products alleging patent infringement or other violations of intellectual property rights. Patent holders may also bring patent infringement suits against companies that are currently marketing and selling approved generic products. Similarly, companies that produce biologics may bring litigation against abbreviated Biologics License Application ("aBLA") filers that seek regulatory approval to manufacture and market biosimilars. Litigation often involves significant expense and can delay or prevent introduction or sale of our generic and/or biosimilar products. If valid and enforceable patents are infringed by our products, we would need to delay selling the infringing generic product unless we could obtain a license from the patent holder, and, if we were already selling the infringing product, cease selling and potentially destroy existing product stock.

There may be situations in which we may make business and legal judgments to market and sell products that are subject to claims of alleged patent infringement prior to final resolution of those claims by the courts, based upon our belief that such patents are invalid, unenforceable, or are not infringed by our marketing and sale of such products. This is referred to in the

pharmaceutical industry as an "at-risk" launch. The risk involved in an at-risk launch can be substantial because, if a patent holder ultimately prevails against us, the remedies available to such holder may include, among other things, damages measured by the profits lost by the patent holder or treble damages, which can be significantly higher than the profits we make from selling the generic or biosimilar version of the product. We may also be harmed by the loss of any value of such inventory that we are unable to market or sell.

We expend a significant amount of resources on research and development, including milestones on in-licensed products, which may not lead to successful product introductions.

Much of our development effort is focused on technically difficult-to-formulate products and/or products that require advanced manufacturing technology. We expend significant resources on R&D primarily to enable us to manufacture and market FDA-approved pharmaceuticals in accordance with FDA regulations. We have entered into, and may in the future enter into, agreements that require us to make significant milestone payments upon achievement of various R&D events and regulatory approvals. As we continue to develop and in-license new products, we will likely incur increased research and licensing expenses. Because of the inherent risk associated with R&D efforts in the industry, particularly with respect to new drugs, our R&D expenditures may not result in the successful introduction of FDA-approved pharmaceutical products. Additionally, after we or our development partners submit an ANDA or aBLA, the FDA may request that additional studies be conducted. As a result, we may be unable to reasonably determine the total R&D costs required to develop a particular product. Finally, we cannot be certain that any investment made in developing products will be recovered, even if we are successful in commercialization. To the extent that we expend significant resources on R&D efforts and are not ultimately able to successfully introduce new products as a result of those efforts, our business, financial position and results of operations may be materially adversely affected.

We depend on our ability to protect our intellectual property and proprietary rights.

Our success depends on our ability to protect and defend the intellectual property rights associated with our current and future products. If we fail to protect our intellectual property adequately, competitors may manufacture and market products similar to, or that may be confused with, our products, and our generic competitors may obtain regulatory approval to make and distribute generic versions of our branded products. Some patent applications in the United States are maintained in secrecy or are not published until the resulting patents issue. We also cannot be certain that patents will be issued with respect to any of our patent applications or that any existing or future patents issued to or licensed by us will provide competitive advantages for our products or will not be challenged, invalidated, circumvented or held unenforceable in proceedings commenced by our competitors or other third parties. Furthermore, our patent rights may not prevent or limit our present and future competitors from developing, making, importing, using or commercializing products that are functionally similar to our products. We rely particularly on trade secrets, trademarks, unpatented proprietary expertise and continuing innovation that we seek to protect, in part, by registering and using marks; and by entering into confidentiality agreements with licensees, suppliers, employees, consultants and other parties. We use this approach to protecting our intellectual property in large part because few of our products are protected by patents. We cannot provide assurance that these agreements will not be breached or circumvented. We also cannot be certain that we will have recourse to adequate remedies in the event of a breach of such agreements. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. We cannot be sure that our trade secrets and proprietary technology will not be independently developed or otherwise become known by our competitors or, if patents are not issued with respect to our internally developed products, that we will be able to maintain the confidentiality of information relating to these products. In addition, efforts to ensure our intellectual property rights may be costly, time-consuming and/or ultimately unsuccessful. We cannot be sure that we will have the resources to protect our own rights against infringement by third parties. Our inability to protect our intellectual property and proprietary rights could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Legal and Regulatory Risks

We are involved in various legal proceedings and may be involved in future legal proceedings, all of which are uncertain, and existing and future proceedings may require us to incur substantial expense to defend and/or expose us to substantial liability.

The development, manufacture and sale of our drug products involves an inherent risk of product liability and other claims and the associated adverse publicity, and insurance against such potential claims is expensive and may be difficult to obtain. Litigation is inherently subject to uncertainties and we may be required to expend substantial amounts in the defense or resolution of this and similar matters. We regularly monitor the use of our products for trends or increases in reports of adverse events or product complaints, and regularly report such matters to the FDA. In some cases, an increase in adverse event reports

may be an indication that there has been a change in a product's specifications or efficacy. Such changes could lead to a recall of the product in question or, in some cases, increases in product liability claims related to the product in question. If the coverage limits for product liability and other insurance policies are not adequate, or if certain of our products are excluded from coverage, a claim brought against us, whether covered by insurance or not, could have a material adverse effect on our business, results of operations, financial condition and cash flows. We also rely on self-insurance to cover product liability and other claims, and these claims may exceed the amounts we have reserved under our self-insurance program.

In the ordinary course of our business, we may also be subject to a variety of other types of claims, proceedings, investigations and litigation initiated by government agencies or third parties. These matters may include compliance matters, product regulation or safety, taxes, employee benefit plans, employment discrimination, health and safety, environmental, antitrust, securities law, customs, import/export, government contract compliance, financial controls or reporting, intellectual property, allegations of misrepresentation, false claims or false statements, commercial claims, claims regarding promotion of our products and services, or other similar matters. In addition, government investigations related to the use of our generic drug products may cause reputational harm to us. Negative publicity, whether accurate or inaccurate, about the efficacy, safety or side effects of our generic drug products or product categories, whether involving us or a competitor, 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. Any such claims, proceedings, investigations or litigation, regardless of the merits, might result in substantial costs to defend or settle, restrictions on product use or sales, or otherwise injure our business.

We manufacture and derive a portion of our revenue from the sale of pharmaceutical products in the opioid class of drugs. The U.S. Department of Health and Human Services has declared the wide spread addiction to and abuse of such products a public health emergency, and in recent months, the federal government has also announced plans to increase federal oversight on opioid sale and consumption. These plans, along with changing public and clinical perceptions of opioid products and the risks relating to their use may result in the imposition of even stricter regulation of such products and further restrictions on their sale and use. For instance, the DEA has recently increased its scrutiny and regulation over the manufacture, distribution and sale of opioid products, which may require us to incur significant expenses to comply with such regulations. We derive substantial revenues from the sale of certain controlled drug substances that are subject to specific aggregate production quotas established and administered by the DEA in accordance with governing laws and regulations. Our inability to secure our quota allocation, the DEA's decision to allocate quota in an amount less than the amount we requested, or a delay by the government in the issuance of the quota for these substances can result in a substantial impact to our revenues.

State governments have also taken steps to impose surcharges or taxes on opioid manufacturers or distributors. Any new or stricter regulations imposed by governmental authorities such as the DEA related to opioid products, as well as a potential increase in opioid-related litigation involving us, could result in material adverse effects on our business and results of operations. Refer to *Note 21. Commitments and Contingencies - Prescription Opioid Litigation* for more information regarding opioid-related litigation involving the Company.

We are subject to United States federal and state laws related to healthcare fraud and abuse and health information privacy and security, and the failure to comply with such laws may adversely affect our business.

In the United States, many of our products are eligible for reimbursement under federal and state health care programs such as Medicaid, Medicare, TRICARE, and/or state pharmaceutical assistance programs, and as a result, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are, and will be, applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business.

The domestic and foreign laws that may affect our ability to operate include, but are not limited to: (i) the U.S. Anti-Kickback Statute, which applies to our marketing and research practices, educational programs, pricing policies and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, as a means of inducing, or in exchange for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; (ii) U.S. federal civil and criminal false claims laws and civil monetary penalty 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; (iii) the U.S. Health Insurance Portability and Accountability Act of 1996, ("HIPAA"), which among other things created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters, and HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and our implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information

and place restrictions on the use of such information for marketing communications; (iv) the U.S. Physician Payments Sunshine Act, which among other things, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under a federal healthcare program to report annually information related to "payments or other transfers of value" made to physicians, physician assistants, advanced practice nurses and teaching hospitals, and ownership and investment interests held by certain healthcare professionals and their immediate family members, and similar state laws; (v) the government pricing rules applicable to the Medicaid, Medicare Part B, 340B Drug Pricing Program, the U.S. Department of Veterans Affairs program, the TRICARE program, and state price reporting laws; and (vi) state and foreign law equivalents of each of the above U.S. 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, and state and foreign laws governing the privacy and security of health and other sensitive information in certain circumstances, such as the requirements under the European Union's General Data Protection Regulation and certain U.S. state privacy laws, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Violations of certain of these laws, including the fraud and abuse laws may result in severe penalties against us and/or our responsible employees, including jail sentences, large fines, and the exclusion of our products from reimbursement under federal and state programs. Additionally, these risks may be compounded by our rapid international expansion. Defense of litigation claims and government investigations can be costly, time-consuming, and distract management, and it is possible that we could incur judgments or enter into settlements that would require us to change the way we operate our business. We are committed to conducting the sales and marketing of our products in compliance with the healthcare fraud and abuse laws, but certain applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity, a governmental authority may take a position contrary to a position we have taken, or should an employee violate these laws without our knowledge, a governmental authority may impose civil and/or criminal sanctions.

Any adverse outcome in these types of actions, or the imposition of penalties or sanctions for failing to comply with fraud and abuse laws, could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows. Some of the statutes and regulations that govern our activities, such as federal and state anti-kickback and false claims laws, are broad in scope, and while exemptions and safe harbors protecting certain common activities exist, they are often narrowly drawn. While we manage our business activities to comply with these statutory provisions, due to their breadth, complexity and, in certain cases, uncertainty of application, it is possible that our activities could be subject to challenge by various government agencies. In particular, the FDA, the DOJ and other agencies have increased their enforcement activities with respect to the sales, marketing, research and similar activities of pharmaceutical companies in recent years, and many pharmaceutical companies have been subject to government investigations related to these practices. A determination that we are in violation of these and/or other government regulations and legal requirements may result in civil damages and penalties, criminal fines and prosecution, administrative remedies, the recall of products, the total or partial suspension of manufacturing and/or distribution activities, seizure of products, injunctions, whistleblower lawsuits, failure to obtain approval of pending product applications, withdrawal of existing product approvals, exclusion from participation in government healthcare programs and other sanctions.

Any of these types of investigations or enforcement actions could affect our ability to commercially distribute our products and could materially and adversely affect our business, financial condition, results of operations and cash flows.

Approvals for our new generic drug products may be delayed or become more difficult to obtain if the FDA institutes changes to its approval requirements.

The FDA may institute changes to its ANDA approval requirements, such as implementing new or additional fees similar to the fees imposed by the GDUFA and its second iteration (GDUFA II), which may make it more difficult or expensive for us to obtain approval for our new generic products. The FDA may also implement other changes that may directly affect some of our ANDA filings pending approval from the FDA, such as changes to guidance from the FDA regarding bioequivalency requirements for particular drugs. Such changes may cause our development of such generic drugs to be significantly more difficult or result in delays in FDA approval or result in our decision to abandon or terminate certain projects. Any changes in FDA requirements may make it more difficult for us to file ANDAs or obtain approval of our ANDAs and generate revenues and thus have a material adverse effect on our business, results of operations and financial condition.

Healthcare reform and a reduction in the coverage and reimbursement levels by governmental authorities, HMOs, MCOs or other third-party payers may adversely affect our business.

As part of commercializing our products, we have obtained authorization to receive reimbursement at varying levels for the cost of certain products and related treatments from governmental authorities and private health insurers and other organizations, such as health maintenance organizations ("HMOs") and managed care organizations ("MCOs"). The trend toward managed

healthcare in the United States, the growth of organizations such as HMOs and MCOs, and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of pharmaceutical products, resulting in lower prices and a reduction in product demand. The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 were signed into law on March 23, 2010 and March 30, 2010, respectively. These laws are referred to herein as "healthcare reform." A number of provisions of the healthcare reform laws continue to have a negative impact on the price of our products sold to U.S. government entities. For example, the legislation includes measures that (i) significantly increase Medicaid rebates through both the expansion of the program; (ii) substantially expand the Public Health System (340B) program to allow other entities to purchase prescription drugs at substantial discounts; (iii) extend the Medicaid rebate rate to a significant portion of Managed Medicaid enrollees; (iv) apply a 75% discount to Medicare Part D beneficiary spending in the coverage gap for branded and authorized generic prescription drugs; and (v) levy a significant excise tax on the industry to fund healthcare reform. Such cost containment measures and healthcare reform affect our ability to sell our products and have a material adverse effect on our business, results of operations and financial condition. Additionally, the Medicare Part D Prescription Drug Benefit established a voluntary outpatient prescription drug benefit for Medicare beneficiaries (primarily the elderly over 65 and the disabled). These beneficiaries may enroll in private drug plans. There are multiple types of Part D plans and numerous plan sponsors, each with its own formulary and product access requirements. The plans have considerable discretion in establishing formularies and tiered co-pay structures and in placing prior authorization and other restrictions on the utilization of specific products. In addition, Part D plan sponsors are permitted and encouraged to negotiate rebates with manufacturers. The Medicare Part D program, which went into effect January 1, 2006, is administered by the CMS within the Department of Health and Human Services.

The CMS has issued extensive regulations and other sub-regulatory guidance documents implementing the Medicare Part D benefit, and the OIG has issued regulations and other guidance in connection with the Medicare Part D program. The federal government can be expected to continue to issue guidance and regulations regarding the obligations of Part D sponsors and their subcontractors. Participating drug plans may establish drug formularies that exclude coverage of specific drugs and payment levels for drugs negotiated with Part D drug plans may be lower than reimbursement levels available through private health plans or other payers. Moreover, beneficiary co-insurance requirements could influence which products are recommended by physicians and selected by patients. There is no guarantee that any drug that we market will be offered by drug plans participating under the Medicare Part D program or of the terms of any such coverage, or that covered drugs will be reimbursed at amounts that reflect current or historical levels. Additionally, any reimbursement granted may not be maintained, or limits on reimbursement available from third-party payers may reduce the demand for, or negatively affect the price of those products, which could significantly harm our business, results of operations, financial condition and cash flows. We may also be subject to lawsuits relating to reimbursement programs that could be costly to defend, divert management's attention and adversely affect our operating results. Most state Medicaid programs have established preferred drug lists, and the process, criteria and timeframe for obtaining placement on the preferred drug list varies from state to state. Under the Medicaid drug rebate program, a manufacturer must pay a rebate for Medicaid utilization of a product. The rebate for single source products (including authorized generics) is based on the greater of (i) a specified percentage of the product's average manufacturer price or (ii) the difference between the product's average manufacturer price and the best price offered by the manufacturer. The rebate for multiple source products is a specified percentage of the product's average manufacturer price. In addition, many states have established supplemental rebate programs as a condition for including a drug product on a preferred drug list. The profitability of our products may depend on the extent to which they appear on the preferred drug lists of a significant number of state Medicaid programs and the amount of the rebates that must be paid to such states. The IRA may also impact prices of certain of our pharmaceuticals and the return on investment of biosimilars. In addition, there is significant fiscal pressure on the Medicaid program, and amendments to lower the pharmaceutical costs of the program are possible. Such amendments could materially adversely affect our anticipated revenues and results of operations. Due to the uncertainties regarding the outcome of future healthcare reform initiatives and their enactment and implementation, we cannot predict which, if any, of the future reform proposals will be adopted or the effect such adoption may have on our business. Future rulemaking and reform, including repeal of existing law, with respect to the healthcare and pharmaceutical industries, could increase rebates, reduce prices or the rate of price increases for healthcare products and services, or require additional reporting and disclosure. We cannot predict the timing or impact of any future rule making, reform or repeal of healthcare laws.

We depend on third-party agreements for a portion of our product offerings and any failure to maintain these arrangements or enter into similar arrangements with new partners could result in a material adverse effect.

We have broadened our product offering by entering into a variety of third-party agreements covering any combination of joint development, supply, marketing and/or distribution of products. We cannot provide assurance that the development, supply, marketing and/or distribution efforts of our contractual partners will continue to be successful, that we will be able to renew such agreements or that we will be able to enter into new agreements for additional products. Any alteration to, or termination of, our current distribution and marketing agreements, failure to enter into new and similar agreements, or interruption of our

product supply under the such agreements, could have a material adverse effect on our business, condition (financial and otherwise), prospects or results of operations.

The testing required for the regulatory approval of our products is conducted primarily by independent third parties. Any failure by any of these third parties to perform this testing properly and in a timely manner may have an adverse effect upon our ability to obtain regulatory approvals.

Our applications for regulatory approval of our products, including both internally developed and in-licensed products, incorporate the results of testing and other information that is conducted or gathered primarily by independent third parties (including, for example, manufacturers of raw materials, testing laboratories, contract research organizations or independent research facilities). Our ability to obtain and maintain regulatory approval of the products being tested is dependent upon the quality of the work performed by these third parties, the quality of the third parties' facilities, and the accuracy of the information provided by third parties. We have little or no control over any of these factors. If this testing is not performed properly, our ability to obtain or maintain regulatory approvals, and to launch or continue selling products, could be restricted or delayed.

Our reporting and payment obligations under the Medicaid rebate program and other governmental purchasing and rebate programs are complex and may involve subjective decisions. Any determination that we have failed to comply with those obligations could subject us to penalties and sanctions, which could have a material adverse effect on our business.

The regulations applicable to us regarding reporting and payment obligations with respect to Medicaid reimbursement and rebates and other governmental programs are complex. Our calculations and methodologies are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could adversely affect us and our business. In addition, 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 error and misjudgment. Any governmental agencies that have commenced (or that may commence) an investigation of us could impose, based on a claim of violation of anti-fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare). Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with respect 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 that we have taken and may impose civil and/or criminal sanctions on us. Any such penalties, sanctions, or exclusion from federal health care programs could have a material adverse effect on our business, financial position and results of operations. From time to time we conduct routine reviews of our government pricing calculations. These reviews may have an impact on government price reporting and rebate calculations used to comply with various government regulations regarding reporting and payment obligations.

Investigations and litigation concerning the calculation of average wholesale prices may adversely affect our business.

Many government and third-party payers, including Medicare, Medicaid, HMOs and others, reimburse doctors and others for the purchase of certain prescription drugs based on a drug's average wholesale price ("AWP"). In the past several years, state and federal government agencies have conducted ongoing investigations of manufacturers' reporting practices with respect to AWP, as a result of which certain agencies have suggested that reporting of inflated AWP by manufacturers has led to excessive payments for prescription drugs. Numerous pharmaceutical companies have been named as defendants in actions brought by various State Attorneys General and have faced state law *qui tam* actions brought on behalf of various states, alleging generally that the defendants defrauded state Medicaid systems by purportedly reporting or causing the reporting of AWP and/or "Wholesale Acquisition Costs" that exceeded the actual selling price of the defendants' prescription drugs. These cases generally seek some combination of actual damages, and/or double damages, treble damages, compensatory damages, statutory damages, civil penalties, disgorgement of excessive profits, restitution, disbursements, counsel fees and costs, litigation expenses, investigative costs, injunctive relief, punitive damages, imposition of a constructive trust, accounting of profits or gains derived through the alleged conduct, expert fees, interest and other relief that the court may have deemed proper.

We can give no assurance that we will be able to settle current or future actions on terms that we deem reasonable, or that such settlements or adverse judgments, if entered, will not exceed the amount of any reserve. Accordingly, such actions could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows.

Failure to comply with our government contracting regulations could adversely affect our business and results of operations.

In January 2020, we completed the acquisition of AvKARE, Inc. and Dixon Shane, LLC d/b/a R&S Northeast LLC. For further details, refer to *Note 3. Acquisitions*. AvKARE generates a substantial amount of its net revenue from government contracts. Contracts with federal, state, and local governmental customers are subject to various procurement regulations, contract provisions and other requirements relating to their formation, administration and performance, and are subject to regular audits and investigations. Any failure by us to comply with the government contracting regulations could result in the imposition of various civil and criminal penalties, which may include termination of contracts, forfeiture of profits, suspension of payments, fines and suspension or debarment from future government business. Such failures could also cause reputational damage to our business. In addition, some of AvKARE's contracts provide for termination by the government, without cause. If one or more of our government contracts is suspended or terminated or if we are suspended, debarred or otherwise restricted from future government work, our business, results of operations and financial condition could suffer.

Economic, Political and Financial Risks

Our current operations in, and potential expansion into additional, international markets subjects us to increased regulatory oversight both in those international markets and domestically as well as regulatory, economic, social and political uncertainties, which could cause a material adverse effect on our business, financial position and results of operations.

We are subject to certain risks associated with having substantial assets and operations located in foreign jurisdictions, including our operations in India and Ireland, as well as related to our licensed activities expected to be rolled out across parts of Europe, Australia and New Zealand. Over the past several years, we have significantly expanded our Indian operations, and we may in the future expand our international business and operations in these jurisdictions or into jurisdictions in which we have limited operating experience, including with respect to seeking regulatory approvals, marketing or selling products.

Our international operations may be adversely affected by general economic conditions (including inflation, expropriation and other government actions), economic and fiscal policy (including changes in exchange rates and controls, interest rates and taxation policies), changes in intellectual property protections and remedies, trade regulations, tax laws, and increased government regulation (including those affecting approval, production, pricing, and marketing of, reimbursement for and access to our products). With respect to India, our operations could also be adversely affected by any reversal of India's recent economic liberalization and deregulation policies, as well as social instability and other political, economic or diplomatic developments in the future. Certain jurisdictions have, from time to time, experienced instances of civil unrest and hostilities, both internally and with neighboring countries. Rioting, military activity, terrorist attacks, armed hostilities or unstable government and legal systems could cause our operations in such jurisdictions to be adversely affected or suspended. We generally do not have insurance for losses and interruptions caused by terrorist attacks, military conflicts and wars. In addition, our international operations may subject us to heightened scrutiny under the Foreign Corrupt Practices Act or similar anti-bribery laws, and could subject us to liability under such laws despite our efforts to comply. Some emerging market countries may be particularly vulnerable to periods of financial or political instability or significant currency fluctuations or may have limited resources for healthcare spending. As a result of these and other factors, our strategy to grow in emerging markets may not be successful, and growth rates in these markets may not be sustainable. Government financing and economic pressures can lead to negative pricing pressure in various markets where governments take an active role in setting prices, access criteria (e.g., through health technology assessments) or other means of cost control. Further, notwithstanding our compliance programs, there can be no assurances that our policies will prevent our employees or agents from violating any applicable laws or protect us from any such violations. Additionally, we cannot predict the nature, scope or impact of any future regulatory requirements that may apply to our expanding international operations or how foreign governments will interpret existing or new laws.

We may make acquisitions of, or investments in, complementary businesses or products, which may be on terms that may not turn out to be commercially advantageous, or may require additional debt or equity financing, which could increase our leverage and dilute equity holders.

While we regularly review the potential acquisition of technologies, products, product rights and complementary businesses and are currently evaluating, and intend to continue to evaluate, potential product and/or company acquisitions and other business development opportunities, we may not be able to identify suitable acquisition or investment candidates. In addition, to the extent that we do identify candidates that we believe to be suitable, we cannot provide any assurance that we will be able to reach an agreement with the selling party or parties or consummate the transaction on terms that are commercially advantageous to us or at all. If we make any acquisitions or investments, we may finance such acquisitions or investments through our cash reserves, debt financing, which may increase our leverage, or by issuing additional equity interests, which

could dilute the holdings of our then-existing shareholders. If, due to capital constraints, we require financing, we cannot provide any assurance that we will be able to obtain such financing when needed on acceptable terms or at all.

Global economic conditions could harm us.

Global efforts to contain health care costs continue to exert pressure on product pricing and market access to pharmaceutical products. In many international markets, government-mandated pricing actions have reduced prices of patented drugs, and it is possible that the U.S. may adopt similar measures to reduce drug prices to consumers. Some countries may be subject to periods of financial instability, may have reduced resources to spend on healthcare or may be subject to economic sanctions, and our business in these countries may be disproportionately affected by these changes. Continued concerns about the systemic impact of potential geopolitical issues and economic policy uncertainty, particularly in areas in which we operate, could potentially cause economic and market instability in the future and could adversely affect our business, including our financial performance.

Challenging economic conditions could also result in tighter credit conditions. The cost and availability of credit may be adversely affected by illiquid credit markets and wider credit spreads, which could adversely affect the ability of our third-party distributors, partners, manufacturers and suppliers to buy inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations and adversely affect our financial performance.

We have increased exposure to tax liabilities, including foreign tax liabilities.

As a U.S. company with subsidiaries in, among other countries, India, Switzerland, Ireland and the U.K., we are subject to, or potentially subject to, income and other taxes in these jurisdictions as well as the United States. Significant judgment is required in determining our worldwide provision for income taxes and other tax liabilities. Changes in tax laws or tax rulings may have a significant adverse impact on our effective tax rate. In addition, we have potential tax exposures resulting from the varying application of statutes, regulations and interpretations, which include exposures on intercompany terms of cross-border arrangements among foreign subsidiaries in relation to various aspects of our business, including R&D activities and manufacturing. Tax authorities in various jurisdictions may disagree with, and subsequently challenge, the amount of profits taxed in such jurisdictions. Any such challenges may result in increased tax liability, including accrued interest and penalties, which would cause our tax expense to increase and may have a material adverse effect on our business, financial position and results of operations and our ability to satisfy our debt obligations.

In certain circumstances, we issue price adjustments and other sales allowances to our customers. Although we may establish reserves based on our estimates of these amounts, if estimates are incorrect and the reserves are inadequate, it may result in adjustments to these reserves that may have a material adverse effect on our financial position and results of operations.

As described above, the first company to file an ANDA containing a Paragraph IV certification that successfully challenges the patent(s) on a branded product may be granted 180 days of generic market exclusivity by the FDA for such generic product. At the expiration of such exclusivity period, other generic distributors may enter the market, resulting in a significant price decline for the drug (in some instances, price declines have exceeded 90%). When we experience price declines following a period of generic marketing exclusivity, or at any time when a competitor enters the market or offers a lower price with respect to a product we are selling, we may, at our discretion, decide to lower the price of our product to retain market share and provide price adjustments to our customers for the difference between our new (lower) price and the price at which we previously sold the product which is still held in inventory by such customers. We accrue for these adjustments when the expected value of an adjustment is greater than zero, based on contractual pricing, actual net sales, accrual rates based on historical average rates, and estimates of the level of inventory of its products in the distribution channel that remain subject to these adjustments. There are also circumstances under which we may decide not to provide price adjustments to certain customers, and consequently, as a matter of business strategy, we may risk a greater level of sale returns of products in a customer's existing inventory and lose future sales volume to competitors rather than reduce our pricing.

Based on estimates, we establish reserves for sales allowances including, but not limited to: sales discounts and returns, chargebacks, sales volume rebates, shelf stocks, re-procurement charges, cash discounts, and Medicaid rebate obligations at the time of sale. Although we believe our reserves are adequate as of the date of this report, we cannot provide assurances that our reserves will ultimately prove to be adequate. Increases in sales allowances may exceed our estimates for a variety of reasons, including unanticipated competition or an unexpected change in one or more of our contractual relationships. We will continue to evaluate the effects of competition and will record a price adjustment reserve if and when we deem it necessary. Any failure

to establish adequate reserves with respect to sales allowances may result in a material adverse effect on our financial position and results of operations.

If we determine that our goodwill and other intangible assets have become impaired, we may record significant impairment charges, which would adversely affect our results of operations.

Goodwill and other intangible assets represent a significant portion of our assets. Goodwill is the excess of cost over the fair market value of net assets acquired in business combinations. In the future, goodwill and intangible assets may increase as a result of future acquisitions. We review our goodwill and indefinite lived intangible assets at least annually for impairment. We review our intangible assets with finite lives for recoverability whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. Impairment may result from, among other things, deterioration in the performance of acquired businesses, adverse market conditions and adverse changes in applicable laws or regulations, including changes that restrict the activities of an acquired business.

Generic pharmaceuticals have faced regular and increasing price erosion each year, placing even greater importance on our ability to continually introduce new products. If these trends continue or worsen, or if we experience further difficulty in this market or the specialty market, our revenues and profits in our Generics and Specialty segments may continue to be affected adversely. A decline in our market capitalization, even if otherwise due to macroeconomic or industry-wide factors, could put pressure on the carrying value of our goodwill in both our Generics and Specialty segments and cause the Company to conduct an interim impairment test. A determination that all or a portion of our goodwill or other intangible assets is impaired, although a non-cash charge against earnings, could have a material adverse effect on our results of operations and financial condition.

Risks Related to Our Tax Receivable Agreement

We are required under a tax receivable agreement to make cash payments in respect of certain tax benefits to which we may become entitled, and we expect that the payments we will be required to make will be substantial.

We are a party to a tax receivable agreement (“TRA”) with each of the members of the group, together with their affiliates and certain assignees, who owned Amneal when it was a private company (“Members” or the “Amneal Group”), dated May 4, 2018. Under the TRA, we will be required to make cash payments to the Members and their permitted transferees equal to 85% of certain tax benefits, if any, that we actually realize, or in certain circumstances are deemed to realize, as a result of redemptions or exchanges of Amneal common units and the corresponding number of shares of Class B Common Stock for Class A Common Stock by the Members and their permitted transferees as set forth in the agreement. The amount of the cash payments that we will be required to make under the TRA could be significant. Any payments made by us to the Members and their permitted transferees under the TRA will generally reduce the amount of overall cash flow that might have otherwise been available to us.

As discussed in *Note 7, Income Taxes* we have determined it is more-likely-than-not we will be unable to utilize all of our deferred tax assets (“DTAs”) subject to the TRA and, therefore, reversed the substantially all of the liability under the TRA related to the tax savings we may realize from common units sold or exchanged through December 31, 2019. We reversed the accrued TRA liability of \$192.8 million, which resulted in a gain recorded in other (expense) income, net for the year ended December 31, 2019. For the year ended December 31, 2022, we recorded an expense associated with the TRA in other income, net of \$0.6 million of which all of that amount is a liability as of December 31, 2022. If utilization of these DTAs becomes more-likely-than-not in the future, at such time, we could incur obligations incremental to and substantially larger than the approximately \$202.7 million contingent TRA liability as of December 31, 2022. However, if the tax attributes are not utilized in future years, it is reasonably possible no amounts would be paid under the TRA. Should we determine that a DTA with a valuation allowance is realizable in a subsequent period, the related valuation allowance will be released and if a resulting TRA payment is determined to be probable, a corresponding liability will be recorded. As a result, our future results of operations and earnings could be significantly impacted as results of these matters.

The timing and amount of any payments under the TRA may vary, depending upon a number of factors including the timing and number of Amneal common units sold or exchanged for our Class A Common stock, the price of our Class A Common Stock on the date of sale or exchange, the timing and amount of our taxable income, and the tax rate in effect at the time of realization of the taxable income (the TRA liability is determined based on a percentage of the corporate tax savings from the use of the TRA’s attributes). Further sales or exchanges occurring subsequent to December 31, 2022 could result in future Amneal tax deductions and obligations to pay 85% of such benefits to the holders of Amneal common units.

In certain cases, payments under the TRA to the Members or their permitted transferees may be accelerated or significantly exceed the actual benefits we realize in respect of the tax attributes subject to the TRA.

The TRA provides that upon certain mergers, asset sales, other forms of business combinations or other changes of control or if, at any time, we elect an early termination of the TRA, then our obligations under the TRA to make payments would be based on certain assumptions, including an assumption that we would have sufficient taxable income to fully utilize all potential future tax benefits that are subject to the TRA.

As a result of the foregoing, we could be required to make payments under the TRA that (i) are greater than the actual benefits we ultimately realize in respect of the tax benefits that are subject to the TRA and (ii) are based on the present value of the anticipated future tax benefits that are the subject of the TRA, which payment may be required to be made significantly in advance of the actual realization, if any, of such future tax benefits. In these situations, our obligations under the TRA could have a substantial negative impact on our liquidity and could have the effect of delaying or preventing certain mergers, asset sales, other forms of business combinations or other changes of control. There can be no assurance that we will be able to fund or finance our obligations under the TRA.

We will not be reimbursed for any payments made to the Members or their permitted transferees under the TRA in the event that any tax benefits are disallowed.

Payments under the TRA will be based on the tax reporting positions that we determine, and the Internal Revenue Service or another tax authority may challenge all or part of the tax benefits we claim, as well as other related tax positions we take, and a court could sustain such challenge. If the outcome of any such challenge would reasonably be expected to materially adversely affect a recipient's rights or obligations (including the amount or timing of payments) under the TRA, then we will not be permitted to settle or fail to contest such challenge without the consent of the Members. We will not be reimbursed for any cash payments previously made to the Members or their permitted transferees under the TRA in the event that any tax benefits initially claimed by us and for which payment has been made to the Members or their permitted transferees are subsequently challenged by a taxing authority and are ultimately disallowed. Instead, any excess cash payments made by us to the Members or their permitted transferees will be netted against any future cash payments that we might otherwise be required to make to Holdings or its permitted transferees under the terms of the TRA. However, we might not determine that we have effectively made an excess cash payment to the Members or their permitted transferees for a number of years following the initial time of such payment. As a result, payments could be made under the TRA in excess of the tax savings that we ultimately realize in respect of the tax attributes with respect to the Members or their permitted transferees.

Risks Related to Our Class A Common Stock

We are controlled by the Amneal Group. The interests of the Amneal Group may differ from the interests of our other stockholders.

As of December 31, 2022, the Amneal Group controlled the majority of the voting power of all of our outstanding shares of common stock. Accordingly, the Amneal Group has substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation, or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of the Company, even if such a change of control would benefit our other stockholders. This concentrated control could discourage a potential investor from seeking to acquire Class A Common Stock and, as a result, might harm the market price of that Class A Common Stock.

Through its control of a majority of our voting power and the provisions set forth in our charter, bylaws and the Company's Second Amended and Restated Stockholders Agreement, dated December 16, 2017 (as amended to date, the "Stockholders Agreement"), the Amneal Group has the ability to designate and elect a majority of our board of directors. As of December 31, 2022, six out of eleven members of our board of directors, have been designated by the Amneal Group. The Amneal Group has control over all matters submitted to our stockholders for approval, including changes in capital structure, transactions requiring stockholder approval under Delaware law and corporate governance, subject to the terms of the Stockholders Agreement relating to the Amneal Group's agreement to vote in favor of directors not designated by the Amneal Group and such other matters that are set forth in the Stockholders Agreement. The Amneal Group may have different interests than our other stockholders and may make decisions adverse to such interests.

In the ordinary course of their business activities, the Amneal Group may engage in activities where their interests conflict with our interests or those of our other stockholders. Our certificate of incorporation provides that the Amneal Group have no duty to refrain from engaging in the same business activities or similar business activities or lines of business in which we operate. The Amneal Group also may pursue business opportunities with any of our clients, customers or vendors, that may be complementary to our business and, as a result, those acquisition opportunities may not be available to us.

The Amneal Group could also transfer control of us to a third-party by transferring its shares. In addition, the Company believes members of the Amneal Group have pledged Amneal Common Units and the corresponding shares of Class B Common Stock to secure borrowings, and other members of the Amneal Group could enter into similar arrangements. In connection with these arrangements, we have entered into agreements with certain Amneal Group members and the lending institutions to whom their securities may be pledged. The voluntary or forced sale of some or all of these units or shares pursuant to a margin call or otherwise could cause our stock price to decline and negatively impact our business. Similarly, a voluntary or forced sale could cause us to lose our “controlled company” status under the New York Stock Exchange listing requirements, which would require us to comply over a transition period with certain corporate governance requirements from which we are currently exempt, including having a fully independent compensation committee. If all of the Amneal Common Units and corresponding shares of Class B stock were pledged to secure borrowings, a complete foreclosure could result in a change of control.

Future sales of shares by the Amneal Group could cause our Class A Common Stock price to decline.

The majority of our Common Stock is held by the Amneal Group and is eligible for sale or transfer (subject to certain continuing restrictions). The Amneal Group may elect to sell their shares. If some or all of these shares are sold, or if it is perceived that they will be sold, the trading price of our Class A Common Stock could decline.

We are a holding company with nominal net worth and depend on dividends and distributions from our subsidiaries.

We are a holding company with nominal net worth and will not have any material assets or conduct any business operations other than our investments in our subsidiaries. Our business operations are conducted primarily out of our direct operating subsidiary, Amneal, and its subsidiaries. As a result, our ability to satisfy our financial obligations and, notwithstanding any restrictions on payment of dividends under our existing indebtedness, our ability to pay dividends, if any, is dependent upon cash dividends and distributions or other transfers from our subsidiaries, including from Amneal.

Our charter provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit the ability of our stockholders to obtain a favorable judicial forum for disputes with us or our current or former directors, officers or employees.

Our charter provides that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if such court does not have jurisdiction, the Superior Court of the State of Delaware or the federal district court for the District of Delaware) will be the sole and exclusive forum for any derivative action or proceeding brought on behalf of the Company, any action asserting a claim of breach of fiduciary duty owed by any of our current or former director or officer to us or our stockholders, any action asserting a claim arising pursuant to any provision of the Delaware General Corporate Law (“DGCL”), our charter or bylaws or any action asserting a claim governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our current or former directors, officers or other employees, which may discourage such lawsuits against us and our current or former directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our charter to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition. The choice of forum provision in our charter will not preclude or contract the scope of exclusive federal or concurrent jurisdiction for actions brought under the federal securities laws, including the Securities Exchange Act of 1934, as amended, or the Securities Act of 1933, as amended, or the respective rules and regulations promulgated thereunder.

Anti-takeover provisions under Delaware law could make an acquisition of the Company more difficult and may prevent attempts by our stockholders to replace or remove our management.

Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of the outstanding voting stock of the Company from merging or combining with us unless certain conditions are met. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be

considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then 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 management.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

We expect that we will retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our Class A Common Stock will be the sole source of gain for our stockholders for the foreseeable future. The payment of future cash dividends, if any, will be at the discretion of our Board of Directors and will be dependent upon our earnings, financial condition, capital requirements and other factors as our Board of Directors may deem relevant.

General Risk Factors

We may need to raise additional funds in the future which may not be available on acceptable terms or at all.

We may consider issuing additional debt or equity securities in the future to fund potential acquisitions or investments, to refinance existing debt, or for general corporate purposes. If we issue equity, convertible preferred equity or convertible debt securities to raise additional funds, our stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our stockholders. If we incur additional debt, we may increase our leverage relative to our earnings or to our equity capitalization, requiring us to pay additional interest expenses and potentially lowering our credit ratings. We may not be able to market such issuances on favorable terms, or at all, in which case, we may not be able to develop or enhance our products, execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer requirements.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results, timely file our periodic reports, maintain our reporting status or prevent fraud.

We are required to comply with Section 404 of the Sarbanes-Oxley Act, which requires public companies to conduct an annual review and evaluation of their internal controls and attestations of the effectiveness of such internal controls by independent auditors. 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 that will need to be evaluated frequently. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act or the inability of our independent registered public accounting firm to express an opinion as to the effectiveness of our internal control over financial reporting could have a material adverse effect on our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock. In addition, if our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Our management or our independent registered public accounting firm may also identify material weaknesses in our internal control over financial reporting in the future. The existence of material weaknesses in internal control may result in current and potential stockholders and alliance and collaboration agreement partners losing confidence in our financial reporting, which could harm our business, the market price of our common stock, and our ability to retain our current, or obtain new, alliance and collaboration agreement partners.

In addition, our internal controls over financial reporting may not prevent or detect misstatements because of their inherent limitations, including the possibility of human error, the circumvention or overriding of controls or fraud. Even effective internal controls can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements. If we fail to maintain adequate internal controls, including any failure to implement required new or improved controls, or if we experience difficulties in their implementation, we could fail to meet our financial reporting obligations and our business, financial results and reputation could be harmed.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Amneal owns or leases numerous properties in domestic and foreign locations. Amneal's principal properties include manufacturing facilities, R&D laboratories, warehouses, and corporate offices. Our properties are generally used to support the operations of our Generics, Specialty and AvKARE segments.

Our significant properties are as follows:

Property Address	Legal Status	Purpose
Bridgewater, New Jersey	Leased	Executive Office
Glasgow, Kentucky	Leased	Administrative, Distribution and Warehouse
Glasgow, Kentucky	Leased	Warehouse
Yaphank, New York	Leased	Warehouse
Glasgow, Kentucky	Owned	Warehouse
Piscataway, New Jersey	Leased	Warehouse
Piscataway, New Jersey	Leased	Manufacturing
Piscataway, New Jersey	Leased	R&D, manufacturing
Branchburg, New Jersey	Leased	Manufacturing
Branchburg, New Jersey	Leased	Manufacturing
Piscataway, New Jersey	Leased	Manufacturing
Branchburg, New Jersey	Leased	Warehouse
East Hanover, New Jersey	Leased	Packaging
Bridgewater, New Jersey	Leased	R&D
Yaphank, New York	Leased	Manufacturing, R&D, Quality and Regulatory
Pulaski, Tennessee	Leased	Warehouse and office space
Philadelphia, Pennsylvania	Leased	Warehouse and office space
Fountain Run, Kentucky	Leased	Warehouse and office space
Cashel Co, Tipperary, Ireland	Owned	R&D, Manufacturing
Ahmedabad, Gujarat, India	Owned	Oral Solids Manufacturing and R&D
Matoda, Gujarat, India	Leased	Oral Solids and Injectables Manufacturing and R&D
Ahmedabad, Gujarat, India	Leased	R&D (Injectables), Corporate Office
Ahmedabad, Gujarat, India	Leased	Corporate Office
Ahmedabad, Gujarat, India	Leased	Warehouse
Mahabubnagar, Telangana, India	Leased	Oncology R&D and Manufacturing
Visakhapatnam, Andhra Pradesh, India	Owned	API Manufacturing and R&D
Bharuch, Gujarat, India	Leased	API Manufacturing
Ahmedabad, Gujarat, India	Leased	R&D
Mehsana, Gujarat, India	Owned	Injectables Manufacturing
Ahmedabad, Gujarat, India	Leased	Office space
Ahmedabad, Gujarat, India	Owned	Biologics manufacturing
Ahmedabad, Gujarat, India	Owned	Injectables Manufacturing and R&D
Mumbai, Maharashtra, India	Leased	Office Space
Ahmedabad, Gujarat, India	Leased	Warehouse

Item 3. Legal Proceedings

Information pertaining to legal proceedings can be found in *Note 21. Commitments and Contingencies* and is incorporated by reference herein.

Item 4. Mine Safety Disclosures

Not applicable.

