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File Pursuant to Rule 424(b)(3)
Registration No. 333-224702

PROSPECTUS SUPPLEMENT NO. 6
(To Prospectus Dated May 9, 2018)

AMNEAL PHARMACEUTICALS, INC.

This Prospectus Supplement No. 6 (this "Supplement No. 6") is part of the prospectus of Amneal Pharmaceuticals, Inc. (the "Company"), dated May 9, 2018 (the "Prospectus"). This Supplement No. 6 supplements, modifies or supersedes certain information contained in the Prospectus. Any statement in the Prospectus that is modified or superseded is not deemed to constitute a part of the Prospectus, except as modified or superseded by this Supplement No. 6. Except to the extent that the information in this Supplement No. 6 modifies or supersedes the information contained in the Prospectus, this Supplement No. 6 should be read, and will be delivered, with the Prospectus. This Prospectus Supplement No. 6 is not complete without, and may not be utilized except in connection with, the Prospectus.

The purpose of this Supplement No. 6 is to update and supplement the information in the Prospectus with the information contained in Amneal Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q, as filed with the Securities and Exchange Commission ("SEC") on November 7, 2018, which is attached hereto.

Investing in our securities involves risks that are described in the "Risk Factors" section beginning on page 11 of the Prospectus.

Neither the SEC nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is November 13, 2018.

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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2018

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.)**
Amneal Pharmaceuticals, Inc. 400 Crossing Boulevard, Bridgewater, NJ	
(Address of principal executive offices)	**08807 (Zip Code)**

(908) 947-3120
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of October 31, 2018, there were 114,977,648 shares of Class A common stock outstanding, 171,260,707 shares of Class B common stock outstanding and 12,328,767 shares of Class B-1 common stock outstanding, all with a par value of $0.01.

Amneal Pharmaceuticals, Inc.
Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018
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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net revenue	$ 476,487	$ 254,733	$ 1,165,463	$ 740,285
Cost of goods sold	276,382	119,720	642,468	365,523
Gross profit	200,105	135,013	522,995	374,762
Selling, general and administrative	78,075	27,440	156,199	82,080
Research and development	42,999	41,323	137,543	127,926
Intellectual property legal development expenses	4,401	6,693	13,024	17,786
Legal settlement gain	—	(21,467)	—	(21,467)
Acquisition, transaction-related and integration expenses	2,231	2,271	216,873	2,353
Restructuring (benefit) expenses	(2,156)	—	42,309	—
Operating income (loss)	74,555	78,753	(42,953)	166,084
Other (expense) income:				
Interest expense, net	(43,018)	(19,218)	(100,691)	(51,105)
Foreign exchange (loss) gain	(5,137)	(4,178)	(22,518)	25,751
Loss on extinguishment of debt	—	—	(19,667)	(2,531)
Loss on sale of certain international businesses	(2,812)	(28,880)	(2,812)	(28,880)
Other (expense) income	(1,014)	(93)	725	(71)
Total other expense, net	(51,981)	(52,369)	(144,963)	(56,836)
Income (loss) before income taxes	22,574	26,384	(187,916)	109,248
Provision for (benefit from) income taxes	5,109	(738)	(6,943)	2,117
Net income (loss)	17,465	27,122	(180,973)	107,131
Less: Net (income) loss attributable to Amneal Pharmaceuticals LLC pre-Combination	—	(26,780)	148,806	(106,079)
Less: Net (income) loss attributable to non-controlling interests	(10,577)	(342)	21,191	(1,052)
Net income (loss) attributable to Amneal Pharmaceuticals, Inc. before accretion of redeemable non-controlling interest	6,888	—	(10,976)	—
Accretion of redeemable non-controlling interest	64	—	(1,176)	—
Net income (loss) attributable to Amneal Pharmaceuticals, Inc.	$ 6,952	$ —	$ (12,152)	$ —
Net income (loss) per share attributable to Amneal Pharmaceuticals, Inc.'s common stockholders:				
Class A and Class B-1 basic	$ 0.05		$ (0.10)	
Class A and Class B-1 diluted	$ 0.05		$ (0.10)	
Weighted-average common shares outstanding:				
Class A and Class B-1 basic	127,247		127,196	
Class A and Class B-1 diluted	128,222		127,196	