PART II.

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

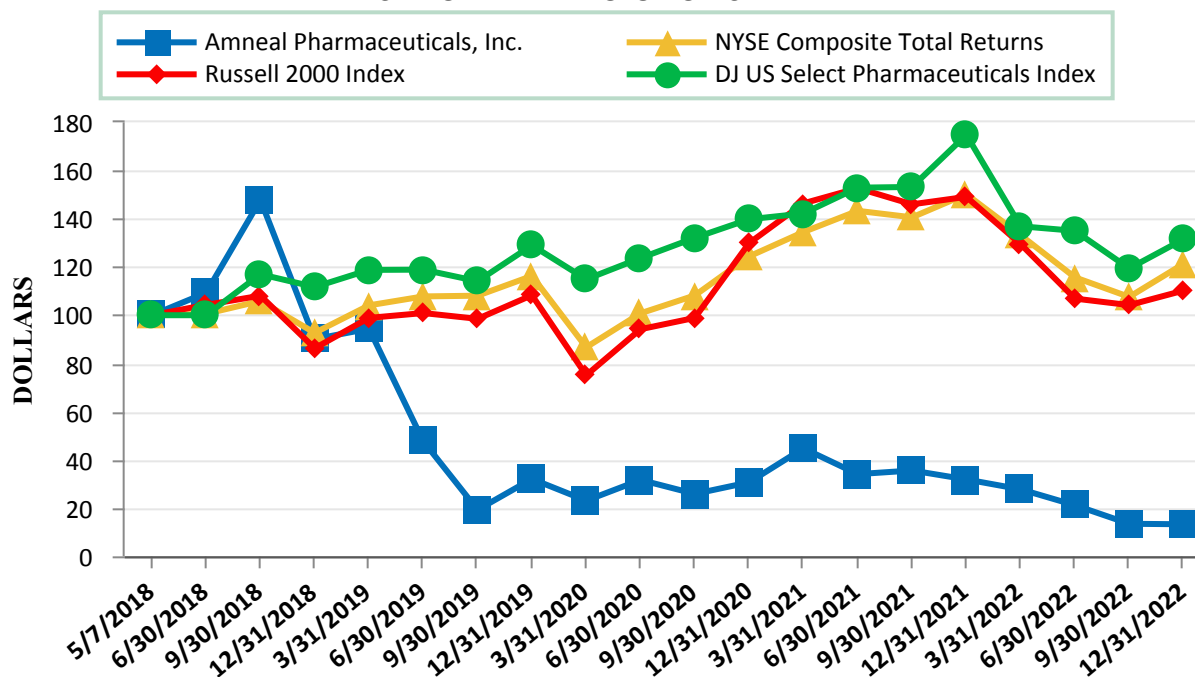
Market Information and Holders

The principal market for our Class A Common Stock is the New York Stock Exchange ("NYSE"). Our Class A Common Stock has been traded on the NYSE under the symbol “AMRX” since it began trading on May 7, 2018. According to the records of our transfer agent, we had 147 holders of record of our Class A Common Stock as of February 14, 2022. A substantially greater number of holders of our Class A Common Stock are “street name” or beneficial holders, whose shares of record are held by banks, brokers, and other financial institutions. As of February 14, 2022, there were 32 record holders of our Class B Common Stock. All of our issued and outstanding Class B Common Stock is held by the Amneal Group. Our Class B Common Stock is not listed or traded on any stock exchange.

Performance Graph

Set forth below is a line graph comparing the change in the cumulative total shareholder return on our Class A Common Stock with the cumulative total returns of the NYSE Composite Index, the Russell 2000 Index and the Dow Jones U.S. Pharmaceuticals Index for the period from May 7, 2018, the day our Class A Common Stock began trading on the NYSE, to December 31, 2022, assuming the investment of \$100 on May 7, 2018, and the reinvestment of dividends. The Class A Common Stock price performance shown on the graph only reflects the change in our Class A Common Stock price relative to the noted indices and is not necessarily indicative of future price performance.

**COMPARISON OF CUMULATIVE RETURN SINCE THE COMBINATION
AMONG AMNEAL PHARMACEUTICALS, INC., RUSSELL 2000 INDEX,
NEW YORK STOCK EXCHANGE COMPOSITE TOTAL RETURNS AND DOW JONES US
SELECT PHARMACEUTICALS INDEX**



Dividends

We have never paid cash dividends on any class of our common stock and have no present plans to do so. Our current policy is to retain all earnings, if any, for use in the operation of our business or to reduce our debt.

Issuer Purchases of Equity Securities

We did not purchase any shares of our Class A Common Stock during the three months ended December 31, 2022.

Item 6. Reserved

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

Amneal Pharmaceuticals, Inc. (the “Company”, “we,” “us,” or “our”) is a global pharmaceutical company that develops, manufactures, markets and distributes a diverse portfolio of essential medicines, including complex generics, injectables, biosimilars and specialty branded pharmaceuticals. We operate principally in the United States, India, and Ireland, and sell to wholesalers, distributors, hospitals, chain pharmacies and individual pharmacies, either directly or indirectly. We are a holding company, whose principal assets are common units (“Amneal Common Units”) of Amneal Pharmaceuticals, LLC (“Amneal”).

The group, together with their affiliates and certain assignees, who owned Amneal when it was a private company (the “Amneal Group”) held 50.1% of Amneal Common Units and the Company held the remaining 49.9% as of December 31, 2022. Although the Company has a minority economic interest in Amneal, it is Amneal’s sole managing member, having the sole voting power to make all of Amneal’s business decisions and control its management. Therefore, the Company consolidates the financial statements of Amneal and its subsidiaries. The Company records non-controlling interests for the portion of Amneal’s economic interests that it does not hold.

The following discussion and analysis contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth under *Item 1A. Risk Factors* and under the heading Forward-Looking Statements in this Annual Report on Form 10-K. The following discussion and analysis, as well as other sections in this report, should be read in conjunction with the consolidated financial statements and related notes to consolidated financial statements included elsewhere herein.

For a discussion of our financial condition and results of operations for the year ended December 31, 2021 compared to the year ended December 31, 2020, see “*Results of Operations*” and “*Liquidity and Capital Resources*” under *Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations* in our 2021 Annual Report on Form 10-K, which discussion is incorporated herein by reference.

Overview

Segments

We have three reportable segments: Generics, Specialty, and AvKARE.

Generics

Our Generics segment includes over 250 product families covering an extensive range of dosage forms and delivery systems, including both immediate and extended release oral solids, powders, liquids, sterile injectables, nasal sprays, inhalation and respiratory products, ophthalmics, films, transdermal patches and topicals. We focus on developing products with substantial barriers-to-entry resulting from complex drug formulations or manufacturing, or legal or regulatory challenges. Generic products, particularly in the United States (“U.S.”), generally contribute most significantly to revenues and gross margins at the time of their launch, and even more so in periods of market exclusivity, or in periods of limited generic competition. As such, the timing of new product introductions can have a significant impact on the Company’s financial results. The entrance into the market of additional competition generally has a negative impact on the volume and / or pricing of the affected products. Additionally, pricing is determined by market place dynamics and is often affected by factors outside of the Company’s control.

Specialty

Our Specialty segment is engaged in the development, promotion, sale and distribution of proprietary branded pharmaceutical products, with a focus on products addressing CNS disorders, including Parkinson’s disease, and endocrine disorders. Our portfolio of products includes Rytary®, an extended release oral capsule formulation of carbidopa-levodopa for the treatment of Parkinson’s disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication. In addition to Rytary®, our promoted Specialty portfolio also includes Unithroid® (levothyroxine sodium), for the treatment of hypothyroidism, which is sold under a license and distribution agreement with Jerome Stevens Pharmaceuticals, Inc., and Lyvispah® (baclofen), a unique dissolvable granule formulation used to treat muscle stiffness, spasms and pain from multiple sclerosis.

Our Specialty products are marketed through skilled specialty sales and marketing teams, who call on neurologists, movement disorder specialists, endocrinologists and primary care physicians in key markets throughout the U.S. Our Specialty segment also has a number of product candidates that are in varying stages of development.

For Specialty products, the majority of the product's commercial value is usually realized during the period in which the product has market exclusivity. In the U.S., when market exclusivity expires and generic versions of a product are approved and marketed, there can often be very substantial and rapid declines in the branded product's sales.

AvKARE

Our AvKARE segment provides pharmaceuticals, medical and surgical products and services primarily to governmental agencies. AvKARE is a re-packager of bottle and unit dose pharmaceuticals under the registered names of AvKARE and AvPAK, which service the Department of Defense and Department of Veteran Affairs as well as institutional customers. AvKARE is also a wholesale distributor of pharmaceuticals, over the counter products and medical supplies to institutional customers which are located throughout the U.S. focused primarily on offering 340b-qualified entities products to provide consistency in care and pricing.

The Pharmaceutical Industry

The pharmaceutical industry is highly competitive and highly regulated. As a result, we face a number of industry-specific factors and challenges, which can significantly impact our results. For a more detailed explanation of our business and its risks, refer to *Item 1. Business* and *Item 1A. Risk Factors* in this Form 10-K.

Inflation

While it is difficult to accurately measure the impact of inflation, we estimate our business experienced an increase in costs due to inflation of approximately \$30.0 million for the year ended December 31, 2022. We expect an inflationary impact of approximately \$15.0 million for the year ending December 31, 2023. Notwithstanding our estimates, rising inflationary pressures due to higher input costs, including higher material, transportation, labor and other costs, could exceed our expectations and may adversely impact our operating results in future periods.

COVID-19 Pandemic

In March 2020, the World Health Organization designated the outbreak of a novel strain of coronavirus ("COVID-19") as a global pandemic. Governments and businesses around the world took unprecedented actions to mitigate the spread of COVID-19, including imposing restrictions on movement and travel such as quarantines and shelter-in-place requirements, and restricting or prohibiting outright some or all commercial and business activity, including the manufacture and distribution of certain goods and the provision of non-essential services.

The occurrence of regional epidemics or a global pandemic, such as the COVID-19 pandemic, have had and may continue to have an adverse effect on how we and our customers are operating our respective businesses and our operating results. Our operations have also been and may in the future be negatively affected by a range of external factors related to the pandemic that are not within our control, including the emergence and spread of more transmissible variants. The extent to which global pandemics, such as the COVID-19 pandemic, impact our financial condition or results of operations will depend on factors such as the duration and scope of the pandemic, as well as whether there is a material impact on the businesses or productivity of our customers, partners, employee, suppliers and other partners. To the extent that the pandemic harms our business and results of operations, many of the risks described in *Item 1A. Risk Factors* in this Form 10-K may be heightened

Results of Operations

Consolidated Results

The following table sets forth our summarized, consolidated results of operations (dollars in thousands):

	Years Ended December 31,		Increase (Decrease)	
	2022	2021	\$	%
Net revenue	\$ 2,212,304	\$ 2,093,669	\$ 118,635	5.7%
Cost of goods sold	1,416,485	1,302,004	114,481	8.8%
Cost of goods sold impairment charges	11,111	22,692	(11,581)	(51.0)%
Gross profit	784,708	768,973	15,735	2.0%
Selling, general and administrative	399,700	365,504	34,196	9.4%
Research and development	195,688	201,847	(6,159)	(3.1)%
In-process research and development impairment charges	12,970	710	12,260	nm
Intellectual property legal development expenses	4,358	7,716	(3,358)	(43.5)%
Acquisition, transaction-related and integration expenses	709	8,055	(7,346)	(91.2)%
Restructuring and other charges	1,421	1,857	(436)	(23.5)%
Change in fair value of contingent consideration	731	200	531	nm
(Insurance recoveries) charges for property losses and associated expenses, net	(1,911)	5,368	(7,279)	(135.6)%
Charges related to legal matters, net	269,930	25,000	244,930	nm
Other operating income	(3,960)	—	(3,960)	nm
Operating (loss) income	(94,928)	152,716	(247,644)	(162.2)%
Total other expense, net	(153,199)	(121,350)	(31,849)	26.2%
(Loss) income before income taxes	(248,127)	31,366	(279,493)	nm
Provision for income taxes	6,662	11,196	(4,534)	(40.5)%
Net (loss) income	<u>\$ (254,789)</u>	<u>\$ 20,170</u>	<u>\$ (274,959)</u>	<u>nm</u>

nm - not meaningful

Net Revenue

Net revenue for the year ended December 31, 2022 increased by 5.7%, or \$118.6 million, compared to the prior year, and was attributable to growth in net revenue in both the Generics and AvKARE segments, partially offset by a slight decrease in net revenue in the Specialty segment as follows:

- Generics net revenue for the year ended December 31, 2022 increased by 4.8%, or \$65.7 million, as compared to the prior year, primarily due to new products launched in 2022 and 2021 that contributed net revenue growth of \$42.4 million, the favorable year-over-year impact of lower returns relating to Oseltamivir (generic Tamiflu®), volume growth, and \$8.0 million in license revenue from an agreement with Orion Corporation (“Orion”), partially offset by continued price erosion. Refer to *Note 5. Alliance and Collaboration* for additional information on the agreement with Orion.
- AvKARE net revenue for the year ended December 31, 2022 increased 16.4%, or \$57.1 million, compared to the prior year, driven by growth in our distribution channel.
- Specialty net revenue for the year ended December 31, 2022 decreased 1.1%, or \$4.2 million, compared to the prior year, driven by the loss of exclusivity of Zomig® nasal spray and a decline in our other non-promoted products. Net revenue from our promoted products, including Unithroid® and Rytary®, increased 33% and 8%, respectively, as prescription growth remained strong for both products.

Cost of Goods Sold and Gross Profit

Cost of goods sold, including impairment charges, increased 7.8%, or \$102.9 million, for the year ended December 31, 2022 as compared to the prior year, and was attributable to increased Generics and AvKARE volume, inflation and a year-over-year reduction in operating efficiency, partially offset by the loss of exclusivity on Zomig® nasal spray and a reduction in marketed

product intangible asset impairment charges. Year-over-year, inflation increased cost of goods sold by approximately \$17.0 million, primarily related to freight charges.

Gross profit for the year ended December 31, 2022 was \$784.7 million (35.5% of net revenue) as compared to gross profit of \$769.0 million (36.7% of net revenue) for the prior year. Our gross profit as a percentage of net revenue decreased as compared to the prior year primarily as a result of the factors noted above.

Selling, General and Administrative

Selling, general and administrative (“SG&A”) expenses for the year ended December 31, 2022 increased 9.4%, or \$34.2 million, compared to the prior period. The increase was primarily due to an increase in employee compensation, costs associated with our biosimilar launches, including a \$5.0 million expense associated with a biosimilar regulatory approval, the launches of our new specialty products and increased logistics costs.

Research and Development

R&D expenses for the year ended December 31, 2022 decreased 3.1%, or \$6.2 million, compared to the prior year. The decrease was primarily attributable to a decrease in in-licensing and upfront milestone payments of \$15.3 million and reduced project spend primarily related to IPX203, partially offset by inflation, costs related to complex generics of \$17.9 million associated with acquired businesses in 2021.

In-Process Research and Development Impairment Charges

IPR&D impairment charges of \$13.0 million for the year ended December 31, 2022 were related to one Generics asset which experienced a delay in its expected launch date and one Generics asset which experienced significant expected price erosion, both of which resulted in significantly lower than expected future cash flows. IPR&D impairment charges of \$0.7 million in the prior year were related to one Generics asset which experienced a delay in its expected launch date, resulting in significantly lower than expected future cash flows.

Intellectual Property Legal Development Expenses

Intellectual property legal development expenses for the year ended December 31, 2022 were \$4.4 million as compared to \$7.7 million in the prior year. These costs include, but are not limited to, formulation assessments, patent challenge opinions and strategy, and litigation expenses to defend our intellectual property. The \$3.3 million decrease from the prior year was due to the timing of specific cases. Expenses may vary based upon the number of individual cases and corresponding litigation outstanding in a particular period.

Acquisition, Transaction-Related and Integration Expenses

Acquisition, transaction-related and integration expenses, primarily consisting of legal, investment banking and consulting fees, were \$0.7 million for the year ended December 31, 2022, as compared to \$8.1 million in the prior year.

Acquisition, transaction-related and integration expenses for the year ended December 31, 2022 were primarily related to the Saol Acquisition. For the year ended December 31, 2021, acquisition, transaction-related and integration expenses primarily related to the acquisitions and integration of Puniska and KSP, and the integration of the businesses that comprise our AvKARE segment. Refer to *Note 3. Acquisitions* for additional information.

(Insurance Recoveries) Charges for Property Losses and Associated Expenses, Net

On September 1, 2021, Tropical Storm Ida brought extreme rainfall and flash flooding to New Jersey that caused damage to two of our facilities. We concluded that all inventory on-hand at the time of the flooding was damaged and unsellable and that a majority of the equipment was damaged beyond repair. In addition, we incurred significant costs to repair both facilities. Accordingly, we recorded \$10.4 million of charges for property losses and associated expenses in our Generics segment for the year ended December 31, 2021. For the years ended December 31, 2022 and December 31, 2021, we recorded insurance recoveries of \$1.9 million and \$5.0 million, respectively, as a reduction of property losses and associated expenses in our Generics segment. Refer to *Note 27. (Insurance Recoveries) Charges for Property Losses and Associated Expenses, Net* for additional information.

Charges Related to Legal Matters, Net

For the year ended December 31, 2022, we recorded charges of \$269.9 million, primarily for corporate Opana® ER antitrust litigation of \$262.8 million and Generics segment civil prescription opioid litigation of \$18.0 million, partially offset by corporate insurance recoveries associated with securities class actions of \$15.5 million. For the year ended December 31, 2021, we recorded a net charge of \$25.0 million for corporate securities class actions. For further details, refer to *Note 21. Commitments and Contingencies*.

Other Operating Income

Other operating income for the year ended December 31, 2022 of \$4.0 million was comprised of income earned from the India Production Linked Incentive Scheme for the Pharmaceutical Sector in our Generics segment. Refer to *Note 6. Government Grants* for additional information.

Total Other Expense, Net

Total other expense, net was \$153.2 million for the year ended December 31, 2022, as compared to \$121.4 million in the prior year. Overall, the increase of \$31.8 million from the prior year was primarily due to a \$22.1 million increase in interest expense as a result of higher rates on our variable rate debt and a \$12.0 million increase in net foreign exchange losses related to the Indian rupee and the Euro.

Provision For Income Taxes

The provision for income taxes was \$6.7 million and \$11.2 million for the years ended December 31, 2022 and 2021, respectively. The effective tax rates for the years ended December 31, 2022 and 2021 were (2.7%) and 35.7%, respectively. The year-over-year change in the provision for income taxes was primarily related to the timing and mix of income, and to the release of reserves for uncertain tax positions under FIN 48 (codified at ASC 740-10, *Income Taxes*).

Generics

The following table sets forth the results of operations for our Generics segment (dollars in thousands):

	Years Ended December 31,		Increase (Decrease)	
	2022	2021	\$	%
Net revenue	\$ 1,432,073	\$ 1,366,338	\$ 65,735	4.8%
Cost of goods sold	890,245	825,568	64,677	7.8%
Cost of goods sold impairment charges	5,786	22,692	(16,906)	(74.5)%
Gross profit	536,042	518,078	17,964	3.5%
Selling, general and administrative	109,781	64,500	45,281	70.2%
Research and development	167,509	158,365	9,144	5.8%
In-process research and development impairment charges	12,970	710	12,260	nm
Intellectual property legal development expenses	4,251	7,562	(3,311)	(43.8)%
Acquisition, transaction-related and integration expenses	25	—	25	nm
Restructuring and other charges	821	80	741	nm
(Insurance recoveries) charges for property losses and associated expenses, net	(1,911)	5,368	(7,279)	(135.6)%
Charges related to legal matters, net	22,400	—	22,400	nm
Other operating income	(3,960)	—	(3,960)	nm
Operating income	\$ 224,156	\$ 281,493	\$ (57,337)	(20.4)%

nm - not meaningful

Net Revenue

Generics net revenue for the year ended December 31, 2022 increased by 4.8%, or \$65.7 million, as compared to the prior year, primarily due to new products launched in 2022 and 2021 that contributed net revenue growth of \$42.4 million, the favorable year-over-year impact of lower returns relating to Osetamivir (generic Tamiflu®), volume growth, and \$8.0 million in license

revenue from the agreement with Orion, partially offset by continued price erosion. Refer to *Note 5. Alliance and Collaboration* for additional information on the agreement with Orion.

Cost of Goods Sold and Gross Profit

Generics cost of goods sold, including impairment charges increased 5.6%, or \$47.8 million, for the year ended December 31, 2022 as compared to the prior year. The increase was primarily attributable to increased volume, inflation, and a year-over-year reduction in operating efficiency, partially offset by a reduction in marketed product intangible asset impairment charges. Year-over-year, inflation increased cost of goods sold by approximately \$17.0 million, primarily related to freight costs.

Generics gross profit for the year ended December 31, 2022 was \$536.0 million (37.4% of net revenue) as compared to gross profit of \$518.1 million (37.9% of net revenue) for the prior year as a result of the factors described above.

Selling, General, and Administrative

Generics SG&A for the year ended December 31, 2022 increased by 70.2% or \$45.3 million, compared to the prior year. The increase was primarily attributable to an increase in employee compensation, costs associated with our biosimilar launches, including the Saol Acquisition and a \$5.0 million expense associated with a biosimilar regulatory approval, and increased freight due to rising fuel costs.

Research and Development

Generics R&D expense for the year ended December 31, 2022 increased 5.8%, or \$9.1 million, as compared to the prior year. The increase was primarily associated with increased project spending as our complex portfolio continued to advance, inflation, and the costs related to complex generics of \$16.3 million associated with acquired businesses in 2021, partially offset by a decrease in in-licensing and upfront milestone payments of \$12.4 million.

In-Process Research and Development Impairment Charges

Generics IPR&D impairment charges of \$13.0 million for the year ended December 31, 2022 were related to one asset that experienced a delay in its expected launch date and one asset that experienced significant expected price erosion, both of which resulted in significantly lower than expected future cash flows. Generics IPR&D impairment charges of \$0.7 million in the prior year were related to one asset that experienced a delay in its expected launch date, resulting in significantly lower than expected future cash flows.

Intellectual Property Legal Development Expenses

Generics intellectual property legal development expenses for the year ended December 31, 2022 were \$4.3 million as compared to \$7.6 million in the prior year. These costs include, but are not limited to, formulation assessments, patent challenge opinions and strategy, and litigation expenses to defend our intellectual property. The \$3.3 million decrease from the prior year was due to the timing of specific cases. Expenses may vary based upon the number of individual cases and corresponding litigation outstanding in a particular period.

(Insurance Recoveries) Charges for Property Losses and Associated Expenses, Net

On September 1, 2021, Tropical Storm Ida brought extreme rainfall and flash flooding to New Jersey that caused damage to two of our facilities. We concluded that all inventory on-hand at the time of the flooding was damaged and unsellable and that a majority of the equipment was damaged beyond repair. In addition, we incurred significant costs to repair both facilities. Accordingly, we recorded \$10.4 million of charges for property losses and associated expenses in our Generics segment for the year ended December 31, 2021. For the years ended December 31, 2022 and December 31, 2021, we recorded insurance recoveries associated with property and equipment of \$1.9 million and \$5.0 million, respectively, as a reduction of property losses and associated expenses in our Generics segment. Refer to *Note 27. (Insurance Recoveries) Charges for Property Losses and Associated Expenses, Net* for additional information.

Charges Related to Legal Matters, Net

Generics charges related to legal matters, net for the year ended December 31, 2022 were \$22.4 million and were primarily comprised of \$18.0 million of charges for civil prescription opioid litigation. Refer to *Note 21. Commitments and Contingencies* for additional information.

Other Operating Income

Generics other operating income for the year ended December 31, 2022 of \$4.0 million was comprised of income earned from the India Production Linked Incentive Scheme for the Pharmaceutical Sector. Refer to *Note 6. Government Grants* for additional information.

Specialty

The following table sets forth the results of operations for our Specialty segment (dollars in thousands):

	Years Ended December 31,		Increase (Decrease)	
	2022	2021	\$	%
Net revenue	\$ 374,121	\$ 378,319	\$ (4,198)	(1.1)%
Cost of goods sold	177,107	193,562	(16,455)	(8.5)%
Cost of goods sold impairment charges	5,325	—	5,325	nm
Gross profit	191,689	184,757	6,932	3.8%
Selling, general and administrative	90,031	84,481	5,550	6.6%
Research and development	28,179	43,482	(15,303)	(35.2)%
Intellectual property legal development expenses	107	154	(47)	(30.5)%
Acquisition, transaction-related and integration expenses	49	16	33	nm
Change in fair value of contingent consideration	731	200	531	nm
Operating income	\$ 72,592	\$ 56,424	\$ 16,168	28.7%

nm - not meaningful

Net Revenue

Specialty net revenue for the year ended December 31, 2022 decreased 1.1%, or \$4.2 million, compared to the prior year, driven by the loss of exclusivity of Zomig® nasal spray and a decline in our other non-promoted products. Net revenue from our promoted products, including Unithroid® and Rytary®, increased 33% and 8%, respectively, as prescription growth remained strong for both products.

Cost of Goods Sold and Gross Profit

Specialty cost of goods sold, including impairment charges, for the year ended December 31, 2022 decreased 5.8%, or \$11.1 million, as compared to the prior year. Specialty gross profit for the year ended December 31, 2022 was \$191.7 million (51.2% of net revenue) as compared to gross profit of \$184.8 million (48.8% of net revenue) for the prior year. The increase in gross margin was due to growth in higher margin products, offsetting declines in net revenue for Zomig® nasal spray, which has a higher cost structure and lower margin than the overall Specialty portfolio.

Selling, General, and Administrative

Specialty SG&A expense for the year ended December 31, 2022 increased \$5.6 million, or 6.6%, as compared to the prior year, driven by an increase in expenses related to upcoming launches of specialty products and the launch of Lyvispah™ during 2022.

Research and Development

Specialty R&D expense for the year ended December 31, 2022 decreased 35.2% or \$15.3 million, compared to the prior year, driven by lower project costs as our IPX203 study wound down and a decrease in in-licensing and upfront milestone payments of \$2.9 million.

AvKARE

The following table sets forth the results of operations for our AvKARE segment (dollars in thousands):

	Years Ended December, 31		Increase (Decrease)	
	2022	2021	\$	%
Net revenue	\$ 406,110	\$ 349,012	\$ 57,098	16.4%
Cost of goods sold	349,133	282,874	66,259	23.4%
Gross profit	56,977	66,138	(9,161)	(13.9)%
Selling, general and administrative	53,659	57,918	(4,259)	(7.4)%
Acquisition, transaction-related and integration expenses	—	1,422	(1,422)	(100.0)%
Operating income (loss)	<u>\$ 3,318</u>	<u>\$ 6,798</u>	<u>\$ (3,480)</u>	<u>(51.2)%</u>

Net Revenue

AvKARE net revenue for the year ended December 31, 2022 increased 16.4%, or \$57.1 million, compared to the prior year, driven by growth in our distribution channel.

Cost of Goods Sold and Gross Profit

AvKARE cost of goods sold for the year ended December 31, 2022 increased 23.4%, or \$66.3 million, compared to the prior year. AvKARE gross profit for the year ended December 31, 2022 was \$57.0 million (14.0% of net revenue) as compared to gross profit of \$66.1 million (19.0% of net revenue) for the prior year. The year-over-year decrease in gross profit as a percentage of net revenue primarily related to the increase in sales through our lower margin distribution channel. The year-over-year decrease in gross profit was primarily related to a decrease in government label sales.

Selling, General, and Administrative

AvKARE SG&A expense for the year ended December 31, 2022 decreased 7.4%, or \$4.3 million, compared to the prior year, primarily due to a year-over-year decrease in amortization expense.

Acquisition, Transaction-Related and Integration Expenses

Acquisition, transaction-related and integration expenses for the year ended December 31, 2021 were comprised of finance integration expenses associated with the acquisitions of the businesses comprising our AvKARE segment. Refer to *Note 3. Acquisition* for additional information.

Liquidity and Capital Resources

Our primary source of liquidity is cash generated from operations, available cash and borrowings under debt financing arrangements, including \$285.9 million of available capacity on our New Revolving Credit Facility as of December 31, 2022, as defined in *Note 16. Debt*. We believe these sources are sufficient to fund our planned operations, meet our interest and contractual obligations and provide sufficient liquidity over the next 12 months. However, our ability to satisfy our working capital requirements and debt obligations will depend upon economic conditions, our ability to negotiate and maintain satisfactory terms under our borrowing and debt facilities in the future, and demand for our products, which are factors that may be out of our control. Our primary uses of capital resources are to fund operating activities, including R&D expenses associated with new product filings, and pharmaceutical product manufacturing expenses, license payments, spending on production facility expansions, capital equipment, acquisitions, and legal settlements.

We estimate that we will invest approximately \$50.0 million to \$60.0 million during 2023 for capital expenditures to support and grow our existing operations, primarily related to investments in manufacturing equipment, information technology and facilities.

Debt Instruments

Over the next 12 months, we expect to make substantial payments for monthly interest and quarterly principal amounts due for our debt instruments, including our Term Loan and Rondo Term Loan, contractual payments for leased premises, and payments for legal settlements. Annually, we are also required to calculate the amount of excess cash flows, as defined in the Term Loan agreement. Based on the results of the excess cash flows calculation for the year ended December 31, 2020, the Company made a \$14.4 million additional principal payment towards our Term Loan March 2021. Based on the results of the excess cash flows calculation for the years ended December 31, 2022 and 2021, no excess cash flows principal payments were required. Related to our Rondo Term Loan, we made prepayments totaling \$58.3 million towards the outstanding principal during the year ended December 31, 2022, in addition to planned principal payments. Refer to *Note 16. Debt* for additional information.

Tax Receivable Agreement

We are party to a tax receivable agreement (“TRA”) that requires us to make cash payments to the Members other than the Company, in respect of certain tax benefits that we may realize or may be deemed to realize as a result of sales or exchanges of Amneal common units by the Members. The timing and amount of any payments under the TRA will also vary, depending upon a number of factors including the timing and number of Amneal common units sold or exchanged for our class A Common Stock, the price of our class A Common Stock on the date of sale or exchange, the timing and amount of our taxable income, and the tax rate in effect at the time of realization of our taxable income. The tax receivable agreement also requires that we make an accelerated payment to the Members equal to the present value of all future payments due under the agreement upon certain change of control and similar transactions. Further sales or exchanges occurring subsequent to December 31, 2022 could result in future Amneal tax deductions and obligations to pay 85% of such benefits to the holders of Amneal common units. These obligations could be incremental to and substantially larger than the approximate \$202.7 million contingent liability as of December 31, 2022. As a result of the foregoing, our obligations under the tax receivable agreement could have a substantial negative impact on our liquidity. For further information, refer to *Item 1A. Risk Factors* and *Note 7. Income Taxes*.

Tax-related Distributions to Amneal Members

In addition, pursuant to the limited liability operating agreement of Amneal, as amended, in connection with any tax period, we are required to make distributions to Amneal's members, on a pro rata basis in proportion to the number of Amneal Common Units held by each member, of cash until each member (other than Amneal) has received an amount at least equal to its assumed tax liability and Amneal has received an amount sufficient to enable it to timely satisfy all of its U.S. federal, state and local and non-U.S. tax liabilities, and meet its obligations pursuant to the tax receivable agreement. During the years ended December 31, 2022 and 2021, we made tax distributions of \$10.6 million and \$53.5 million, respectively, to Amneal's members.

Cash Balances

At December 31, 2022, our cash and cash equivalents consist of cash on deposit and highly liquid investments. A portion of our cash flows are derived outside the U.S. As a result, we are subject to market risk associated with changes in foreign exchange rates. We maintain cash balances at both U.S. based and foreign country based commercial banks. At various times during the year, our cash balances held in the United States may exceed amounts that are insured by the Federal Deposit Insurance Corporation. We make our investments in accordance with our investment policy. The primary objectives of our investment policy are liquidity and safety of principal.

Cash Flows

For a discussion comparing of our cash flows for the fiscal years 2021 to 2020, see *Cash Flows* under *Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* in our 2021 Annual Report on Form 10-K.

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The following table sets forth our summarized, consolidated cash flows for the years ended December 31, 2022 and 2021 (in thousands):

	Years Ended December 31,		Increase (Decrease)	
	2022	2021	\$	%
Cash provided by (used in):				
Operating activities	\$ 65,100	\$ 241,820	\$ (176,720)	(73.1)%
Investing activities	(174,309)	(194,182)	19,873	(10.2)%
Financing activities	(106,620)	(138,122)	31,502	(22.8)%
Effect of exchange rate changes on cash	(5,683)	102	(5,785)	(5671.6)%
Net decrease in cash, cash equivalents, and restricted cash	<u>\$ (221,512)</u>	<u>\$ (90,382)</u>	<u>\$ (131,130)</u>	145.1 %

Cash Flows from Operating Activities

Net cash provided by operating activities was \$65.1 million for the year ended December 31, 2022 as compared to \$241.8 million for the prior year. The year-over-year decrease was primarily driven by \$140.6 million in payments associated with the Opana® ER antitrust litigation and the securities class action - Cambridge Retirement System v. Amneal, in addition to the corresponding legal fees. Refer to *Note 21. Commitments and Contingencies* for additional information.

Cash Flows from Investing Activities

Net cash used in investing activities was \$174.3 million for the year ended December 31, 2022 compared to \$194.2 million for the prior year. The \$19.9 million year-over-year decrease was primarily due to a decrease of \$61.8 million in cash paid for business acquisitions (refer to *Note 3. Acquisitions* for additional information), partially offset by a \$40.1 million increase in cash paid for intangible assets associated with marketed product licenses.

Cash Flows from Financing Activities

Net cash used in financing activities was \$106.6 million for the year ended December 31, 2022 as compared to net cash used in financing activities of \$138.1 million for prior year. The year-over-year decrease of \$31.5 million was primarily due to \$85.0 million of borrowings under the New Revolving Credit Facility and a \$39.6 million decrease in tax distributions, partially offset by \$44.5 million paid for deferred consideration associated with the acquisition of Kashiv Specialty Pharmaceuticals, LLC and Puniska Healthcare Pvt. Ltd. (refer to *Note 3. Acquisitions*) and an increase in principal payments made on borrowings of \$45.2 million, including repayment of \$25.0 million of borrowings under the New Revolving Credit Facility (refer to *Note 16. Debt*).

Commitments and Contractual Obligations

Our contractual obligations as of December 31, 2022 were as follows (in thousands):

Contractual Obligations	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Term Loan and other ⁽¹⁾	\$ 2,563,876	\$ 27,000	\$ 2,536,876	\$ —	\$ —
Interest payments on Term Loan ⁽¹⁾	487,155	209,487	277,668	—	—
Operating lease obligations ⁽²⁾	76,028	15,843	30,822	17,813	11,550
Financing lease obligation ⁽³⁾	118,209	7,976	13,379	11,634	85,220
Rondo Term Loan ⁽⁴⁾	72,000	9,000	63,000	—	—
Interest payments on Rondo Term Loan ⁽⁴⁾	7,986	4,120	3,866	—	—
New Revolving Credit Facility ⁽⁵⁾	60,000	60,000	—	—	—
Interest payments on New Revolving Credit Facility ⁽⁵⁾	4,259	4,259	—	—	—
Opana ER® antitrust litigation settlements ⁽⁶⁾	133,944	83,944	50,000	—	—
Interest associated with Opana ER® antitrust litigation settlements ⁽⁶⁾	3,951	1,536	2,415	—	—
Total	<u>\$ 3,527,408</u>	<u>\$ 423,165</u>	<u>\$ 2,978,026</u>	<u>\$ 29,447</u>	<u>\$ 96,770</u>

- (1) A description of our Term Loan due May 2025, and related debt service and interest requirements is contained in *Note 16. Debt*. Interest on our Term Loan was calculated based on applicable rates at December 31, 2022, excluding the impact of our interest rate swap.
- (2) Amounts represent future minimum rental payments under non-cancelable facility leases. A discussion of our operating lease obligations is contained in *Note 18. Leases*.
- (3) Amounts primarily represent future minimum rental payments under non-cancelable financing lease obligation for a production facility in New York. A discussion of our financing lease obligations is contained in *Note 18. Leases*.
- (4) Rondo Term Loan relates to the Rondo Acquisitions (each as defined in *Note 3. Acquisitions*). Interest on the Rondo Term Loan was calculated based on the applicable rate at December 31, 2022. A discussion of the Rondo Term Loan, and related debt service and interest requirements is contained in *Note 16. Debt*.
- (5) Represents the amount due on the New Revolving Credit Facility (as defined in *Note 16. Debt*). Interest on the New Revolving Credit Facility was calculated based on the applicable rate at December 31, 2022. A discussion of the New Revolving Credit Facility is contained in *Note 16. Debt*.
- (6) Refer to *Note 21. Commitments and Contingencies* for additional information.

The foregoing table does not include milestone payments potentially payable by the Company under its collaboration agreements and potential payments under the Company's contingent consideration arrangements. Such payments are dependent upon the occurrence of specific and contingent events, and not the passage of time. A discussion of our significant contingent milestones is contained in *Note 5. Alliance and Collaboration* and *Note 24. Related Party Transactions* and a discussion of our contingent consideration arrangements is contained in *Note 3. Acquisitions* and *Note 19. Fair Value Measurements*. Additionally, the foregoing table does not include \$44.2 million of aggregate principal and related interest due on the Sellers Notes (as defined in *Note 3. Acquisitions*) because the timing of the associated payments is dependent on the occurrence of future events. Refer to the section *Rondo Acquisitions Financing – Notes Payable-Related Party* in *Note 16. Debt* for a discussion of the terms of this indebtedness and descriptions of terms.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of December 31, 2022.

Critical Accounting Policies

Our significant accounting policies are described in *Note 2. Summary of Significant Accounting Policies*.

Included within these policies are certain policies which contain critical accounting estimates and, therefore, have been deemed to be "critical accounting policies." Critical accounting estimates are those which require management to make assumptions about matters that were uncertain at the time the estimate was made and for which the use of different estimates, which reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur from period to period could have a material impact on our financial condition or results of operations. We have identified the following to be our critical accounting policies: sales-related deductions, business combinations (including contingent consideration) impairment of goodwill and intangible assets, income taxes and contingencies.

Sales-Related Deductions

Our gross product revenue is subject to a variety of deductions, which are estimated and recorded in the same period that the revenue is recognized, and primarily represent chargebacks, rebates, group purchasing organization fees, prompt payment (cash) discounts, consideration payable to the customer, billbacks, Medicaid and other government pricing programs, price protection and shelf stock adjustments, and sales returns. Those deductions represent estimates of rebates and discounts related to gross sales for the reporting period and, as such, knowledge and judgment of market conditions and practice are required when estimating the impact of these revenue deductions on gross sales for a reporting period.

Historically, our changes of estimates reflecting actual results or updated expectations have not been material to our overall business. If any of our ratios, factors, assessments, experiences or judgments are not indicative or accurate predictors of our future experience, our results could be materially affected. The sensitivity of our estimates can vary by program, type of customer and geographic location. However, estimates associated with governmental allowances, Medicaid and other performance-based contract rebates are most at risk for material adjustment because of the extensive time delay between the recording of the accrual and its ultimate settlement, an interval that can generally range up to one year. Because of this time lag, in any given quarter, our adjustments to actual can incorporate revisions of several prior quarters.

Business Combinations

We account for acquired businesses using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recorded at the date of acquisition at their respective fair values. The consolidated financial statements and results of operations reflect an acquired business after the completion of the acquisition. The fair value of the consideration paid is assigned to the underlying net assets of the acquired business based on their respective fair values as determined using a market participant concept. Any excess of the purchase price over the fair value of net assets and other identifiable intangible assets acquired is recorded as goodwill.

Intangible assets are amortized over the estimated useful life of the asset. Significant judgments are used in determining the estimated fair values assigned to the assets acquired and liabilities assumed and in determining estimates of useful lives of long-lived assets. Fair value determinations and useful life estimates are based on, among other factors, estimates of expected future net cash flows, estimates of appropriate discount rates used to present value expected future net cash flow streams, the assessment of each asset's life cycle, competitive trends impacting the asset and each cash flow stream, as well as other factors. These judgments can materially impact the estimates used to allocate acquisition date fair values to assets acquired and liabilities assumed and the future useful lives. For these and other reasons, actual results may vary significantly from estimated results.

Impairment of Goodwill and Intangible Assets

Goodwill

Goodwill, which represents the excess of purchase price over the fair value of net assets acquired, is carried at cost. Goodwill is not amortized; rather, it is subject to a periodic assessment for impairment by applying a fair value based test. We test goodwill for possible impairment annually during the fourth quarter, or whenever events or circumstances indicate that the carrying amount may not be recoverable.

In order to test goodwill for impairment, an entity is permitted to first assess qualitative factors to determine whether a quantitative assessment of goodwill is necessary. The qualitative factors considered by the Company may include, but are not limited to, general economic conditions, the Company's outlook, market performance of the Company's industry and recent and forecasted financial performance. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that a reporting unit's fair value is less than its carrying amount. Otherwise, no further impairment testing is required. If a quantitative assessment is required, the Company determines the fair value of its reporting unit using a combination of the income and market approaches. If the net book value of the reporting unit exceeds its fair value, the Company recognizes a goodwill impairment charge for the reporting unit equal to the lesser of (i) the total goodwill allocated to that reporting unit and (ii) the amount by which that reporting unit's carrying amount exceeds its fair value.

Goodwill is allocated and evaluated for impairment at the reporting unit level, which is defined as an operating segment or one level below an operating segment. Our reportable segments are the same as the respective operating segments and reporting units. As of December 31, 2022, \$366.3 million, \$163.1 million, and \$69.5 million of goodwill was allocated to our Specialty, Generics, and AvKARE segments, respectively. During the fourth quarter of 2022, we tested each of the reporting units for impairment using a quantitative assessment. The determination of fair value in the quantitative assessment required us to make significant estimates and assumptions. These estimates and assumptions primarily included, but were not limited to: the selection of appropriate peer group companies, the discount rate, terminal growth rates, forecasts of revenue, operating income, depreciation and amortization, restructuring charges and capital expenditures. For more information see *Note 13. Goodwill and Other Intangible Assets*. There was no impairment of goodwill in any reporting unit for the year ended December 31, 2022.

Significant judgment is used in determining the assumptions utilized in our quantitative assessment. Accordingly, any changes in assumptions described above could have a material impact on our consolidated results of operations. Additionally, for each of our reporting units, there are a number of future events and factors that may impact future results and the outcome of subsequent goodwill impairment testing. For a list of these factors, see Item 1A. *Risk Factors*.

Intangible Assets

We review our long-lived assets, including intangible assets with finite lives, for recoverability whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. We evaluate assets for potential impairment by comparing estimated future undiscounted net cash flows to the carrying amount of the asset. If the carrying amount of the assets exceeds the estimated future undiscounted cash flows, impairment is measured based on the difference between the carrying amount of the assets and fair value which is generally an expected present value cash flow technique. Our

policy in determining whether an impairment indicator exists comprises measurable operating performance criteria as well as other qualitative measures. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. Factors that we consider in deciding when to perform an impairment review include significant under-performance of a product in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in our use of the assets. If our assumptions are not correct, there could be an impairment loss in subsequent periods or, in the case of a change in the estimated useful life of the asset, a change in amortization expense.

Intangible assets with indefinite lives, including IPR&D, are tested for impairment if impairment indicators arise and, at a minimum, annually. However, an entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that an indefinite-lived intangible asset's fair value is less than its carrying amount. Otherwise, no further impairment testing is required. The indefinite-lived intangible asset impairment test consists of a one-step analysis that compares the fair value of the intangible asset with its carrying amount. If the carrying amount of an intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. We consider many factors in evaluating whether the value of its intangible assets with indefinite lives may not be recoverable, including, but not limited to the discount rate, terminal growth rates, general economic conditions, our outlook and market performance of our industry and recent and forecasted financial performance.

For the year ended December 31, 2022, we recognized a total of \$24.1 million of intangible asset impairment charges, of which \$11.1 million was recognized in cost of goods sold and \$13.0 million was recognized in IPR&D. The impairment charges for the year ended December 31, 2022 primarily related to three currently marketed products and two IPR&D products. Cost of sales impairment charges for the year ended December 31, 2022 of \$11.1 million related to currently marketed products, of which (i) one product experienced significant price erosion during 2022, resulting in significantly lower than expected future cash flows and negative margins, (ii) the supply agreement of one product was terminated during 2022 and therefore the asset was not recoverable and (iii) one product was no longer expected to be sold to a key customer, and therefore the asset was not recoverable. IPR&D impairment charges for the year ended December 31, 2022 of \$13.0 million related to (i) one asset that experienced a delay in its expected launch date and (ii) one asset that experienced significant expected price erosion, both of which resulted in significantly lower than expected future cash flows.

Income Taxes

We record valuation allowances against our DTAs when it is more likely than not that all or a portion of a DTA will not be realized. We routinely evaluate the realizability of our DTAs by assessing the likelihood that our DTAs will be recovered based on all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, estimates of future taxable income, tax planning strategies and results of operations. Estimating future taxable income is inherently uncertain and requires judgment. In projecting future taxable income, we consider our historical results and incorporate certain assumptions, including projected new product launches, revenue growth, and operating margins, among others.

A valuation allowance, if needed, reduces DTAs to the amount expected to be realized. When determining the amount of net DTAs that are more likely than not to be realized, we assess all available positive and negative evidence. This evidence includes, but is not limited to, prior earnings history, projected future earnings, carryback and carry-forward periods and the feasibility of ongoing tax strategies that could potentially enhance the likelihood of the realization of a DTA. The weight given to the positive and negative evidence is commensurate with the extent the evidence may be objectively verified. As such, it is generally difficult for positive evidence regarding projected future taxable income to outweigh objective negative evidence of recent financial reporting losses.

As of December 31, 2022, based upon all available objective and verifiable evidence both positive and negative, including historical levels of pre-tax income (loss) both on a consolidated basis and tax reporting entity basis, legislative developments, expectations and risks associated with estimates of future pre-tax income, and prudent and feasible tax planning strategies, we determined that it is more likely than not that we will not realize the benefits of our gross DTAs. Accordingly, as of December 31, 2022, this valuation allowance was \$434.9 million and reduced the carrying value of these gross DTAs, net of the impact of the reversal of taxable temporary differences, to zero.

As described in *Note 7. Income Taxes*, we are a party to a TRA under which we are generally required to pay to the other holders of Amneal Common Units 85% of the applicable tax savings, if any, in U.S. federal and state income tax that we are deemed to realize as a result of certain tax attributes of their Amneal Common Units sold to us (or exchanged in a taxable sale) and that are created as a result of (i) the sales of their Amneal Common Units for shares of Class A common stock and (ii) tax benefits attributable to payments made under the TRA.

The timing and amount of any payments under the TRA may vary, depending upon a number of factors including the timing and number of Amneal common units sold or exchanged for our Class A Common Stock, the price of our Class A Common Stock on the date of sale or exchange, the timing and amount of our taxable income, and the tax rate in effect at the time of realization of the our taxable income (the TRA liability is determined based on a percentage of the corporate tax savings from the use of the TRA's attributes). Further sales or exchanges occurring subsequent to December 31, 2022 could result in future Amneal tax deductions and obligations to pay 85% of such benefits to the holders of Amneal common units.

The projection of future taxable income involves significant judgment. Actual taxable income may differ materially from our estimates, which could significantly impact our liabilities under the TRA. As noted above, we have determined it is more-likely-than-not we will be unable to utilize all of our DTAs subject to the TRA; therefore, as of December 31, 2022 and 2021, we had not recognized the entire contingent liability under the TRA related to the tax savings we may realize from common units sold or exchanged. If utilization of these DTAs becomes more-likely-than-not in the future, at such time, these TRA liabilities (which amount to approximately \$202.7 million as of December 31, 2022, as a result of basis adjustments under Internal Revenue Code Section 754) will be recorded through charges to our statements of operations. However, if the tax attributes are not utilized in future years, it is reasonably possible no amounts would be paid under the TRA in excess of the \$0.6 million accrued as of December 31, 2022. Should we determine that a DTA with a valuation allowance is realizable in a subsequent period, the related valuation allowance will be reversed and if a resulting TRA payment is determined to be probable, a corresponding TRA liability will be recorded.

Contingencies

We are involved in various litigation, government investigations and other legal proceedings that arise from time to time in the ordinary course of business. Our legal proceedings are complex, constantly evolving and subject to uncertainty. As such, we cannot predict the outcome or impact of our legal proceedings.

While we believe we have valid claims and/or defenses for the matters described in *Note 21. Commitments and Contingencies*, the nature of litigation is unpredictable and the outcome of the proceedings could include damages, fines, penalties and injunctive or administrative remedies. For any proceedings where losses are probable and reasonably capable of estimation, we accrue for a potential loss. When we have a probable loss for which a reasonable estimate of the liability is a range of losses and no amount within that range is a better estimate than any other amount, we record the loss at the low end of the range. While these accruals have been deemed reasonable by our management, the assessment process relies heavily on estimates and assumptions that may ultimately prove inaccurate or incomplete. Additionally, unforeseen circumstances or events may lead us to subsequently change our estimates and assumptions. The process of analyzing, assessing and establishing reserve estimates relative to legal proceedings involves a high degree of judgment.

The ultimate resolution of any or all claims, legal proceedings or investigations are inherently uncertain and difficult to predict, could differ materially from our estimates and could have a material adverse effect on our results of operations and/or cash flows in any given accounting period, or on the Company's overall financial condition.

For further details, see *Note 21. Commitments and Contingencies*.

Recently Issued Accounting Standards

Recently issued accounting standards are discussed in *Note 2. Summary of Significant Accounting Policies*.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our cash is held on deposit in demand accounts at large financial institutions in amounts in excess of the FDIC insurance coverage limit of \$250,000 per depositor, per FDIC-insured bank, per ownership category. Our cash equivalents are comprised of highly rated money market funds. We had no short-term investments as of December 31, 2022 or December 31, 2021.

Financial instruments that potentially subject us to concentrations of credit risk consist principally of cash equivalents and accounts receivable. We limit our credit risk associated with cash equivalents by placing investments with high credit quality securities, including U.S. government securities, treasury bills, corporate debt, short-term commercial paper and highly rated money market funds. As discussed in *Note 16. Debt*, we are party to a term loan with a principal amount of \$2.7 billion and an asset backed revolving credit facility under which loans and letters of credit up to a principal amount of \$285.9 million are available as of December 31, 2022 (principal amount of up to \$20.9 million remains available for letters of credit). The proceeds for any loans made under our asset backed revolving credit facility are available for capital expenditures, acquisitions, working capital needs and other general corporate purposes.

We limit our credit risk with respect to accounts receivable by performing credit evaluations when deemed necessary. We do not require collateral to secure amounts owed to us by our customers.

By the nature of our global operations, we are exposed to cash flow and earnings fluctuations resulting from foreign exchange rate variation. These exposures are transactional and translational in nature. Since we manufacture and sell our products throughout the world, we believe our foreign currency risk is diversified. Principal drivers of this diversified foreign exchange exposure include the European Euro, Indian Rupee, and the Swiss Franc. Our transactional exposure arises from the purchase and sale of goods and services in currencies other than the functional currency of our operational units. We also have exposure related to the translation of financial statements of our foreign divisions into U.S. dollars, our functional currency. The financial statements of our operations outside the U.S. are measured using the local currency as the functional currency. Adjustments to translate the assets and liabilities of these foreign operations into U.S. dollars are accumulated as a component of other comprehensive income/(loss). Transaction gains and losses are included in the determination of our net income in our statements of operations. Such foreign currency transaction gains and losses include fluctuations related to long term intercompany loans that are payable in the foreseeable future.

While it is difficult to accurately measure the impact of inflation, we estimate our business experienced an increase in costs due to inflation of approximately \$30.0 million for the year ended December 31, 2022. We expect an inflationary impact of approximately \$15.0 million for the year ending December 31, 2023. However, rising inflationary pressures due to higher input costs, including higher material, transportation, labor and other costs, could exceed our expectations and may adversely impact our operating results in future periods.

In the normal course of operations, we are exposed to market risks relating to our long-term debt arising from adverse changes in interest rates. Market risk is defined for these purposes as the potential change in the fair value of a financial asset or liability resulting from an adverse movement in interest rates. Changes in interest rates impact fixed and variable rate debt differently. For fixed rate debt, a change in interest rates will impact only the fair value of the debt, whereas for variable rate debt, a change in the interest rates will impact interest expense and cash flows.

At December 31, 2022 and 2021, we had \$2.64 billion and \$2.73 billion, respectively, of variable rate debt. Our debt as of December 31, 2022 comprised of our Term Loan, with principal outstanding of \$2.56 billion, and our Rondo Term Loan, with principal outstanding of \$72.0 million. We estimated the fair values of the Term Loan and Rondo Term loan using quoted prices in active markets and yields for the same or similar types of borrowings, taking into account the underlying terms of the debt instruments. At both December 31, 2022 and 2021, we estimated the fair value of the Term Loan to be \$2.3 billion and \$2.6 billion, respectively. We estimated the fair value of the Rondo Term loan to be \$70.9 million and \$138.9 million at December 31, 2022 and 2021, respectively.

In October 2019, we entered into an interest rate lock agreement for a total notional amount of \$1.3 billion whereby we exchanged floating for fixed rate interest payments for our LIBOR based borrowing under our Term Loan. At inception and at year end, we assessed hedge effectiveness and determined it to continue to be highly effective. We also reviewed the credit standing of the counterparty at year end and deemed the counterparties to have the ability to honor their obligations. The fair value of the variable-to-fixed interest rate swap was an asset of \$85.6 million as of December 31, 2022. We estimated that a hypothetical 100 basis point increase in the forward one-month LIBOR curve would potentially increase the fair value of the variable-to-fixed interest rate swap to \$114.0 million while a hypothetical 100 basis point decrease in the forward one-month LIBOR curve would potentially decrease the fair value to \$58.2 million as of December 31, 2022.

Increases or decreases in interest rates would affect our annual interest expense. Based on the principal amount of the Term Loan outstanding as of December 31, 2022, a hypothetical 100 basis point increase or decrease in interest rates would have affected our annual interest expense by approximately \$26.0 million (before the impact of the interest rate lock agreement discussed above). Based on the principal amount of the Rondo Term Loan outstanding as of December 31, 2022, a hypothetical 100 basis point increase or decrease in interest rates would have affected our annual interest expense by approximately \$0.7 million.

Item 8. Financial Statements and Supplementary Data

The consolidated financial statements listed in *Item 15. Exhibits, Financial Statement Schedules* are filed as part of this Annual Report on Form 10-K and incorporated by reference herein.

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

Not applicable.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) that are designed to ensure information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our Co-Chief Executive Officers and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our Co-Chief Executive Officers and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based upon that evaluation, our Co-Chief Executive Officers and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2022.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on the assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2022. Ernst & Young LLP has independently assessed the effectiveness of our internal control over financial reporting and its report is included below.

Changes in Internal Control over Financial Reporting

During the quarter ended December 31, 2022, there were no changes in internal control over financial reporting which materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitation on Effective Controls

Management, including our Co-Chief Executive Officers and Chief Financial Officer, does not expect that our disclosure controls and procedures or its system of internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed or operated, can provide only reasonable, but not absolute, assurance that the objectives of the system of internal control are met. The design of our control system reflects the fact that there are resource constraints, and that the benefits of such control system must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control failures 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 simple error or mistake. Additionally, controls can be circumvented by the intentional acts of individuals, by collusion of two or more people, or by management override of the controls. The design of any system of controls is also based in part on certain assumptions about the likelihood of future events, and there can be no assurance that the design of any particular control will always succeed in achieving its objective under all potential future conditions.

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control Over Financial Reporting

We have audited Amneal Pharmaceuticals Inc.'s internal control over financial reporting as of December 31, 2022, 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, Amneal Pharmaceuticals, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, 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, 2022 and 2021, the related consolidated statements of operations, comprehensive (loss) income, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2022, and the related notes and our report dated March 3, 2023 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

Iselin, New Jersey
March 3, 2023

Item 9B. Other Information

On February 27, 2023, the Compensation Committee of the Board of Directors approved an amendment to each of the employment agreements of Anastasios Konidaris, Andrew Boyer, and Nikita Shah to extend the termination date to March 31, 2025.

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

Not applicable.

PART III.

Item 10. Directors, Executive Officers and Corporate Governance

The information required in this Item 10 will be included in the following sections in the 2023 Proxy Statement, which sections are incorporated in this Item 10 by reference: “Proposal No. 1-Election of Directors”, “Our Management”, “Committees of the Board of Directors”, “Audit Committee” and, if included in the 2023 Proxy Statement, “Delinquent Section 16(a) Reports”.

Code of Business Conduct for Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer. We have adopted a Code of Business Conduct that applies to all of our employees, officers and directors. The full text of our Code of Business Conduct is available at the investors section of our website, <http://investors.amneal.com>. We intend to disclose any amendment to, or waiver from, a provision of the Code of Business Conduct that applies to our principal executive officer, principal financial officer or principal accounting officer in the investors section of our website.

Item 11. Executive Compensation

The information required in this Item 11 will be included in the following sections in the 2023 Proxy Statement, which sections are incorporated in this Item 11 by reference to the extent required by this Item 11: “Compensation Discussion and Analysis,” “Executive Compensation,” “Director Compensation,” “The Board’s Role in Risk Oversight,” “Compensation Committee Interlocks and Insider Participation” and “Report of the Compensation Committee.” Notwithstanding the foregoing, the information in the section entitled “Report of the Compensation Committee” and “Pay Versus Performance” is only “furnished” herein and shall not be deemed “filed” for purposes of Section 18 of the Exchange Act.

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

Except as set forth below, the information required in this Item 12 will be included in the section entitled “Beneficial Ownership” in the 2023 Proxy Statement, which section is incorporated in this Item 12 by reference.

Securities Authorized for Issuance Under Equity Compensation Plans. The following table summarizes information, as of December 31, 2022, relating to the Amneal Pharmaceuticals, Inc. 2018 Incentive Award Plan, which was approved by the Company’s stockholders and which authorizes the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, other stock or cash-based awards and dividend equivalent awards to employees, non-employee directors and consultants.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	20,577,054 (1)	4.38 (2)	10,005,452
Equity compensation plans not approved by security holders	—	—	—
Total	20,577,054	4.38	10,005,452

- (1) Equity compensation plans approved by security holders which are included in column (a) of the table are the 2018 Incentive Award Plan (including 2,620,065 shares of Class A Common Stock to be issued upon exercise of outstanding options and 17,928,613 shares of Class A Common Stock to be issued upon vesting and settlement of outstanding restricted stock units (“RSUs”) and market performance-based restricted stock units (“MPRSUs”) subject to continued employment) and 28,376 of options remaining from the Impax option conversion associated with the acquisition of Impax on May 4, 2018. RSUs and MPRSUs included in column (a) of the table represent the full number of RSUs and MPRSUs awarded and outstanding whereas the number of shares of Class A Common Stock to

be issued upon vesting will be lower than what is reflected on the table because the value of shares required to meet employee tax withholding requirements are not issued.

- (2) Column (b) relates to stock options and does not include any exercise price for RSUs and MPRSUs because their value is dependent upon attainment of continued employment or service and they are settled for shares of Class A Common Stock on a one-for-one basis.

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

The information required in this Item 13 will be included in the following sections in the 2023 Proxy Statement, which sections are incorporated in this Item 13 by reference: “Certain Related Parties and Related Party Transactions,” “Controlled Company Status” and “Committees of the Board of Directors.”

Item 14. Principal Accounting Fees and Services

The independent registered public accounting firm is Ernst & Young LLP, Iselin, NJ, PCAOB ID 42 .

The information required in this Item 14 will be included in the section entitled “Independent Registered Public Accounting Firm Fees” in the 2023 Proxy Statement, which section is incorporated in this Item 14 by reference.

PART IV.

Item 15. Exhibits, Financial Statement Schedules

(a)(1) Consolidated Financial Statements

Index to financial statements and supplementary data filed as part of this Report.

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(a)(2) Financial Statement Schedules

All schedules are omitted because they are not required or because the required information is included in the Consolidated Financial Statements or notes thereto.

(a)(3) Exhibits

See the "Exhibit Index" prior to the signature page of this Annual Report on Form 10-K.

Item 16. Form 10-K Summary

None.

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Amneal Pharmaceuticals, Inc. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive (loss) income, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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 March 3, 2023 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 Matters

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

Medicaid Rebates

Description of the Matter

As discussed in Note 4 to the consolidated financial statements, the Company recognizes revenue from product sales based on amounts due from customers net of allowances for variable consideration, which include, among others, rebates mandated by law under Medicaid and other government pricing programs. The Company includes an estimate of variable consideration in its transaction price at the time of sale, when control of the product transfers to the customer. The Company estimates its Medicaid and other government pricing accruals based on monthly sales, historical experience of claims submitted by the various states and jurisdictions, historical rebate rates and estimated lag time of the rebate invoices. At December 31, 2022, the Company had \$86 million in accrued Medicaid and commercial rebates, which are presented within accounts payable and accrued expenses on the consolidated balance sheet.

Auditing the allowances for Medicaid rebates was complex and challenging due to the significant estimation involved in management's assumptions to calculate expected future claims and the amount of projected shipments from wholesalers that will be dispensed to eligible benefit plan participants, as well as the complexity of governmental pricing calculations. The allowances for Medicaid rebates are sensitive to these significant assumptions and calculations.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over management's review of the allowances for Medicaid rebates. For example, we tested controls over management's review of the significant assumptions including the completeness and accuracy of inputs utilized in significant assumptions as well as controls over management's review of the application of the government pricing regulations.

To test the allowances for Medicaid rebates, we performed audit procedures that included, among others, evaluating the methodologies used and testing the significant assumptions discussed above. We compared the significant assumptions used by management to historical trends, evaluated the change in the accruals from prior periods, and assessed the historical accuracy of management's estimates against actual results. We also tested the completeness and accuracy of the underlying data used in the Company's calculations through third-party invoices, claims data and actual cash payments. In addition, we involved our government pricing subject matter professionals to assist in evaluating management's methodology and calculations used to measure certain estimated rebates.

Sales Returns

Description of the Matter

As discussed in Note 4 of the consolidated financial statements, the Company permits the return of product under certain circumstances, including product expiration, shipping errors, damaged product, and product recalls. The Company accrues for the customer's right to return as part of its variable consideration at the time of sale, when control of the product transfers to the customer. The Company's product returns accrual is primarily based on estimates of future product returns, estimates of the level of inventory of its products in the distribution channel that remain subject to returns, estimated lag time of returns and historical return rates. At December 31, 2022, the Company had \$145 million in accrued returns allowance, which are presented within accounts payable and accrued expenses on the consolidated balance sheet.

Auditing the allowance for sales returns was complex due to the significant estimation required in determining inventory in the distribution channel that will not ultimately be sold to the end user and returned. The allowances for sales returns is sensitive to the level of inventory and turnover of inventory in the distribution channel, which could exceed future market demand and be subject to return.

*How We Addressed the
Matter in Our Audit*

We obtained an understanding, evaluated the design and tested the operating effectiveness of the Company's controls over the estimation of sales returns. For example, we tested controls over management's review of the significant assumptions including review of the inventory on hand in the distribution channel, estimated lag time of returns, and the completeness and accuracy of inputs utilized in the estimate of sales returns.

To test the estimated sales return reserve, we performed audit procedures that included, among others, testing the historical return rate and estimated lag time of returns and verifying the completeness and accuracy of sales data and sales returns data used in calculating the historical return rate and lag time. In addition, we tested the Company's quarterly analysis of inventory in the distribution channel and analytically reviewed daily sales at period end for unusual activity. We also performed direct inquiries with management including the Sales and Legal departments, obtained representations confirming key contract terms at period end from the executive sales representatives, and agreed representations obtained to executed contracts and reserve calculations.

Impairment of Intangible Assets with Finite Lives

Description of the Matter

At December 31, 2022, the Company's net intangible assets with finite lives were \$705 million. As discussed in Notes 2 and 13 to the consolidated financial statements, net intangible assets with finite lives are assessed for recoverability whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. The Company evaluates assets for potential impairment by comparing estimated future undiscounted net cash flows to the carrying amount of the asset. If the carrying amount of the assets exceeds the estimated future undiscounted cash flows, impairment is measured based on the difference between the carrying amount of the assets and fair value.

Auditing the Company's impairment tests for intangible assets with finite lives was complex and highly judgmental due to the significant estimation in management's assumptions to calculate the undiscounted cash flows and the fair value estimate. These assumptions can significantly affect the undiscounted cash flows and fair value of the intangible asset with finite lives.

*How We Addressed the
Matter in Our Audit*

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's impairment assessment for intangible assets with finite lives. For example, we tested controls over management's review of the significant inputs and assumptions used in the calculations of undiscounted cash flows and fair value.

To test the Company's impairment assessment for intangible assets with finite lives, we performed audit procedures that included, among others, testing the significant assumptions discussed above, including the completeness and accuracy of the underlying data used by the Company in its analyses. We compared the significant assumptions used by management to current industry and economic trends, historical financial results and other relevant factors. We involved our valuation specialists to assist in the assessment of the Company's discount rate for the fair value estimate of intangible assets with finite lives when the carrying amount of the assets exceeds the estimated future undiscounted cash flows. We performed sensitivity analyses related to the discount rate to evaluate the change in the fair value relative to the carrying value when measuring the resulting impairment. We also assessed the historical accuracy of management's projections.

Impairment of Goodwill and Other Indefinite-lived Intangible Assets

Description of the Matter

At December 31, 2022, the Company's goodwill was \$599 million and indefinite-lived intangible assets, consisting of in-process research and development (IPR&D) was \$391 million. As discussed in Notes 2 and 13 of the consolidated financial statements, goodwill and IPR&D are tested by the Company's management for impairment at least annually, during the fourth quarter, unless events or circumstances indicate the carrying amount may not be recoverable. Goodwill is tested for impairment at the reporting unit level.

Auditing the Company's impairment tests for goodwill and IPR&D was complex and highly judgmental due to the significant estimation required in determining the fair value of the reporting units for goodwill and the fair value of IPR&D assets. Specifically, the fair value estimates of the reporting units are sensitive to assumptions such as net sales growth rates, discount rate, and long-term growth rates. The fair value estimate for IPR&D is sensitive to significant assumptions including the probability of successful product completion, expected cash flows and cost of capital. The fair value estimates of goodwill and IPR&D are affected by such factors as industry, market performance, and financial forecasts.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's goodwill and IPR&D impairment assessment. For example, we tested controls over management's review of the significant inputs and assumptions used in the reporting unit and IPR&D valuations.

To test the estimated fair value of the Company's reporting units and IPR&D, we performed audit procedures that included, among others, assessing the methodologies used and testing the significant assumptions discussed above, including the completeness and accuracy of the underlying data used by the Company in its analyses. We compared the significant assumptions used by management to current industry and economic trends, historical financial results and other relevant factors. We performed sensitivity analyses of significant assumptions to evaluate the change in the fair value of the reporting units and IPR&D resulting from changes in the inputs and assumptions. We also assessed the historical accuracy of management's projections. In addition, we involved our valuation specialists to assist in our evaluation of the valuation methodology and significant assumptions described above used to develop the fair value estimates. We also performed inquiries of the R&D personnel that oversee the on-going IPR&D projects to assess whether there were any indicators that the IPR&D project had been abandoned or significantly delayed that may suggest the IPR&D intangible asset may be impaired. In addition, we evaluated the reconciliation of the estimated aggregate fair value of the reporting units to the market capitalization of the Company.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2008.

Iselin, New Jersey
March 3, 2023

Amneal Pharmaceuticals, Inc.
Consolidated Statements of Operations
(in thousands, except per share amounts)

	Years Ended December 31,		
	2022	2021	2020
Net revenue	\$ 2,212,304	\$ 2,093,669	\$ 1,992,523
Cost of goods sold	1,416,485	1,302,004	1,329,551
Cost of goods sold impairment charges	11,111	22,692	34,579
Gross profit	784,708	768,973	628,393
Selling, general and administrative	399,700	365,504	326,727
Research and development	195,688	201,847	179,930
In-process research and development impairment charges	12,970	710	2,680
Intellectual property legal development expenses	4,358	7,716	10,655
Acquisition, transaction-related and integration expenses	709	8,055	8,988
Restructuring and other charges	1,421	1,857	2,398
Change in fair value of contingent consideration	731	200	—
(Insurance recoveries) charges for property losses and associated expenses, net	(1,911)	5,368	—
Charges related to legal matters, net	269,930	25,000	5,860
Other operating income	(3,960)	—	—
Operating (loss) income	(94,928)	152,716	91,155
Other (expense) income:			
Interest expense, net	(158,377)	(136,325)	(145,998)
Foreign exchange (loss) gain, net	(12,364)	(355)	16,350
Loss on refinancing - Revolving Credit Facility	(291)	—	—
Gain on sale of international businesses	—	—	123
Other income, net	17,833	15,330	2,590
Total other expense, net	(153,199)	(121,350)	(126,935)
(Loss) income before income taxes	(248,127)	31,366	(35,780)
Provision for (benefit from) income taxes	6,662	11,196	(104,358)
Net (loss) income	(254,789)	20,170	68,578
Less: Net loss (income) attributable to non-controlling interests	125,241	(9,546)	22,481
Net (loss) income attributable to Amneal Pharmaceuticals, Inc. before accretion of redeemable non-controlling interest	(129,548)	10,624	91,059
Accretion of redeemable non-controlling interest	(438)	—	—
Net (loss) income attributable to Amneal Pharmaceuticals, Inc.	<u>\$ (129,986)</u>	<u>\$ 10,624</u>	<u>\$ 91,059</u>
Net (loss) income per share attributable to Amneal Pharmaceuticals, Inc.'s Class A common stockholders:			
Basic	<u>\$ (0.86)</u>	<u>\$ 0.07</u>	<u>\$ 0.62</u>
Diluted	<u>\$ (0.86)</u>	<u>\$ 0.07</u>	<u>\$ 0.61</u>
Weighted-average common shares outstanding:			
Basic	150,944	148,922	147,443
Diluted	150,944	151,821	148,913

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

Amneal Pharmaceuticals, Inc.
Consolidated Statements of Comprehensive (Loss) Income
(in thousands)

	Years Ended December 31,		
	2022	2021	2020
Net (loss) income	\$ (254,789)	\$ 20,170	\$ 68,578
Less: Net loss (income) attributable to non-controlling interests	125,241	(9,546)	22,481
Net (loss) income attributable to Amneal Pharmaceuticals, Inc. before accretion of redeemable non-controlling interest	(129,548)	10,624	91,059
Accretion of redeemable non-controlling interest	(438)	—	—
Net (loss) income attributable to Amneal Pharmaceuticals, Inc.	(129,986)	10,624	91,059
Other comprehensive (loss) income:			
Foreign currency translation adjustments arising during the period	(26,891)	(8,618)	(13,500)
Unrealized gain (loss) on cash flow hedge, net of tax	97,059	42,430	(70,276)
Less: Other comprehensive (income) loss attributable to non-controlling interests	(35,292)	(17,095)	42,573
Other comprehensive income (loss) attributable to Amneal Pharmaceuticals, Inc.	34,876	16,717	(41,203)
Comprehensive (loss) income attributable to Amneal Pharmaceuticals, Inc.	\$ (95,110)	\$ 27,341	\$ 49,856

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

Amneal Pharmaceuticals, Inc.
Consolidated Balance Sheets
(in thousands)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 25,976	\$ 247,790
Restricted cash	9,251	8,949
Trade accounts receivable, net	741,791	662,583
Inventories	530,735	489,389
Prepaid expenses and other current assets	103,565	110,218
Related party receivables	500	1,179
Total current assets	1,411,818	1,520,108
Property, plant and equipment, net	469,815	514,158
Goodwill	598,853	593,017
Intangible assets, net	1,096,093	1,166,922
Operating lease right-of-use assets	38,211	39,899
Operating lease right-of-use assets - related party	17,910	20,471
Financing lease right-of-use assets	63,424	64,475
Other assets	103,217	20,614
Total assets	<u>\$ 3,799,341</u>	<u>\$ 3,939,664</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 538,199	\$ 525,345
Current portion of liabilities for legal matters	107,483	58,000
Revolving credit facility	60,000	—
Current portion of long-term debt, net	29,961	30,614
Current portion of operating lease liabilities	8,321	9,686
Current portion of operating lease liabilities - related party	2,869	2,636
Current portion of financing lease liabilities	3,488	3,101
Related party payables - short term	2,479	47,861
Total current liabilities	752,800	677,243
Long-term debt, net	2,591,981	2,680,053
Note payable - related party	39,706	38,038
Operating lease liabilities	32,126	32,894
Operating lease liabilities - related party	15,914	18,783
Financing lease liabilities	60,769	60,251
Related party payable - long term	9,649	9,619
Other long-term liabilities	87,468	38,903
Total long-term liabilities	2,837,613	2,878,541
Commitments and contingencies (Notes 5 and 21)		
Redeemable non-controlling interests	24,949	16,907
Stockholders' equity:		
Preferred stock, \$0.01 par value, 2,000 shares authorized; none issued at both December 31, 2022 and 2021	—	—
Class A common stock, \$0.01 par value, 900,000 shares authorized at both December 31, 2022 and 2021; 151,490 and 149,413 shares issued at December 31, 2022 and 2021, respectively	1,514	1,492
Class B common stock, \$0.01 par value, 300,000 shares authorized at both December 31, 2022 and 2021; 152,117 shares issued at both December 31, 2022 and 2021	1,522	1,522
Additional paid-in capital	691,629	658,350
Stockholders' accumulated deficit	(406,183)	(276,197)
Accumulated other comprehensive income (loss)	9,939	(24,827)
Total Amneal Pharmaceuticals, Inc. stockholders' equity	298,421	360,340
Non-controlling interests	(114,442)	6,633
Total stockholders' equity	183,979	366,973
Total liabilities and stockholders' equity	<u>\$ 3,799,341</u>	<u>\$ 3,939,664</u>

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

Amneal Pharmaceuticals, Inc.
Consolidated Statement of Changes in Stockholders' Equity
(in thousands)

	Class A Common Stock		Class B Common Stock		Additional Paid-in Capital	Stockholders' Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Non- Controlling Interests	Total Equity	Redeemable Non- Controlling Interests
	Shares	Amount	Shares	Amount						
Balance at December 31, 2021	149,413	\$ 1,492	152,117	\$ 1,522	\$ 658,350	\$ (276,197)	\$ (24,827)	\$ 6,633	\$ 366,973	\$ 16,907
Net (loss) income	—	—	—	—	—	(129,548)	—	(141,036)	(270,584)	15,795
Foreign currency translation adjustments	—	—	—	—	—	—	(13,394)	(13,497)	(26,891)	—
Stock-based compensation	—	—	—	—	31,847	—	—	—	31,847	—
Exercise of stock options	207	2	—	—	615	—	—	45	662	—
Restricted stock unit vesting, net of shares withheld to cover payroll taxes	1,870	20	—	—	817	—	(110)	(4,289)	(3,562)	—
Tax distributions, net	—	—	—	—	—	—	—	(10,642)	(10,642)	(6,914)
Unrealized gain on cash flow hedge, net of tax	—	—	—	—	—	—	48,270	48,789	97,059	—
Reclassification of redeemable non-controlling interests	—	—	—	—	—	(438)	—	(445)	(883)	883
Acquisition of non-controlling interest from Puniska Acquisition	—	—	—	—	—	—	—	—	—	(1,722)
Balance at December 31, 2022	<u>151,490</u>	<u>\$ 1,514</u>	<u>152,117</u>	<u>\$ 1,522</u>	<u>\$ 691,629</u>	<u>\$ (406,183)</u>	<u>\$ 9,939</u>	<u>\$ (114,442)</u>	<u>\$ 183,979</u>	<u>\$ 24,949</u>

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

Amneal Pharmaceuticals, Inc.
Consolidated Statement of Changes in Stockholders' Equity
(in thousands)

	Class A Common Stock		Class B Common Stock		Additional Paid-in Capital	Stockholders' Accumulated Deficit	Accumulated Other Comprehensive Loss	Non- Controlling Interests	Total Equity	Redeemable Non- Controlling Interests
	Shares	Amount	Shares	Amount						
Balance at December 31, 2020	147,674	\$ 1,475	152,117	\$ 1,522	\$ 628,413	\$ (286,821)	\$ (41,318)	\$ 41,661	\$ 344,932	\$ 11,804
Net income	—	—	—	—	—	10,624	—	2,539	13,163	7,007
Foreign currency translation adjustments	—	—	—	—	—	—	(4,255)	(4,363)	(8,618)	—
Stock-based compensation	—	—	—	—	28,412	—	—	—	28,412	—
Exercise of stock options	342	3	—	—	901	—	(44)	(7)	853	—
Restricted stock unit vesting, net of shares withheld to cover payroll taxes	1,397	14	—	—	624	—	(182)	(3,169)	(2,713)	—
Tax distributions	—	—	—	—	—	—	—	(53,486)	(53,486)	(3,646)
Unrealized gain on cash flow hedge, net of tax	—	—	—	—	—	—	20,972	21,458	42,430	—
Non-controlling interests from KSP Acquisition	—	—	—	—	—	—	—	2,000	2,000	—
Non-controlling interests from Puniska Acquisition	—	—	—	—	—	—	—	—	—	1,742
Balance at December 31, 2021	<u>149,413</u>	<u>\$ 1,492</u>	<u>152,117</u>	<u>\$ 1,522</u>	<u>\$ 658,350</u>	<u>\$ (276,197)</u>	<u>\$ (24,827)</u>	<u>\$ 6,633</u>	<u>\$ 366,973</u>	<u>\$ 16,907</u>

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

Amneal Pharmaceuticals, Inc.
Consolidated Statement of Changes in Stockholders' Equity
(in thousands)

	Class A Common Stock		Class B Common Stock		Additional Paid-in Capital	Stockholders' Accumulated Deficit	Accumulated Other Comprehensive Loss	Non- Controlling Interests	Total Equity	Redeemable Non- Controlling Interests
	Shares	Amount	Shares	Amount						
Balance at December 31, 2019	147,070	\$ 1,470	152,117	\$ 1,522	\$ 606,966	\$ (377,880)	\$ (68)	\$ 114,778	\$ 346,788	\$ —
Net income (loss)	—	—	—	—	—	91,059	—	(23,268)	67,791	787
Foreign currency translation adjustments	—	—	—	—	—	—	(6,643)	(6,857)	(13,500)	—
Stock-based compensation	—	—	—	—	20,750	—	—	—	20,750	—
Exercise of stock options	117	1	—	—	323	—	(15)	12	321	—
Restricted stock unit vesting, net of shares withheld to cover payroll taxes	487	4	—	—	268	—	(32)	(1,103)	(863)	—
Tax distributions	—	—	—	—	—	—	—	(2,779)	(2,779)	(458)
Unrealized loss on cash flow hedge, net of tax	—	—	—	—	—	—	(34,560)	(35,716)	(70,276)	—
Distribution of earnings to and acquisition of non-controlling interests	—	—	—	—	106	—	—	(3,406)	(3,300)	—
Non-controlling interests from Rondo Acquisition	—	—	—	—	—	—	—	—	—	11,475
Balance at December 31, 2020	<u>147,674</u>	<u>\$ 1,475</u>	<u>152,117</u>	<u>\$ 1,522</u>	<u>\$ 628,413</u>	<u>\$ (286,821)</u>	<u>\$ (41,318)</u>	<u>\$ 41,661</u>	<u>\$ 344,932</u>	<u>\$ 11,804</u>

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

Amneal Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,		
	2022	2021	2020
Cash flows from operating activities:			
Net (loss) income	\$ (254,789)	\$ 20,170	\$ 68,578
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Depreciation and amortization	240,175	233,406	235,387
Unrealized foreign currency loss (gain)	15,190	175	(16,728)
Amortization of debt issuance costs and discount	8,595	9,203	8,678
Loss on refinancing - Revolving Credit Facility	291	—	—
Gain on sale of international businesses, net	—	—	(123)
Intangible asset impairment charges	24,081	23,402	37,259
Non-cash restructuring and asset-related (benefit) charges	—	—	(536)
Change in fair value of contingent consideration	731	200	—
Stock-based compensation	31,847	28,412	20,750
Inventory provision	51,096	54,660	75,236
Insurance recoveries for property and equipment losses	(1,000)	(5,000)	—
Non-cash property losses	—	5,152	—
Other operating charges and credits, net	8,828	5,633	11,818
Changes in assets and liabilities:			
Trade accounts receivable, net	(79,717)	(23,621)	16,787
Inventories	(102,396)	(49,015)	(113,782)
Prepaid expenses, other current assets and other assets	9,882	(21,981)	33,312
Related party receivables	646	7,311	412
Accounts payable, accrued expenses and other liabilities	109,568	(43,932)	307
Related party payables	2,072	(2,355)	1,646
Net cash provided by operating activities	65,100	241,820	379,001
Cash flows from investing activities:			
Purchases of property, plant and equipment	(46,407)	(47,728)	(56,445)
Acquisition of intangible assets	(41,800)	(1,700)	(4,350)
Deposits for future acquisition of property, plant, and equipment	(2,388)	(3,211)	(5,391)
Acquisitions of businesses, net of cash acquired	(84,714)	(146,543)	(251,360)
Proceeds from insurance recoveries for property and equipment losses	1,000	5,000	—
Net cash used in investing activities	(174,309)	(194,182)	(317,546)
Cash flows from financing activities:			
Payments of deferred financing and refinancing costs	(1,663)	—	(4,102)
Proceeds from issuance of debt	—	—	180,000
Payments of principal on debt, revolving credit facility, financing leases and other	(123,272)	(78,086)	(35,933)
Borrowings on revolving credit facility	85,000	—	—
Proceeds from exercise of stock options	662	853	321
Employee payroll tax withholding on restricted stock unit vesting	(3,571)	(2,664)	(863)
Payments of deferred consideration for acquisitions - related party	(44,498)	—	—
Acquisition of redeemable non-controlling interests	(1,722)	—	—
Distribution of earnings to and acquisition of non-controlling interest	—	—	(3,300)
Tax distributions to non-controlling interest	(17,556)	(57,132)	(3,237)
Payments of principal on financing lease - related party	—	(93)	(1,079)
Repayment of related party note	—	(1,000)	—
Net cash (used in) provided by financing activities	(106,620)	(138,122)	131,807
Effect of foreign exchange rate on cash	(5,683)	102	1,037
Net (decrease) increase in cash, cash equivalents, and restricted cash	(221,512)	(90,382)	194,299
Cash, cash equivalents, and restricted cash - beginning of period	256,739	347,121	152,822
Cash, cash equivalents, and restricted cash - end of period	\$ 35,227	\$ 256,739	\$ 347,121
Cash and cash equivalents - end of period	\$ 25,976	\$ 247,790	\$ 341,378
Restricted cash - end of period	\$ 9,251	\$ 8,949	\$ 5,743
Cash, cash equivalents, and restricted cash - end of period	\$ 35,227	\$ 256,739	\$ 347,121

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

Amneal Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows (continued)
(in thousands)

	Years Ended December 31,		
	2022	2021	2020
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$ 142,722	\$ 121,747	\$ 130,186
Cash (paid) received, net for income taxes	\$ (12,649)	\$ (15,558)	\$ 100,141
Supplemental disclosure of non-cash investing and financing activity:			
Notes payable for acquisitions - related party	\$ —	\$ 14,162	\$ 36,033
Deferred consideration for acquisition - related party	\$ —	\$ 30,099	\$ —
Contingent consideration for acquisition	\$ 8,796	\$ —	\$ —
Contingent consideration for acquisition - related party	\$ —	\$ 5,700	\$ —
Payable for acquisition of product rights and licenses	\$ —	\$ 300	\$ —

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

Amneal Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements

1. Nature of Operations

Amneal Pharmaceuticals, Inc. (the “Company”) is a global pharmaceutical company that develops, manufactures, markets, and distributes a diverse portfolio of essential medicines, including complex generics and specialty branded pharmaceuticals. The Company operates principally in the United States, India, and Ireland, and sells to wholesalers, distributors, hospitals, chain pharmacies and individual pharmacies, either directly or indirectly. The Company is a holding company, whose principal assets are common units (“Amneal Common Units”) of Amneal Pharmaceuticals, LLC (“Amneal”).

The group, together with their affiliates and certain assignees, who owned Amneal when it was a private company (the “Members” or the “Amneal Group”) held 50.1% of Amneal Common Units and the Company held the remaining 49.9% as of December 31, 2022.

2. Summary of Significant Accounting Policies

Accounting Principles

The financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). All intercompany accounts and transactions have been eliminated.

Principles of Consolidation

Although the Company has a minority economic interest in Amneal, it is Amneal’s sole managing member, having the sole voting power to make all of Amneal’s business decisions and controls its management. Therefore, the Company consolidates the financial statements of Amneal and its subsidiaries. The Company records non-controlling interests for the portion of Amneal’s economic interests that it does not hold.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company's management to make estimates and assumptions that affect the reported financial position at the date of the financial statements and the reported results of operations during the reporting period. Such estimates and assumptions affect the reported amounts of assets, liabilities, revenues and expenses, and disclosure of contingent assets and liabilities in the consolidated financial statements and accompanying notes. The following are some, but not all, of such estimates: the determination of chargebacks, sales returns, rebates, billbacks, valuation of intangible and other assets acquired in business combinations, allowances for accounts receivable, accrued liabilities, liabilities for legal matters, contingent liabilities, initial and subsequent valuation of contingent consideration recognized in business combinations, stock-based compensation, valuation of inventory balances, the determination of useful lives for product rights and the assessment of expected cash flows used in evaluating goodwill and other long-lived assets for impairment. Actual results could differ from those estimates.