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net income (loss)	$ 17,465	$ 27,122	$ (180,973)	$ 107,131
Less: Net (income) loss attributable to Amneal Pharmaceuticals LLC pre-Combination	—	(26,780)	148,806	(106,079)
Less: Net (income) loss attributable to non-controlling interests	(10,577)	(342)	21,191	(1,052)
Net income (loss) attributable to Amneal Pharmaceuticals, Inc. before accretion of redeemable non-controlling interest	6,888	—	(10,976)	—
Accretion of redeemable non-controlling interest	64	—	(1,176)	—
Net income (loss) attributable to Amneal Pharmaceuticals, Inc.	6,952	—	(12,152)	—
Other comprehensive (loss) income:				
Foreign currency translation adjustments	(7,939)	6,725	(8,964)	(4,219)
Less: Other comprehensive (income) loss attributable to Amneal Pharmaceuticals LLC pre- Combination	—	(6,725)	(1,721)	4,219
Less: Other comprehensive loss attributable to non-controlling interests	4,555	—	6,131	—
Other comprehensive loss attributable to Amneal Pharmaceuticals, Inc.	(3,384)	—	(4,554)	—
Comprehensive income (loss) attributable to Amneal Pharmaceuticals, Inc.	$ 3,568	$ —	$ (16,706)	$ —

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

Amneal Pharmaceuticals, Inc.
Consolidated Balance Sheets
(unaudited; in thousands, except per share amounts)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 165,192	$ 74,166
Restricted cash	7,001	3,756
Trade accounts receivable, net	641,029	351,367
Inventories	490,768	284,038
Prepaid expenses and other current assets	126,386	42,396
Related party receivables	925	16,210
Total current assets	1,431,301	771,933
Property, plant and equipment, net	567,498	486,758
Goodwill	410,616	26,444
Intangible assets, net	1,733,020	44,599
Deferred tax asset, net	365,971	898
Other assets	73,642	11,257
Total assets	$ 4,582,048	$ 1,341,889
Liabilities and Stockholders' Equity / Members' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 513,122	$ 194,779
Note payable and accrued interest-related party	78,126	—
Current portion of long-term debt and financing obligations, net	121,694	89,482
Related party payables	36,329	12,622
Total current liabilities	749,271	296,883
Long-term debt and financing obligations, net	2,675,108	1,395,261
Deferred income taxes	1,761	2,491
Liabilities under tax receivable agreement	195,820	—
Other long-term liabilities	44,769	7,793
Related party payable- long term	—	15,043
Total long-term liabilities	2,917,458	1,420,588
Commitments and contingencies (Notes 5 & 18)		
Redeemable non-controlling interest	—	—
Stockholders' equity / members' deficit:		
Members' equity, 189,000 units authorized, issued and outstanding at December 31, 2017	—	2,716
Members' accumulated deficit	—	(382,785)
Preferred stock, $0.01 par value, 2,000 shares authorized; none issued and outstanding at September 30, 2018	—	—
Class A common stock, $0.01 par value, 900,000 shares authorized; 114,974 shares issued and outstanding at September 30, 2018	1,150	—
Class B common stock, $0.01 par value, 300,000 shares authorized; 171,261 shares issued and outstanding at September 30, 2018	1,713	—
Class B-1 common stock, $0.01 par value, 18,000 shares authorized; 12,329 shares issued and outstanding at September 30, 2018	123	—
Additional paid-in capital	520,160	8,562
Stockholders' accumulated deficit	(12,152)	—
Stockholders' accumulated other comprehensive loss	(9,889)	(14,232)
Total Amneal Pharmaceuticals, Inc. stockholders' equity/ members' deficit	501,105	(385,739)
Non-controlling interests	414,214	10,157
Total stockholders' equity/ members' deficit	915,319	(375,582)
Total liabilities and stockholders' equity/ members' deficit	$ 4,582,048	$ 1,341,889

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

Amneal Pharmaceuticals, Inc.
Consolidated Statement of Changes in Stockholders' / Members' Deficit
(unaudited; in thousands)