Revenue Recognition

When assessing its revenue recognition, the Company performs the following five steps: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies the performance obligation. The Company recognizes revenue when it transfers control of its products to customers, in an amount that reflects the consideration to which the Company expects to be entitled to receive in exchange for those products.

From time to time, the Company may enter into arrangements where it licenses certain products to a third-party distributor. Licensing arrangement performance obligations generally include intellectual property (“IP”) rights and research and development (“R&D”) and contract manufacturing services. The Company accounts for IP rights and services separately if they are distinct. The consideration is allocated between IP rights and services based on their relative stand-alone selling prices.

Revenue for distinct IP rights is accounted for based on the nature of the promise to grant the license. In determining whether the Company’s promise is to provide a right to access its IP or a right to use its IP, the Company considers the nature of the IP to which the customer will have rights. IP is either functional IP which has significant standalone functionality or symbolic IP which does not have significant standalone functionality. Revenue from functional IP is recognized at the point in time when

control of the distinct license is transferred to the customer. Revenue from symbolic IP is recognized over the access period to the Company's IP.

Revenue from sales-based milestones and royalties promised in exchange for a license of IP is recognized only when, or as, the later of subsequent sale or the performance obligation to which some or all of the sales-based royalty has been allocated, is satisfied.

For further details on the Company's revenue recognition policies, refer to *Note 4. Revenue Recognition*.

Stock-Based Compensation

The Company's stock-based compensation consists of stock options, restricted stock units ("RSUs") and market performance-based restricted stock units ("MPRSUs") awarded to employees and non-employee directors. Stock options are measured at their fair value on the grant date or date of modification, as applicable. RSUs, including MPRSUs, are measured at the stock price on the grant date or date of modification, as applicable. The Company recognizes compensation expense on a straight-line basis over the requisite service and/or performance period, as applicable. Forfeitures of awards are accounted for as a reduction in stock-based compensation expense in the period such awards are forfeited. The Company's policy is to issue new shares upon option exercises and the vesting of RSUs and MPRSUs.

Contingent consideration

Business acquisitions may include future payments that are contingent upon the occurrence of certain pharmaceutical regulatory milestones or net sales of pharmaceutical products. For acquisitions that are accounted for as a business combination, the obligations for such contingent consideration payments are recorded at fair value on the acquisition date. For contingent milestone payments, the Company uses a probability-weighted income approach utilizing an appropriate discount rate. For contingent tiered royalties on net sales, the Company uses a Monte Carlo simulation model. Contingent consideration liabilities are revalued to fair value at the end of each reporting period. Changes in the fair value of contingent consideration, other than changes due to payments, are recognized as a gain or loss and recorded within change in fair value of contingent consideration in the consolidated statements of operations. Refer to *Note 3. Acquisitions* and *Note 19. Fair Value Measurements* for additional information.

Foreign Currencies

The Company has operations in the U.S., India, Ireland, and other foreign jurisdictions. Generally, the Company's foreign operating subsidiaries' functional currency is the local currency. The results of its non-U.S. dollar based operations are translated to U.S. dollars at the average exchange rates during the period. Assets and liabilities are translated at the rate of exchange prevailing on the balance sheet date. Translation adjustments are included in accumulated other comprehensive income (loss) and non-controlling interests in the consolidated balance sheets and are included in comprehensive (loss) income. Transaction gains and losses are included in net (loss) income in the Company's consolidated statements of operations as a component of foreign exchange (loss) gain, net. Such foreign currency transaction gains and losses include fluctuations related to long term intercompany loans that are payable in the foreseeable future. Translation gains and losses on intercompany balances of a long-term investment nature are included in foreign currency translation adjustments in accumulated other comprehensive income (loss) and non-controlling interests, and comprehensive (loss) income.

Business Combinations

Business combinations are accounted for using the acquisition method of accounting. Under the acquisition method, the acquiring entity in a business combination records the assets acquired and liabilities assumed at the date of acquisition at their fair values. Any excess of the purchase price over the fair value of net assets and other identifiable intangible assets acquired is recorded as goodwill. Acquisition-related costs, primarily professional fees, are expensed as incurred.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash on deposit and highly liquid investments with original maturities of three months or less. A portion of the Company's cash flows are derived outside the U.S. As a result, the Company is subject to market risk associated with changes in foreign exchange rates. The Company maintains cash balances at both U.S.-based and international-based commercial banks. At various times during the year, cash balances in the U.S. may exceed amounts that are insured by the Federal Deposit Insurance Corporation.

Restricted Cash

At December 31, 2022 and 2021, respectively, the Company had restricted cash balances of \$9.3 million and \$8.9 million, respectively, in its bank accounts primarily related to the purchase of certain land and equipment in India.

Accounts Receivable and Allowance for Credit Losses

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The Company limits its credit risk with respect to accounts receivable by performing credit evaluations when deemed necessary. The Company does not require collateral to secure amounts owed to it by its customers.

Trade accounts receivable are stated at their net realizable value. The allowance for credit losses reflects the best estimate of expected credit losses of the accounts receivable portfolio determined on the basis of historical experience, current information, and forecasts of future economic conditions. The Company determines its allowance methodology by pooling receivable balances at the customer level. The Company consider various factors, including its previous loss history, individual credit risk associated to each customer, and the current and future condition of the general economy. These credit risk factors are monitored on a quarterly basis and updated as necessary. To the extent that any individual debtor is identified whose credit quality has deteriorated, the Company establishes allowances based on the individual risk characteristics of such customer. The Company makes concerted efforts to collect all outstanding balances due from customers; however, account balances are charged off against the allowance when management believes it is probable the receivable will not be recovered. The Company does not have any off-balance-sheet credit exposure related to customers.

Chargebacks Received from Manufacturers

When a sale occurs on a contracted item, the difference between the cost the Company pays to the manufacturer of that item and the contract price that the end customer has with the manufacturer is rebated to the Company by the manufacturer as a chargeback. Chargebacks are recorded as a reduction to cost of sales and either a reduction in the amount due to the manufacturer (if there is a right of offset) or as a receivable from the manufacturer.

Inventories

Inventories consist of finished goods held for sale, raw materials, and work in process. Inventories are stated at net realizable value, with cost determined using the first-in, first-out method. Adjustments for excess and obsolete inventories are established based upon historical experience and management's assessment of current product demand. These assessments include inventory obsolescence based on its expiration date, damaged or rejected product, and slow-moving products.

Property, Plant, and Equipment

Property, plant, and equipment are stated at historical cost less accumulated depreciation. Depreciation expense is computed primarily using the straight-line method over the estimated useful lives of the assets, which are as follows:

Asset Classification	Estimated Useful Life
Buildings	30 years
Computer equipment	5 years
Furniture and fixtures	7 years
Leasehold improvements	Shorter of asset's useful life or remaining life of lease
Machinery and equipment	5 - 10 years
Vehicles	5 years

Upon retirement or disposal, the cost of the asset disposed and the accumulated depreciation are removed from the accounts, and any gain or loss is reflected as part of operating income (loss) in the period of disposal. Expenditures that significantly increase value or extend useful lives of property, plant, and equipment are capitalized, whereas those for normal maintenance and repairs are expensed. The Company capitalizes interest on borrowings during the construction period of major capital projects as part of the related asset and amortizes the capitalized interest into earnings over the related asset's remaining useful life.

Leases

All significant lease arrangements are recognized as right-of-use (“ROU”) assets and lease liabilities at lease commencement. ROU assets represent the Company's right to use an underlying asset for the lease term, and lease liabilities represent its 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 the future lease payments using the Company's incremental borrowing rate.

Operating lease expense is recognized on a straight-line basis over the lease term. At each balance sheet date, operating and financing lease liabilities continue to represent the present value of the future payments. Financing lease ROU assets are expensed using the straight-line method, unless another basis is more representative of the pattern of economic benefit, to lease expense. Interest on financing lease liabilities is recognized in interest expense.

Leases with an initial term of 12 months or less (short-term leases) are not recognized in the balance sheet and the related lease payments are recognized as incurred over the lease term. The Company separates lease and non-lease components. A portion of the Company's real estate leases are subject to periodic changes in the Consumer Price Index (“CPI”). The changes to the CPI are treated as variable lease payments and recognized in the period in which the obligation for those payments was incurred.

For further details regarding the Company's leases, refer to *Note 18. Leases*.

In-Process Research and Development

The fair value of in-process research and development (“IPR&D”) acquired in a business combination is determined based on the present value of each research project’s projected cash flows using an income approach. Revenues are estimated based on relevant market size and growth factors, expected industry trends, individual project life cycles and the life of each research project’s underlying marketability. In determining the fair value of each research project, expected cash flows are adjusted for certain risks of completion, including technical and regulatory risk.

The value attributable to IPR&D projects at the time of acquisition is capitalized as an indefinite-lived intangible asset and tested for impairment until the project is completed or abandoned. Upon completion of the project, the indefinite-lived intangible asset is then accounted for as a finite-lived intangible asset and amortized over the estimated useful life of the asset based on the pattern in which the economic benefits are expected to be consumed or otherwise used up or, if that pattern is not readily determinable, on a straight-line basis. If the project is abandoned, the indefinite-lived intangible asset is charged to expense.

Intangible assets with indefinite lives, including IPR&D, are tested for impairment if impairment indicators arise and, at a minimum, annually. However, an entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that an indefinite-lived intangible asset’s fair value is less than its carrying amount. Otherwise, no further impairment testing is required. The indefinite-lived intangible asset impairment test consists of a one-step analysis that compares the fair value of the intangible asset with its carrying amount. If the carrying amount of an intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. The Company considers many factors in evaluating whether the value of its intangible assets with indefinite lives may not be recoverable, including, but not limited to, expected growth rates, the cost of equity and debt capital, general economic conditions, the Company's outlook and market performance of the Company's industry and recent and forecasted financial performance.

Goodwill

Goodwill, which represents the excess of purchase price over the fair value of net assets acquired, is carried at cost. Goodwill is not amortized; rather, it is subject to a periodic assessment for impairment by applying a fair value based test. The Company reviews goodwill for possible impairment annually during the fourth quarter, or whenever events or circumstances indicate that the carrying amount may not be recoverable.

In order to test goodwill for impairment, an entity is permitted to first assess qualitative factors to determine whether a quantitative assessment of goodwill is necessary. The qualitative factors considered by the Company may include, but are not limited to, general economic conditions, the Company’s outlook, market performance of the Company’s industry and recent and forecasted financial performance. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that a reporting unit’s fair value is less than its carrying amount. Otherwise, no further impairment testing is required. If a quantitative assessment is required, the Company determines the fair value of its reporting unit using a combination of the income and market approaches. If the net book value of the reporting unit exceeds its fair

value, the Company recognizes a goodwill impairment charge for the reporting unit equal to the lesser of (i) the total goodwill allocated to that reporting unit and (ii) the amount by which that reporting unit's carrying amount exceeds its fair value. See *Note 13. Goodwill and Other Intangible Assets*, for further discussion of the Company's quantitative assessment of goodwill.

Assumptions and estimates used in the evaluation of impairment may affect the carrying value of long-lived assets, which could result in impairment charges in future periods. Such assumptions include projections of future cash flows and the current fair value of the asset.

Amortization of Intangible Assets with Finite Lives

Intangible assets, other than indefinite-lived intangible assets, are amortized over the estimated useful life of the asset based on the pattern in which the economic benefits are expected to be consumed or otherwise used up or, if that pattern is not readily determinable, on a straight-line basis. The useful life is the period over which the assets are expected to contribute directly or indirectly to future cash flows. Intangible assets are not written-off in the period of acquisition unless they become impaired during that period.

The Company regularly evaluates the remaining useful life of each intangible asset that is being amortized to determine whether events and circumstances warrant a revision to the remaining period of amortization. If the estimate of the intangible asset's remaining useful life is changed, the remaining carrying amount of the intangible asset is amortized prospectively over that revised remaining useful life. See *Note 13. Goodwill and Other Intangible Assets*, for further discussion of the Company's intangible assets.

Impairment of Long-Lived Assets (Including Intangible Assets with Finite Lives)

The Company reviews its long-lived assets, including intangible assets with finite lives, for recoverability whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. The Company evaluates assets for potential impairment by comparing estimated future undiscounted net cash flows to the carrying amount of the asset. If the carrying amount of the assets exceeds the estimated future undiscounted cash flows, impairment is measured based on the difference between the carrying amount of the assets and fair value which is generally an expected present value cash flow technique. Management's policy in determining whether an impairment indicator exists comprises measurable operating performance criteria as well as other qualitative measures. See *Note 13. Goodwill and Other Intangible Assets*, for further discussion of the Company's assessment of intangible asset impairment.

Financial Instruments

The Company minimizes its risks from interest fluctuations through its normal operating and financing activities and, when deemed appropriate through the use of derivative financial instruments. Derivative financial instruments are used to manage risk and are not used for trading or other speculative purposes. The Company does not use leveraged derivative financial instruments. Derivative financial instruments that qualify for hedge accounting must be designated and effective as a hedge of the identified risk exposure at the inception of the contract. Accordingly, changes in fair value of the derivative contract must be highly correlated with changes in fair value of the underlying hedged item at inception of the hedge and over the life of the hedge contract.

All derivatives are recorded on the balance sheet as assets or liabilities and measured at fair value. For derivatives designated as cash flow hedges, the effective portion of the changes in fair value of the derivatives are recorded in accumulated other comprehensive loss, net of income taxes and subsequently amortized as an adjustment to interest expense over the period during which the hedged forecasted transaction affects earnings, which is when the Company recognizes interest expense on the hedged cash flows. Cash flows of such derivative financial instruments are classified consistent with the underlying hedged item.

Highly effective hedging relationships that use interest rate swaps as the hedging instrument and that meet criteria under ASC 815, *Derivatives and Hedging*, may qualify for the "short-cut method" of assessing effectiveness. The short-cut method allows the Company to make the assumption of no ineffectiveness, which means that the change in fair value of the hedged item can be assumed to be equal to the change in fair value of the derivative. Unless critical terms change, no further evaluation of effectiveness is performed for these hedging relationships unless a critical term is changed.

For a hedging relationship that does not qualify for the short-cut method, the Company measures its effectiveness using the "hypothetical derivative method", in which the change in fair value of the hedged item must be measured separately from the change in fair value of the derivative. At inception and quarterly thereafter, the Company formally assesses whether the

derivatives that are used in hedging transactions are highly effective in offsetting changes in the fair value or cash flows of the hedged item. The Company compares the change in the fair value of the actual interest rate derivative to the change in the fair value of a hypothetical interest rate derivative with critical terms that match the hedged interest rate payments. After the initial quantitative assessment, this analysis is performed on a qualitative basis and, if it is determined that the hedging relationship was and continues to be highly effective, no further analysis is required.

All components of each derivative financial instrument's gain or loss are included in the assessment of hedge effectiveness. If it is determined that a derivative ceases to be a highly effective hedge, the Company discontinues hedge accounting and any deferred gains or losses related to a discontinued cash flow hedge shall continue to be reported in accumulated other comprehensive income (loss) net of income taxes, unless it is probable that the forecasted transaction will not occur. If it is probable that the forecasted transaction will not occur by the originally specified time period, the Company discontinues hedge accounting, and any deferred gains or losses reported in accumulated other comprehensive income (loss) are classified into earnings immediately.

The Company is subject to credit risk as a result of nonperformance by counterparties to the derivative agreements. Upon inception and quarterly thereafter, the Company makes judgments on each counterparty's creditworthiness for nonperformance by counterparties.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740, *Accounting for Income Taxes*, which requires the recognition of tax benefits or expenses on temporary differences between the financial reporting and tax bases of its assets and liabilities by applying the enacted tax rates in effect for the year in which the differences are expected to reverse. Such net tax effects on temporary differences are reflected on the Company's consolidated balance sheets as deferred tax assets and liabilities. Deferred tax assets are reduced by a valuation allowance when the Company believes that it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized.

ASC 740-10 prescribes a two-step approach for the recognition and measurement of tax benefits associated with the positions taken or expected to be taken in a tax return that affect amounts reported in the financial statements. The Company has reviewed and will continue to review the conclusions reached regarding uncertain tax positions, which may be subject to review and adjustment at a later date based on ongoing analyses of tax laws, regulations and interpretations thereof. To the extent that the Company's assessment of the conclusions reached regarding uncertain tax positions changes as a result of the evaluation of new information, such change in estimate will be recorded in the period in which such determination is made. The Company reports income tax-related interest and penalties relating to uncertain tax positions, if applicable, as a component of income tax expense.

Comprehensive (Loss) Income

Comprehensive (loss) income includes net (loss) income and all changes in stockholders' equity (except those arising from transactions with stockholders) including foreign currency translation adjustments resulting from the consolidation of foreign subsidiaries' financial statements and unrealized gains (losses) on cash flows hedges, net of income taxes.

Research and Development

R&D activities are expensed as incurred. R&D expenses primarily consist of direct and allocated expenses incurred with the process of formulation, clinical research, and validation associated with new product development. Upfront and milestone payments made to third parties in connection with R&D collaborations are expensed as incurred up to the point of regulatory approval or when there is no alternative future use.

Intellectual Property Legal Development Expenses

The Company expenses external intellectual property legal development expenses as incurred. These costs relate to legal challenges of innovator's patents for invalidity or non-infringement, which are customary in the generic pharmaceutical industry, and are incurred predominately during development of a product and prior to regulatory approval. Associated costs include, but are not limited to, formulation assessments, patent challenge opinions and strategy, and litigation expenses to defend the intellectual property supporting the Company's regulatory filings.

Shipping Costs

The Company records the costs of shipping product to its customers as a component of selling, general, and administrative expenses as incurred. Shipping costs were \$18.7 million, \$18.1 million and \$17.4 million for the years ended December 31, 2022, 2021 and 2020, respectively.

Advertising Costs

Advertising costs are expensed as incurred. Advertising costs are included in selling, general and administrative expenses and were \$16.8 million, \$15.1 million and \$15.6 million for the years ended December 31, 2022, 2021 and 2020, respectively.

Recently Adopted Accounting Pronouncements

In November 2021, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2021-10, *Government Assistance (Topic 832), Disclosures by Business Entities About Government Assistance* (“ASU 2021-10”), which requires entities to provide disclosures on material government assistance transactions for annual reporting periods. The disclosures include information around the nature of the assistance, the related accounting policies used to account for government assistance, the effect of government assistance on the entity’s financial statements, and any significant terms and conditions of the agreements, including commitments and contingencies. ASU 2021-10 is effective for the Company’s annual disclosures as of and for the year ended December 31, 2022, with early adoption permissible. The Company elected to adopt this guidance during the second quarter of 2022 in connection with the recognition of cash incentives related to the India Production Linked Incentive Scheme for the Pharmaceutical Sector (“PLI Scheme”). Refer to *Note 6. Government Grants*, for additional information.

Recently Issued Accounting Pronouncements

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting* (“ASU 2020-04”), which provides elective amendments for entities that have contracts, hedging relationships and other transactions that reference LIBOR or another reference rate expected to be discontinued because of reference rate reform. These amendments were effective immediately and may be applied prospectively to contract modifications made and hedging relationships entered into or evaluated on or before December 31, 2022. In January 2021, the FASB issued ASU 2021-01, *Reference Rate Reform (Topic 848)*, to expand and clarify the scope of Topic 848 to include derivative instruments on discounting transactions. The amendments in this ASU are effective in the same timeframe as ASU 2020-04. In December 2022, the FASB issued ASU 2022-06, *Reference Rate reform (Topic 848): Deferral of the Sunset Date of Topic 848*, which deferred the sunset date of Topic 848, *Reference Rate Reform* to December 31, 2024. The Company is currently evaluating the impact this guidance will have on its consolidated financial statements.

In October 2021, the FASB issued ASU 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers* (“ASU 2021-08”), which requires entities to recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with Topic 606, *Revenue from Contracts with Customers* (“ASC 606”). The update will generally result in an entity recognizing contract assets and contract liabilities at amounts consistent with those recorded by the acquiree immediately before the acquisition date rather than at fair value. ASU 2021-08 is effective on a prospective basis for fiscal years beginning after December 15, 2022, with early adoption permitted. The Company will adopt ASU 2021-08 effective January 1, 2023 and apply the guidance to subsequent acquisitions. The adoption of ASU 2021-08 will only impact the accounting for the Company’s future acquisitions.

Reclassification

The prior period balance related to liabilities for legal proceedings of \$58.0 million, formerly included in accounts payable and accrued expenses as of December 31, 2021, has been reclassified to the balance sheet caption current portion of liabilities for legal matters to conform to the current period presentation in the consolidated balance sheets.

3. Acquisitions

Acquisitions

Saol Baclofen Franchise Acquisition

On December 30, 2021, the Company entered into an asset purchase agreement with certain entities affiliated with Saol International Limited (collectively, “Saol”), a private specialty pharmaceutical company, pursuant to which it agreed to acquire Saol’s baclofen franchise, including Lioresal®, LYVISPAH™, and a pipeline product under development (the “Saol Acquisition”). The Saol Acquisition expanded the Company’s commercial institutional and specialty portfolio in neurology while adding commercial infrastructure in advance of its entry into the biosimilar institutional market. The transaction closed on February 9, 2022.

Consideration for the Saol Acquisition included \$84.7 million, paid at closing with cash on hand, and contingent royalty payments based on annual net sales for certain acquired assets, beginning in 2023. Cash paid at closing included \$1.1 million for inventory acquired in excess of the normalized level, as defined in the asset purchase agreement (working capital adjustment).

For the year ended December 31, 2022, the Company incurred \$0.1 million in transaction costs associated with the Saol Acquisition, which was recorded in acquisition, transaction-related and integration expenses.

The Saol Acquisition was accounted for under the acquisition method of accounting, with Amneal as the accounting acquirer. The purchase price was calculated as follows (in thousands):

Cash	\$ 84,714
Contingent consideration (royalties) ⁽¹⁾	8,796
Fair value of consideration transferred	\$ 93,510

- (1) The estimated fair value of contingent consideration on the acquisition date was \$8.8 million and was based on significant Level 3 inputs that were not observable in the market. Key assumptions included the discount rate, projected year of payments and expected net product sales. Refer to *Note 19. Fair Value Measurements*, for additional information on the methodology and determination of this liability.

The following is a summary of the purchase price allocation for the Saol Acquisition (in thousands):

	Final Fair Values as of February 9, 2022
Inventory	\$ 2,162
Prepaid expenses and other current assets	98
Goodwill	7,553
Intangible assets	83,815
Total assets acquired	93,628
Accounts payable and accrued expenses	118
Fair value of consideration transferred	\$ 93,510

The acquired intangible assets are being amortized over their estimated useful lives as follows (in thousands):

	Final Fair Value	Weighted-Average Useful Life (in years)
Marketed product rights	\$ 83,815	11.5

The estimated fair value of the identifiable intangible assets was determined using the “income approach,” which is a valuation technique that provides an estimate of the fair value of an asset based on market participant expectations of the cash flows an asset would generate over its remaining useful life. The assumptions, including the expected projected cash flows, utilized in the purchase price allocation and in determining the purchase price were based on management's best estimates as of the closing date of the Saol Acquisition on February 9, 2022.

Some of the more significant assumptions inherent in the development of those asset valuations included the estimated net cash flows for each year for each asset (including net revenues, cost of sales, selling and marketing costs and working capital / contributory asset charges), the appropriate discount rate to select in order to measure the risk inherent in each future cash flow stream, the assessment of each asset's life cycle, the potential regulatory and commercial success risks, competitive trends impacting the asset and each cash flow stream, as well as other factors. The underlying assumptions used to prepare the discounted cash flow analysis may change; accordingly, for these and other reasons, actual results may vary significantly from estimated results.

Goodwill is calculated as the excess of the consideration transferred over the net assets recognized. Of the total goodwill acquired in connection with the Saol Acquisition, \$5.2 million was allocated to the Company's Generics segment and \$2.4 million was allocated to the Company's Specialty segment, of which \$4.9 million was deductible for tax purposes.

From the acquisition date of February 9, 2022 to December 31, 2022, the Saol Acquisition contributed net revenue and an operating loss of \$19.8 million and \$7.1 million, respectively.

Puniska Healthcare Pvt. Ltd.

On November 2, 2021, the Company entered into a definitive agreement to acquire Puniska Healthcare Pvt. Ltd. (“Puniska”), a privately held manufacturer of parenteral and injectable drugs in India, and land in a transaction valued at \$93.0 million (the “Puniska Acquisition”). Upon execution of the agreement, the Company paid \$72.9 million with cash on hand to acquire approximately 74% of the equity interests of Puniska on November 2, 2021. Upon approval of the transaction by the government of India in March 2022, the Company paid, with cash on hand, an additional \$1.7 million for the remaining 26% of the equity interests of Puniska (included in redeemable non-controlling interests in the Company's consolidated balance sheet as of December 31, 2021) and \$14.2 million for the satisfaction of a preexisting payable to the sellers (included in related party payables-short term in the Company's consolidated balance sheet as of December 31, 2021). In December 2021, the Company paid \$4.3 million with cash on hand for land associated with the Puniska Acquisition.

For the year ended December 31, 2021 the Company incurred \$1.0 million in transaction costs associated with the Puniska Acquisition, which were recorded in acquisition, transaction-related and integration expenses.

The Puniska Acquisition, excluding the land acquired in December 2021, was accounted for under the acquisition method of accounting, with Amneal as the accounting acquirer. The purchase price was calculated as follows (in thousands):

Cash ⁽¹⁾	\$ 72,880
Payable to sellers ⁽²⁾	14,162
Fair value of consideration transferred	\$ 87,042

(1) Cash includes the payment made upon execution of the agreement.

(2) Due to the short-term nature of the payable to the sellers, the principal amount approximates fair value.

The following is a summary of the purchase price allocation for the Puniska Acquisition (in thousands):

	Final Fair Values as of November 2, 2021
Cash	\$ 165
Trade accounts receivable, net	232
Inventories	1,092
Prepaid expenses and other current assets	4,473
Property, plant and equipment	53,423
Goodwill	30,091
Operating lease-right-of-use assets	234
Other assets	1,303
Total assets acquired	91,013
Accounts payable and accrued expenses	1,732
Operating lease liabilities	234
Other long-term liabilities	263
Total liabilities assumed	2,229
Redeemable non-controlling interests	1,742
Fair value of consideration transferred	\$ 87,042

Goodwill is calculated as the excess of the consideration transferred and fair value of the redeemable non-controlling interests over the net assets recognized. All of the goodwill acquired in connection with the Puniska Acquisition was allocated to the Company's Generics segment and deductible for tax purposes.

From the acquisition date of November 2, 2021 to December 31, 2021, the Puniska Acquisition contributed an operating loss of \$1.8 million.

Kashiv Specialty Pharmaceuticals, LLC Acquisition

On January 11, 2021, the Company and Kashiv Biosciences, LLC (a related party, see *Note 24. Related Party Transactions*) ("Kashiv") entered into a definitive agreement for Amneal to acquire a 98% interest in Kashiv Specialty Pharmaceuticals, LLC ("KSP"), a subsidiary of Kashiv focused on the development of innovative drug delivery platforms, novel 505(b)(2) drugs and complex generics (the "KSP Acquisition").

On April 2, 2021, the Company completed the KSP Acquisition. Under the terms of the transaction, the cash portion of the consideration was \$104.5 million, comprised of a purchase price of \$100.1 million (including initial and deferred consideration) and a working capital adjustment of \$4.4 million. The cash purchase price was funded by cash on hand. For further detail of the purchase price, refer to the table below.

Transaction costs associated with the KSP Acquisition were \$3.1 million for the year ended December 31, 2021 and were included in acquisition, transaction-related and integration expenses.

The KSP Acquisition was accounted for under the acquisition method of accounting, with Amneal as the accounting acquirer.

The purchase price was calculated as follows (in thousands):

Cash, including working capital payments	\$ 74,440
Deferred consideration ⁽¹⁾	30,099
Contingent consideration (regulatory milestones) ⁽²⁾	500
Contingent consideration (royalties) ⁽²⁾	5,200
Settlement of Amneal trade accounts payable due to KSP ⁽³⁾	(7,117)
Fair value of consideration transferred	\$ 103,122

- (1) The deferred consideration is stated at the fair value estimate of \$30.1 million, which is the \$30.5 million contractually stated amount less a \$0.4 million discount. The deferred consideration consists of \$30.0 million which was paid on January 11, 2022 and \$0.5 million, which was paid during three months ended September 30, 2022. As the deferred consideration is non-interest bearing, the Company, using guideline companies and market borrowings with comparable risk profiles, discounted the deferred consideration at 1.7% over the period from April 2, 2021 to the maturity dates, for a fair value of \$30.1 million on the date of acquisition. This discount was amortized to interest expense over the life of the deferred consideration utilizing the effective interest rate method.
- (2) Kashiv is eligible to receive up to an additional \$8.0 million in contingent payments upon the achievement of certain regulatory milestones and potential royalty payments from high single-digits to mid double-digits, depending on the amount of aggregate annual net sales for certain future pharmaceutical products. The estimated fair value of contingent consideration on the acquisition date was \$5.7 million and was based on significant Level 3 inputs that were not observable in the market. Key assumptions included the discount rate, probability of achievement of milestones, projected year of payments and expected net product sales. Refer to *Note 19. Fair Value Measurements*, for additional information on the methodology and determination of this liability.
- (3) Represents trade accounts payable due to KSP that were effectively settled upon closing of the KSP Acquisition.

The following is a summary of the purchase price allocation for the KSP Acquisition (in thousands):

	Final Fair Values as of April 2, 2021
Cash	\$ 112
Restricted cash	500
Prepaid expenses and other current assets	381
Property, plant and equipment	5,375
Goodwill	43,530
Intangible assets	56,400
Operating lease right-of-use assets	9,367
Total assets acquired	115,665
Accounts payable and accrued expenses	1,239
Operating lease liability	9,177
Related party payable	127
Total liabilities assumed	10,543
Non-controlling interests	2,000
Fair value of consideration transferred	\$ 103,122

Total acquired intangible assets of \$56.4 million were comprised of marketed product rights of \$29.4 million and IPR&D of \$27.0 million.

The acquired marketed product rights intangible assets are being amortized over their estimated useful lives as follows (in thousands):

	Fair Value	Weighted-Average Useful Life (in years)
Marketed product rights	\$ 29,400	5.9

The estimated fair value of the IPR&D and identifiable intangible assets was determined using the “income approach”, which is a valuation technique that provides an estimate of the fair value of an asset based on market participant expectations of the cash flows an asset would generate over its remaining useful life. The assumptions, including the expected projected cash flows, utilized in the purchase price allocation and in determining the purchase price were based on management's best estimates as of the closing date of the KSP Acquisition on April 2, 2021.

Some of the more significant assumptions inherent in the development of those asset valuations included the estimated net cash flows for each year for each asset or product (including net revenues, cost of sales, R&D, selling and marketing costs and working capital / contributory asset charges), the appropriate discount rate to select in order to measure the risk inherent in each future cash flow stream, the assessment of each asset's life cycle, the potential regulatory and commercial success risks, competitive trends impacting the asset and each cash flow stream, as well as other factors. The underlying assumptions used to prepare the discounted cash flow analysis may change; accordingly, for these and other reasons, actual results may vary significantly from estimated results.

Goodwill is calculated as the excess of the consideration transferred and fair value of the non-controlling interests over the net assets recognized. Of the total goodwill acquired in connection with the KSP Acquisition, \$40.8 million was allocated to the Company's Generics segment and \$2.7 million was allocated to the Specialty segment, based on the probability weighted cash flows of the assets acquired as of the date of acquisition. None of the goodwill recognized from the KSP Acquisition was deductible for tax purposes.

From the acquisition date of April 2, 2021, to December 31, 2021, the KSP Acquisition contributed an operating loss to the Company's consolidated statements of operations of \$21.3 million, which included approximately \$5.8 million of amortization expense from intangible assets acquired in the KSP Acquisition. Offsetting the operating loss was a reduction of third-party consulting services and the elimination of royalties due to KSP.

AvKARE and R&S Acquisitions

On December 10, 2019, the Company, through its investment in Rondo Partners, LLC (“Rondo”), entered into an equity purchase agreement (“Rondo Equity Purchase Agreement”) and an operating agreement to acquire a 65.1% controlling financing interest in both AvKARE Inc., a Tennessee corporation, and Dixon-Shane, LLC d/b/a R&S Northeast LLC, a Kentucky limited liability company (“R&S”) (collectively the “Rondo Acquisitions”). Prior to closing, AvKARE, Inc. converted to a limited liability company, AvKARE, LLC. AvKARE, LLC is one of the largest private label providers of generic pharmaceuticals in the U.S. federal agency sector, primarily focused on serving the Department of Defense and the Department of Veterans Affairs. R&S is a national pharmaceutical wholesaler focused primarily on offering 340b-qualified entities products to provide consistency in care and pricing.

On January 31, 2020, the Company completed the Rondo Acquisitions. The purchase price of \$294.2 million included cash of \$254.0 million, the issuance of long-term promissory notes to the sellers with an aggregate principal amount of \$44.2 million (estimated fair value of \$35.0 million) (the “Sellers Notes”) and a short-term promissory note (the “Short-Term Seller Note”) with a principal amount of \$1.0 million to the sellers. The cash purchase price was funded by \$76.0 million of cash on hand and debt of \$178.0 million of proceeds from a \$180.0 million term loan. The remaining \$2.0 million consisted of working capital costs. The Company is not party to or a guarantor of the term loan, the Sellers Notes or the Short-Term Seller Note. (Refer to *Note 16. Debt*).

The Rondo Acquisitions were accounted for under the acquisition method of accounting, with Amneal as the accounting acquirer of AvKARE, LLC and R&S. For the year ended December 31, 2020, the Company incurred \$1.0 million in transaction costs associated with the Rondo Acquisitions, which was recorded in acquisition, transaction-related and integration expenses.

From the acquisition date of January 31, 2020 to December 31, 2020, the Rondo Acquisitions contributed total net revenue of approximately \$311.3 million and operating income of \$4.4 million, which included approximately \$31.9 million of

amortization expense from intangible assets acquired in the Rondo Acquisitions, to the Company's consolidated statements of operations.

Unaudited Pro Forma Information

The unaudited pro forma combined results of operations for the years ended December 31, 2021 and 2020 (assuming the closing of the Rondo Acquisitions occurred on January 1, 2019 and the closing of the KSP Acquisition occurred on January 1, 2020) are as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Net revenue	<u>\$ 2,093,861</u>	<u>\$ 2,023,609</u>
Net income	<u>\$ 22,523</u>	<u>\$ 54,083</u>
Net income attributable to Amneal Pharmaceuticals, Inc.	<u>\$ 11,802</u>	<u>\$ 80,643</u>

The pro forma results have been prepared for comparative purposes only and are not necessarily indicative of the actual results of operations had the closing of the Rondo Acquisitions taken place on January 1, 2019 and the closing of the KSP Acquisition taken place on January 1, 2020. Furthermore, the pro forma results do not purport to project the future results of operations of the Company.

Adjustments to arrive at the unaudited pro forma information primarily related to increases in selling, general and administrative expenses for amortization of acquired intangible assets, net of the applicable tax impact.

Acquisition, Transaction-Related and Integration Expenses

For the year ended December 31, 2022, acquisition, transaction-related and integration expenses of \$0.7 million primarily consisted of professional services fees associated with the Saol Acquisition.

For the year ended December 31, 2021, acquisition, transaction-related and integration expenses of \$8.1 million primarily consisted of professional services fees associated with the Puniska Acquisition, the KSP Acquisition, and the Rondo Acquisitions.

For the year ended December 31, 2020, acquisition, transaction-related and integration expenses of \$9.0 million primarily consisted of professional services fees associated with the then pending KSP Acquisition, the Rondo Acquisitions, and systems integrations associated with the acquisition of Impax.

4. Revenue Recognition

Pharmaceutical Product Sales

Performance Obligations

The Company's performance obligation is the supply of finished pharmaceutical products to its customers. The Company's customers consist primarily of major wholesalers, retail pharmacies, managed care organizations, purchasing co-ops, hospitals, government agencies, institutions and pharmaceutical companies. The Company's customer contracts generally consist of both a master agreement, which is signed by the Company and its customer, and a customer submitted purchase order, which is governed by the terms and conditions of the master agreement. Customers purchase product by direct channel sales from the Company or by indirect channel sales through various distribution channels.

Revenue is recognized when the Company transfers control of its products to the customer, which typically occurs at a point-in-time, upon shipment or delivery. Substantially all of the Company's net revenues relate to products which are transferred to the customer at a point-in-time.

The Company offers standard payment terms to its customers and has elected the practical expedient to not adjust the promised amount of consideration for the effects of a significant financing, since the period between when the Company transfers the product to the customer and when the customer pays for that product is one year or less. Taxes collected from customers relating to product sales and remitted to governmental authorities are excluded from revenues. The consideration amounts due from customers as a result of product sales are subject to variable consideration, as described further below.

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The Company offers standard product warranties which provide assurance that the product will function as expected and in accordance with specifications. Customers cannot purchase warranties separately and these warranties do not give rise to a separate performance obligation.

The Company permits the return of product under certain circumstances, mainly upon product expiration, instances of shipping errors or where product is damaged in transit. The Company accrues for the customer's right to return as part of its variable consideration. See below for further details.

Variable Consideration

The Company includes an estimate of variable consideration in its transaction price at the time of sale, when control of the product transfers to the customer. Variable consideration includes but is not limited to: chargebacks, distribution fees, rebates, group purchasing organization ("GPO") fees, prompt payment (cash) discounts, consideration payable to the customer, billbacks, Medicaid and other government pricing programs, price protection and shelf stock adjustments, sales returns, and profit shares.

The Company assesses whether or not an estimate of its variable consideration is constrained and has determined that the constraint does not apply, since it is probable that a significant reversal in the amount of cumulative revenue will not occur in the future when the uncertainty associated with the variable consideration is subsequently resolved. The Company's estimates for variable consideration are adjusted as required at each reporting period for specific known developments that may result in a change in the amount of total consideration it expects to receive.

Chargebacks

In the case an indirect customer purchases product from their preferred wholesaler instead of directly from the Company, and the contract price charged to the indirect customer is lower than the wholesaler pricing, the Company pays the direct customer (wholesaler) a chargeback for the price differential. The Company estimates its chargeback accrual based on its estimates of the level of inventory of its products in the distribution channel that remain subject to chargebacks, current contract terms and historical experience. The estimate of the level of products in the distribution channel is based primarily on data provided by key customers.

Rebates

The Company pays fixed or volume-based rebates to its customers based on a fixed amount, fixed percentage of product sales or based on the achievement of a specified level of purchases. The Company's rebate accruals are based on actual net sales, contractual rebate rates negotiated with customers, and expected purchase volumes / corresponding tiers based on actual sales to date and forecasted amounts.

Group Purchasing Organization Fees

The Company pays fees to GPOs for administrative services that the GPOs perform in connection with the purchases of product by the GPO participants who are the Company's customers. The Company's GPO fee accruals are based on actual net sales, contractual fee rates negotiated with GPOs and the mix of the products in the distribution channel that remain subject to GPO fees.

Prompt Payment (Cash) Discounts

The Company provides customers with prompt payment discounts which may result in adjustments to the price that is invoiced for the product transferred, in the case that payments are made within a defined period. The Company's prompt payment discount accruals are based on actual net sales and contractual discount rates.

Consideration Payable to the Customer

The Company pays administrative and service fees to its customers based on a fixed percentage of the product price. These fees are not in exchange for a distinct good or service and therefore are recognized as a reduction of the transaction price. The Company accrues for these fees based on actual net sales, contractual fee rates negotiated with the customer and the mix of the products in the distribution channel that remain subject to fees.

Billbacks

In the case an indirect customer purchases product from their preferred wholesaler instead of directly from the Company, and the contract price charged to the indirect customer is higher than contractual pricing, the Company pays the indirect customer a billback for the price differential. The Company estimates its billback accrual based on its estimates of the level of inventory of its products in the distribution channel that remain subject to billbacks, current contract terms and historical experience. The estimate of the level of products in the distribution channel is based primarily on data provided by key customers.

Medicaid and Other Government Pricing Programs

The Company complies with required rebates mandated by law under Medicaid and other government pricing programs. The Company estimates its government pricing accruals based on monthly sales, historical experience of claims submitted by the various states and jurisdictions, historical rates and estimated lag time of the rebate invoices.

Price Protection and Shelf Stock Adjustments

The Company provides customers with price protection and shelf stock adjustments which may result in an adjustment to the price charged for the product transferred, based on differences between old and new prices which may be applied to the customer's on-hand inventory at the time of the price change. The Company accrues for these adjustments when its expected value of an adjustment is greater than zero, based on contractual pricing, actual net sales, accrual rates based on historical average rates, and estimates of the level of inventory of its products in the distribution channel that remain subject to these adjustments. The estimate of the level of products in the distribution channel is based primarily on data provided by key customers.

Sales Returns

The Company permits the return of product under certain circumstances, mainly due to product expiration, instances of shipping errors or where product is damaged in transit, and occurrences of product recalls. The Company's product returns accrual is primarily based on estimates of future product returns based generally on actual net sales, estimates of the level of inventory of its products in the distribution channel that remain subject to returns, estimated lag time of returns and historical return rates. The estimate of the level of products in the distribution channel is based primarily on data provided by key customers.

Profit Shares

For certain product sale arrangements, the Company earns a profit share upon the customer's sell-through of the product purchased from the Company. The Company estimates its profit shares based on actual net sales, estimates of the level of inventory of its products in the distribution channel that remain subject to profit shares, and historical rates of profit shares earned. The estimate of the level of products in the distribution channel is based primarily on data provided by key customers.

License Agreements

Refer to *Note 5. Alliance and Collaboration* for further information related to revenue recognition associated with a license agreement with multiple performance obligations.