	Members' Equity	Members' Accumulated Deficit	Preferred Stock Shares	Preferred Stock Amount	Class A Common Stock Shares	Class A Common Stock Amount	Class B Common Stock Shares	Class B Common Stock Amount	Class B-1 Common Stock Shares	Class B-1 Common Stock Amount	Additional Paid-in Capital	Stockholders' Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Non-Controlling Interests	Total Equity	Redeemable Non-Controlling Interest
Balance at January 1, 2018	**$ 2,716**	**$ (382,785)**	**—**	**$ —**	**— $**	**—**	**—**	**$ —**	**—**	**$ —**	**$ 8,562**	**$ —**	**(14,232)**	**$ 10,157**	**$ (375,582)**	**$ —**
Period Prior to the Combination															—	
Net (loss) income	—	(148,806)	—	—	—	—	—	—	—	—	—	—	—	97	(148,709)	—
Cumulative-effective adjustment from adoption of ASU 2014-09 (Topic 606)	—	4,977	—	—	—	—	—	—	—	—	—	—	—	—	4,977	—
Capital contribution from non-controlling interest	—	—	—	—	—	—	—	—	—	—	—	—	—	360	360	—
Distributions to members	—	(182,998)	—	—	—	—	—	—	—	—	(8,562)	—	—	—	(191,560)	—
PPU expense	158,757	—	—	—	—	—	—	—	—	—	—		—	—	158,757	—
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	—	—	—	1,721	—	1,721	—
Capital contribution by Amneal Holdings for employee bonuses	27,742	—	—	—	—	—	—	—	—	—	—	—	—	—	27,742	—
Period Subsequent to the Combination																
Effect of the Combination	(189,215)	709,612	—	— 73,289		733	224,996	2,250	—	—	323,589	—	9,437	626,737	1,483,143	—
Redemption of Class B Common Stock for PIPE	—	—	—	— 34,520		345	(46,849)	(468)	12,329	123	165,180	—	(1,965)	(130,501)	32,714	—
Redemption of Class B Common Stock for distribution to PPU Holders	—	—	—	—	6,886	69	(6,886)	(69)	—	—	24,293	—	(289)	(19,181)	4,823	—
Net (loss) income	—	—	—	—	—	—	—	—	—	—	—	(10,976)	—	(21,355)	(32,331)	6
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	—	—	—	(4,554)	(6,131)	(10,685)	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	5,234	—	—	—	5,234	—
Exercise of stock options	—	—	—	—	279	3	—	—	—	—	3,610	—	(7)	(444)	3,162	—
Reclassification of redeemable non-controlling interest	—	—	—	—	—	—	—	—	—	—	—	(1,176)	—	(10,532)	(11,708)	11,70
Non-controlling interests from acquisition of Gemini	—	—	—	—	—	—	—	—	—	—	—	—	—	2,518	2,518	—
Acquisition of redeemable non-controlling interest	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(11,7
Tax distribution	—	—	—	—	—	—	—	—	—	—	—	—	—	(35,543)	(35,543)	—
Other	—	—	—	—	—	—	—	—	—	—	(1,746)	—	—	(1,968)	(3,714)	—
Balance at September 30, 2018	$ —	$ —	—	$ —	114,974	$ 1,150	171,261	$ 1,713	12,329	$ 123	$ 520,160	$ (12,152)	$ (9,889)	$ 414,214	$ 915,319	$ —

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

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

	Nine Months Ended September 30, 2018	2017
Cash flows from operating activities:		
Net (loss) income	$ (180,973)	$ 107,131
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	89,910	33,094
Unrealized foreign currency loss (gain)	21,560	(27,692)
Amortization of debt issuance costs	4,220	3,895
Loss on extinguishment of debt	19,667	2,531
Loss on sale of certain international businesses	2,812	28,880
Transaction costs paid by Amneal Holdings, LLC	—	2,008
Intangible asset impairment charges	8,474	—
Deferred tax provision	(9,111)	(534)
Stock-based compensation and PPU expense	163,991	—
Inventory provision	20,755	1,510
Other operating charges and credits, net	(1,955)	431
Changes in assets and liabilities:		
Trade accounts receivable, net	(74,711)	48,468
Inventories	(53,708)	(25,186)
Prepaid expenses, other current assets and other assets	9,803	(18,604)
Related party receivables	10,828	1,397
Accounts payable, accrued expenses and other liabilities	(26,858)	5,583
Related party payables	(14,125)	6,010
Net cash (used in) provided by operating activities	(9,421)	168,922
Investing activities:		
Purchases of property, plant and equipment	(63,065)	(70,153)
Acquisition of product rights and licenses	(14,000)	(19,500)
Acquisitions, net of cash acquired	(324,634)	—
Net cash used in investing activities	(401,699)	(89,653)
Financing activities:		
Payments of deferred financing costs and debt extinguishment costs	(54,955)	(5,026)
Proceeds from issuance of debt	1,325,383	250,000
Payments of principal on debt, financing obligations and capital leases	(610,482)	(10,260)
Net borrowings on revolving credit line	25,000	25,000
Proceeds from exercise of stock options	3,162	—
Equity contributions	27,742	40
Capital contribution from non-controlling interest	360	—
Acquisition of redeemable non-controlling interest	(11,775)	—
Distributions to members	(182,998)	(355,265)
Repayment of related party note	(14,842)	—
Net cash provided by (used in) financing activities	506,595	(95,511)
Effect of foreign exchange rate on cash	(1,204)	50
Net increase (decrease) in cash, cash equivalents, and restricted cash	94,271	(16,192)
Cash, cash equivalents, and restricted cash - beginning of period	77,922	37,546
Cash, cash equivalents, and restricted cash - end of period	$ 172,193	$ 21,354
Cash and cash equivalents - end of period	$ 165,192	$ 19,348
Restricted cash - end of period	7,001	2,006
Cash, cash equivalents, and restricted cash - end of period	$ 172,193	$ 21,354
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 89,075	$ 47,968
Income taxes paid	$ 5,379	$ 4,017
Supplemental disclosure of non-cash investing and financing activity:		
Tax distribution to non-controlling interest	$ 35,543	$ —
Distribution to members	$ 8,562	$ —
Receivable from the sale of certain international businesses	$ —	$ 18,283

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

Amneal Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
(unaudited)

1. Nature of Operations and Basis of Presentation

Amneal Pharmaceuticals, Inc., formerly known as Atlas Holdings, Inc. (the "Company"), was formed along with its wholly owned subsidiary, K2 Merger Sub Corporation, a Delaware corporation ("Merger Sub"), on October 4, 2017, for the purpose of facilitating the combination of Impax Laboratories, Inc. (now Impax Laboratories, LLC), a Delaware corporation then listed on the Nasdaq Stock Market ("Impax") and Amneal Pharmaceuticals LLC, a Delaware limited liability company ("Amneal").

Amneal was formed in 2002 and operates through various subsidiaries. Amneal is a vertically integrated developer, manufacturer, and seller of generic pharmaceutical products. Amneal's pharmaceutical research includes analytical and formulation development and stability. Amneal has operations in the United States, Switzerland, India, Ireland and the United Kingdom, and certain other countries, primarily in Western Europe. Amneal sells to wholesalers, distributors, hospitals, chain pharmacies and individual pharmacies, either directly or indirectly.

On October 17, 2017, Amneal, Impax, the Company and Merger Sub entered into the Business Combination Agreement, as amended on November 21, 2017 and December 16, 2017 (the "BCA").

On May 4, 2018, pursuant to the BCA, Impax and Amneal combined the generics and specialty pharmaceutical business of Impax with the generic drug development and manufacturing business of Amneal to create the Company as a new generics and specialty pharmaceutical company, through the following transactions (together, the "Combination," and the closing of the Combination, the "Closing"): (i) Merger Sub merged with and into Impax, with Impax surviving as a direct wholly owned subsidiary of the Company, (ii) each share of Impax's common stock, par value $0.01 per share ("Impax Common Stock"), issued and outstanding immediately prior to the Closing, other than Impax Common Stock held by Impax in treasury, by the Company or by any of their respective subsidiaries, was converted into the right to receive one fully paid and non-assessable share of Class A common stock of the Company, par value $0.01 per share ("Class A Common Stock"), (iii) Impax converted to a Delaware limited liability company, (iv) the Company contributed to Amneal all of the Company's equity interests in Impax, in exchange for Amneal common units ("Amneal Common Units"), (v) the Company issued an aggregate number of shares of Class B common stock of the Company, par value $0.01 per share ("Class B Common Stock," and collectively, with the Class A Common Stock and Class B-1 common stock of the Company, par value $0.01, ("Class B-1 Common Stock"), the "Company Common Stock" to APHC Holdings, LLC, (formerly Amneal Holdings, LLC), the parent entity of Amneal as of the Closing ("Holdings"), and (vi) the Company became the managing member of Amneal.