Concentration of Revenue

The following table summarizes the percentages of net revenues from each of the Company's customers that individually accounted for 10% or more of its net revenues:

	For the year ended December 31,		
	2022	2021	2020
Customer A	21 %	21 %	23 %
Customer B	18 %	20 %	17 %
Customer C	22 %	24 %	23 %
Customer D	10 %	10 %	11 %

Disaggregated Revenue

The Company's significant therapeutic classes for each of its reportable segments, as determined based on net revenue for each of the years ended December 31, 2022, 2021 and 2020 are set forth below (in thousands):

	Year ended December 31,		
	2022	2021	2020
Generics			
Anti-Infective	\$ 23,193	\$ 30,501	\$ 40,381
Hormonal/Allergy	444,909	427,077	355,581
Antiviral ⁽¹⁾	40,601	4,832	25,724
Central Nervous System	393,281	381,110	422,405
Cardiovascular System	118,183	141,866	114,226
Gastroenterology	70,796	76,497	78,165
Oncology	64,285	103,327	61,113
Metabolic Disease/Endocrine	41,128	38,462	45,004
Respiratory	41,085	35,965	37,389
Dermatology	66,553	55,474	58,168
Other therapeutic classes	118,573	69,928	102,721
License agreement ⁽²⁾	8,018	—	—
International and other	1,468	1,299	2,333
Total Generics net revenue	1,432,073	1,366,338	1,343,210
Specialty			
Hormonal/Allergy	91,465	68,397	54,631
Central Nervous System	255,656	277,196	285,737
Other therapeutic classes	27,000	32,726	15,199
Total Specialty net revenue	374,121	378,319	355,567
AvKARE ⁽³⁾			
Distribution	260,560	192,921	161,673
Government Label	98,234	118,379	104,054
Institutional	27,742	25,176	18,546
Other	19,574	12,536	9,473
Total AvKARE net revenue	406,110	349,012	293,746
Total net revenue	\$ 2,212,304	\$ 2,093,669	\$ 1,992,523

⁽¹⁾ Antiviral net revenue for the year ended December 31, 2021 decreased from the prior year primarily due to a decline in Oseltamivir (generic Tamiflu®) sales from lower demand and increased returns activity above historical levels as a result of decreased influenza activity during the onset of the COVID-19 pandemic.

⁽²⁾ Refer to *Note 5. Alliance and Collaboration* for information on revenue recognized under a license agreement.

⁽³⁾ The AvKARE segment consists of the businesses acquired in the Rondo Acquisitions on January 31, 2020. Net revenue for the year ended December 31, 2020 represents eleven months of activity.

A rollforward of the major categories of sales-related deductions for the years ended December 31, 2022, 2021 and 2020 is as follows (in thousands):

	Contract Charge- backs and Sales Volume Allowances	Cash Discount Allowances	Accrued Returns Allowance	Accrued Medicaid and Commercial Rebates
Balance at December 31, 2019	\$ 829,807	\$ 34,308	\$ 150,361	\$ 114,960
Impact of the Rondo Acquisitions	12,444	944	11,606	10
Provision related to sales recorded in the period	3,930,682	118,525	110,556	133,748
Credits/payments issued during the period	(4,144,129)	(131,087)	(97,539)	(117,630)
Balance at December 31, 2020	628,804	22,690	174,984	131,088
Provision related to sales recorded in the period	3,164,331	107,810	105,127	137,452
Credits/payments issued during the period	(3,289,233)	(106,858)	(118,133)	(182,803)
Balance at December 31, 2021	503,902	23,642	161,978	85,737
Provision related to sales recorded in the period	3,416,149	112,609	84,306	129,203
Credits/payments issued during the period	(3,346,459)	(108,797)	(101,224)	(128,910)
Balance at December 31, 2022	<u>\$ 573,592</u>	<u>\$ 27,454</u>	<u>\$ 145,060</u>	<u>\$ 86,030</u>

5. Alliance and Collaboration

The Company has entered into several alliance, collaboration, license, distribution and similar agreements with respect to certain of its products and services with third-party pharmaceutical companies. The consolidated statements of operations include revenue recognized under agreements the Company has entered into to develop marketing and/or distribution relationships with its partners to fully leverage the technology platform and revenue recognized under development agreements which generally obligate the Company to provide R&D services over multiple periods. The Company's significant arrangements are discussed below.

License Agreement

On December 28, 2022, Amneal signed a long-term license agreement with Orion Corporation (“Orion”), a globally operating Finnish pharmaceutical company, to commercialize a number of our complex generic products in most parts of Europe, Australia and New Zealand (the “Orion Agreement”). The initial term of the Orion Agreement commences upon commercial launch of the products and will continue for eight years. The Orion Agreement will automatically renew for successive two-year terms unless either party declines such renewal in writing at least one year in advance.

Under the terms of the Orion Agreement, Amneal granted Orion licenses to certain generic products commercially available in the U.S. today and select high-value pipeline products currently under development. In addition, Amneal will be responsible for the performance of all R&D activities to be conducted to obtain regulatory approval for each product. Amneal is entitled to be reimbursed for a percentage of mutually agreed upon R&D expenses from Orion. Orion will be responsible for preparing and filing regulatory documentation, along with paying any application fees seeking regulatory approval for the products.

Upon achieving regulatory approval for products, Amneal will be responsible for manufacturing and supplying products to Orion. Orion will be responsible for all commercialization and marketing activities for the territories described above. Amneal will earn revenue for supplying products to Orion at the greater of: (i) cost plus a stated margin, or (ii) a fixed percentage of the net selling price, as defined in the Orion Agreement.

Upon signing of the Orion Agreement, Amneal was entitled to an upfront, non-refundable payment of €20.0 million, or \$21.4 million, based on the exchange rate as of December 31, 2022. Amneal is eligible to receive certain one-time sales-based milestones in the aggregate of €45.0 million, or \$48.2 million, based on the exchange rate as of December 31, 2022, contingent upon whether Orion achieves certain annual sales targets.

The Orion Agreement is within the scope of ASC Topic 808, *Collaborative Arrangements* (“ASC 808”). The Company identified performance obligations related to: 1) the grant of a license of functional IP, 2.) the performance of R&D activities, and 3.) the supply of products. The Company evaluated that the grant of licenses is in the scope of ASC 606, whereas the performance of R&D activities is in the scope of ASC 730-20, *Research and Development Arrangements*, because the

Company determined that performing R&D activities on behalf of other parties is not part of the ordinary activities of its business. The Company will record reimbursement received from Orion for R&D activities as a reduction of R&D expense. The Company concluded each future purchase order from Orion represents a separate contract. Amneal will record revenue related to each purchase order when it transfers control of the products to Orion. As of December 31, 2022, Amneal has not performed any reimbursable R&D activities under the Orion Agreement or supplied any products to Orion.

The Company determined that the transaction price under the arrangement was the upfront payment of \$21.4 million, which was allocated to the performance obligations based on their relative standalone selling prices. The remaining sales-based milestones payments of \$48.2 million are variable consideration and were not included in the transaction price because they were fully constrained under ASC 606.

As of December 31, 2022, the Company recorded a \$21.4 million receivable in prepaid expenses and other current assets for the upfront payment due from Orion, which was received in January 2023. For the year ended December 31, 2022, the Company recognized \$8.0 million in license revenue related to the delivery of functional IP, which was recorded in net revenues. The remaining \$13.4 million of the transaction price was allocated to the R&D activities performance obligation and was recorded as deferred income, of which \$6.7 million was recorded in accounts payable and accrued expenses and \$6.7 million was recorded in other long-term liabilities as of December 31, 2022. Deferred income related to R&D activities will be recognized, along with the amounts reimbursed by Orion, as reductions to R&D expense in future periods as services are performed.

Levothyroxine License and Supply Agreement; Transition Agreement

On August 16, 2018, the Company entered into a license and supply agreement with Jerome Stevens Pharmaceuticals, Inc. (“JSP”) for levothyroxine sodium tablets (“Levothyroxine”). This agreement designated the Company as JSP’s exclusive commercial partner for Levothyroxine in the U.S. market for a 10-year term commencing on March 22, 2019. Under this license and supply agreement with JSP, the Company accrued the up-front license payment of \$50.0 million on March 22, 2019, which was paid in April 2019. The agreement also provides for the Company to pay a profit share to JSP based on net profits of the Company’s sales of Levothyroxine, after considering product costs.

As a result of significant price erosion associated with the Levothyroxine products licensed from JSP, the Company recorded a \$17.7 million cost of goods sold impairment charge for the year ended December 31, 2021 to recognize an impairment on the entire unamortized balance of the up-front license payment (refer to *Note 13. Goodwill and Other Intangible Assets* for additional information).

Biosimilar Licensing and Supply Agreement

On May 7, 2018, the Company entered into a licensing and supply agreement with Mabxience S.L., for its biosimilar candidate for Avastin® (bevacizumab). The supply agreement was subsequently amended on March 2, 2021 and the licensing agreement was amended on March 4, 2021. The Company will be the exclusive partner in the U.S. market. The Company will pay up-front, development and regulatory milestone payments as well as commercial milestone payments on reaching pre-agreed sales targets in the market to Mabxience, up to \$78.3 million. For the years ended December 31, 2021 and 2020, the Company recognized \$11.7 million and \$4.5 million, respectively, of milestones in R&D expense related to the agreement (none for the year ended December 31, 2022).

On April 13, 2022, the Food and Drug Administration (“FDA”) approved the Company’s biologics license application for bevacizumab-maly, a biosimilar referencing Avastin®. In connection with this regulatory approval and associated activity, the Company paid milestones of \$26.5 million during the year ended December 31, 2022, which were capitalized as product rights intangible assets and are being amortized to cost of sales over their estimated useful lives of 7 years.

Distribution, License, Development and Supply Agreement with AstraZeneca UK Limited

In January 2012, Impax entered into an agreement with AstraZeneca UK Limited (“AstraZeneca”) to distribute branded products under the terms of a distribution, license, development and supply agreement (the “AZ Agreement”). The parties subsequently entered into a First Amendment to the AZ Agreement dated May 31, 2016 (as amended, the “AZ Amendment”). Under the terms of the AZ Agreement, AstraZeneca granted to Impax an exclusive license to commercialize the tablet, orally disintegrating tablet and nasal spray formulations of Zomig® (zolmitriptan) products for the treatment of migraine headaches in the United States and in certain U.S. territories, except during an initial transition period when AstraZeneca fulfilled all orders of Zomig® products on Impax’s behalf and AstraZeneca paid to Impax the gross profit on such Zomig® products. Pursuant to the AZ Amendment, under certain conditions, and depending on the nature and terms of the study agreed to with the FDA, Impax agreed to conduct, at its own expense, the juvenile toxicity study and pediatric study required by the FDA under the

Pediatric Research Equity Act (“PREA”) for approval of the nasal formulation of Zomig® for the acute treatment of migraine in pediatric patients ages six through eleven years old, as further described in the study protocol mutually agreed to by the parties (the “PREA Study”). In consideration for Impax conducting the PREA Study at its own expense, the AZ Amendment provided for the total royalty payments payable by Impax to AstraZeneca on net sales of Zomig® products under the AZ Agreement to be reduced by an aggregate amount of \$30.0 million to be received in quarterly amounts specified in the Amendment beginning from the quarter ended June 30, 2016 through the quarter ended December 31, 2020. In the event the royalty reduction amounts exceeded the royalty payments payable by Impax to AstraZeneca pursuant to the AZ Agreement in any given quarter, AstraZeneca was required to pay Impax an amount equal to the difference between the royalty reduction amount and the royalty payment payable by Impax to AstraZeneca. Impax’s commitment to perform the PREA Study could have been terminated, without penalty, under certain circumstances as set forth in the AZ Amendment. The Company recognized the amounts received from AstraZeneca for the PREA Study as a reduction of R&D expense. The PREA study was completed during March 2021.

In May 2013, Impax’s exclusivity period for branded Zomig® tablets and orally disintegrating tablets expired and Impax launched authorized generic versions of those products in the United States. The pediatric exclusivity of the AstraZeneca patent licensed to Impax for Zomig® Spray expired in May 2021 and the Company lost market exclusivity in the fourth quarter of 2021. As discussed above, pursuant to the AZ Amendment, the total royalty payments payable by Impax to AstraZeneca on net sales of Zomig® products under the AZ Agreement was reduced by certain specified amounts beginning from the quarter ended June 30, 2016 through the quarter ended December 31, 2020, with such reduced royalty amounts totaling an aggregate amount of \$30.0 million. The Company recorded cost of goods sold for royalties under this agreement of \$1.4 million, \$12.5 million, and \$17.2 million for the years ended December 31, 2022, 2021 and 2020, respectively.

Agreements with Kashiv Biosciences, LLC

For detail on the Company’s related party agreements with Kashiv Biosciences, LLC, refer to *Note 24. Related Party Transactions*.

6. Government Grants

In November 2021, Amneal Pharmaceuticals Private Limited, a subsidiary of the Company in India, was selected as one of 55 companies to participate in the PLI Scheme. The Government of India established the PLI Scheme to make India’s domestic manufacturing more globally competitive and to create global champions within the pharmaceutical sector by encouraging investment and product diversification with a focus on manufacturing complex and high value goods.

Under the PLI Scheme, the Company is eligible to receive up to 10.0 billion Indian rupees, or approximately \$120.8 million (based on conversion rates as of December 31, 2022), over a maximum six-year period, starting in 2022. To be eligible to receive the cash incentives, Amneal must achieve (i) minimum cumulative expenditures towards developmental and/or capital investments; and (ii) a minimum percentage growth in sales of eligible products.

The Company has concluded the PLI Scheme is government assistance in the form of a grant and, in the absence of specific accounting guidance under U.S. GAAP, the Company has analogized to International Accounting Standards 20, *Accounting for Government Grants and Disclosure of Government Assistance*. The Company evaluated the PLI Scheme to be a grant related to income and will recognize the cash incentives on a systematic basis in other operating income. For the year ended December 31, 2022, the Company recognized approximately \$4.0 million of income associated with the PLI Scheme, all of which was recorded as a receivable from the government of India in prepaid and other current assets as of December 31, 2022.

7. Income Taxes

Amneal is a limited liability company that is treated as a partnership for U.S. federal and most applicable state and local income tax purposes. As a partnership, Amneal is not subject to U.S. federal and certain state and local income taxes. Any taxable income or loss generated by Amneal is passed through to and included in the taxable income or loss of its members, including the Company, on a pro rata basis subject to applicable tax regulations. The Company is subject to U.S. federal income taxes, in addition to state and local income taxes with respect to its allocable share of any taxable income or loss of Amneal, as well as any stand-alone income or loss generated by the Company. Amneal provides for income taxes in the various foreign jurisdictions in which it operates.

The Company recorded a deferred tax asset for its outside basis difference in its investment in Amneal on May 4, 2018. The Company recorded a deferred tax asset related to the net operating loss of Impax from January 1, 2018 through May 4, 2018, as well as certain federal and state credits and interest carryforwards of Impax that were attributable to the Company.

The Company records its valuation allowances against its deferred tax assets (“DTAs”) when it is more likely than not that all or a portion of a DTA will not be realized. The Company routinely evaluates the realizability of its DTAs by assessing the likelihood that its DTAs will be recovered based on all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, estimates of future taxable income, tax planning strategies and results of operations. Estimating future taxable income is inherently uncertain and requires judgment. In projecting future taxable income, the Company considers its historical results and incorporates certain assumptions, including projected new product launches, revenue growth, and operating margins, among others.

The Company established a valuation allowance based upon all available objective and verifiable evidence both positive and negative, including historical levels of pre-tax income (loss) both on a consolidated basis and tax reporting entity basis, legislative developments, expectations and risks associated with estimates of future pre-tax income, and prudent and feasible tax planning strategies. Since first establishing a valuation allowance, the Company has generated cumulative consolidated three year pre-tax losses through December 31, 2022. As a result of the losses through December 31, 2022, the Company determined that it is more likely than not that it will not realize the benefits of its gross DTAs and therefore maintained its valuation allowance. As of December 31, 2022, this valuation allowance was \$434.9 million, and it reduced the carrying value of these gross DTAs, net of the impact of the reversal of taxable temporary differences, to zero.

In connection with the acquisition of Impax, the Company entered into a tax receivable agreement (“TRA”) for which it is generally required to pay the other holders of Amneal Common Units 85% of the applicable tax savings, if any, in U.S. federal and state income tax that it is deemed to realize as a result of certain tax attributes of their Amneal Common Units sold to the Company (or exchanged in a taxable sale) and that are created as a result of (i) the sales of their Amneal Common Units for shares of Class A Common Stock and (ii) tax benefits attributable to payments made under the TRA. In conjunction with the valuation allowance recorded on the DTAs, the Company reversed the accrued TRA liability of \$192.8 million, which resulted in a gain recorded in other (expense) income, net for the year ended December 31, 2019.

The timing and amount of any payments under the TRA may vary, depending upon a number of factors including the timing and number of Amneal common units sold or exchanged for the Company's Class A Common Stock, the price of the Company's Class A Common Stock on the date of sale or exchange, the timing and amount of the Company's taxable income, and the tax rate in effect at the time of realization of the Company's taxable income (the TRA liability is determined based on a percentage of the corporate tax savings from the use of the TRA's attributes). Further sales or exchanges occurring subsequent to December 31, 2022 could result in future Amneal tax deductions and obligations to pay 85% of such benefits to the holders of Amneal Common Units. These obligations could be incremental to and substantially larger than the approximate \$202.7 million contingent liability as of December 31, 2022 described below. Under certain conditions, such as a change of control or other early termination event, the Company could be obligated to make TRA payments in advance of tax benefits being realized.

As noted above, the Company has determined it is more-likely-than-not it will be unable to utilize its DTAs subject to TRA; therefore, as of December 31, 2022, the Company has not recognized the entire contingent liability under the TRA related to the tax savings it may realize from common units sold or exchanged. If utilization of these DTAs becomes more-likely- than-not in the future, at such time, these TRA liabilities (which amounted to approximately \$202.7 million at December 31, 2022) will be recorded through charges in the Company's consolidated statements of operations.

Each year, we evaluate the realizability of the deferred tax assets resulting from the sale or exchange of Amneal Common Units for Class A common stock. Although the deferred tax assets are not determined to be realizable, as of December 31, 2022, the Company had assessed that a TRA liability of \$0.6 million had become probable. Accordingly, the Company recorded an expense associated with the TRA in other income, net of \$0.6 million for the year ended December 31, 2022. In subsequent periods, the Company will continue to evaluate whether any future TRA payments become probable and can be estimated and, if so, the estimate of payment will be accrued.

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”). The CARES Act is an emergency economic stimulus package in response to the COVID-19 pandemic which, among other things, includes provisions relating to income and non-income-based tax laws. As a result of the CARES Act, the Company carried back approximately \$345.0 million in NOLs generated in 2018 to prior taxable income years. In carrying back the 2018 loss to an earlier year, the Company was able to benefit the losses at a 35% tax rate rather than the current U.S. corporate tax rate of 21%. Accordingly, the Company recorded a discrete income tax benefit of \$110.0 million for the year ended December 31, 2020. During July 2020, the Company received a cash refund for \$106.0 million of the \$110.0 million NOL carryback, plus interest of approximately \$4.0 million, with an additional \$2.0 million received in February of 2021. The remainder of the NOL carryback is expected to be received before December 31, 2023.

For the years ended December 31, 2022, 2021 and 2020 the Company's provision for (benefit from) income taxes and effective tax rates were \$6.7 million and (2.7)%, \$11.2 million and 35.7%, and \$(104.4) million and 291.7%, respectively.

The Company and its subsidiaries file income tax returns in the U.S. federal, and various state, local and foreign jurisdictions. The Internal Revenue Services (“IRS”) has completed an income tax audit for the 2018 tax return, the year of the Company’s CARES Act carryback. The Company sustained the entire carryback and therefore, the statute is closed for 2018 and prior years. The Company’s 2019 through 2021 tax years remain open to IRS exam. In the U.S., income tax returns are generally subject to examination for a period of three years. Neither the Company nor any of its other affiliates is currently under audit by the IRS. The Amneal partnership is currently under examination in certain states and the Company does not expect any material adjustments as of December 31, 2022.

The components of the Company's (loss) income before income taxes were as follows (in thousands):

	Years Ended December 31,		
	2022	2021	2020
United States	\$ (260,616)	\$ (10,540)	\$ (99,966)
International	12,489	41,906	64,186
Total (loss) income before income taxes	<u>\$ (248,127)</u>	<u>\$ 31,366</u>	<u>\$ (35,780)</u>

The provision for (benefit from) income taxes was comprised of the following (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Current:			
Domestic	\$ (1,073)	\$ 1,311	\$ (113,754)
Foreign	7,735	9,885	9,396
Total current income tax	<u>\$ 6,662</u>	<u>\$ 11,196</u>	<u>\$ (104,358)</u>

For the years ended December 31, 2022, 2021, and 2020, the Company did not record a provision for deferred income taxes as a result of recording a full valuation allowance on its DTAs.

The Company’s effective tax rates were as follows:

	Years Ended December 31,		
	2022	2021	2020
Federal income tax at the statutory rate	21.0 %	21.0 %	21.0 %
State income tax, net of federal benefit	(0.8)	4.2	(2.0)
Income not subject to tax	(10.7)	6.4	(29.8)
Foreign rate differential	(3.4)	17.3	(7.1)
Permanent book/tax differences	(0.3)	4.8	—
CARES Act	—	—	139.9
Valuation allowance	(10.3)	(13.5)	163.2
Other	1.8	(4.5)	6.5
Effective income tax rate	<u>(2.7)%</u>	<u>35.7 %</u>	<u>291.7 %</u>

The change in effective income tax rate for the year ended December 31, 2022 compared to the year ended December 31, 2021 was primarily due to the timing and mix of income and to the release of reserves for uncertain tax positions.

The change in effective income tax rate for the year ended December 31, 2021 compared to the year ended December 31, 2020 was primarily due to the \$110.0 million benefit from the carryback of U.S. Federal DTAs under the CARES Act for the year ended December 31, 2020 described above.

The following table summarizes the changes in the Company's valuation allowance on deferred tax assets (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Balance at the beginning of the period	\$ 416,588	\$ 422,812	\$ 470,193
Increase (decrease) due to net operating losses and temporary differences	25,589	(10,828)	(54,971)
Increase due to stock-based compensation	224	5,513	—
Decrease recorded against goodwill	(1,590)	—	—
Increase (decrease) recorded against additional paid-in capital	2,720	2,842	(1,631)
(Decrease) increase recorded against other comprehensive income	(8,636)	(3,751)	9,221
Balance at the end of the period	<u>\$ 434,895</u>	<u>\$ 416,588</u>	<u>\$ 422,812</u>

At December 31, 2022, the Company had approximately \$136.4 million of foreign net operating loss carry forwards. These net operating loss carry forwards will partially expire, if unused, between 2029 and 2031. At December 31, 2022, the Company had approximately \$253.8 million of federal and \$173.8 million of state net operating loss carry forwards. The federal net operating losses are generally allowed to be carried forward indefinitely, and the majority of the state net operating losses will expire, if unused, between 2034 and 2042. At December 31, 2022, the Company had approximately \$13.3 million of federal R&D credit carry forwards and \$12.3 million of state R&D credit carry forwards. The majority of the federal R&D credit carry forwards will expire if unused, between 2034 and 2042 and the majority of state credits can be carried forward indefinitely.

The tax effects of temporary differences that give rise to deferred taxes were as follows (in thousands):

	December 31, 2022	December 31, 2021
Deferred tax assets:		
Partnership interest in Amneal	\$ 203,336	\$ 200,872
Projected imputed interest on TRA	25,255	25,615
Net operating loss carryforward	82,338	73,861
IRC Section 163(j) interest carryforward	54,996	46,407
Capitalized costs	2,505	1,300
Accrued expenses	431	498
Stock-based compensation	5,737	5,513
Intangible assets	23,967	28,380
Tax credits and other	36,330	34,142
Total deferred tax assets	<u>434,895</u>	<u>416,588</u>
Valuation allowance	<u>(434,895)</u>	<u>(416,588)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

The Company's Indian subsidiaries are primarily export-oriented and in some cases are eligible for certain limited income tax holiday benefits granted by the government of India for export activities conducted within Special Economic Zones, or SEZs, up to March 31, 2023. Indian profits ineligible for SEZ benefits are subject to corporate income tax at the rate of 34.9%. In addition, all Indian profits, including those generated within SEZs, are subject to the Minimum Alternate Tax (MAT), at the rate of 21.5%. For the years ended December 31, 2022, 2021 and 2020, the effect of income tax holidays granted by the Indian government reduced the overall provision for income taxes, increased the benefit from income taxes and increased net income/decreased net loss by approximately \$5.0 million, \$3.0 million, and \$3.0 million, respectively. After the expiration of SEZ benefit, the Company will claim a reduced tax rate in India of approximately 25.17%.

The Company accounts for income tax contingencies using the benefit recognition model. The Company will recognize a benefit if a tax position is more likely than not to be sustained upon audit, based solely on the technical merits. The benefit is measured by determining the amount that is greater than 50% likely of being realized upon settlement, presuming that the tax position is examined by the appropriate taxing authority that has full knowledge of all relevant information. The amount of unrecognized tax benefits at December 31, 2022, 2021, and 2020, was \$3.6 million, \$5.5 million and \$5.4 million, respectively, of which \$3.5 million, \$5.4 million and \$5.0 million, respectively, would impact the Company's effective tax rate if recognized. The Company currently does not believe that the total amount of unrecognized tax benefits will increase or decrease

significantly over the next 12 months. Interest expense related to income taxes is included in provision for (benefit from) income taxes. Net interest expense (benefit) related to unrecognized tax benefits for the years ended December 31, 2022, 2021 and 2020 was \$(0.7) million, \$0.1 million and \$(0.3) million, respectively. Accrued interest expense as of December 31, 2022, 2021, and 2020 was \$0.1 million, \$0.8 million, and \$0.8 million, respectively. Income tax penalties are included in provision for (benefit from) income taxes. Accrued tax penalties as of December 31, 2022, 2021 and 2020 were immaterial.

A rollforward of unrecognized tax benefits for the years ended December 31, 2022, 2021 and 2020 is as follows (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Unrecognized tax benefits at the beginning of the period	\$ 5,489	\$ 5,368	\$ 6,176
Gross change for current period positions	110	131	125
Gross change for prior period positions	(1,983)	(10)	443
Decrease due to settlements and payments	—	—	(1,376)
Unrecognized tax benefits at the end of the period	<u>\$ 3,616</u>	<u>\$ 5,489</u>	<u>\$ 5,368</u>

In India, the income tax return for the fiscal year ending March 31, 2019 is currently being reviewed by tax authorities as part of the normal procedures, and the Company is not expecting any material adjustments. There are no other income tax returns in the process of examination, administrative appeal, or litigation. Income tax returns are generally subject to examination for a period of 3 years, 5 years, and 4 years after the tax year in India, Switzerland, and Ireland, respectively.

Applicable foreign taxes (including withholding taxes) have not been provided on the approximately \$111.0 million of undistributed earnings of foreign subsidiaries as of December 31, 2022. These earnings have been and currently are considered to be indefinitely reinvested. Quantification of additional taxes that may be payable on distribution is not practicable.

The Company continuously monitors government proposals to make changes to tax laws, including comprehensive tax reform in the United States and proposed legislation in certain foreign jurisdictions resulting from the adoption of the Organization for Economic Cooperation and Development policies. If legislative changes are enacted in other countries, any of these proposals may include increasing or decreasing existing statutory tax rates. A change in statutory tax rates in any country would result in the revaluation of Amneal's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted.

8. (Loss) Earnings per Share

Basic (loss) earnings per share of Class A common stock is computed by dividing net (loss) earnings attributable to Amneal Pharmaceuticals, Inc. by the weighted-average number of shares of Class A common stock outstanding during the period. Diluted (loss) earnings per share of Class A common stock is computed by dividing net (loss) earnings attributable to Amneal Pharmaceuticals, Inc. by the weighted-average number of shares of Class A common stock outstanding during the period, adjusted to give effect to potentially dilutive securities.

The following table sets forth reconciliations of the numerators and denominators used to compute basic and diluted (loss) earnings per share of Class A common stock (in thousands, except per share amounts):

	Years Ended December 31,		
	2022	2021	2020
Numerator:			
Net (loss) income attributable to Amneal Pharmaceuticals, Inc.	\$ (129,986)	\$ 10,624	\$ 91,059
Denominator:			
Weighted-average shares outstanding - basic	150,944	148,922	147,443
Effect of dilutive securities			
Stock options	—	767	348
Restricted stock units	—	2,132	1,122
Weighted-average shares outstanding - diluted	150,944	151,821	148,913
Net (loss) earnings per share attributable to Amneal Pharmaceuticals, Inc.'s Class A common stockholders:			
Basic	\$ (0.86)	\$ 0.07	\$ 0.62
Diluted	\$ (0.86)	\$ 0.07	\$ 0.61

Shares of the Company's Class B common stock do not share in the earnings or losses of the Company and, therefore, are not participating securities. As such, separate presentation of basic and diluted (loss) earnings per share of Class B common stock under the two-class method has not been presented.

The following table presents potentially dilutive securities excluded from the computations of diluted (loss) earnings per share of Class A common stock (in thousands).

	Years Ended December 31,		
	2022	2021	2020
Stock options	2,648 (1)	347 (3)	671 (3)
Restricted stock units	10,755 (1)	—	—
Performance stock units	7,174 (1)	5,055 (4)	2,973 (4)
Shares of Class B common stock	152,117 (2)	152,117 (2)	152,117 (2)

- (1) Excluded from the computation of diluted loss per share of Class A common stock for the years ended December 31, 2022 because the effect of their inclusion would have been anti-dilutive since there was a net loss attributable to the Company for the year ended December 31, 2022.
- (2) Shares of Class B common stock are considered potentially dilutive shares of Class A common stock. Shares of Class B common stock have been excluded from the computations of diluted (loss) earnings per share of Class A common stock for each of the years ended December 31, 2022, 2021 and 2020 because the effect of their inclusion would have been anti-dilutive under the if-converted method.
- (3) Excluded from the computation of diluted earnings per share of Class A common stock for the years ended December 31, 2021 and 2020 because the exercise price of the stock options exceeded the average market price of the Class A common stock during the period (out-of-the-money).
- (4) Excluded from the computation of diluted earnings per share of Class A common stock for the years ended December 31, 2021 and 2020 because the performance vesting conditions were not met.

9. Trade Accounts Receivable, Net

Trade accounts receivable, net is comprised of the following (in thousands):

	December 31, 2022	December 31, 2021
Gross accounts receivable	\$ 1,344,959	\$ 1,191,792
Allowance for credit losses	(2,122)	(1,665)
Contract charge-backs and sales volume allowances ⁽¹⁾	(573,592)	(503,902)
Cash discount allowances	(27,454)	(23,642)
Subtotal	(603,168)	(529,209)
Trade accounts receivable, net	<u>\$ 741,791</u>	<u>\$ 662,583</u>

⁽¹⁾ Refer to *Note 4. Revenue Recognition* for additional information.

Concentration of Receivables

Trade accounts receivables from customers representing 10% or more of the Company's total trade accounts receivable were as follows:

	December 31, 2022	December 31, 2021
Customer A	41 %	37 %
Customer B	25 %	24 %
Customer C	21 %	25 %

10. Inventories

Inventories are comprised of the following (in thousands):

	December 31, 2022	December 31, 2021
Raw materials	\$ 224,607	\$ 214,508
Work in process	58,522	47,802
Finished goods	247,606	227,079
Total inventories	<u>\$ 530,735</u>	<u>\$ 489,389</u>

11. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets are comprised of the following (in thousands):

	December 31, 2022	December 31, 2021
Deposits and advances	\$ 1,821	\$ 1,174
Prepaid insurance	8,090	7,962
Prepaid regulatory fees	5,298	3,710
Escrow deposits for legal settlements ⁽¹⁾	—	33,000
Income and other tax receivables	12,881	8,850
Prepaid taxes	16,593	16,085
Other current receivables ⁽²⁾	33,133	9,770
Other prepaid assets	17,144	17,309
Chargebacks receivable ⁽³⁾	8,605	12,358
Total prepaid expenses and other current assets	<u>\$ 103,565</u>	<u>\$ 110,218</u>

⁽¹⁾ Escrow deposits for legal settlements included preliminary settlement escrow deposits by the Company's insurers of \$33.0 million as of December 31, 2021, associated with insured securities class action lawsuits. Refer to *Note 21. Commitments and Contingencies* for additional details regarding these matters. This escrow deposit was used to satisfy the securities class action *Fleming v. Impax* in 2022.

⁽²⁾ Other current receivables as of December 31, 2022 include a \$21.4 million receivable for an upfront payment associated with the Orion Agreement which was collected in January 2023. Refer to *Note 5. Alliance and Collaboration* for additional information.

⁽³⁾ When a sale occurs on a contract item, the difference between the cost paid to the manufacturer by the Company and the contract cost that the end customer has with the manufacturer is rebated back to the Company by the manufacturer. The Company establishes a chargeback (rebate) receivable and a reduction to cost of goods sold in the same period as the related sale.

12. Property, Plant, and Equipment, Net

Property, plant, and equipment, net was comprised of the following (in thousands):

	December 31, 2022	December 31, 2021
Land	\$ 10,706	\$ 11,540
Buildings	225,630	230,994
Leasehold improvements	124,668	123,508
Machinery and equipment	411,572	414,098
Furniture and fixtures	13,823	12,745
Vehicles	1,699	1,485
Computer equipment	58,344	56,087
Construction-in-progress	69,344	58,263
Total property, plant, and equipment	915,786	908,720
Less: Accumulated depreciation	(445,971)	(394,562)
Property, plant, and equipment, net	<u>\$ 469,815</u>	<u>\$ 514,158</u>

Depreciation recognized by the Company was as follows (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Depreciation	<u>\$ 68,112</u>	<u>\$ 60,705</u>	<u>\$ 60,420</u>

13. Goodwill and Other Intangible Assets

The changes in goodwill were as follows (in thousands):

	Years Ended December 31,	
	2022	2021
Balance, beginning of period	\$ 593,017	\$ 522,814
Goodwill acquired during the period	7,553	70,584
Adjustment during the period for the Puniska Acquisition	3,075	—
Currency translation	(4,792)	(381)
Balance, end of period	<u>\$ 598,853</u>	<u>\$ 593,017</u>

As of December 31, 2022, \$366.3 million, \$163.1 million, and \$69.5 million of goodwill was allocated to the Specialty, Generics, and AvKARE segments, respectively. As of December 31, 2021, \$363.9 million, \$159.6 million, and \$69.5 million of goodwill was allocated to the Specialty, Generics, and AvKARE segments, respectively. For the year ended December 31, 2022, goodwill acquired during the period was associated with the Saol Acquisition. For the year ended December 31, 2021, the addition to goodwill was associated with the Puniska Acquisition and the KSP Acquisition. Refer to *Note 3. Acquisitions* for additional information about the Saol Acquisition, Puniska Acquisition and the KSP Acquisition.

Annual Goodwill Impairment Test

The Company performed a quantitative annual goodwill impairment test for each reporting unit on October 1, 2022, the measurement date. The analysis performed included estimating the fair value of each reporting unit using both the income and market approaches. Based on the results of the annual impairment test, the Company determined that the estimated fair values of the Generics, Specialty and AvKARE reporting units exceeded their respective carrying amounts as of the measurement date; therefore, the Company did not record an impairment charge for the year ended December 31, 2022. There were no indicators of goodwill impairment during the year ended December 31, 2022, including the period subsequent to the measurement date.

In performing the annual goodwill impairment test, the Company utilized long-term growth rates for its reporting units ranging from no growth to 1.0% and discount rates ranging from 11.5% to 15.1% in its estimation of fair value. As of December 31, 2022, the estimated fair value of the Generics reporting unit was in excess of its carrying value by approximately 57%, the estimated fair value of the Specialty reporting unit was in excess of its carrying value by approximately 28% and the estimated fair value of the AvKARE reporting unit was in excess of its carrying value by approximately 148%. A 500-basis point increase in the assumed discount rates utilized in each test would not have resulted in a goodwill impairment charge in any of the Company's reporting units.

While management believes the assumptions used were reasonable and commensurate with the views of a market participant, changes in key assumptions for these reporting units, including increasing the discount rate, lowering forecasts for revenue and operating margin or lowering the long-term growth rate, could result in a future impairment.

Intangible assets were comprised of the following (in thousands):

	Weighted-Average Amortization Period (in years)	December 31, 2022			December 31, 2021		
		Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Amortizing intangible assets:							
Product rights	7.5	\$1,222,762	\$ (573,281)	\$ 649,481	\$1,122,612	\$ (436,902)	\$ 685,710
Other intangible assets	4.1	133,800	(77,943)	55,857	133,800	(58,013)	75,787
Total		<u>1,356,562</u>	<u>(651,224)</u>	<u>705,338</u>	<u>1,256,412</u>	<u>(494,915)</u>	<u>761,497</u>
In-process research and development		390,755	—	390,755	405,425	—	405,425
Total intangible assets		<u>\$1,747,317</u>	<u>\$ (651,224)</u>	<u>\$1,096,093</u>	<u>\$1,661,837</u>	<u>\$ (494,915)</u>	<u>\$1,166,922</u>

For the year ended December 31, 2022, the Company recognized a total of \$24.1 million of intangible asset impairment charges, of which \$11.1 million was recognized in cost of goods sold and \$13.0 million was recognized in in-process research and development. The impairment charges for the year ended December 31, 2022 primarily related to three currently marketed products and two IPR&D products. Cost of sales impairment charges for the year ended December 31, 2022 of \$11.1 million related to currently marketed products of which (i) one product experienced significant price erosion during 2022, resulting in significantly lower than expected future cash flows and negative margins, (ii) the supply agreement of one product was terminated during 2022 and therefore the asset was not recoverable and (iii) one product was no longer expected to be sold to a key customer, and therefore the asset was not recoverable. IPR&D impairment charges for the year ended December 31, 2022 of \$13.0 million related to (i) one asset that experienced a delay in its expected launch date and (ii) one asset that experienced significant expected price erosion, both of which resulted in significantly lower than expected future cash flows.

For the year ended December 31, 2021, the Company recognized a total of \$23.4 million of intangible asset impairment charges, of which \$22.7 million was recognized in cost of goods sold and \$0.7 million was recognized in in-process research and development. The impairment charges for the year ended December 31, 2021 were primarily related to seven currently marketed products and one IPR&D product. For the currently marketed products, five products experienced significant price erosion during 2021, resulting in significantly lower than expected future cash flows and negative margins. Of the five currently marketed products that experienced significant price erosion during 2021, Levothyroxine contributed \$17.7 million of the \$22.7 million in cost of goods sold impairment charges (refer to *Note 5. Alliance and Collaboration* for additional information about the Company's Levothyroxine license with JSP). Additionally, the supply agreements for two currently marketed products were terminated early due to market conditions. The IPR&D impairment charge of \$0.7 million was related to one product that experienced a delay in its expected launch date, resulting in significantly lower than expected future cash flows.

For the year ended December 31, 2020, the Company recognized a total of \$37.3 million of intangible asset impairment charges, of which \$34.6 million was recognized in cost of goods sold and \$2.7 million was recognized in in-process research and development. The impairment charges for the year ended December 31, 2020 were primarily related to six currently marketed products and four IPR&D products. For the currently marketed products, four products experienced significant price erosion during 2020, resulting in significantly lower than expected future cash flows and negative margins, one product had its contract terminated and one product's supply agreement ended under an early termination due to market conditions. The IPR&D charges were associated with four products, three of which experienced significant price erosion for the products, resulting in significantly lower than expected future cash flows, and the other of which was canceled due to the withdrawal of the Company's development partner.

Amortization expense related to intangible assets recognized was as follows (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Amortization	<u>\$ 172,063</u>	<u>\$ 172,701</u>	<u>\$ 174,967</u>

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The following table presents future amortization expense for the next five years and thereafter, excluding \$390.8 million of IPR&D intangible assets (in thousands).

	Future Amortization
2023	\$ 163,473
2024	161,169
2025	122,478
2026	71,743
2027	50,180
Thereafter	136,295
Total	\$ 705,338

14. Other Assets

Other assets are comprised of the following (in thousands):

	December 31, 2022	December 31, 2021
Interest rate swap ⁽¹⁾	\$ 85,586	\$ —
Security deposits	3,523	3,895
Long-term prepaid expenses	3,711	5,896
Deferred revolving credit facility costs	2,206	1,603
Other long-term assets	8,191	9,220
Total	\$ 103,217	\$ 20,614

⁽¹⁾ Refer to *Note 19. Fair Value Measurements* and *Note 20. Financial Instruments* for information about the Company's interest rate swap.

15. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses were comprised of the following (in thousands):

	December 31, 2022	December 31, 2021 ⁽²⁾
Accounts payable	\$ 165,980	\$ 131,084
Accrued returns allowance ⁽¹⁾	145,060	161,978
Accrued compensation	54,038	62,098
Accrued Medicaid and commercial rebates ⁽¹⁾	86,030	85,737
Accrued royalties	19,309	20,893
Commercial chargebacks and rebates	10,226	10,226
Accrued professional fees	11,386	9,926
Taxes payable	359	2,523
Accrued other	45,811	40,880
Total accounts payable and accrued expenses	\$ 538,199	\$ 525,345

⁽¹⁾ Refer to *Note 4. Revenue Recognition* for additional information.

⁽²⁾ The prior period balance related to liabilities for legal proceedings of \$58.0 million (refer to *Note 21. Commitments and Contingencies*), formerly included in accounts payable and accrued expenses as of December 31, 2021, has been reclassified to the balance sheet caption current portion of liabilities for legal matters to conform to the current period presentation in the consolidated balance sheets.

16. Debt

The following is a summary of the Company's term loan indebtedness (in thousands):

	December 31, 2022	December 31, 2021
Term Loan due May 2025	\$ 2,563,876	\$ 2,590,876
Rondo Term Loan due January 2025	72,000	139,250
Other	—	624
Total debt	2,635,876	2,730,750
Less: debt issuance costs	(13,934)	(20,083)
Total debt, net of debt issuance costs	2,621,942	2,710,667
Less: current portion of long-term debt	(29,961)	(30,614)
Total long-term debt, net	<u>\$ 2,591,981</u>	<u>\$ 2,680,053</u>

Senior Secured Credit Facilities

On May 4, 2018 the Company entered into a senior credit agreement that provided a term loan ("Term Loan") with a principal amount of \$2.7 billion and an asset backed revolving credit facility ("Revolving Credit Facility") under which loans and letters of credit up to a principal amount of \$500.0 million were available (principal amount of up to \$25.0 million was available for letters of credit). On June 2, 2022, the Company entered into a revolving credit agreement (the "New Credit Agreement") that amended the Revolving Credit Facility and reduced the principal amount of loans and letters of credit to \$350.0 million (the "New Revolving Credit Facility"). The Term Loan, Revolving Credit Facility and the New Revolving Credit Facility are collectively referred to as the "Senior Secured Credit Facilities". Refer to below section titled *New Credit Agreement* for further details regarding the New Revolving Credit Facility.

The Term Loan is repayable in equal quarterly installments at a rate of 1.00% of the original principal amount annually, with the balance payable at maturity on May 4, 2025. The Term Loan bears a variable annual interest rate, which is a LIBOR-designated rate plus 3.5% at December 31, 2022. In October 2019, the Company entered into an interest rate lock agreement for a total notional amount of \$1.3 billion to hedge part of the Company's interest rate exposure associated with the variability in future cash flows from changes in the one-month LIBOR associated with its Term Loan. For further details, refer to *Note 20. Financial Instruments*.