Immediately upon the Closing, holders of Impax Common Stock prior to the Closing collectively held approximately 25% of the Company and Holdings held a majority interest in the Company with an effective voting interest of approximately 75% on a fully diluted and as converted basis through its ownership of Class B Common Stock. Holdings also held a corresponding number of Amneal Common Units, which entitled it to approximately 75% of the economic interests in the combined businesses of Impax and Amneal. The Company held an interest in Amneal of approximately 25% and became its managing member.

In connection with the Combination, on May 4, 2018, Holdings entered into definitive purchase agreements which provided for a private placement of certain shares of Class A Common Stock and Class B-1 Common Stock (the "PIPE Investment") with select institutional investors (the "PIPE Investors"). Pursuant to the terms of the purchase agreements, upon the Closing, Holdings exercised its right to cause the Company to redeem approximately 15% of its ownership interests in the Company in exchange for 34.5 million shares of Class A Common Stock and 12.3 million unregistered shares of Class B-1 Common Stock (the "Redemption"). The shares of Class A Common Stock and Class B-1 Common Stock received in the Redemption were sold immediately following the Closing by Holdings to the PIPE Investors at a per share purchase price of $18.25 for gross proceeds of $855.0 million. Following the PIPE Investment, the PIPE Investors owned collectively approximately 15% of the Company Common Stock on a fully diluted and as converted basis. On May 4, 2018, Holdings also caused Amneal to redeem (the "Closing Date Redemption") 6.9 million of Amneal Common Units held by Holdings for a like number of shares of Class A Common Stock, for future distribution to certain direct and indirect members of Holdings who were or are employees of the Company and to whom were previously issued (prior to the Closing) profit participation units ("PPUs") in Amneal. As a result of the PIPE Investment and Closing Date Redemption, the voting and economic interest of approximately 75% held by Holdings immediately upon Closing was reduced by approximately 18%. The overall interest percentage held by non-controlling interest holders upon the consummation of the Combination, PIPE Investment and Closing Date Redemption was approximately 57%. As of September 30, 2018, the overall interest percentage held by non-controlling interest holders was approximately 57%.

On July 5, 2018, Holdings distributed to its members all Amneal Common Units and shares of Class B Common Stock held by Holdings. As a result, as of September 30, 2018, Holdings did not hold any equity interest in Amneal or the Company. The members of Holdings to whom Amneal Common Units and shares of Class B Common Stock were distributed are hereinafter referred to as the "Amneal Group."

The Company is a holding company, whose principal assets are Amneal Common Units.

The accompanying unaudited consolidated financial statements should be read in conjunction with Amneal's annual financial statements for the year ended December 31, 2017 included in the Company's Registration Statement on Form S-1, as amended, filed with the Securities and Exchange Commission on May 7, 2018. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with generally accepted accounting principles in the U.S. ("U.S. GAAP") have been omitted from the accompanying unaudited consolidated financial statements. In the opinion of the Company, the accompanying unaudited consolidated financial statements contain all adjustments, consisting of only normal recurring adjustments, necessary for a fair statement of its financial position as of September 30, 2018, and its results of operations and comprehensive income (loss) for the three and nine months ended September 30, 2018 and 2017, and changes in stockholders'/ members' deficit and cash flows for the nine months ended September 30, 2018 and 2017. The consolidated balance sheet at December 31, 2017 was derived from audited annual financial statements but does not contain all of the footnote disclosures from the annual financial statements.

2. Summary of Significant Accounting Policies

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 control its management. Therefore, the Company consolidates the financial statements of Amneal and its subsidiaries. The Company's consolidated financial statements are a continuation of Amneal's financial statements, with adjustments to equity to reflect the Combination, the PIPE and non-controlling interests for the portion of Amneal's economic interests that is not held by the Company. Prior to the closing of the Combination and PIPE, the Company did not conduct any activities other than those incidental to the formation of it and Merger Sub and the matters contemplated by the BCA and had no operations and no material assets or liabilities.

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, bill backs, allowances for accounts receivable, accrued liabilities, 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

On January 1, 2018, the Company adopted Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers and associated ASUs (collectively "Topic 606"), which sets forth a new five-step revenue recognition model which replaces the prior revenue recognition guidance in its entirety and is intended to eliminate numerous industry-specific sections of revenue recognition guidance that have historically existed.

When assessing its revenue recognition, the Company performs the following five steps in accordance with Topic 606: (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. For further details on the Company's revenue recognition policies under Topic 606, refer to Note 4. Revenue Recognition.