The Term Loan requires regular principal payments of \$6.75 million quarterly in 2023, 2024, and 2025, with the balance of the Term Loan payable at maturity on May 4, 2025. Annually, the Company is also required to calculate the amount of excess cash flows, as defined in the Term Loan agreement. Based on the results of the excess cash flows calculation for the year ended December 31, 2020, the Company made a \$14.4 million additional principal payment in March 2021. Based on the results of the excess cash flows calculation for the years ended December 31, 2022 and 2021, no additional principal payments were due.

The proceeds from the Term Loan were used to finance, in part, the cost of the acquisition of Impax and to pay off Amneal's debt and substantially all of Impax's debt at the close of the acquisition of Impax.

The proceeds of any loans made under the Senior Secured Credit Facilities can be used for capital expenditures, acquisitions, working capital needs and other general purposes, subject to covenants as described below.

The Company incurred costs associated with the Term Loan due May 2025 of \$38.1 million and the Revolving Credit Facility of \$4.6 million, which were capitalized and are being amortized over the life of the applicable debt agreement to interest expense using the effective interest method. Subject to the refinancing, there was a decrease in the borrowing capacity of certain lenders between the New Revolving Credit Facility and the Revolving Credit Facility. As a result, the Company recorded a \$0.3 million charge for the year ended December 31, 2022 in loss on refinancing. Additionally, the Company incurred costs of \$1.6 million associated with the New Credit Agreement, which were capitalized as deferred financing costs with the remaining unamortized costs associated with the Revolving Credit Facility, and will be amortized over the life of the New Credit Agreement. The Term Loan has been recorded in the balance sheet net of issuance costs. Costs associated with the New Revolving Credit Facility have been recorded in other assets. For each of the years ended December 31, 2022, 2021 and 2020, amortization of deferred financing costs related to the Term Loan, the New Revolving Credit Facility and the Revolving Credit Facility was \$6.1 million, \$6.4 million and \$6.5 million, respectively.

The Senior Secured Credit Facilities contain a number of covenants that, among other things, create liens on Amneal's and its subsidiaries' assets. The Senior Secured Credit Facilities contain certain negative covenants that, among other things and subject to certain exceptions, restrict Amneal's and its subsidiaries' ability to incur additional debt or guarantees, grant liens, make loans, acquisitions or other investments, dispose of assets, merge, dissolve, liquidate or consolidate, pay dividends or other payments on capital stock, make optional payments or modify certain debt instruments, modify certain organizational documents, enter into arrangements that restrict the ability to pay dividends or grant liens, or enter into or consummate transactions with affiliates. The Senior Secured Credit Facilities contain customary events of default, subject to certain exceptions. Upon the occurrence of certain events of default, the obligations under the Senior Secured Credit Facilities may be accelerated and the commitments may be terminated. At December 31, 2022, Amneal was in compliance with all covenants associated with the Senior Secured Credit Facilities. A discussion of the covenants associated with the New Credit Agreement is below.

New Credit Agreement

The New Credit Agreement (i) replaced the Revolving Credit Facility with the New Revolving Credit Facility, a \$350.0 million senior secured revolving credit facility that matures on June 2, 2027, (ii) provides for up to \$25.0 million of the New Revolving Credit Facility to be available for the purpose of issuing letters of credit, (iii) provides for up to \$35.0 million of the New Revolving Credit Facility to be available for the purpose of issuing swingline loans, (iv) allows the Company to request an incremental increase in the revolving facility commitments by up to \$150.0 million, and (v) terminated the revolving credit facility commitments of lenders under the Revolving Credit Facility.

Interest is payable on the New Revolving Credit Facility at a rate equal to the alternate base rate ("ABR") or the secured overnight financing rate ("SOFR"), plus an applicable margin, in each case, subject to an ABR floor of 1.00% or a SOFR floor of 0.00%, as applicable. The applicable margin for the New Revolving Credit Facility is initially 0.25% per annum for ABR loans and 1.25% per annum for SOFR loans. The applicable margin on borrowings under the New Revolving Credit Facility thereafter will adjust ranging from 0.25% to 0.50% per annum for ABR loans and from 1.25% to 1.50% per annum for SOFR loans determined by the average historical excess availability. The proceeds of any loans made under the New Revolving Credit Facility can be used for capital expenditures, acquisitions, working capital needs and other general purposes, subject to covenants as described below. The Company pays a commitment fee based on the average daily unused amount of the New Revolving Credit Facility at a rate of 0.25% per annum. As of December 31, 2022, the interest rate for borrowings under the New Revolving Credit Facility was approximately 5.9%.

The New Credit Agreement contains certain negative covenants that, among other things and subject to certain exceptions, restrict the Company's and certain subsidiaries' ability to incur additional debt or guarantees, grant liens, make loans, acquisitions or other investments, dispose of assets, merge, dissolve, liquidate or consolidate, pay dividends or other payments on capital stock, make optional payments or modify certain debt instruments, modify certain organizational documents, enter into arrangements that restrict the ability to pay dividends or grant liens, or enter into or consummate transactions with affiliates. The New Revolving Credit Facility also includes a financial covenant whereby the Company must maintain a minimum fixed-charge coverage ratio if certain borrowing conditions are met. The New Revolving Credit Facility contains customary events of default, subject to certain exceptions. Upon the occurrence of certain events of default, the obligations under the New Revolving Credit Facility may be accelerated and the commitments may be terminated.

As of December 31, 2022, the Company had \$60.0 million in borrowings and \$285.9 million of available capacity under the New Revolving Credit Facility

Acquisition Financing - Revolving Credit and Term Loan Agreement

On January 31, 2020, in connection with the Rondo Acquisitions, Rondo Intermediate Holdings, LLC ("Rondo Holdings"), a wholly-owned subsidiary of Rondo, entered into a revolving credit and term loan agreement ("Rondo Credit Facility") that provided a term loan ("Rondo Term Loan") with a principal amount of \$180.0 million and a revolving credit facility ("Rondo Revolving Credit Facility") which loans up to a principal amount of \$30.0 million. The Rondo Term Loan is repayable in equal quarterly installments at a rate of 5.0% of the original principal amount annually, with the balance payable at maturity on January 31, 2025. The Rondo Credit Facility bears a variable annual interest rate, which originated as one-month LIBOR plus 3.0%. During September 2021, the Company prepaid \$25.0 million of outstanding principal of the Rondo Term Loan, which permitted the variable rate to be repriced. At December 31, 2022, the variable annual interest rate is one-month LIBOR plus 2.5%. Additionally, the annual interest rate for borrowings under the Rondo Credit Facility may be reduced or increased by 0.25% based on step-downs and step-ups determined by the total net leverage ratio, as defined in that agreement. At December 31, 2022, the Company had no outstanding borrowings under the Rondo Revolving Credit Facility.

A commitment fee based on the average daily unused amount of the Rondo Credit Facility is assessed at a rate based on total net leverage ratio, between 0.25% and 0.50% per annum. At December 31, 2022, the Rondo Credit Facility commitment fee rate was 0.25% per annum.

Costs associated with the Rondo Term Loan of \$3.5 million and the Rondo Credit Facility of \$0.6 million have been capitalized and are being amortized over the life of the applicable debt instrument to interest expense using the effective interest method. The Rondo Term Loan has been recorded in the balance sheet net of issuance costs. Costs associated with the Rondo Revolving Credit Facility have been recorded in other assets. For the year ended December 31, 2022, amortization of deferred financing costs associated with the Rondo Credit Facility was less than \$1.0 million.

The Rondo Credit Facility contains a number of covenants that, among other things, create liens on the equity securities and assets of Rondo Holdings, Rondo, AvKARE, LLC and R&S. The Rondo Credit Facility contains certain negative, affirmative and financial covenants that, among other things, restrict the ability to incur additional debt, grant liens, transact in mergers and acquisitions, make certain investments and payments or engage in certain transactions with affiliates. The Rondo Credit Facility also contains customary events of default. Upon the occurrence of certain events of default, the obligations under the Rondo Credit Facility may be accelerated and/or the interest rate may be increased. At December 31, 2022, Rondo was in compliance with all covenants. The Company is not party to the Rondo Credit Facility and is not a guarantor of any debt incurred thereunder. The Rondo Term Loan requires principal payments of \$9.0 million per year for the next two years and the balance payable at maturity on January 31, 2025.

During the year ended December 31, 2022, the Company repaid \$67.3 million of outstanding principal of the Rondo Term Loan. Additionally, the Company repaid the remaining \$0.6 million in principal of other debt obligations in June 2022.

Rondo Acquisitions Financing – Notes Payable-Related Party

On January 31, 2020, the closing date of the Rondo Acquisitions, Rondo or its subsidiary, Rondo Top Holdings, LLC, issued the Sellers Notes with a stated aggregate principal amount of \$44.2 million and the Short-Term Sellers Note with a stated principal amount of \$1.0 million. The Sellers Notes are unsecured and accrue interest at a rate of 5% per annum, not compounded, until June 30, 2025. The Sellers Notes are subject to prepayment at the option of Rondo, as the obligor, without premium or penalty. Mandatory payment of the outstanding principal and interest is due on June 30, 2025 if certain financial targets are achieved, the borrowers' cash flows are sufficient (as defined in the Sellers Notes) and repayment is not prohibited by senior debt. If repayment of all outstanding principal and accrued interest on the Sellers Notes is not made on June 30, 2025, the requirements for repayment are revisited on June 30 of each subsequent year until all principal and accrued interest are satisfied no later than January 31, 2030 or earlier, upon a change in control, as defined. The Short-Term Sellers Note was also unsecured, accrued interest at a rate of 1.6%, and was paid during February 2021.

In accordance with ASC 805, *Business Combinations*, all consideration transferred was measured at its acquisition-date fair value. The Sellers Notes were stated at the fair value estimate of \$35.0 million, which was estimated using the Monte-Carlo simulation approach under the option pricing framework. The Short-Term Sellers Note of \$1.0 million was recorded at the stated principal amount of \$1.0 million, which approximated fair value. The \$9.2 million discount on the Sellers Notes will be amortized to interest expense using the effective interest method from January 31, 2020 to June 30, 2025 and the carrying value of the Sellers Notes will accrete to the stated principal amount of \$44.2 million. During the year ended December 31, 2022, amortization of the discount related to the Sellers Notes was \$1.7 million.

The Company is not party to or a guarantor of the Sellers Notes. The Sellers Notes were recorded in notes payable-related party within long-term liabilities as of December 31, 2022 and 2021.

17. Other Long-Term Liabilities

Other long-term liabilities were comprised of the following (in thousands):

	December 31, 2022	December 31, 2021
Interest rate swap ⁽¹⁾	\$ —	\$ 11,473
Uncertain tax positions	563	3,177
Long-term portion of liabilities for legal matters	49,442	—
Long-term compensation ⁽²⁾	16,737	21,589
Contingent consideration	11,997	—
Other long-term liabilities	8,729	2,664
Total other long-term liabilities	\$ 87,468	\$ 38,903

⁽¹⁾ Refer to *Note 19. Fair Value Measurements* and *Note 20. Financial Instruments* for information about the Company's interest rate swap.

⁽²⁾ Includes \$7.6 million and \$11.8 million of long-term deferred compensation plan liabilities (refer to *Note 19. Fair Value Measurements*) as of December 31, 2022 and 2021, respectively, and \$9.1 million and \$8.0 million of long-term employee benefits for the Company's international employees as of December 31, 2022 and 2021, respectively.

18. Leases

The majority of the Company's operating and financing lease portfolio consists of corporate offices, manufacturing sites, warehouse space, R&D facilities, and land. The Company's leases have remaining lease terms of 1 year to 22 years (excluding international land easements with remaining terms of approximately 28-97 years). Rent expense for the years ended December 31, 2022, 2021 and 2020 was \$22.6 million, \$19.8 million, and \$26.3 million, respectively.

During the year ended December 31, 2020, the Company recorded \$0.6 million for the impairment of the operating lease right-of-use asset associated with the Company's Blue Bell, PA facility due to the closure of that site. There were no impairments of operating lease right-of-use assets for the years ended December 31, 2022 and December 31, 2021.

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

	Years Ended December 31,		
	2022	2021	2020
Operating lease cost ⁽¹⁾	\$ 17,800	\$ 15,057	21,664
Finance lease cost:			
Amortization of right-of-use assets	4,808	4,713	4,487
Interest on lease liabilities	4,508	4,601	4,773
Total finance lease cost	9,316	9,314	9,260
Total lease cost	\$ 27,116	\$ 24,371	\$ 30,924

(1) Includes variable and short-term lease costs.

Supplemental balance sheet information related to the Company's leases was as follows (in thousands):

	December 31, 2022	December 31, 2021
Operating leases		
Operating lease right-of-use assets	\$ 38,211	\$ 39,899
Operating lease right-of-use assets - related party ⁽¹⁾	17,910	20,471
Total operating lease right-of-use assets	<u>\$ 56,121</u>	<u>\$ 60,370</u>
Operating lease liabilities	\$ 32,126	\$ 32,894
Operating lease liabilities - related party ⁽¹⁾	15,914	18,783
Current portion of operating lease liabilities	8,321	9,686
Current portion of operating lease liabilities - related party ⁽¹⁾	2,869	2,636
Total operating lease liabilities	<u>\$ 59,230</u>	<u>\$ 63,999</u>
Financing leases		
Financing lease right of use assets	<u>\$ 63,424</u>	<u>\$ 64,475</u>
Financing lease liabilities	\$ 60,769	\$ 60,251
Current portion of financing lease liabilities	3,488	3,101
Total financing lease liabilities	<u>\$ 64,257</u>	<u>\$ 63,352</u>

⁽¹⁾ Refer to *Note 24. Related Party Transactions* for information about related party leases.

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

	Years Ended December 31,	
	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from finance leases	\$ 4,539	\$ 4,601
Operating cash flows from operating leases	\$ 16,217	\$ 15,006
Financing cash flows from finance leases	\$ 3,484	\$ 3,179
Non-cash activity:		
Right-of-use assets obtained in exchange for new operating lease liabilities	\$ 7,504	\$ 12,006
Right-of-use assets obtained in exchange for new financing lease liabilities	\$ 4,606	\$ 1,072

The table below reflects the weighted average remaining lease term and weighted average discount rate for the Company's operating and finance leases:

	December 31, 2022	December 31, 2021
Weighted average remaining lease term - operating leases	5 years	5 years
Weighted average remaining lease term - finance leases	19 years	21 years
Weighted average discount rate - operating leases	8.5%	6.9%
Weighted average discount rate - finance leases	7.2%	7.1%

Maturities of lease liabilities as of December 31, 2022 were as follow (in thousands):

	Operating Leases	Financing Leases
2023	\$ 15,843	\$ 7,976
2024	16,558	6,913
2025	14,264	6,466
2026	10,393	5,989
2027	7,420	5,645
Thereafter	11,550	85,220
Total lease payments	76,028	118,209
Less: Imputed interest	(16,798)	(53,952)
Total	<u>\$ 59,230</u>	<u>\$ 64,257</u>

Maturities of lease liabilities as of December 31, 2021 were as follows (in thousands):

	Operating Leases	Financing Leases
2022	\$ 16,136	\$ 7,492
2023	16,412	6,726
2024	15,215	5,572
2025	11,363	5,474
2026	7,400	5,474
Thereafter	9,712	89,862
Total lease payments	76,238	120,600
Less: Imputed interest	(12,239)	(57,248)
Total	<u>\$ 63,999</u>	<u>\$ 63,352</u>

19. Fair Value Measurements

Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement that should be determined using assumptions that market participants would use in pricing an asset or liability. Valuation techniques used to measure fair value should maximize the use of observable inputs and minimize the use of unobservable inputs. To measure fair value, the Company uses the following fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable:

Level 1 – Quoted prices in active markets for identical assets or liabilities.

Level 2 – Inputs other than Level 1 that are observable for the asset or liability, either directly or indirectly, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data by correlation or other means.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Value is determined using pricing models, discounted cash flow methodologies, or similar techniques and also includes instruments for which the determination of fair value requires significant judgment or estimation.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company evaluates its financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level of classification for each reporting period. The following table sets forth the Company's financial assets and liabilities that were measured at fair value on a recurring basis (in thousands):

	Fair Value Measurement Based on			
	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
December 31, 2022				
Assets				
Interest Rate Swap ⁽¹⁾	\$ 85,586	\$ —	\$ 85,586	\$ —
Liabilities				
Deferred compensation plan liabilities ⁽²⁾	\$ 9,674	\$ —	\$ 9,674	\$ —
Contingent consideration liability ⁽³⁾	\$ 15,427	\$ —	\$ —	\$ 15,427
December 31, 2021				
Liabilities				
Interest Rate Swap ⁽¹⁾	\$ 11,473	\$ —	\$ 11,473	\$ —
Deferred compensation plan liabilities ⁽²⁾	\$ 13,883	\$ —	\$ 13,883	\$ —
Contingent consideration liability ⁽³⁾	\$ 5,900	\$ —	\$ —	\$ 5,900

- (1) The fair value measurement of the Company's interest rate swap classified within Level 2 of the fair value hierarchy is a model-derived valuation as of a given date in which all significant inputs are observable in active markets including certain financial information and certain assumptions regarding past, present, and future market conditions. Refer to *Note 20. Financial Instruments* for information about the Company's interest rate swap.
- (2) As of December 31, 2022, deferred compensation plan liabilities of \$2.1 million and \$7.6 million were recorded in current and non-current liabilities, respectively. As of December 31, 2021, deferred compensation plan liabilities of \$2.1 million and \$11.8 million were recorded in current and non-current liabilities, respectively. These liabilities are recorded at the value of the amount owed to the plan participants, with changes in value recognized as compensation expense. The calculation of the deferred compensation plan obligation is derived from observable market data by reference to hypothetical investments selected by the participants.
- (3) The fair value measurement of contingent consideration liability has been classified as a Level 3 recurring liability as its valuation requires judgment and estimation of factors that are not currently observable in the market. If different assumptions were used for various inputs, the estimated fair value could be higher or lower than what the Company determined. As of December 31, 2022, the contingent consideration liability associated with the Saol Acquisition included \$0.1 million recorded in accounts payable and accrued expenses and \$12.0 million recorded in other-longer term liabilities. As of December 31, 2022 and 2021, the contingent consideration liability associated with the KSP Acquisition was valued at approximately \$3.3 million and \$5.9 million, respectively, and recorded within related party payables - long term. Refer to *Note 3. Acquisitions* for additional information related to contingent consideration associated with the KSP Acquisition and the Saol Acquisition.

There were no transfers between levels in the fair value hierarchy during the year ended December 31, 2022.

Contingent consideration

On April 2, 2021, the Company completed the KSP Acquisition, which provided for contingent milestone payments of up to an aggregate of \$8.0 million (undiscounted) upon the achievement of certain regulatory milestones, as well as contingent royalty payments that are tiered depending on the net sales amount of aggregate annual net sales for certain future pharmaceutical products.

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On February 9, 2022, the Company completed the Saol Acquisition, which provides for contingent royalty payments that are tiered depending on the aggregate annual net sales for certain pharmaceutical products, beginning in 2023.

The following table provides a reconciliation of the contingent consideration liability measured at fair value on a recurring basis using significant unobservable inputs (Level 3) (in thousands):

	Year Ended December 31, 2022	Year Ended December 31, 2021
Balance, beginning of period	\$ 5,900	\$ —
Addition due to the Saol Acquisition	8,796	—
Addition due to the KSP Acquisition	—	5,700
Net change in fair value during period	731	200
Balance, end of period	\$ 15,427	\$ 5,900

The fair value measurement of the contingent consideration liabilities was determined based on significant unobservable inputs, including the discount rate, estimated probabilities of success, timing of achieving specified regulatory milestones and the estimated amount of future sales of the acquired products. The contingent consideration liability is estimated by applying a probability-weighted expected payment model for contingent milestone payments and a Monte Carlo simulation model for contingent royalty payments, which are then discounted to present value. Changes to fair value of the contingent consideration liabilities can result from changes to one or a number of the aforementioned inputs. If different assumptions were used for various inputs, the estimated fair value could be higher or lower than what the Company determined.

The following table summarizes the significant unobservable inputs used in the fair value measurement of our contingent consideration liabilities as of December 31, 2022 and 2021:

Contingent Consideration Liability	Fair Value as of December 31, 2022 (in thousands)	Unobservable input	Range		Weighted Average ⁽¹⁾
Regulatory Milestones (KSP Acquisition)	\$ 390	Discount rate	7.2 %	8.5 %	7.3 %
		Probability of payment	1.8 %	20.0 %	18.6 %
		Projected year of payment	2024	2026	2024
Royalties (KSP Acquisition)	\$ 2,900	Discount rate	12.5 %	12.5 %	12.5 %
		Probability of payment	1.8 %	20.0 %	18.6 %
		Projected year of payment	2024	2033	2028
Royalties (Saol Acquisition)	\$ 12,137	Discount rate	17.8 %	17.8 %	17.8 %
		Projected year of payment	2023	2033	2027

Contingent Consideration Liability	Fair Value as of December 31, 2021 (in thousands)	Unobservable input	Range		Weighted Average ⁽¹⁾
Regulatory Milestones (KSP Acquisition)	\$ 500	Discount rate	2.2 %-	4.4%	2.4%
		Probability of payment	1.8 %-	20.0%	16.7%
		Projected year of payment	2023 -	2027	2023
Royalties (KSP Acquisition)	\$ 5,400	Discount rate	11.5 %-	11.5%	11.5%
		Probability of payment	1.8 %-	20.0%	18.0%
		Projected year of payment	2023 -	2032	2029

(1) Unobservable inputs were weighted by the relative fair value of each product candidate acquired.

Assets and Liabilities Not Measured at Fair Value on a Recurring Basis

The carrying amounts of cash, accounts receivable and accounts payable approximate their fair values due to the short-term maturity of these instruments.

The Term Loan is in the Level 2 category within the fair value level hierarchy. The fair value was determined using market data for valuation. The fair value of the Term Loan at December 31, 2022 and 2021 was approximately \$2.3 billion and \$2.6 billion, respectively.

The Rondo Term Loan is in the Level 2 category within the fair value level hierarchy. The fair value of the Rondo Term Loan at December 31, 2022 and 2021 was approximately \$70.9 million and \$138.9 million, respectively.

The Sellers Notes are in the Level 2 category within the fair value level hierarchy. At December 31, 2022 and 2021 the fair value of the Sellers Notes were \$39.1 million and \$37.9 million, respectively.

Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

There were no non-recurring fair value measurements during the years ended December 31, 2022 and 2021.

20. Financial Instruments

The Company uses an interest rate swap to manage its exposure to market risks for changes in interest rates.

Interest Rate Risk

Interest income earned on cash and cash equivalents may fluctuate as interest rates change; however, due to their relatively short maturities, the Company does not hedge these assets or their investment cash flows and the impact of interest rate risk is not material. The Company is exposed to interest rate risk on its debt obligations. The Company's debt obligations consist of variable-rate and fixed-rate debt instruments (for further details, refer to *Note 16. Debt*). The Company's primary objective is to achieve the lowest overall cost of funding while managing the variability in cash outflows within an acceptable range. In order to achieve this objective, the Company has entered into an interest rate swap on the Term Loan.

Interest Rate Derivative – Cash Flow Hedge

The interest rate swap involves the periodic exchange of payments without the exchange of underlying principal or notional amounts. In October 2019, the Company entered into an interest rate lock agreement for a total notional amount of \$1.3 billion to hedge part of the Company's interest rate exposure associated with the variability in future cash flows from changes in the one-month LIBOR associated with its Term Loan.

As of December 31, 2022, the total gain, net of income taxes, related to the Company's cash flow hedge was \$85.6 million, of which \$42.3 million was recognized in accumulated other comprehensive income and \$43.3 million was recognized in non-controlling interests. As of December 31, 2021, the total loss, net of income taxes, related to the Company's cash flow hedge was \$11.5 million, of which \$6.0 million was recognized in accumulated other comprehensive loss and \$5.5 million was recognized in non-controlling interests.

A summary of the fair values of derivative instruments in the consolidated balance sheets was as follows (in thousands):

Derivatives Designated as Hedging Instruments	December 31, 2022		December 31, 2021	
	Balance Sheet Classification	Fair Value	Balance Sheet Classification	Fair Value
Variable-to-fixed interest rate swap	Other Assets	\$ 85,586	Other long-term liabilities	\$ 11,473

21. Commitments and Contingencies

Commitments

Commercial Manufacturing, Collaboration, License, and Distribution Agreements

The Company continues to seek to enhance its product line and develop a balanced portfolio of differentiated products through product acquisitions and in-licensing. Accordingly, the Company, in certain instances, may be contractually obligated to make potential future development, regulatory, and commercial milestone, royalty and/or profit sharing payments in conjunction with collaborative agreements or acquisitions that the Company has entered into with third parties. The Company has also licensed certain technologies or intellectual property from various third parties. The Company is generally required to make upfront payments as well as other payments upon successful completion of regulatory or sales milestones. The agreements generally permit the Company to terminate the agreement with no significant continuing obligation. The Company could be required to make significant payments pursuant to these arrangements. These payments are contingent upon the occurrence of certain future events and, given the nature of these events, it is unclear when, if ever, the Company may be required to pay such amounts. Further, the timing of any future payment is not reasonably estimable. Refer to *Note 5. Alliance and Collaboration* for additional information. Certain of these arrangements are with related parties. Refer to *Note 24. Related Party Transactions* for additional information.

Contingencies

Legal Proceedings

The Company's legal proceedings are complex, constantly evolving, and subject to uncertainty. As such, the Company cannot predict the outcome or impact of its significant legal proceedings which are set forth below. Additionally, the Company manufactures and derives a portion of its revenue from the sale of pharmaceutical products in the opioid class of drugs and may therefore face claims arising from the regulation and/or consumption of such products. While the Company believes it has meritorious claims and/or defenses to the matters described below (and intends to vigorously prosecute and defend them), the nature and cost of litigation is unpredictable, and an unfavorable outcome of such proceedings could include damages, fines, penalties and injunctive or administrative remedies. For any proceedings where losses are probable and reasonably capable of estimation, the Company accrues a potential loss. When the Company has a probable loss for which a reasonable estimate of the liability is a range of losses and no amount within that range is a better estimate than any other amount, the Company records the loss at the low end of the range. While these accruals have been deemed reasonable by the Company's management, the assessment process relies heavily on estimates and assumptions that may ultimately prove inaccurate or incomplete. Additionally, unforeseen circumstances or events may lead the Company to subsequently change its estimates and assumptions. Unless otherwise indicated below, the Company is unable at this time to estimate the possible loss or the range of loss, if any, associated with such legal proceedings and claims. Any such claims, proceedings, investigations or litigation, regardless of the merits, might result in substantial costs to defend or settle, borrowings under our debt agreements, restrictions on product use or sales, or otherwise harm our business. The ultimate resolution of any or all claims, legal proceedings or investigations are inherently uncertain and difficult to predict, could differ materially from our estimates and could have a material adverse effect on the Company's results of operations and/or cash flows in any given accounting period, or on the Company's overall financial condition. The Company currently intends to vigorously prosecute and/or defend these proceedings as appropriate. From time to time, however, the Company may settle or otherwise resolve these matters on terms and conditions that it believes to be in its best interest. An insurance recovery, if any, is recorded in the period in which it is probable the recovery will be realized.

Charges (insurance recoveries) related to legal matters, net were comprised of the following (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Opana ER® antitrust litigation	\$ 262,837	\$ —	\$ —
Civil prescription opioid litigation	17,993	—	—
Securities class action - Cambridge Retirement System v. Amneal	(15,500)	25,000	—
Galeas v. Amneal	1,200	—	—
Other	3,400	—	5,860
Total	<u>\$ 269,930</u>	<u>\$ 25,000</u>	<u>\$ 5,860</u>

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Liabilities for legal matters were comprised of the following (in thousands):

Matter	Year Ended December 31,	
	2022	2021
Opana ER® antitrust litigation ⁽¹⁾	\$ 83,944	\$ —
Opana ER® antitrust litigation - accrued interest	1,423	—
Civil prescription opioid litigation	17,993	—
Securities class action - Fleming v. Impax ⁽²⁾	—	33,000
Securities class action - Cambridge Retirement System v. Amneal ⁽³⁾	—	25,000
Galeas v. Amneal	1,200	—
Other	2,923	—
Current portion of liabilities for legal matters	<u>\$ 107,483</u>	<u>\$ 58,000</u>
Opana ER® antitrust litigation ⁽¹⁾	\$ 50,000	\$ —
Imputed interest	(1,405)	—
Accrued interest	847	—
Long-term portion of liabilities for legal matters (included in other long-term liabilities)	<u>\$ 49,442</u>	<u>\$ —</u>

⁽¹⁾ During 2022, the Company paid \$131.1 million of the \$265.0 million settlement to certain plaintiffs pursuant to the Opana ER® antitrust litigation settlement agreements (see below under *Opana ER® Antitrust Litigation* for additional information).

⁽²⁾ Upon final approval by the court, the securities class action Fleming v. Impax was settled for \$33.0 million during 2022 using a security deposit funded by insurance in 2021 (refer to *Note 11. Prepaid Expenses and Other Current Assets*). See below for additional information.

⁽³⁾ Upon final approval by the Court, the securities class action Cambridge Retirement System v. Amneal was settled during 2022 for \$25.0 million with cash paid by the Company of \$9.5 million and insurance recoveries of \$15.5 million. See below for additional information.

As of December 31, 2022, the remaining payments associated with the Opana ER® antitrust litigation settlement agreements are as follows:

	Amount Due
January 2023	\$ 83,944
January 2024	50,000
	<u>\$ 133,944</u>

3% interest is payable on the amounts due in January 2023 and January 2024. The Company includes the interest accrual on these amounts as a component of the current portion of liabilities for legal matters. Additional interest of 2.7% was imputed on the \$50.0 million long-term liability due in January 2024, resulting in an initial discount of \$2.2 million, which is being amortized to interest expense over the life of the liability using the effective interest method.

Refer to the respective discussions below for additional information on the significant matters in the tables above.

Medicaid Reimbursement and Price Reporting Matters

The Company is required to provide pricing information to state agencies, including agencies that administer federal Medicaid programs. Certain state agencies have alleged that manufacturers have reported improper pricing information, which allegedly caused them to overpay reimbursement costs. Other agencies have alleged that manufacturers have failed to timely file required reports concerning pricing information. Liabilities are periodically established by the Company for any potential claims or settlements of overpayment. The Company intends to vigorously defend against any such claims. The ultimate settlement of any potential liability for such claims may be higher or lower than estimated.

Patent Litigation

There is substantial litigation in the pharmaceutical, biological, and biotechnology industries with respect to the manufacture, use, and sale of new products which are the subject of conflicting patent and intellectual property claims. One or more patents

often cover the brand name products for which the Company is developing generic versions and the Company typically has patent rights covering the Company's branded products.

Under federal law, when a drug developer files an Abbreviated New Drug Application ("ANDA") for a generic drug seeking approval before expiration of a patent which has been listed with the FDA as covering the brand name product, the developer must certify its product will not infringe the listed patent(s) and/or the listed patent is invalid or unenforceable (commonly referred to as a "Paragraph IV" certification). Notices of such certification must be provided to the patent holder, who may file a suit for patent infringement within 45 days of the patent holder's receipt of such notice. If the patent holder files suit within the 45-day period, the FDA can review and tentatively approve the ANDA, but generally is prevented from granting final marketing approval of the product until a final judgment in the action has been rendered in favor of the generic drug developer, or 30 months from the date the notice was received, whichever is sooner. The Company's Generics segment is typically subject to patent infringement litigation brought by branded pharmaceutical manufacturers in connection with the Company's Paragraph IV certifications seeking an order delaying the approval of the Company's ANDA until expiration of the patent(s) at issue in the litigation.

The uncertainties inherent in patent litigation make the outcome of such litigation difficult to predict. For the Company's Generics segment, the potential consequences in the event of an unfavorable outcome in such litigation include delaying launch of its generic products until patent expiration. If the Company were to launch its generic product prior to successful resolution of a patent litigation, the Company could be liable for potential damages measured by the profits lost by the branded product manufacturer rather than the profits earned by the Company if it is found to infringe a valid, enforceable patent, or enhanced treble damages in cases of willful infringement. For the Company's Specialty segment, an unfavorable outcome may significantly accelerate generic competition ahead of expiration of the patents covering the Company's branded products. All such litigation typically involves significant expense.

The Company is generally responsible for all of the patent litigation fees and costs associated with current and future products not covered by its alliance and collaboration agreements. The Company has agreed to share legal expenses with respect to third-party and Company products under the terms of certain of the alliance and collaboration agreements. The Company records the costs of patent litigation as expense in the period when incurred for products it has developed, as well as for products which are the subject of an alliance or collaboration agreement with a third-party.

Patent Defense Matter

Biogen International GmbH, et al. v. Amneal Pharmaceuticals LLC, et al. (Dimethyl Fumarate)

In June 2017, Biogen International GmbH ("Biogen") filed suit against Amneal and various other generic manufacturers in the United States District Court for the District of Delaware ("D. Del.") alleging patent infringement based on the filing of ANDAs by Amneal and others for generic alternatives to Biogen's Tecfidera® (dimethyl fumarate) capsules product (Biogen International GmbH, et al. v. Amneal Pharmaceuticals LLC, et al., No. 1:17-cv-00823-MN). Biogen also filed suit in June 2017 against Mylan Pharmaceuticals Inc. ("Mylan") in the United States District Court for the Northern District of West Virginia ("N.D. W. Va.") relating to Mylan's own ANDA for Tecfidera®. On June 18, 2020, the N.D. W. Va. court issued an order finding the sole Biogen patent at issue invalid. Biogen appealed the order (the "Mylan Appeal") to the United States Court of Appeals for the Federal Circuit (the "Federal Circuit"). On September 22, 2020, the D. Del. court entered judgment in favor of the defendants (including Amneal), adopting the finding of invalidity made by the N.D. W. Va. court. Biogen appealed the D. Del. Order ("the Amneal Consolidated Appeal"). Amneal, like Mylan and several other generic manufacturers, launched its generic dimethyl fumarate capsule products "at-risk," pending the outcome of Biogen's appeal of the N.D. W. Va. order.

On November 30, 2021, the Federal Circuit affirmed the N.D. W. Va. court's order that Biogen's patent is invalid; on March 23, 2022, issued a mandate in the Mylan Appeal as to the invalidity of the patent; and on June 16, 2022, Biogen filed a cert petition with the Supreme Court of the United States (the "U.S. Supreme Court") which was denied on October 3, 2022. On October 31, 2022, the Federal Circuit dismissed Biogen's consolidated appeals.

Other Litigation Related to the Company's Business

Opana ER® FTC Matters

On February 25, 2014, Impax received a Civil Investigative Demand (“CID”) from the Federal Trade Commission (“FTC”) concerning its investigation into the drug Opana® ER and its generic equivalents. On March 30, 2016, the FTC filed a complaint against Impax, Endo Pharmaceuticals Inc. (“Endo”), and others in the United States District Court for the Eastern District of Pennsylvania, alleging that Impax and Endo violated antitrust laws when they entered into a June 2010 settlement agreement that resolved patent litigation in connection with the submission of Impax’s ANDA for generic original Opana® ER. In October 2016, the Court granted Impax’s motion to sever, formally terminating the suit against Impax. In January 2017, the FTC filed a Part 3 Administrative Complaint against Impax with similar allegations regarding the 2010 settlement. Following trial, in May 2018, the Administrative Law Judge ruled in favor of Impax and dismissed the Complaint in its entirety. FTC Complaint Counsel appealed the decision to the full Commission, and in March 2019, the FTC issued an Opinion & Order reversing the Administrative Law Judge’s decision. The Opinion & Order did not provide for any monetary damages but enjoined Impax from entering into future agreements containing certain terms. Impax filed a Petition for Review of the FTC’s Opinion & Order with the United States Court of Appeals for the Fifth Circuit, and on April 13, 2021, the Fifth Circuit issued a decision denying Impax’s Petition for Review, effectively affirming the FTC’s Opinion & Order. On September 10, 2021, Impax filed a petition for writ of certiorari in the Supreme Court, which was denied in December 2021.

On July 12, 2019, the Company received a CID from the FTC concerning an August 2017 settlement agreement between Impax and Endo, which resolved a subsequent patent infringement and breach of contract dispute between the parties regarding the above-referenced June 2010 settlement agreement related to Opana® ER. The Company cooperated with the FTC regarding the CID. On January 25, 2021, the FTC filed a complaint against Endo, Impax and Amneal in the United States District Court for the District of Columbia, alleging that the 2017 settlement violated antitrust laws. In April 2021, the Company filed a motion to dismiss the FTC’s complaint, and that motion is currently pending. The Company believes it has strong defenses to the FTC’s allegations and intends to vigorously defend the action, however, no assurance can be given as to the timing or outcome of the litigation.

Opana ER® Antitrust Litigation

From June 2014 to April 2015, a number of complaints styled as class actions on behalf of direct purchasers and indirect purchasers (or end-payors) and several separate individual complaints on behalf of certain direct purchasers (the “opt-out plaintiffs”) of Opana ER® were filed against Endo and Impax.

In December 2014, the United States Judicial Panel on Multidistrict Litigation (the “JPML”) transferred the actions to the United States District Court for the Northern District of Illinois (“N.D. Ill.”) for coordinated pretrial proceedings, as In Re: Opana ER Antitrust Litigation (MDL No. 2580) (“MDL”). In each case, the complaints allege that Endo engaged in an anticompetitive scheme by, among other things, entering into an anticompetitive settlement agreement with Impax to delay generic competition of Opana ER® and in violation of state and federal antitrust laws. Plaintiffs seek, among other things, unspecified monetary damages and equitable relief, including disgorgement and restitution.

In June 2022, Impax entered into a preliminary settlement agreement with the class of direct purchasers that, if all conditions are satisfied, would result in the resolution of substantially all the direct purchasers’ and individual complainants’ underlying claims and lawsuits in the MDL. At the same time, Impax entered into a settlement agreement with individual complainants that resolved all of their claims and lawsuits in the MDL. Subsequently, Impax entered into a separate preliminary settlement agreement with the class of indirect purchasers that, if all conditions are satisfied, would result in the resolution of substantially all the indirect purchasers’ underlying claims and lawsuits in the MDL. The direct purchaser plaintiffs, indirect purchaser plaintiffs, and individual complainants are referred to herein collectively as “the Plaintiffs.” On November 3, 2022, the N.D. Ill. approved the direct purchasers’ settlement. On December 15, 2022, the N.D. Ill. approved the indirect purchasers’ settlement.

Pursuant to the settlement agreements, the Company has agreed to pay a total of \$265.0 million between 2022 and mid-January 2024 to resolve substantially all the Plaintiffs’ claims. 3% interest is due on \$150.0 million payable between December 2022 and mid-January 2024. The settlement agreements are not an admission of liability or fault by Impax, the Company or its subsidiaries. Upon court approval of the final settlement agreements as discussed above, substantially all the claims and lawsuits in the litigation were resolved. During the year ended December 31, 2022, the Company recorded a pre-tax charge of \$262.8 million associated with the settlement agreements. Imputed interest of \$2.2 million will be recognized to interest expense during the payment period.

Sergeants Benevolent Association Health & Welfare Fund v. Actavis, PLC, et. al.

In August 2015, a complaint styled as a class action was filed against Forest Laboratories (a subsidiary of Actavis plc) and numerous generic drug manufacturers, including Amneal, in the United States District Court for the Southern District of New York involving patent litigation settlement agreements between Forest Laboratories and the generic drug manufacturers concerning generic versions of Forest's Namenda® IR product. The complaint (as amended on February 12, 2016) asserts federal and state antitrust claims on behalf of indirect purchasers, who allege in relevant part that during the class period they indirectly purchased Namenda® IR or its generic equivalents in various states at higher prices than they would have absent the defendants' allegedly unlawful anticompetitive conduct. Plaintiff seeks, among other things, unspecified monetary damages, and equitable relief, including disgorgement and restitution. On September 13, 2016, the Court stayed the indirect purchaser plaintiff's claims pending factual development or resolution of claims brought in a separate, related complaint by direct purchasers (in which the Company is not a defendant). On September 10, 2018, the Court lifted the stay and referred the case to the assigned Magistrate Judge for supervision of supplemental, non-duplicative discovery in advance of mediation to be scheduled in 2019. The parties thereafter participated in supplemental discovery, as well as supplemental motion-to-dismiss briefing. On December 26, 2018, the Court granted in part and denied in part motions to dismiss the indirect purchaser plaintiff's claims. On January 7, 2019, Amneal, its relevant co-defendants, and the indirect purchaser plaintiff informed the Magistrate Judge that they had agreed to mediation, which occurred in April 2019. In June 2019, the Company reached a settlement with the plaintiff, subject to Court approval. On September 10, 2019, the Court entered an order preliminarily approving the settlement and indefinitely staying the case as to the settling defendants (including the Company), until the disposition of the claims against the non-settling defendants. The remaining defendants subsequently also settled with the plaintiff. The plaintiff filed proposed materials seeking final approval of all settlements, including with the Company, and to finally resolve the case. The Court has scheduled a fairness hearing on the proposed settlement, which is set to take place on March 23, 2023. The amount of the settlement was not material to the Company's consolidated financial statements.

United States Department of Justice Investigations

On November 6, 2014, Impax disclosed that one of its sales representatives received a grand jury subpoena from the Antitrust Division of the United States Department of Justice (the "DOJ"). On March 13, 2015, Impax received a grand jury subpoena from the DOJ requesting the production of information and documents regarding the sales, marketing, and pricing of four generic prescription medications. Impax has cooperated in the investigation and produced documents and information in response to the subpoenas from 2014 to 2016. However, no assurance can be given as to the timing or outcome of the investigation.

On April 30, 2018, Impax received a CID from the Civil Division of the DOJ (the "Civil Division"). The CID requests the production of information and documents regarding the pricing and sale of Impax's pharmaceuticals and interactions with other generic pharmaceutical manufacturers regarding whether generic pharmaceutical manufacturers engaged in market allocation and price-fixing agreements, paid illegal remuneration, and caused false claims to be submitted to the Federal government. Impax has cooperated with the Civil Division's investigation. However, no assurance can be given as to the timing or outcome of the investigation.

In Re Generic Pharmaceuticals Pricing Antitrust Litigation

Since March 2016, multiple putative antitrust class action complaints have been filed on behalf of direct purchasers, indirect purchasers (or end-payors), and indirect resellers, as well as individual complaints on behalf of certain direct and indirect purchasers, and municipalities (the "opt-out plaintiffs") against manufacturers of generic drugs, including Impax and the Company. The complaints allege a conspiracy to fix, maintain, stabilize, and/or raise prices, rig bids, and allocate markets or customers for various generic drugs in violation of federal and state antitrust and consumer protection laws. Plaintiffs seek unspecified monetary damages and equitable relief, including disgorgement and restitution. The lawsuits have been consolidated in an MDL in the United States District Court for the Eastern District of Pennsylvania (*In re Generic Pharmaceuticals Pricing Antitrust Litigation*, No. 2724, (E.D. Pa.)).

On May 10, 2019, Attorneys General of 43 States and the Commonwealth of Puerto Rico filed a complaint in the United States District Court for the District of Connecticut against various manufacturers and individuals, including the Company, alleging a conspiracy to fix, maintain, stabilize, and/or raise prices, rig bids, and allocate markets or customers for multiple generic drugs. On November 1, 2019, the State Attorneys General filed an Amended Complaint on behalf of nine additional states and territories. On June 10, 2020, Attorneys General of 46 States, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Territory of Guam, the U.S. Virgin Islands, and the District of Columbia filed a new complaint against various manufacturers and individuals, including the Company, alleging a conspiracy to fix prices, rig bids, and allocate markets or customers for additional generic drugs. Plaintiff States seek unspecified monetary damages and penalties and

equitable relief, including disgorgement and restitution. On September 9, 2021, the State Attorneys General filed an Amended Complaint on behalf of California in addition to the original Plaintiff States.

Both the May 10, 2019 and June 10, 2019 lawsuits have been incorporated into MDL No. 2724, and the June 10, 2020 lawsuit has been selected for bellwether status. On March 30, 2022, the State of Alabama voluntarily dismissed all its claims in the two actions against all defendants, including the Company, without prejudice. On February 21, 2023, the Territory of Guam voluntarily dismissed all its claims in the two actions against all defendants, including the Company, with prejudice. On February 27, 2023, the Court addressed defendants' motions to dismiss the June 10, 2020 bellwether action, holding that the states may not pursue certain federal remedies, and otherwise denying Amneal's joint and individual motion to dismiss. The court did not analyze the substance of the states' state law claims, reserving those issues for a separate ruling.

Fact and document discovery in MDL No. 2724 are proceeding. The court has entered a Pretrial Order setting a schedule for the bellwether cases, which includes a June 1, 2023 deadline for bellwether fact discovery and a March 13, 2023 deadline for the filing of summary judgement motions. No trial date has been set.

On June 3, 2020, the Company and Impax were also named in a putative class action complaint filed in the Federal Court of Canada in Toronto, Ontario against numerous generic pharmaceutical manufacturers, on behalf of a putative class of individuals who purchased generic drugs in the private sector from 2012 to the present (*Kathryn Eaton v. Teva Canada Limited, et. al.*, No. T-607-20). The complaint alleges price fixing, among other claims. On August 23, 2022, plaintiff filed a second amended complaint. The case has otherwise not progressed to date.

Civil Prescription Opioid Litigation

The Company and certain of its affiliates have been named as defendants in various matters filed in state and federal courts relating to the sale of prescription opioid pain relievers. Plaintiffs in these actions include state Attorneys General, county and municipal governments, hospitals, Native American tribes, pension funds, third-party payors and individuals. Plaintiffs seek unspecified monetary damages and other forms of relief based on various causes of action, including negligence, public nuisance, unjust enrichment, and civil conspiracy, as well as alleged violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), state and federal controlled substances laws and other statutes. All cases involving the Company also name other manufacturers, distributors and retail pharmacies as defendants, and there are numerous other cases involving allegations relating to prescription opioid pain relievers against other manufacturers, distributors and retail pharmacies in which the Company and its affiliates are not named. Nearly all cases pending in federal district courts have been consolidated for pre-trial proceedings in an MDL in the United States District Court for the Northern District of Ohio (*In re: National Prescription Opiate Litigation*, Case No. 17-mdl-2804). There are approximately 914 cases in the MDL in which the Company or its affiliates have been named as defendants. The Company is also named in approximately 77 state court cases pending in ten states. The Company has filed motions to dismiss in many of these cases. No firm trial dates have been set except in Alabama (July 24, 2023) and Texas (May 20, 2024 (Dallas County) and September 30, 2024 (Bexar County)). The Company was not involved in the September 2022 trial in New Mexico previously reported because of the tentative settlement the Company reached with the New Mexico Attorney General in May 2022 to resolve the New Mexico Attorney General's claims against the Company. The Company anticipates a final determination approving the settlement in 2023.

On August 3, 2022, the Company and certain of its affiliates were named as defendants in a Complaint filed in Tennessee state court, along with numerous other manufacturers, distributors, retailers, and healthcare providers, in which it is alleged the defendants are liable in civil damages to six minors who allegedly were born with neonatal abstinence syndrome ("NAS") allegedly as a result of their biological mothers' alleged use of diverted prescription opioid medications. The plaintiffs' claim against each defendant in that case requires plaintiffs to prove by clear and convincing evidence that the defendant intentionally participated in Tennessee in that state's illegal drug market as defined in the Tennessee Drug Dealer Liability Act. The case is currently stayed, but the Company intends to file a motion to dismiss the complaint when the case resumes. The Company also was named in two NAS cases in West Virginia state court which have been consolidated with other West Virginia state court NAS cases before the West Virginia Mass Litigation Panel ("WV MLP"). On November 1, 2022, the Company entered into a preliminary settlement agreement to resolve all pending litigation brought by West Virginia political subdivisions. The Company filed a motion to dismiss the complaints on February 3, 2023.

Based on the preliminary settlement agreements with the states of New Mexico and West Virginia and an assessment of the information currently available, the Company recorded an \$18.0 million charge for the year ended December 31, 2022, related to the majority of the MDL and state court cases. For the remaining cases, primarily brought by hospitals, pension funds, third-party payors and individuals, the Company has not recorded a liability as of December 31, 2022 because it concluded that a loss was not probable and estimable.

New York Attorney General Subpoena

On January 13, 2023, the Company received an investigatory subpoena from the Attorney General of the State of New York. The subpoena seeks documents broadly relating to the Company's opioid business. The Company intends to comply with the subpoena.

Securities Class Actions

On April 17, 2017, New York Hotel Trades Council & Hotel Association of New York City, Inc. Pension Fund filed an amended putative class action complaint in the United States District Court for the Northern District of California against Impax and four former Impax officers alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 (*Fleming v. Impax Laboratories Inc.*, et al., No. 4:16-cv-6557-HSG). Plaintiff alleges that Impax (1) concealed collusion with competitors to fix the price of the generic drug digoxin; (2) concealed anticipated erosion in the price of generic drug diclofenac; and (3) overstated the value of the generic drug budesonide. In August 2019, the Court granted Impax's motion to dismiss Plaintiff's second amended complaint in its entirety. Plaintiff appealed to the United States Court of Appeals for the Ninth Circuit, and on January 11, 2021, the Ninth Circuit issued an unpublished opinion affirming in part and reversing in part the District Court's decision. Defendants subsequently filed a motion for rehearing with the Ninth Circuit, and Plaintiff filed a motion to intervene seeking to add Sheet Metal Workers' Pension Fund of Southern California, Arizona and Nevada ("Sheet Metal Workers") as an additional named Plaintiff. The Ninth Circuit denied the motions, and on April 1, 2021, the case was remanded to the District Court. On April 19, 2021, the Company filed a motion to dismiss the remaining claims and an opposition to Sheet Metal Workers' renewed motion to intervene. In June 2021, the parties reached a tentative agreement to settle all claims in the case for \$33 million, subject to certain terms and conditions and subject to court approval. The district court entered an order granting preliminary approval of the settlement on November 22, 2021 and held a fairness hearing on March 31, 2022. On July 15, 2022, the district court entered an order granting final approval of the settlement. On July 21, 2022, a stipulated final judgment was entered, effectively terminating this matter before the district court. The settlement was fully covered by insurance and was paid from an escrow account. Refer to *Note 11. Prepaid Expenses and Other Current Assets* for amounts deposited into a settlement escrow account as of December 31, 2021.

On December 18, 2019, Cambridge Retirement System filed a putative class action complaint in the Superior Court of New Jersey, Somerset County against the Company and certain current or former officers alleging violations of Sections 11, 12(a)(2) and 15 of the Securities Act of 1933 (*Cambridge Retirement System v. Amneal Pharmaceuticals, Inc.*, et al., No. SOM-L-1701-19). Plaintiffs allege that the May 7, 2018, amended registration statement and prospectus issued in connection with the Amneal/Impax business combination was materially false and/or misleading because it failed to disclose that Amneal allegedly engaged in anticompetitive conduct to fix generic drug prices. Plaintiffs filed a motion for class certification on October 30, 2020, and in April 2021 filed a second amended complaint including similar allegations regarding a November 2017 registration statement and prospectus issued in connection with the Amneal/Impax business combination. In February 2022, the parties reached a tentative agreement to settle the claims, subject to, among other things, the negotiation and court approval of a definitive settlement agreement. On March 28, 2022, the parties executed a settlement agreement for \$25.0 million. On April 29, 2022, the court preliminarily approved the settlement. On August 16, 2022, the court gave final approval to the settlement.

For the year ended December 31, 2021, the Company recorded a \$25.0 million charge for the settlement. For the year ended December 31, 2022, the Company recorded insurance recoveries of \$15.5 million associated with the settlement. The final settlement of \$25.0 million was paid from an escrow account which was funded both by insurance recoveries of \$15.5 million and cash paid by the Company of \$9.5 million. Refer to *Note 11. Prepaid Expenses and Other Current Assets* for amounts deposited into a settlement escrow account as of December 31, 2021.

United States Department of Justice / Drug Enforcement Administration Subpoenas

On July 7, 2017, Amneal Pharmaceuticals of New York, LLC received an administrative subpoena issued by the Long Island, NY District Office of the Drug Enforcement Administration (the "DEA") requesting information related to compliance with certain recordkeeping and reporting requirements. On or about April 12, 2019 and May 28, 2019, the Company received grand jury subpoenas from the U.S. Attorney's Office for the Eastern District of New York (the "USAO") relating to similar topics concerning the Company's suspicious order monitoring program and its compliance with the Controlled Substances Act. The Company is cooperating with the USAO in responding to the subpoenas and has entered civil and criminal tolling agreements with the USAO through approximately May 14, 2023. It is not possible to determine the exact outcome of these investigations.

On March 14, 2019, Amneal received a subpoena (the "Subpoena") from an Assistant U.S. Attorney ("AUSA") for the Southern District of Florida. The Subpoena requests information and documents generally related to the marketing, sale, and

distribution of oxycodone. The Company intends to cooperate with the AUSA regarding the Subpoena. However, no assurance can be given as to the timing or outcome of its underlying investigation.

On October 7, 2019, Amneal received a subpoena from the New York State Department of Financial Services seeking documents and information related to sales of opioid products in the state of New York. The Company is cooperating with the request and providing responsive information. It is not possible to determine the exact outcome of this investigation.

Ranitidine Litigation

The Company and its affiliates have been named as defendants, along with numerous other pharmaceutical manufacturers, wholesale distributors, and retail pharmacy chains, in *In re Zantac/Ranitidine NDMA Litigation* (MDL No. 2924), pending in the Southern District of Florida. Plaintiffs allege that defendants failed to disclose and/or concealed the alleged inherent presence of N-Nitrosodimethylamine (or “NDMA”) in brand-name Zantac® or generic ranitidine and the alleged associated risk of cancer. Consolidated groups of (a) personal injury plaintiffs, (b) economic loss/medical monitoring class action plaintiffs, and (c) third-party payor plaintiffs have each filed master complaints against brand and generic pharmaceutical manufacturers, distributors, retailers, and repackagers of ranitidine-containing products. The Company or its affiliates have been named in the three master complaints and approximately 313 personal injury short form complaints. On December 31, 2020, the Court dismissed in full the three master complaints against the generic manufacturers, including the Company and its affiliates, with leave to file amended complaints on certain claims relating to manufacturing, storage, and transportation. Plaintiffs filed amended complaints in February 2021, and Defendants filed various motions to dismiss the amended complaints in March 2021. On July 8, 2021, the MDL dismissed all claims against the generic drug manufacturers, including the Company and its affiliates, without leave to file further amended complaints. Plaintiffs have appealed the MDL court’s dismissal to the 11th Circuit Court of Appeals, which has consolidated the appeals of the personal injury cases. The 11th Circuit Court of Appeals has not established a briefing schedule yet in the appeals of the personal injury cases appeals.

On June 18, 2020, Amneal was named in a lawsuit filed in New Mexico brought by the New Mexico Attorney General alleging claims of public nuisance, negligence, and violations of consumer protection laws against various brand and generic manufacturers and store-brand distributors of Zantac®/Ranitidine. Plaintiff seeks unspecified compensatory and punitive damages, as well as abatement, medical monitoring, restitution, and injunctive relief. The Company filed a motion to dismiss on May 17, 2021, and filed a notice of supplemental authority based on the MDL court’s July 2021 dismissal order. The Court denied the motion on August 17, 2021. The Company filed a motion to dismiss based on lack of personal jurisdiction on January 26, 2022. On September 22, 2022, the Court ordered the parties to participate in 90 days of reciprocal jurisdictional discovery. Plaintiff filed a supplemental brief on personal jurisdiction on January 23, 2023, and Amneal filed a response on February 6, 2023.

On November 12, 2020, Amneal was named in a public nuisance and consumer protection lawsuit filed in state court in Baltimore, Maryland, on behalf of the Mayor and City Council of Baltimore. Defendants removed the case to federal court and on April 1, 2021, the case was remanded to state court. On August 23, 2021, the Company filed a motion to dismiss, which was granted.

On October 1, 2021, Amneal and Amneal Pharmaceuticals of New York, LLC, were named as defendants in two Pennsylvania state court complaints, along with twenty-five other defendants, including brand-name manufacturers, generic manufacturers, and one Pennsylvania-based pharmacy. The complaint track cases are being coordinated in the Philadelphia County Court of Common Pleas with other Pennsylvania ranitidine cases in which the Company is not a party under what is known as a Mass Tort Program (MTP). The Complaints track the dismissed master personal injury complaint from the MDL and were removed and subsequently transferred to the MDL on November 9, 2021. The cases were remanded to Pennsylvania state court on April 22, 2022. The Company filed preliminary objections in one case on May 18, 2022, which remain pending, and intends to file preliminary objections in the second case following a coordinated briefing schedule. Amneal entities have been named in three additional cases filed on September 27, 2022, each of which will be part of the MTP. Amneal entities were named in two additional cases filed on December 31, 2022, which were removed to federal court on January 4, 2023.

In a lawsuit filed on February 8, 2022 by Gary Ross in Illinois state court, Amneal and Amneal Pharmaceuticals of New York, LLC, were named as defendants, along with twenty other defendants, including brand-name manufacturers, generic manufacturers, and retailers in which plaintiff claimed personal injury from use of ranitidine. The generic drug manufacturers filed a motion to dismiss in that case on March 28, 2022 which remains pending. On March 1, 2022, plaintiff Barbara Martin filed a lawsuit in Illinois state court naming Amneal, Amneal Pharmaceuticals of New York, LLC, and Amneal Pharmaceuticals, Inc., along with seven other defendants, including brand-name manufacturers, generic manufacturers, and retailers. Plaintiff has attempted to serve only Amneal Pharmaceuticals of New York, LLC. The Company filed a motion to

dismiss on May 6, 2022. In addition, the Company and/or its affiliates, as well as multiple other defendants including other generic drug manufacturers, have been named as defendants in six multi-plaintiff cases filed in three different Illinois counties in which plaintiffs allege injuries in the form of various cancers from the use of ranitidine. The cases have been consolidated in a statewide consolidated proceeding in Cook County, Illinois. At the appropriate time, the Company intends to file motions to dismiss in those cases.

The Company and/or its affiliates, as well as multiple other defendants including other generic drug manufacturers, have been named in seven multi-plaintiff cases filed in California during August and September 2022, in which plaintiffs allege injuries in the form of various cancers from the use of ranitidine. The cases were transferred to Judicial Council Coordination Proceedings pending in Alameda County, California. At the appropriate time, the Company intends to file motions to dismiss in those cases.

On September 26, 2022, Amneal Pharmaceuticals of New York, LLC was named as one of multiple defendants in a single-plaintiff case filed in Suffolk County, New York, alleging injuries in the form of bladder cancer from the use of ranitidine. At the appropriate time, the Company intends to file a motion to dismiss.

Metformin Litigation

Amneal and AvKARE, Inc. were named as defendants, along with numerous other manufacturers, retail pharmacies, and wholesalers, in several putative class action lawsuits pending in the United States District Court for the District of New Jersey (“D.N.J.”), consolidated as *In Re Metformin Marketing and Sales Practices Litigation* (No. 2:20-cv-02324-MCA-MAH). The lawsuits all allege that defendants made and sold to putative class members generic metformin products that were “adulterated” or “contaminated” with NDMA.

An economic loss complaint filed on behalf of consumers and third-party payors who purchased or paid or made reimbursements for metformin alleges that plaintiffs suffered economic losses in connection with their purchases or reimbursements due to the purported contamination. On May 20, 2021, the Court granted Defendants’ motion to dismiss the economic loss complaint, and Plaintiffs filed an amended complaint on June 21, 2021. Defendants again moved to dismiss, and the motion was fully briefed on October 18, 2021. Additionally, medical monitoring class action complaints were filed on behalf of consumers who consumed allegedly contaminated metformin allege “cellular damage, genetic harm, and/or are at an increased risk of developing cancer” and seek medical monitoring, including evaluation and treatment. These cases are currently stayed.

On March 29, 2021, a plaintiff filed a complaint in the United States District Court for the Middle District of Alabama asserting claims against manufacturers of Valsartan, Losartan, and Metformin based on the alleged presence of nitrosamines in those products. The only allegations against Amneal concern Metformin. (*Davis v. Camber Pharmaceuticals, Inc., et al.*, C.A. No. 2:21-00254 (M.D. Ala.) (the “Davis Action”)). On May 5, 2021, the JPML transferred the Davis Action into the *In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation* multi-district litigation for pretrial proceedings.

Xyrem® (Sodium Oxybate) Antitrust Litigation

Amneal has been named as a defendant, along with Jazz Pharmaceuticals, Inc. (“Jazz”) and numerous other manufacturers of generic versions of Jazz’s Xyrem® (sodium oxybate), in several putative class action lawsuits filed in the United States District Court for the Northern District of California and the United States District Court for the Southern District of New York, alleging that the generic manufacturers entered into anticompetitive agreements with Jazz in connection with settling patent litigation related to Xyrem®. Plaintiffs seek unspecified monetary damages and penalties as well as equitable relief, including disgorgement and restitution. On December 16, 2020, the JPML transferred the actions to the United States District Court for the Northern District of California for consolidated pretrial proceedings consolidated as *In re Xyrem (Sodium Oxybate) Antitrust Litigation* (No. 5:20-md-02966-LHK). Plaintiffs filed a consolidated amended class complaint in March 2021, which Defendants moved to dismiss. On August 13, 2021, the District Court granted in part and denied in part Defendants’ motion, dismissing the federal damages claims and a number of state-law claims, while permitting the remaining claims to proceed. On January 9, 2023, Amneal reached a settlement in principle with the putative class plaintiffs and executed a settlement agreement on February 28, 2023. The remaining opt-out plaintiffs in the federal case are United Healthcare Services, Inc., Humana Inc., Molina Healthcare Inc., and Health Care Services Corporation. Discovery closed on January 30, 2023, and class certification briefing is currently scheduled to culminate with a hearing set for April 19, 2023. In a separate action in California state court filed by Aetna, another opt-out plaintiff, the court held that it lacks jurisdiction over several defendants, including Amneal, on December 27, 2022. On January 27, 2023, Aetna filed an amended complaint identifying several parties, including Amneal, as alleged non-party co-conspirators.

Value Drug Company v. Takeda Pharmaceuticals U.S.A., Inc.

On August 5, 2021, Value Drug Company filed a purported class action lawsuit in the United States District Court for the Eastern District of Pennsylvania against Takeda Pharmaceuticals U.S.A., Inc. (“Takeda”) and numerous other manufacturers of generic versions of Takeda’s Colcris® (colchicine), including Amneal, alleging that the generic manufacturers conspired with Takeda to restrict output of generic Colcris® in order to maintain higher prices, in violation of the antitrust laws. The Company, along with the other defendants, moved to dismiss for failure to state a claim, and on December 28, 2021, the Court granted the motion in full, with leave to amend. On January 18, 2022, Plaintiff filed its amended complaint, making substantively the same antitrust allegations, but alleging that the violations were effectuated by either a single overarching conspiracy or a series of bilateral conspiracies. The Company moved to dismiss the amended complaint for failure to state a claim. On March 30, 2022, the Court granted in part and denied in part defendants’ motion, dismissing the newly pled bilateral conspiracy claims but allowing the revised overarching conspiracy claim to proceed against all defendants. On November 23, 2022, the Court denied plaintiff’s motion for class certification without prejudice. Plaintiff filed its renewed motion for class certification on December 22, 2022. Following opposition and reply briefing, the Court held a hearing on the renewed motion for class certification on February 7, 2023. The Court also granted Defendants the opportunity to submit a supplemental brief in opposition to the renewed motion for class certification, which was filed on February 14, 2023. Defendants filed two motions for summary judgment on January 13, 2023, one filed by Takeda, and another filed jointly by Amneal, Watson, and Teva. Defendants also filed motions to exclude the opinions of five of Plaintiff’s six experts. Plaintiff filed a motion for partial summary judgment on January 13, 2023. Plaintiff did not file any motions to exclude any of Defendants’ experts. Briefing on the motions for summary judgment and motions to exclude expert testimony was completed on February 6, 2023. On January 18, 2023, the Court issued an order vacating all trial-related deadlines and requiring Defendants to file a joint notice as to potential revised trial dates within ten days of the Court’s decision on Plaintiff’s renewed motion for class certification.

Galeas v. Amneal Pharmaceuticals, Inc.

On July 27, 2021, Cesy Galeas filed a purported class action lawsuit in the U.S. District Court for the Eastern District of New York against Amneal Pharmaceuticals, Inc., alleging that the payment schedule for certain workers violated New York Labor Law. Specifically, the purported class, which presently consists of one named plaintiff contends that the Company paid the employees all owed wages, but did so bi-weekly, instead of weekly. In March 2022, the parties reached an agreement to settle the claims for \$1.2 million, subject to, among other things, court approval of the contemplated settlement agreement. The parties dismissed the federal litigation and re-filed the litigation in New York Supreme Court, Nassau County, for purposes of settlement approval, and filed a motion to approve the settlement agreement on July 13, 2022 and the Court granted the same on September 28, 2022. A third-party administrator completed administering the notification process for class members with instructions on how to submit claims. The Court held a fairness hearing on February 28, 2023, during which no potential claimants raised objections. The Court approved the settlement on March 1, 2023. The third party administrator will distribute the settlement funds in accordance with the agreement. The Company recorded a \$1.2 million charge associated with this matter during the year ended December 31, 2022.

Russell Thiele, et al. v. Kashiv Biosciences, LLC, et.al.

On March 22, 2022, two purported Amneal Pharmaceuticals, Inc. stockholders filed a stockholder derivative lawsuit in the Court of Chancery of the State of Delaware against Kashiv and certain members of the Company’s Board of Directors. The Company is named as a nominal defendant. The suit alleges that the Company’s January 2021 acquisition of a 98% interest in KSP, then a wholly owned subsidiary of Kashiv, was unfair to the Company, that the defendant Directors breached fiduciary duties of loyalty and good faith in connection with the transaction, and that the transaction unjustly enriched Kashiv and certain of the defendants who had a financial interest in Kashiv. The suit, which is allegedly brought on the Company’s behalf, seeks among other remedies rescission of the transaction and unspecified monetary damages. Defendants moved to dismiss the complaint for failure to state a claim and failure to plead demand futility on June 3, 2022, and Plaintiffs filed an amended complaint on July 29, 2022. Defendants moved to dismiss the amended complaint on September 23, 2022, on the same grounds set forth in the original motion to dismiss. The motion remains pending.

22. Stockholders' Equity

Voting Rights

Holders of Class A Common Stock and Class B Common Stock are entitled to one vote for each share of stock held, except as required by law. Holders of Class A Common Stock and Class B Common Stock vote together as a single class on each matter submitted to a stockholder vote. Holders of Class A Common Stock and Class B Common Stock are not entitled to vote on any

amendment to the Company's Charter that relates solely to the terms of one or more outstanding series of preferred stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote on such terms pursuant to the Company's Charter or law.

Dividend Rights

The holders of Class A Common Stock are entitled to receive dividends, if any, payable in cash, property, or securities of the Company, as may be declared by the Company's board of directors, out of funds legally available for the payment of dividends, subject to any preferential or other rights of the holders of any outstanding shares of preferred stock. The holders of Class B Common Stock will not be entitled to receive any dividends.

Participation Rights

Under the Company's Charter, the holders of Class A Common Stock and Class B Common Stock have no participation rights. However, the Company's Second Amended and Restated Stockholders Agreement dated as of December 31, 2017 (the "Stockholders Agreement") provides that if the Company proposes to issue any securities, other than in certain issuances, the Members will have the right to purchase a *pro rata* share of such securities, based on the number of shares of common stock owned by the Members before such issuance.

Issuance and Restrictions on Company Common Stock

Pursuant to the Third Amended and Restated Limited Liability Company Agreement of Amneal dated May 4, 2018 (the "Limited Liability Company Agreement"), Amneal will issue to the Company an additional Amneal common unit for each additional share of Class A Common Stock issued by the Company. Additionally, pursuant to the Charter, shares of Class B Common Stock will be issued to the Members and their permitted transferees only to the extent necessary in certain circumstances to maintain a one-to-one ratio between the number of Amneal Common Units and the number of shares of Class B Common Stock held by such members. Shares of Class B Common Stock are transferable only for no consideration to the Company for automatic retirement or in accordance with the Stockholders Agreement and the Limited Liability Company Agreement.

Liquidation Rights

On the liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders of Class A Common Stock are entitled to share equally in all assets of the Company available for distribution among the stockholders of the Company after payment to all creditors and subject to any preferential or other rights of the holders of any outstanding shares of preferred stock. The holders of Class B common stock are not entitled to share in such net assets.

Redemption

The Limited Liability Company Agreement provides that holders of Amneal Common Units may, from time to time, require the Company to redeem all or a portion of their interests for newly issued shares of Class A Common Stock on a one-for-one basis. Upon receipt of a redemption request, the Company may, instead, elect to effect an exchange of Amneal Common Units directly with the holder. Additionally, the Company may elect to settle any such redemption or exchange in shares of Class A Common stock or in cash. In the event of a cash settlement, the Company would issue new shares of Class A Common Stock and use the proceeds from the sale of these newly issued shares of Class A Common Stock to fund the cash settlement, which, in effect, limits the amount of the cash payments to the redeeming member. In connection with any redemption, the Company will receive a corresponding number of Amneal Common Units, increasing the Company's total ownership interest in Amneal. Additionally, an equivalent number of shares of Class B Common Stock will be surrendered and canceled.

Preferred Stock

Under the Company's certificate of incorporation, the Company's Board of Directors has the authority to issue preferred stock and set its rights and preferences. As of December 31, 2022, no preferred stock had been issued.

Non-Controlling Interests

As discussed in *Note 2. Summary of Significant Accounting Policies*, the Company consolidates the financial statements of Amneal and its subsidiaries and records non-controlling interests for the portion of Amneal's economic interests that is not held

by the Company. Non-controlling interests are adjusted for capital transactions that impact the non-publicly held economic interests in Amneal.

Under the terms of Amneal's limited liability company agreement, as amended, Amneal is obligated to make tax distributions to its members. For the years ended December 31, 2022, 2021, and 2020, tax distributions of \$10.6 million, \$53.5 million, and \$2.8 million, respectively, were recorded as reductions of non-controlling interests. There was no liability for tax distributions payable to Members as of December 31, 2022 and 2021.

During September 2020, the Company made a \$3.3 million payment to the non-controlling interest holders in one of Amneal's non-public subsidiaries, Gemini Laboratories, LLC, to distribute earnings of \$0.8 million and acquire their ownership interests in the non-public subsidiary for \$2.5 million.

As discussed in *Note 3. Acquisitions*, the Company acquired a 98% interest in KSP on April 2, 2021. The sellers of KSP, a related party, hold the remaining interest. The Company will attribute 2% of the net income or loss of KSP to these non-controlling interests.

Redeemable Non-Controlling Interests - AvKARE, LLC and R&S

As discussed in *Note 3. Acquisitions*, the Company acquired a 65.1% interest in Rondo on January 31, 2020. The sellers of AvKARE, LLC and R&S hold the remaining 34.9% interest ("Rondo Class B Units"). Beginning on January 1, 2026, the holders of the Rondo Class B Units have the right ("Put Right") to require the Company to acquire the Rondo Class B Units for a purchase price that is based on a multiple of Rondo's earnings before income taxes, depreciation, and amortization (EBITDA) if certain financial targets and other conditions are met. Additionally, beginning on January 31, 2020, the Company has the right to acquire the Rondo Class B Units based on the same value and conditions as the Put Right. The Rondo Class B Units are also redeemable by the holders upon a change in control.

Since the redemption of the Rondo Class B Units is outside of the Company's control, the units have been presented outside of stockholders' equity as redeemable non-controlling interests. Upon closing of the Acquisitions on January 31, 2020, these redeemable non-controlling interests were recorded at an estimated fair value of \$11.5 million. The fair value of the redeemable non-controlling interests was estimated using the Monte-Carlo simulation approach under the option pricing framework, which considers the redemption rights of both the Company and the holders of the Rondo Class B Units.

The Company will attribute 34.9% of the net income of Rondo to the redeemable non-controlling interests. The Company will also accrete the redeemable non-controlling interests to redemption value upon an event that makes redemption certain. For the years ended December 31, 2022 and 2021, tax distributions of \$6.9 million and \$3.6 million, respectively, were recorded as reductions of redeemable non-controlling interests. As of December 31, 2022 and 2021, there were no amounts due for tax distributions related to these redeemable non-controlling interests.

Redeemable Non-Controlling Interests - Puniska

As discussed in *Note 3. Acquisitions*, the Company acquired a 74% interest in Puniska on November 2, 2021. Amneal was required pursuant to the purchase agreement to acquire the remaining 26% of Puniska upon approval of the transaction by the government of India. Since approval of the government of India was outside of the Company's control, upon closing of the Puniska Acquisition, the equity interests of Puniska that the Company did not own were presented outside of stockholders' equity as redeemable non-controlling interests. The Company attributed 26% of the net losses of Puniska to the redeemable non-controlling interests.

Upon approval of the transaction by the government of India in March 2022, the Company paid the \$1.7 million redemption value for the remaining 26% of the equity interests of Puniska. For the year ended December 31, 2022, the Company recorded accretion of \$0.9 million to increase the redeemable non-controlling interests to redemption value.

Changes in Accumulated Other Comprehensive Loss by Component (in thousands):

	Foreign currency translation adjustment	Unrealized gain (loss) on cash flow hedge, net of tax	Accumulated other comprehensive (loss) income
Balance December 31, 2020	\$ (14,497)	\$ (26,821)	\$ (41,318)
Other comprehensive income before reclassification	(4,255)	20,972	16,717
Reallocation of ownership interests	(93)	(133)	(226)
Balance December 31, 2021	(18,845)	(5,982)	(24,827)
Other comprehensive income before reclassification	(13,394)	48,270	34,876
Reallocation of ownership interests	(143)	33	(110)
Balance December 31, 2022	<u>\$ (32,382)</u>	<u>\$ 42,321</u>	<u>\$ 9,939</u>

23. Stock-Based Compensation*Amneal Pharmaceuticals, Inc. 2018 Incentive Award Plan*

In May 2018, the Company adopted the Amneal Pharmaceuticals, Inc. 2018 Incentive Award Plan (“2018 Plan”) under which the Company may grant stock options, restricted stock units and other equity-based awards to employees and non-employee directors providing services to the Company and its subsidiaries. The stock option, RSU and MPRSU award grants are made in accordance with the Company’s 2018 Plan and are subject to forfeiture if the vesting conditions are not met. On May 5, 2020, the stockholders of the Company approved an amendment to the 2018 Plan which authorized an additional 14 million shares of Class A common stock available for issuance under the 2018 Plan.

The aggregate number of shares of Class A common stock authorized for issuance pursuant to the Company’s 2018 Plan is 37 million shares. As of December 31, 2022, the Company had 10,005,452 shares available for issuance under the 2018 Plan.

The Company recognizes the grant date fair value of each option and share of restricted stock unit over its vesting period. Stock options and RSU awards are granted under the Company’s 2018 Plan and generally vest over a 4 year period and, in the case of stock options, have a term of 10 years.

The following table summarizes all of the Company’s stock option activity for the years ended December 31, 2022, 2021, and 2020:

Stock Options	Number of Shares Under Option	Weighted- Average Exercise Price per Share	Weighted- Average Remaining Contractual Life	Aggregate Intrinsic Value (in millions)
Outstanding at December 31, 2019	6,177,126	\$ 8.87		
Options exercised	(116,681)	2.75		
Options forfeited	(2,249,216)	16.09		
Outstanding at December 31, 2020	<u>3,811,229</u>	\$ 4.80	7.9	\$ 5.6
Options exercised	(342,350)	2.76		
Options forfeited	(417,379)	11.09		
Outstanding at December 31, 2021	<u>3,051,500</u>	\$ 4.17	7.0	\$ 5.3
Options exercised	(207,452)	2.75		
Options forfeited	(195,607)	2.77		
Outstanding at December 31, 2022	<u>2,648,441</u>	\$ 4.38	6.0	\$ —
Options exercisable at December 31, 2022	<u>2,288,371</u>	\$ 4.64	6.0	\$ —

The intrinsic value of options exercised during the year ended December 31, 2022 was approximately \$0.1 million. There were no options granted in the years ended December 31, 2022, 2021 and 2020.

The following table summarizes all of the Company's restricted stock unit activity for the years ended December 31, 2022, 2021, and 2020:

Restricted Stock Units	Number of Restricted Stock Units	Weighted- Average Grant Date Fair Value	Weighted- Average Remaining Years	Aggregate Intrinsic Value (in millions)
Non-vested at December 31, 2019	2,637,358	\$ 12.16		
Granted	8,414,762	3.67		
Vested	(692,868)	12.33		
Forfeited	(1,226,700)	6.48		
Non-vested at December 31, 2020	9,132,552	\$ 5.09	1.7	\$ 41.7
Granted	6,870,481	5.86		
Vested	(1,906,607)	5.97		
Forfeited	(912,826)	6.68		
Non-vested at December 31, 2021	13,183,600	\$ 5.25	1.4	\$ 63.7
Granted	10,117,037	4.54		
Vested	(2,697,134)	5.95		
Forfeited	(2,674,890)	5.07		
Non-vested at December 31, 2022	17,928,613	\$ 4.77	1.3	\$ 35.7

The table above includes 3,053,738 MPRSUs granted to executives during 2022. Vesting of these awards is contingent upon the Company's achievement of stock price hurdles over the performance period starting March 1, 2022 and requires the employee's continued employment or service through February 28, 2025. The MPRSUs cliff vest at the end of the 3 year period and have a maximum potential to vest at 200% (6,107,476 shares) based on the Company's stock price performance. The related share-based compensation expense is determined based on the estimated fair value of the underlying shares on the date of grant and is recognized straight-line over the vesting term. The estimated fair value per share of the MPRSUs was \$6.22 and was calculated using a Monte Carlo simulation model. 2,731,612 of these MPRSUs remain outstanding and unvested at December 31, 2022.

The table above also includes 2,331,211 MPRSUs granted to executives during 2021. Vesting of these awards is contingent upon the Company's achievement of stock price hurdles over the performance period starting March 1, 2021 and requires the employee's continued employment or service through February 29, 2024. The MPRSUs cliff vest at the end of the three-year period and have a maximum potential to vest at 200% (4,662,422 shares) based on the Company's stock price performance. The related share-based compensation expense is determined based on the estimated fair value of the underlying shares on the date of grant and is recognized straight-line over the vesting term. The estimated fair value per share of the MPRSUs ranged from \$5.31 and \$8.58 and was calculated using a Monte Carlo simulation model. 2,010,449 of these MPRSUs remained outstanding and unvested at December 31, 2022.

In addition, the table above includes 2,977,711 MPRSUs granted to executives during the first quarter of 2020. Vesting of these awards is contingent upon the Company's achievement of stock price hurdles over the performance period starting March 1, 2020 and requires the employee's continued employment or service through February 28, 2023. The MPRSUs cliff vest at the end of the three-year period and have a maximum potential to vest at 200% (5,955,422 shares) based on the Company's stock price performance. The related share-based compensation expense is determined based on the estimated fair value of the underlying shares on the date of grant and is recognized straight-line over the vesting term. The estimated fair value per share of the MPRSUs ranged from \$2.13 and \$3.63 and was calculated using a Monte Carlo simulation model. 2,431,462 of these MPRSUs remained outstanding and unvested at December 31, 2022.

As of December 31, 2022, the Company had total unrecognized stock-based compensation expense of \$50.4 million related to all of its stock-based awards, which is expected to be recognized over a weighted average period of 1.8 years.

The amount of stock-based compensation expense recognized by the Company was as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Cost of goods sold	\$ 4,811	\$ 4,688	\$ 4,166
Selling, general and administrative	20,746	18,718	13,343
Research and development	6,290	5,006	3,241
Total	<u>\$ 31,847</u>	<u>\$ 28,412</u>	<u>\$ 20,750</u>

24. Related Party Transactions

The Company has various business agreements with certain third-party companies in which there is some common ownership and/or management between those entities, on the one hand, and the Company, on the other hand. The Company has no direct ownership or management in any of such related party companies. The following table summarizes the Company's related party transactions (in thousands):

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Related Party and Nature of Transaction		Caption in Balance Sheet and Statement of Operations	Year ended December 31,		
			2022	2021	2020
A Kashiv Biosciences LLC					
i.	Parking space lease	Cost of goods sold	\$ 100	\$ 99	\$ 99
ii.	License and commercialization agreement - Filgrastim and Pegfilgrastim - regulatory approval milestone for Filgrastim	Selling, general and administrative	5,000	—	—
ii.	License and commercialization agreement - Filgrastim and Pegfilgrastim - regulatory approval milestone for Pegfilgrastim-pbbk	Intangible asset	15,000	—	—
ii.	License and commercialization agreement - Filgrastim and Pegfilgrastim - research and development milestone	Research and development	—	—	1,000
ii.	Inventory purchases under license and commercialization agreement - Filgrastim and Pegfilgrastim	Inventory and cost of goods sold	260	—	—
iii.	Development and commercialization agreement - Ganirelix Acetate and Cetorelix Acetate	Research and development	1,761	1,362	1,550
iv.	Transition services associated with the KSP Acquisition	Selling, general and administrative	—	255	—
v.	Development and commercialization - consulting - various products	Research and development	2	628	196
vi.	Development supply agreement	Research and development	—	—	—
vii.	Development and commercialization agreements - Levothyroxine Sodium and Posaconazole	Research and development	—	—	2,688
viii.	K127 development and commercialization agreement*	Research and development	—	3,000	2,000
ix.	Commercial product support for EluRyng and other products*	Cost of goods sold and research and development	—	1,239	6,130
x.	Profit sharing - various products*	Cost of goods sold	—	2,680	11,189
xi.	Development and commercialization agreements - various products*	Research and development	—	150	206
Total			<u>\$ 22,123</u>	<u>\$ 9,413</u>	<u>\$ 25,058</u>
B LAX Hotel, LLC					
Financing lease		Inventory and cost of goods sold	\$ —	\$ 217	\$ 2,608
Interest component of financing lease		Interest expense	—	362	4,395
Total			<u>\$ —</u>	<u>\$ 579</u>	<u>\$ 7,003</u>
C	Kanan, LLC - operating lease	Inventory and cost of goods sold	\$ 2,104	\$ 2,103	\$ 2,093
D	Sutaria Family Realty, LLC - operating lease	Inventory and cost of goods sold	\$ 1,211	\$ 1,179	\$ 1,142
E	PharmaSophia, LLC - research and development services income	Research and development	\$ (45)	\$ (329)	\$ (521)
E	PharmaSophia, LLC - license and commercialization agreement	Research and development	\$ 1,093	\$ —	\$ —
F	Fosun International Limited - license and supply agreement	Net revenue	\$ —	\$ (200)	\$ —
G	Apace KY, LLC d/b/a Apace Packaging LLC - packaging agreement	Inventory and cost of goods sold	\$ 2,742	\$ 11,380	\$ 11,570
H	Tracy Properties LLC - operating lease	Selling, general and administrative	\$ 565	\$ 532	\$ 497
I	AzaTech Pharma LLC - supply agreement	Inventory and cost of goods sold	\$ 4,963	\$ 5,156	\$ 4,506
J	AvPROP, LLC - operating lease	Selling, general and administrative	\$ 178	\$ 165	\$ 142
K	Tarsadia Investments, LLC - financial consulting services	Selling, general and administrative	\$ —	\$ —	\$ —
L	Avtar Investments, LLC - consulting services	Selling, general and administrative	\$ 216	\$ 361	\$ 982
M	TPG Operations, LLC - consulting services	Selling, general and administrative	\$ 19	\$ 249	\$ —
N	Alkermes Plc	Inventory and cost of goods sold	\$ 235	\$ 138	\$ —
O	R&S Solutions LLC - logistics services	Selling, general and administrative	\$ 85	\$ 183	\$ 80
P	Zep Inc.	Net revenue	\$ —	\$ —	\$ (637)
Q	Sellers of Gemini Laboratories, LLC - acquisition agreement	Non-controlling interests	\$ —	\$ —	\$ 3,300
R	Asana Biosciences, LLC	Research and development	\$ (5)	\$ (4)	\$ —
U	Members - tax receivable agreement	Other expense	\$ 631	\$ —	\$ —

*Agreement between Amneal and Kashiv was acquired with KSP and has become a transaction among Amneal's consolidated subsidiaries subsequent to the transaction closing on April 2, 2021. The disclosure relates to the historical agreement as a related party transaction through April 2, 2021 (refer to Note 3. *Acquisitions* for additional information).

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The following table summarizes the amounts due to or from the Company for related party transactions (in thousands):

		December 31, 2022	December 31, 2021
E	PharmaSophia, LLC - research and development agreement	\$ —	\$ 1,081
T	Sellers of AvKARE LLC and R&S - state tax indemnification	486	68
A	Kashiv - various agreements	12	14
G	Apac KY, LLC d/b/a Apac Packaging LLC - packaging agreement	—	16
R	Asana BioSciences, LLC	2	—
	Related party receivables - short term	\$ 500	\$ 1,179
A	Kashiv - deferred consideration associated with the KSP Acquisition	\$ —	\$ 30,500
A	Kashiv - various agreements	110	314
S	Sellers of Puniska - consideration for acquisition	—	14,225
G	Apac Packaging, LLC - packaging agreement	756	560
I	AzaTech Pharma LLC - supply agreement	863	1,783
L	Avtar Investments LLC - consulting services	72	37
T	Sellers of AvKARE LLC and R&S - accrued interest on Sellers Notes	442	442
U	Members - tax receivable agreement	201	—
O	R&S Solutions LLC - logistics services	7	—
N	Alkermes Plc	28	—
H	Tracy Properties LLC	—	—
	Related party payables - short term	\$ 2,479	\$ 47,861
A	Kashiv - contingent consideration	\$ 3,290	\$ 5,900
T	Sellers of AvKARE LLC and R&S - accrued interest on Sellers Notes	5,929	3,719
U	Members - tax receivable agreement	430	—
	Related party payables - long term	\$ 9,649	\$ 9,619

Related Party Descriptions

(A) Kashiv Biosciences LLC

Kashiv is an independent contract development organization focused primarily on the development of 505(b)(2) NDA products. Amneal has various business agreements with Kashiv. Certain executive officers of the Company beneficially own, directly and through certain revocable or irrevocable trusts for the benefit of their immediate families, outstanding equity securities of Kashiv. In addition, they serve on the Board of Managers of Kashiv.

On January 11, 2021, the Company and Kashiv entered into a definitive agreement for Amneal to acquire a 98% interest in KSP, a subsidiary of Kashiv focused on the development of complex generics, innovative drug delivery platforms and novel 505(b)(2) drugs. The acquisition closed on April 2, 2021 and included contingent payments for achievement of certain regulatory milestones and potential royalty payments base on annual net sales for certain future pharmaceutical products. Certain of the contracts between Amneal and Kashiv were acquired in this transaction and have become transactions among Amneal's consolidated subsidiaries subsequent to the transaction closing. Refer to *Note 3. Acquisitions* for further details on the KSP acquisition.

Below is a summary of the related party arrangements held between the Company and Kashiv which were not impacted by the KSP Acquisition:

- i. The parties entered into a lease for parking spaces in Piscataway, NJ. The annual lease cost is \$0.1 million per year.
- ii. In 2017 Kashiv and Amneal entered into an exclusive license and commercialization agreement (the "Kashiv Biosimilar Agreement") to distribute and sell two biosimilar products, Filgrastim and Pegfilgrastim, in the U.S. Kashiv is responsible for development, regulatory filings, obtaining FDA approval, and manufacturing, and Amneal is responsible for marketing, selling, and pricing activities. The term of the agreement is 10 years from the respective product's launch date.

The Kashiv Biosimilar Agreement provided for potential future milestone payments to Kashiv of up to \$183.0 million, as follows: (i) up to \$22.5 million relating to regulatory approval and execution, (ii) up to \$43.0 million for successful delivery of commercial launch inventory, (iii) up to \$50.0 million depending on the number of competitors at launch for one product, and (iv) between \$15.0 million and \$67.5 million for the achievement of cumulative net sales for both products.

In July 2022, the Company and Kashiv amended the Kashiv Biosimilar Agreement to, among other things, (i) eliminate milestones related to the manufacturing and delivery of the Kashiv products, (ii) revise the net sales milestones to provide for future milestone payments by the Company to Kashiv of up to \$37.5 million for the achievement of cumulative combined net sales goals for both products, and (iii) adjust the supply price of product that Kashiv manufactures and supplies to the Company, which will lower the cost per unit of both products.

The remaining milestones are subject to reaching certain commercial sales volume objectives. In addition, the agreement provides for Amneal to pay a profit share equal to 50% of net profits, after considering manufacturing and marketing costs.

On May 27, 2022, the FDA approved the Company's biologic license application, associated with the amended Kashiv Biosimilar Agreement, for Pegfilgrastim-pbbk. In connection with this regulatory approval and associated activity, the Company incurred a milestone of \$15.0 million during the year ended December 31, 2022, payable to Kashiv. The milestone was capitalized as an intangible asset and will be amortized to cost of sales over an estimated useful life of 8.3 years. The Company paid Kashiv \$15.0 million in August 2022 related to this milestone.

The Company recognized a \$5.0 million milestone in selling, general and administrative expense upon FDA approval of Filgrastim in February 2022.

- iii. Amneal and Kashiv entered into a product development agreement for the development and commercialization of two generic peptide products, Ganirelix Acetate and Cetorelix Acetate. Under the agreement, the intellectual property and ANDA for these products are owned by Amneal, and Kashiv will receive a profit share for all sales of the products made by Amneal. In connection with the agreement, Amneal made an upfront payment of \$1.1 million in August 2020. The agreement also provides for potential future milestone payments to Kashiv of (i) up to \$2.1 million relating to development milestones, and (ii) up to \$0.3 million relating to regulatory filings. The milestones are subject to certain performance conditions which may or may not be achieved, including FDA filings. In addition, Amneal agreed to pay \$2.6 million of development fees to Kashiv as the development work is completed.
- iv. As discussed in *Note 3. Acquisitions*, the purchase price for the KSP Acquisition included a contractually stated amount of deferred consideration of \$30.5 million. As of December 31, 2021, deferred consideration of \$30.5 million was recorded in related party payable-short term. Amneal paid all of the deferred consideration in 2022. Additionally, as of December 31, 2022 and 2021, a contingent consideration liability of \$3.3 million and \$5.9 million, respectively, associated with the KSP Acquisition was recorded in related party payable-long term. For the year ended December 31, 2021, the Company recorded \$0.3 million of expenses for transition services associated with the KSP Acquisition provided by Kashiv.
- v. Amneal has various consulting arrangements with Kashiv to collaborate on the development and commercialization of certain generic pharmaceutical products.
- vi. In December 2022, Amneal and Kashiv entered into a development supply agreement specific to four generic product candidates. Amneal will be responsible to manufacture batch products, as well as to perform certain developmental activities on behalf of Kashiv. Kashiv, as owner of the IP, will be responsible for regulatory filings, obtaining FDA approval, marketing, selling, and pricing activities. Pursuant to the terms of the development supply agreement, Amneal is eligible to earn up to \$2.4 million related to the aforementioned services. During the year ended December 31, 2022, the Company did not record any revenue related to this agreement.

- vii. Pursuant to a product development agreement, Amneal and Kashiv agreed to collaborate on the development and commercialization of Levothyroxine Sodium. Under the agreement, the intellectual property and ANDA for this product is owned by Amneal, and Kashiv received a profit share for all sales of the product made by Amneal. Amneal is precluded from selling the product made by Kashiv during the term of the license and supply agreement with Jerome Stevens Pharmaceuticals (refer to *Note 5. Alliances and Collaboration*). Under the terms of the amended agreement with Kashiv, Amneal paid \$2.0 million in July 2019 and may be required to pay up to an additional \$18.0 million upon certain regulatory milestones being met.

Amneal and Kashiv entered into a product development agreement for the development and commercialization of Posaconazole. Under this agreement, the intellectual property and ANDA for this product is owned by Amneal and Kashiv is to receive a profit share for all sales of the product made by Amneal. In connection with the agreement, Amneal paid an upfront amount of \$0.3 million in May 2020 for execution of the agreement which was expensed in research and development. The agreement also provides for potential future milestone payments to Kashiv of (i) up to \$0.8 million relating to development milestones, (ii) up to \$0.3 million relating to regulatory approval, and (iii) up to \$1.0 million for the achievement of cumulative net sales. The milestones were subject to certain performance conditions which may or may not be achieved, including FDA filing, FDA approval and commercial sales volume objectives.

The following disclosures relate to agreements between Amneal and Kashiv that were acquired as part of the KSP Acquisition. These agreements became a transaction among Amneal's consolidated subsidiaries subsequent to the closing of the KSP Acquisition on April 2, 2021. These below transactions were considered related party transactions through April 2, 2021 (refer to *Note 3. Acquisitions* for additional information).

- viii. Amneal and Kashiv entered into a licensing agreement for the development and commercialization of Kashiv's orphan drug K127 (pyridostigmine) for the treatment of Myasthenia Gravis. Under the terms of the agreement, Kashiv was responsible for all development and clinical work required to secure Food and Drug Administration approval and Amneal was responsible for filing the NDA and commercializing the product. The Company made an upfront payment of approximately \$1.5 million to Kashiv in December 2019, and Kashiv was eligible to receive development and regulatory milestones totaling approximately \$16.5 million. Kashiv was also eligible to receive tiered royalties from the low double-digits to mid-teens on net sales of K127.
- ix. On February 20, 2020, the Company and Kashiv entered into a master services agreement covering certain services that Kashiv provided the Company for commercial product support related to EluRyng and other products, including Ranitidine and Nitrofurantoin.
- x. Amneal had various development, commercialization and consulting arrangements with Kashiv to collaborate on the development and commercialization of certain generic pharmaceutical products. Kashiv received a percentage of net profits with respect to Amneal's sales of these products.
- xi. Amneal had various development, commercialization and consulting arrangements with Kashiv to collaborate on the development and commercialization of certain generic pharmaceutical products. This activity related to the total reimbursable expenses associated with these arrangements.

(B) LAX Hotel, LLC

The Company had a financing lease with LAX Hotel, LLC for two buildings located in Long Island, New York, which are used as an integrated manufacturing and office facility. The Company leased these buildings from LAX Hotel, LLC from 2012 until January 2021. LAX Hotel, LLC had been controlled by a member of the Amneal Group, who also serves as observer on the Company's Board of Directors. As a result, this lease had been historically accounted for as a related party financing lease.

During January 2021, LAX Hotel, LLC sold its interests in the leased buildings to an unrelated third-party. Therefore, this lease is no longer a related party transaction, and the corresponding financing lease right-of-use asset and liability were reclassified in the consolidated balance sheet as of December 31, 2021 to reflect this change. For annual payments required under the terms of non-cancelable lease agreements over the next five years and thereafter, refer to *Note 12. Leases*.

(C) Kanan, LLC

Kanan, LLC ("Kanan") is a real estate company that owns Amneal's manufacturing facilities located at 65 Readington Road, Branchburg, New Jersey, 131 Chambers Brook Road, Branchburg, New Jersey and 1 New England Avenue, Piscataway, New Jersey. Certain executive officers of the Company beneficially own, through certain revocable trusts, equity securities of Kanan.

In addition, they serve on the Board of Managers of Kanan. Amneal leases these facilities from Kanan under two separate triple-net lease agreements that expire in 2027 and 2031, respectively, at an annual rental cost of approximately \$2.0 million combined, subject to CPI rent escalation adjustments as provided in the lease agreements.

(D) Sutaria Family Realty, LLC

Industrial Real Estate Holdings NY, LLC (“IRE”) is a real estate management entity, which was the sub-landlord of Amneal’s leased manufacturing facility located at 75 Adams Avenue, Hauppauge, New York. IRE is controlled by a member of the Amneal Group who also serves as an observer on our Board of Directors. Effective June 1, 2020, the lease was assigned to the Company with the consent of the landlord, Sutaria Family Realty, LLC, which is also a related party because a member of Company management is a beneficial owner. Concurrently with the assignment of the lease, the Company exercised a renewal option for \$0.1 million to extend the lease by 5 years until March 31, 2026. Monthly rent payments are \$0.1 million and increase by 3% annually.

(E) PharmaSophia, LLC

PharmaSophia, LLC (“PharmaSophia”) is a joint venture formed by Nava Pharma, LLC (“Nava”) and Oakwood Laboratories, LLC for the purpose of developing certain products. Certain executive officers of the Company beneficially own, directly and through certain revocable or irrevocable trusts for the benefit of their immediate families, outstanding equity securities of Nava. Nava beneficially owns 50% of the outstanding equity securities of PharmaSophia. In addition, these executive officers also serve on the Board of Managers of PharmaSophia.

PharmaSophia and Nava are parties to an R&D agreement pursuant to which Nava provides R&D services to PharmaSophia (the “Nava Agreement”). Nava subcontracted this obligation to Amneal under a subcontract R&D services agreement pursuant to which Amneal provides R&D services to Nava in connection with the products being developed by PharmaSophia.

In October 2022, PharmaSophia and Amneal entered into an exclusive license and commercialization agreement (the “PharmaSophia Agreement”) to develop, manufacture, and sell one injectable product. Under the terms of the agreement, Amneal committed to spend up to \$6.0 million to further develop the product, including all related expenses up to submission of the ANDA, which will be owned by Amneal. Also under the terms of the PharmaSophia Agreement, PharmaSophia settled a liability of \$1.1 million payable to Amneal under the terms of the Nava Agreement by reducing the amount of Amneal’s committed spending under the terms of the PharmaSophia Agreement to \$4.9 million. Amneal recorded \$1.1 million of research and development expense for the year ended December 31, 2022 as a result of the settlement. PharmaSophia will receive a 50% profit share for all sales of product made by Amneal under the PharmaSophia Agreement.

(F) Fosun International Limited

Fosun International Limited (“Fosun”) is a Chinese international conglomerate and investment company that is a shareholder of the Company. On June 6, 2019, the Company entered into a license and supply agreement with a subsidiary of Fosun, which is a Chinese pharmaceutical company. Under the terms of the agreement, the Company will hold the imported drug license required for pharmaceutical products manufactured outside of China and will supply Fosun with finished, packaged products for Fosun to then sell in the China market. Fosun will be responsible for obtaining regulatory approval in China and for shipping the product from Amneal’s facility to Fosun’s customers in China. In consideration for access to the Company’s U.S. regulatory filings to support its China regulatory filings and for the supply of product, Fosun paid the Company a \$1.0 million non-refundable fee, net of tax, in July 2019 and will be required to pay the Company \$0.3 million for each of eight products upon the first commercial sale of each in China in addition to a supply price and a profit share.

On August 12, 2021, the Company entered into an active pharmaceutical ingredient (“API”) co-development agreement with a subsidiary of Fosun. Under the terms of the agreement, the Company provided Fosun a license to manufacture and sell two pharmaceutical products outside of the United States. Fosun will be responsible for obtaining regulatory approval outside the United States. Fosun paid the Company a \$0.2 million non-refundable fee which was recognized in 2021 as revenue and will be required to pay the Company \$0.1 million for each of the two products upon the first commercial sale of each in China in addition to a profit share.

(G) Apace KY, LLC d/b/a Apace Packaging LLC

Apace KY, LLC d/b/a Apace Packaging LLC (“Apace”) provides packaging solutions pursuant to an exclusive packaging agreement. Apace markets its services which include bottling and blistering for the pharmaceutical industry. A member of Company management beneficially owns outstanding equity securities of Apace.

(H) Tracy Properties LLC

R&S leases operating facilities, office and warehouse space from Tracy Properties LLC (“Tracy”). A member of Company management beneficially owns outstanding equity securities of Tracy.

(I) AzaTech Pharma, LLC

R&S purchases inventory from AzaTech Pharma LLC (“AzaTech”) for resale. A member of Company management beneficially owns outstanding equity securities of AzaTech.

(J) AvPROP, LLC

AvKARE LLC leases its operating facilities from AvPROP, LLC (“AvPROP”). A member of Company management beneficially owns outstanding equity securities of AvPROP.

(K) Tarsadia Investments, LLC

Tarsadia Investments, LLC (“Tarsadia”) is a private investment firm that provides financial services and is a significant shareholder of the Company. A member of Amneal Group, and an observer to the Board, is the Chairman and Founder of Tarsadia. Another member of the Amneal Group, and a member of the Board, is a Managing Director of Tarsadia. Tarsadia offers capital and strategic support for companies with substantial growth potential primarily in the healthcare, financial services, real estate, and clean technology sectors. The Company entered into an agreement in which Tarsadia will provide financial consulting services. The services are not expected to have a material impact to the Company’s financial statements.

(L) Avtar Investments, LLC

Avtar Investments, LLC (“Avtar”) is a private investment firm. Certain executive officers of the Company beneficially own, directly and through certain revocable or irrevocable trusts for the benefit of their immediate families, outstanding equity securities of Avtar. During April 2020, the Company entered into an agreement in which Avtar will provide consulting services.

(M) TPG Operations, LLC

TPG Operations LLC (“TPG”) is a private investment firm that provides financial services and is a significant stockholder of the Company. An observer of our Board is a managing director of TPG. TPG offers capital and strategic support for companies with substantial growth potential primarily in the healthcare, financial services, real estate, and clean technology sectors. In March 2020, the Company entered into an agreement in which TPG provided financial consulting services for a period of 7 months. The agreement was subsequently extended until March 2022.

(N) Alkermes Plc

Rondo Partners LLC purchases inventory from Alkermes Plc for resale. A member of the Board also sits on the board of directors for Alkermes Plc.

(O) R&S Solutions LLC

R&S Solutions LLC provides logistic services to the Company. A member of Company management beneficially owns outstanding equity securities of R&S Solutions LLC.

(P) Zep Inc.

Zep Inc. (“Zep”) is a producer and distributor of maintenance and cleaning solutions for retail, food and beverage, industrial and institutional, and vehicle care customers. An executive officer of the Company serves as a director of Zep. During May 2020, AvKARE entered into an agreement to supply cleaning products to Zep.

(Q) Gemini Laboratories, LLC

During September 2020, the Company made a \$3.3 million payment to the non-controlling interest holders in one of Amneal’s non-public subsidiaries, Gemini Laboratories, LLC, to distribute earnings of \$0.8 million and acquire their ownership interests in the non-public subsidiary for \$2.5 million.

(R) Asana Biosciences, LLC

Asana Biosciences, LLC (“Asana”) is an early stage drug discovery and R&D company focusing on several therapeutic areas, including oncology, pain and inflammation. Certain executive officers of the Company beneficially own, directly and through certain revocable or irrevocable trusts for the benefit of their immediate families, outstanding equity securities of Asana. In addition, they serve on the Board of Managers of Asana. From time to time, Amneal provides R&D services to Asana under a development and manufacturing agreement and storage services under a storage agreement.

(S) Puniska Acquisition

The purchase price for the Puniska Acquisition included \$14.2 million due to the sellers, which was outstanding at December 31, 2021 (paid by Amneal in 2022), for the satisfaction of a preexisting payable upon approval of the transaction by the government of India. Further, the Company paid \$1.7 million for the remaining 26% equity interest of Puniska (included in redeemable non-controlling interests in the Company’s consolidated balance sheet as of December 31, 2021) upon approval of the Puniska Acquisition by the government of India in 2022. Refer to *Note. 3 Acquisitions* for related party transactions associated with the Puniska Acquisition.

(T) Sellers of AvKARE LLC and R&S

Tax Indemnification – Rondo Acquisitions

In accordance with the Rondo Equity Purchase Agreement, the Company will be indemnified by the sellers of AvKARE, LLC and R&S for \$0.1 million of state taxes paid on behalf of the sellers for a tax period prior to the closing of the Rondo Acquisition. As a result, the Company recorded \$0.1 million of related party receivables - short term as of December 31, 2021.

Notes Payable – Related Party

Certain holders of the Rondo Class B Units are also holders of the Sellers Notes and were holders of the Short-Term Sellers Note, which Amneal repaid in 2021. For additional information, refer to *Note 16. Debt*.

Refer to *Note. 3 Acquisitions* and *Note 22. Stockholders’ Equity* for related party transactions associated with the Rondo Acquisitions.

Tax Distributions

Under the terms of the limited liability company agreement between the Company and the holders of the Rondo Class B Units, Rondo is obligated to make tax distributions to those holders, subject to certain limitations as defined in the Rondo Credit Facility. For further details, refer to *Note 22. Stockholders’ Equity*.

(U) Tax Receivable Agreement

In connection with the acquisition of Impax, the Company entered into a tax receivable agreement for which it is generally required to pay the other holders of Amneal Common Units 85% of the applicable tax savings, if any, in U.S. federal and state income tax that it is deemed to realize as a result of certain tax attributes of their Amneal Common Units sold to the Company (or exchanged in a taxable sale) and that are created as a result of (i) the sales of their Amneal Common Units for shares of Class A Common Stock and (ii) tax benefits attributable to payments made under the TRA. Refer to *Note 7. Income Taxes* for additional information.

(V) Tax Distributions to Members

Under the terms of the Limited Liability Company Agreement, Amneal is obligated to make tax distributions to its members, which are also holders of non-controlling interests in the Company. For further details, refer to *Note 22. Stockholders’ Equity* and *Note. 7 Income Taxes* for further details.

25. Employee Benefit Plans

The Company has voluntary defined contribution plans covering eligible employees in the United States which provide for a Company match. For the years ended December 31, 2022, 2021 and 2020, the Company made matching contributions of \$9.5 million, \$8.9 million and \$7.7 million, respectively.

The Company also has a deferred compensation plan for certain former executives and employees of Impax, some of whom are currently employed by the Company. In January 2019, the Company announced that it will no longer accept contributions from employees or make matching contributions for the deferred compensation plan. Deferred compensation liabilities are recorded at the value of the amount owed to the plan participants, with changes in value recognized as compensation expense. The calculation of the deferred compensation plan obligation is derived by reference to hypothetical investments selected by the participants and is included in accounts payable and accrued expenses and other long-term liabilities. Refer to *Note 19. Fair Value Measurements* for additional information.

26. Segment Information

The Company has three reportable segments: Generics, Specialty, and AvKARE.

Generics

The Company's Generics segment includes a retail and institutional portfolio of over 250 product families covering an extensive range of dosage forms and delivery systems, including both immediate and extended release oral solids, powders, liquids, sterile injectables, nasal sprays, inhalation and respiratory products, biosimilar products, ophthalmics, films, transdermal patches and topicals.

Specialty

The Company's Specialty segment is engaged in the development, promotion, sale and distribution of proprietary branded pharmaceutical products, with a focus on products addressing central nervous system disorders, including Parkinson's disease, and endocrine disorders.

AvKARE

The Company's AvKARE segment provides pharmaceuticals, medical and surgical products and services primarily to governmental agencies, primarily focused on serving the Department of Defense and the Department of Veterans Affairs. AvKARE is also a wholesale distributor of bottle and unit dose pharmaceuticals under the registered names of AvKARE and AvPAK, and medical and surgical products. AvKARE is also a packager and wholesale distributor of pharmaceuticals and vitamins to its retail and institutional customers who are located throughout the United States focused primarily on offering 340b-qualified entities products to provide consistency in care and pricing.

Chief Operating Decision Makers

The Company's chief operating decision makers evaluate the financial performance of the Company's segments based upon segment operating income (loss). Items below operating income (loss) are not reported by segment, since they are excluded from the measure of segment profitability reviewed by the Company's chief operating decision maker. Additionally, general and administrative expenses, certain selling expenses, certain litigation settlements, and non-operating income and expenses are included in "Corporate and Other." The Company does not report balance sheet information by segment since it is not reviewed by the Company's chief operating decision makers.

The tables below present segment information reconciled to total Company financial results, with segment operating income or loss, including gross profit less direct selling expenses, R&D expenses, and other operating expenses to the extent specifically identified by segment (in thousands):

Year Ended December 31, 2022	Generics ⁽¹⁾	Specialty	AvKARE ⁽¹⁾	Corporate and Other	Total Company
Net revenue ⁽²⁾	\$ 1,432,073	\$ 374,121	\$ 406,110	\$ —	\$ 2,212,304
Cost of goods sold	890,245	177,107	349,133	—	1,416,485
Cost of goods sold impairment charges	5,786	5,325	—	—	11,111
Gross profit	536,042	191,689	56,977	—	784,708
Selling, general and administrative	109,781	90,031	53,659	146,229	399,700
Research and development	167,509	28,179	—	—	195,688
In-process research and development impairment charges	12,970	—	—	—	12,970
Intellectual property legal development expenses	4,251	107	—	—	4,358
Acquisition, transaction-related and integration expenses	25	49	—	635	709
Restructuring and other charges	821	—	—	600	1,421
Change in fair value of contingent consideration	—	731	—	—	731
(Insurance recoveries) charges for property losses and associated expenses, net	(1,911)	—	—	—	(1,911)
Charges related to legal matters, net	22,400	—	—	247,530	269,930
Other operating income	(3,960)	—	—	—	(3,960)
Operating income (loss)	\$ 224,156	\$ 72,592	\$ 3,318	\$ (394,994)	\$ (94,928)

Year Ended December 31, 2021	Generics ⁽¹⁾	Specialty	AvKARE ⁽¹⁾	Corporate and Other	Total Company
Net revenue ⁽²⁾	\$ 1,366,338	\$ 378,319	\$ 349,012	\$ —	\$ 2,093,669
Cost of goods sold	825,568	193,562	282,874	—	1,302,004
Cost of goods sold impairment charges	22,692	—	—	—	22,692
Gross profit	518,078	184,757	66,138	—	768,973
Selling, general and administrative	64,500	84,481	57,918	158,605	365,504
Research and development	158,365	43,482	—	—	201,847
In-process research and development impairment charges	710	—	—	—	710
Intellectual property legal development expenses	7,562	154	—	—	7,716
Acquisition, transaction-related and integration expenses	—	16	1,422	6,617	8,055
Restructuring and other charges	80	—	—	1,777	1,857
Change in fair value of contingent consideration	—	200	—	—	200
(Insurance recoveries) charges for property losses and associated expenses, net	5,368	—	—	—	5,368
Charges related to legal matters, net	—	—	—	25,000	25,000
Operating income (loss)	\$ 281,493	\$ 56,424	\$ 6,798	\$ (191,999)	\$ 152,716

Year Ended December 31, 2020	Generics ⁽¹⁾	Specialty	AvKARE ⁽¹⁾	Corporate and Other	Total Company
Net revenue ⁽²⁾	\$ 1,343,210	\$ 355,567	\$ 293,746	\$ —	\$ 1,992,523
Cost of goods sold	894,422	192,910	242,219	—	1,329,551
Cost of goods sold impairment charges	34,579	—	—	—	34,579
Gross profit	414,209	162,657	51,527	—	628,393
Selling, general and administrative	56,134	75,917	58,544	136,132	326,727
Research and development	150,068	29,862	—	—	179,930
In-process research and development impairment charges	2,680	—	—	—	2,680
Intellectual property legal development expenses	10,647	8	—	—	10,655
Acquisition, transaction-related and integration expenses	328	85	641	7,934	8,988
Restructuring and other charges	(614)	—	—	3,012	2,398
Charges related to legal matters, net	5,610	250	—	—	5,860
Operating income (loss)	\$ 189,356	\$ 56,535	\$ (7,658)	\$ (147,078)	\$ 91,155

⁽¹⁾ Operating results for the sale of Amneal products by AvKARE were included in Generics effective with the closing of the Rondo Acquisitions on January 31, 2020.

⁽²⁾ Net revenue from external customers is attributed to countries based on the location of the product shipment. For the years ended December 31, 2022, 2021, and 2020, net revenue from external customers attributed to foreign countries was immaterial.

Long-Lived Assets

Long-lived assets, which are comprised of property, plant and equipment, net and operating and financing lease right-of-use assets, are attributed based on physical location. Long-lived assets by country were as follows (in thousands):

	December 31, 2022	December 31, 2021
United States	\$ 354,504	\$ 388,818
India	180,325	189,885
Ireland	54,531	60,300
	\$ 589,360	\$ 639,003

27. (Insurance Recoveries) Charges for Property Losses and Associated Expenses, Net

On September 1, 2021, Tropical Storm Ida brought extreme rainfall and flash flooding to New Jersey that caused damage to two of the Company's facilities. The Company concluded that all inventory on-hand at the time of the flooding was damaged and unsellable and that a majority of the equipment was damaged beyond repair. In addition, the Company incurred significant costs to repair both facilities. Accordingly, the Company recorded \$10.4 million of charges for property losses and associated expenses for the year ended December 31, 2021.

The Company has insurance policies for property damage, inventory losses and business interruption. Insurance recoveries are recorded in the periods when it is probable they will be realized. During the year ended December 31, 2022 and 2021, insurance recoveries of \$1.9 million and \$5.0 million, respectively, associated with property damage and equipment losses were received and recorded as a reduction of property losses and associated expenses. (Insurance recoveries) charges for property losses and associated expenses was comprised of the following (in thousands):

	Years Ended December 31,	
	2022	2021
Impairment of equipment	\$ —	\$ 4,202
Impairment of inventory	—	950
Repairs and maintenance expenses	—	3,716
Salaries and benefits	—	1,500
Total property losses and associated expenses	—	10,368
Less: Insurance recoveries received	(1,911)	(5,000)
(Insurance recoveries) charges for property losses and associated expenses, net	\$ (1,911)	\$ 5,368

28. Subsequent Event

Under the terms of the Opana ER® antitrust litigation settlement agreements (refer to *Note 21. Commitments and Contingencies*), the Company paid \$83.9 million which was primarily funded by \$80.0 million of borrowings under the New Revolving Credit Facility in January 2023.

EXHIBIT INDEX

Exhibit No.	Description of Document
<u>2.1</u>	<u>Business Combination Agreement, dated as of October 17, 2017, by and among Amneal Pharmaceuticals LLC, Impax Laboratories, Inc., Atlas Holdings, Inc. and K2 Merger Sub Corporation (incorporated by reference to Exhibit 2.1 to the Company's Registration Statement on Form S-1, filed on May 7, 2018).</u>
<u>2.1.1</u>	<u>Amendment No. 1, dated as of November 21, 2017, to the Business Combination Agreement, dated as of as of October 17, 2017, by and among Amneal Pharmaceuticals LLC, Impax Laboratories, Inc., Atlas Holdings, Inc. and K2 Merger Sub Corporation (incorporated by reference to Exhibit 2.2 to the Company's Registration Statement on Form S-1, filed on May 7, 2018).</u>
<u>2.1.2</u>	<u>Amendment No. 2, dated as of December 16, 2017, to the Business Combination Agreement, dated as of as of October 17, 2017, as amended by Amendment No. 1 dated as of November 21, 2017 by and among Amneal Pharmaceuticals LLC, Impax Laboratories, Inc., Atlas Holdings, Inc. and K2 Merger Sub Corporation (incorporated by reference to Exhibit 2.3 to the Company's Registration Statement on Form S-1 filed on May 7, 2018).</u>
<u>2.2</u>	<u>Purchase and Sale Agreement, dated as of May 7, 2018, by and between Amneal Pharmaceuticals LLC, Gemini Laboratories, LLC, the parties signatory thereto and the Sellers' Representative (incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K filed on May 7, 2018).</u>
<u>2.3</u>	<u>Equity Purchase Agreement, dated December 10, 2019, by and among the Jerry Brian Shirley Business Trust, the Darren Thomas Shirley Business Trust, the Steve Shirley Business Trust, the Jerry Shirley Business Trust, Troy Mizell, Darrell Calvert, AvKARE, Dixon-Shane, LLC d/b/a R&S Northeast LLC and Rondo Acquisition LLC. In accordance with the instructions to Item 601(b)(2) of Regulation S-K, the schedules and exhibits to the Equity Purchase Agreement are not filed herewith. The Equity Purchase Agreement identifies such schedules and exhibits, including the general nature of their content. The Company undertakes to provide such schedules and exhibits to the SEC upon request (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on December 10, 2019).</u>
<u>2.4</u>	<u>Membership Interest Purchase Agreement, dated January 11, 2021, by and among Kashiv BioSciences, LLC and Amneal Pharmaceuticals LLC (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on January 12, 2021).</u>
<u>2.5</u>	<u>Share Purchase Agreement, dated November 2, 2021, by and among Puniska Healthcare Pvt. Ltd. and Amneal Pharmaceuticals Private Limited (incorporated by reference to Exhibit 2.5 of the Company's Annual Report on Form 10-K filed on March 1, 2022).</u>
<u>2.6</u>	<u>Asset Purchase Agreement, dated December 30, 2021, by and among Amneal Pharmaceuticals LLC and Saol Therapeutics (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on January 5, 2022).</u>
<u>3.1</u>	<u>Second Amended and Restated Certificate of Incorporation of Amneal Pharmaceuticals, Inc. adopted as of May 5, 2021 (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, filed on May 7, 2021).</u>
<u>3.2</u>	<u>Amended and Restated Bylaws of Amneal Pharmaceuticals, Inc. adopted as of February 12, 2021 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on February 16, 2021).</u>
<u>4.1</u>	<u>Second Supplemental Indenture dated as of May 4, 2018 to the Indenture dated as of June 30, 2015 by and between Impax Laboratories, LLC and Wilmington Trust, N.A. (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on May 7, 2018).</u>
<u>4.2</u>	<u>Description of Registrant's Securities (incorporated by reference to Exhibit 4.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed on March 2, 2020).</u>
<u>10.1</u>	<u>Term Loan Credit Agreement, dated as of May 4, 2018, by and among Amneal Pharmaceuticals LLC, as the borrower, JP Morgan Chase Bank, N.A., as administrative agent and collateral agent, and the lenders and other parties party thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 7, 2018).</u>
<u>10.2</u>	<u>Revolving Credit Agreement, dated as of May 4, 2018, by and among Amneal Pharmaceuticals LLC, as the borrower, the other loan parties from time to time, JP Morgan Chase Bank, N.A., as administrative agent and collateral agent and the lenders and other parties party thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on May 7, 2018).</u>
<u>10.3</u>	<u>Term Loan Guarantee and Collateral Agreement, dated as of May 4, 2018, by and among the loan parties from time to time party thereto and JPMorgan Chase Bank, N.A., as administrative agent and collateral agent (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on May 7, 2018).</u>

<u>10.4</u>	<u>Revolving Loan Guarantee and Collateral Agreement, dated as of May 4, 2018, by and among the loan parties from time to time party thereto and JPMorgan Chase Bank, N.A., as administrative agent and collateral agent (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on May 7, 2018).</u>
<u>10.4.1</u>	<u>Revolving Credit Agreement, dated as of June 2, 2022, by and among Amneal Pharmaceuticals LLC, as the borrower, Truist Bank, as administrative agent and collateral agent and the lenders and other parties party thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 2, 2022)</u>
<u>10.4.2</u>	<u>ABL Guarantee and Collateral Agreement, dated as of June 2, 2022, by and among the loan parties from time-to-time party thereto and Truist Bank, as administrative agent and collateral agent (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 2, 2022)</u>
<u>10.5</u>	<u>Third Amended and Restated Limited Liability Company Agreement of Amneal Pharmaceuticals LLC adopted as of May 4, 2018 (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on May 7, 2018).</u>
<u>10.5.1</u>	<u>Amendment No. 1 to Third Amended and Restated Limited Liability Company Agreement of Amneal Pharmaceuticals LLC, dated as of February 14, 2019, with effect as of May 4, 2018 incorporated by reference to Exhibit 10.5.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2018, filed on March 1, 2019.</u>
<u>10.6</u>	<u>Tax Receivable Agreement, dated as of May 4, 2018, by and among Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC and the Members of Amneal Pharmaceuticals LLC from time to time party thereto (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K, filed on May 7, 2018).</u>
<u>10.7</u>	<u>Form of Indemnification and Advancement Agreement for the directors and officers of the Company (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K, filed on May 7, 2018).</u> [†]
<u>10.8</u>	<u>Form of Amneal Pharmaceuticals, Inc. 2018 Incentive Award Plan Stock Option Grant Notice and Stock Option Agreement (incorporated by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K, filed on May 7, 2018).</u> [†]
<u>10.9</u>	<u>Form of Amneal Pharmaceuticals, Inc. 2018 Incentive Award Plan Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement (incorporated by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K, filed on May 7, 2018).</u> [†]
<u>10.10</u>	<u>Form of Amneal Pharmaceuticals, Inc. 2018 Incentive Award Plan Performance Restricted Stock Unit Grant Notice and Performance Restricted Stock Unit Agreement (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the year ended December 31, 2018, filed on March 1, 2019).</u> [†]
<u>10.11</u>	<u>Amneal Pharmaceuticals Inc. 2018 Incentive Award Plan (amended and restated) (incorporated by reference to Exhibit 99.1 to the Company's Registration Statement on Form S-8, filed on August 17, 2020).</u> [†]
<u>10.12</u>	<u>Form of Amneal Pharmaceuticals, Inc. 2018 Incentive Award Plan Performance Restricted Stock Unit Grant Notice and Performance Restricted Stock Unit Agreement (2020) (incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ended December 31, 2020, filed on March 1, 2021).</u> [†]
<u>10.13</u>	<u>Employment Agreement, dated January 24, 2018, by and among Amneal Pharmaceuticals LLC, Amneal Holdings, LLC and Andrew Boyer (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1, filed on May 7, 2018).</u> [†]
<u>10.13.1</u>	<u>Modification No. 1 to Employment Agreement, dated July 29, 2020, by and among Amneal Pharmaceuticals Inc. and Andrew Boyer (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed on November 6, 2020).</u> [†]
<u>10.14</u>	<u>Unsecured Promissory Note, dated as of May 7, 2018, issued by Amneal Pharmaceuticals LLC to the Sellers (as defined therein) (incorporated by reference to Exhibit 10.13 to the Company's Current Report on Form 8-K, filed on May 7, 2018).</u>
<u>10.15</u>	<u>Impax Laboratories, Inc. Executive Non-Qualified Deferred Compensation Plan, amended and restated effective January 1, 2008 (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1, filed on May 7, 2018).</u> [†]
<u>10.15.1</u>	<u>Amendment to Impax Laboratories, Inc. Executive Non-Qualified Deferred Compensation Plan, effective as of January 1, 2009 (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1, filed on May 7, 2018).</u> [†]

<u>10.16</u>	<u>Second Amended and Restated Stockholders Agreement, dated as of December 16, 2017, among Atlas Holdings, Inc., Amneal Pharmaceuticals Holdings Company LLC, AP Class D Member, LLC, AP Class E Member, LLC and AH PPU Management, LLC (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1, filed on May 7, 2018).</u>
<u>10.17</u>	<u>Amendment No. 1, dated as of August 2, 2019, to Second Amended and Restated Stockholders Agreement, by and among Amneal Pharmaceuticals Holding Company, LLC, a Delaware limited liability company, AP Class D Member, LLC, a Delaware limited liability company, AP Class E Member, LLC, a Delaware limited liability company, AH PPU Management, LLC, a Delaware limited liability company, and Amneal Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed on August 5, 2019).</u>
<u>10.18</u>	<u>Form of Tripartite Letter Agreement Credit Suisse (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed on August 5, 2019).</u>
<u>10.19</u>	<u>Form of Tripartite Acknowledgment and Agreement Morgan Stanley (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed on August 5, 2019).</u>
<u>10.20</u>	<u>Employment Agreement dated March 11, 2020, by and among Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals, Inc. and Anastasios (Tasos) G. Konidaris (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 12, 2020).</u> †
<u>10.21</u>	<u>Amended and Restated Operating Agreement of Rondo Partners, LLC (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed on February 3, 2020).</u>
<u>10.22</u>	<u>Revolving Credit and Term Loan Agreement, dated as of January 31, 2020, by and among Rondo Intermediate Holdings and LLC and Rondo Holdings, LLC, the lenders from time to time party thereto, and Trust Bank, as Administrative Agent (incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K, filed on February 3, 2020).</u>
<u>10.23</u>	<u>Guaranty and Security Agreement, dated as of January 31, 2020, by and among Rondo Intermediate Holdings, LLC, and Rondo Holdings, LLC, AvKARE, R&S Northeast, and the Administrative Agent (incorporated by reference to Exhibit 2.3 to the Company's Current Report on Form 8-K, filed on February 3, 2020).</u>
<u>10.24</u>	<u>Amneal Pharmaceuticals LLC Severance Plan and Summary Plan Description (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, filed on August 6, 2020).</u> †
<u>10.25</u>	<u>Employment Agreement by and among Amneal Pharmaceuticals, Inc. and Nikita Shah, dated as of July 29, 2020 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, filed on May 7, 2021).</u> †
<u>10.26</u>	<u>Amneal Pharmaceuticals, Inc. Non-Employee Director Compensation Policy, as amended and restated on August 4, 2022 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed on August 8, 2022).</u> †
<u>21.1</u>	<u>Subsidiaries of the registrant.</u> *
<u>23.1</u>	<u>Consent of Independent Registered Public Accounting Firm.</u>
<u>31.1</u>	<u>Certification of Co-Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u> *
<u>31.2</u>	<u>Certification of Co-Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u> *
<u>31.3</u>	<u>Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u> *
<u>32.1</u>	<u>Certification of the Co-Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u> * **
<u>32.2</u>	<u>Certification of the Co-Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u> * **
<u>32.3</u>	<u>Certification of the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u> * **
<u>101</u>	<u>The following materials from the Company's Annual Report on Form 10-K for the year ended December 31, 2022, formatted in inline XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive (Loss) Income, (iv) Consolidated Statements of Changes in Stockholders' Equity, (v) Consolidated Statements of Cash Flows, and (vi) Notes to Consolidated Financial Statements.</u>

104 Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith

** This certificate is being furnished solely to accompany the report pursuant to 18 U.S.C. 1350 and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

*** Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

† Denotes management compensatory plan or arrangement.

The agreements and other documents filed as exhibits to this report are not intended to provide factual information or other disclosure other than the terms of the agreements or other documents themselves, and you should not rely on them for that purpose. In particular, any representations and warranties made by the Company in these agreements or other documents were made solely within the specific context of the relevant agreement or document and may not describe the actual state of affairs at the date they were made or at any other time.

SIGNATURES

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

Date: March 3, 2023

Amneal Pharmaceuticals, Inc.

By: /s/ Anastasios Konidaris

Anastasios Konidaris

Executive Vice President, Chief Financial Officer
(Principal Financial and Accounting Officer)

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Chirag Patel</u> Chirag Patel	President, Co- Chief Executive Officer and Director (Co-Principal Executive Officer)	March 3, 2023
<u>/s/ Chintu Patel</u> Chintu Patel	Co- Chief Executive Officer and Director (Co-Principal Executive Officer)	March 3, 2023
<u>/s/ Anastasios Konidaris</u> Anastasios Konidaris	Executive Vice President, Chief Financial Officer (Principal Financial and Accounting Officer)	March 3, 2023
<u>/s/ Paul M. Meister</u> Paul M. Meister	Chairman of the Board and Director	March 3, 2023
<u>/s/ Jeffrey P. George</u> Jeffrey P. George	Director	March 3, 2023
<u>/s/ Emily Peterson Alva</u> Emily Peterson Alva	Director	March 3, 2023
<u>/s/ J. Kevin Buchi</u> J. Kevin Buchi	Director	March 3, 2023
<u>/s/ John J. Kiely, Jr.</u> John J. Kiely, Jr.	Director	March 3, 2023
<u>/s/ Ted Nark</u> Ted Nark	Director	March 3, 2023
<u>/s/ Gautam Patel</u> Gautam Patel	Director	March 3, 2023
<u>/s/ Shlomo Yanai</u> Shlomo Yanai	Director	March 3, 2023
<u>/s/ Deb Autor</u> Deb Autor	Director	March 3, 2023