A rollforward of the major categories of sales-related deductions for the nine months ended September 30, 2018 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 January 1, 2018	$ 453,703	$ 20,408	$ 45,175	$ 12,911
Liabilities assumed from acquisitions	221,561	11,781	98,533	49,743
Provision related to sales recorded in the period	2,372,877	81,208	52,444	78,073
Credits issued during the period	(2,422,623)	(83,721)	(56,454)	(51,785)
Balance at September 30, 2018	$ 625,518	$ 29,676	$ 139,698	$ 88,942

Stock-Based Compensation

The Company's stock-based compensation consists of stock options and restricted stock units ("RSUs") 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 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 RSU vestings.

Foreign Currencies

The Company has operations in the U.S., Switzerland, India, the U.K., Ireland, and other international jurisdictions. 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. Investment accounts are translated at historical exchange rates. Translation adjustments are accumulated in a separate component of stockholders'/members' deficit in the consolidated balance sheet and are included in the determination of comprehensive income. Transaction gains and losses are included in the determination of net income (loss) in the Company consolidated statements of operations as a component of foreign exchange gains and losses. Such foreign currency transaction gains and losses include fluctuations related to long term intercompany loans that are payable in the foreseeable future.

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 foreign 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 ("FDIC").

Restricted Cash

At September 30, 2018 and December 31, 2017, respectively, the Company had restricted cash balances of $7.0 million and $3.8 million in its bank accounts primarily related to the purchase of certain land and equipment.

Accounts Receivable and Allowance for Doubtful Accounts

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is management's best estimate of the amount of probable collection losses in the Company's existing accounts receivable. Management determines the allowance based on historical experience along with the present knowledge of potentially uncollectible accounts. 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.

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	7 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.

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 on a straight-line basis over its estimated useful life. 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.

The impairment model prescribes a two-step method for determining goodwill impairment. However, an entity is permitted to first assess qualitative factors to determine whether the two-step goodwill impairment test 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. In the first step, the Company determines the fair value of its reporting unit using a discounted cash flow analysis. If the net book value of the reporting unit exceeds its fair value, the Company then performs the second step of the impairment test, which requires allocation of the reporting unit's fair value to all of its assets and liabilities using the acquisition method prescribed under authoritative guidance for business combinations with any residual fair value being allocated to goodwill. An impairment charge is recognized when the implied fair value of the Company's reporting unit's goodwill is less than its carrying amount.

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.

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.

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.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740, Accounting for Income Taxes ("ASC 740"), 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 Income (Loss)

Comprehensive income (loss) includes net income and all changes in equity for cumulative translation adjustments resulting from the consolidation of foreign subsidiaries' financial statements.

Research and Development

Research and development ("R&D") activities are expensed as incurred. Primarily R&D costs 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 $6.1 million and $14.7 million for the three and nine months ended September 30, 2018, respectively. Shipping costs were $3.2 million and $6.5 million for the three and nine months ended September 30, 2017, respectively.

Reclassifications

Certain prior period balances have been reclassified to conform to the current period presentation, including combining depreciation and amortization expense into the respective cost of goods sold, selling, general and administrative and research and development expense presentation on the consolidated statements of operations, as well as combining accounts payable and accrued expenses and combining long-term debt, financing obligations and revolving credit facility in the balance sheet presentation.

Recently Adopted Accounting Pronouncements

In May 2017, the FASB issued Accounting Standards Update ("ASU") 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*, which provides guidance about which changes to the terms or conditions of a stock-based payment award require an entity to apply modification accounting in Topic 718. The guidance will be effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted. The amendments in this ASU should be applied prospectively to an award modified on or after the adoption date. The Company adopted ASU 2017-09 on January 1, 2018 and it did not have an effect on the Company's consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash (a consensus of the FASB Emerging Issues Task Force)*, to clarify how entities should present restricted cash and restricted cash equivalents in the statement of cash flows. The guidance requires entities to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows.

As a result, entities will no longer present transfers between cash and cash equivalents and restricted cash and restricted cash equivalents in the statement of cash flows. The guidance should be applied retrospectively and is effective for the annual period beginning after December 15, 2018. The Company early adopted ASU 2016-18 on January 1, 2018. This guidance was applied retrospectively and, accordingly, prior period amounts have been revised.

In October 2016, the FASB issued ASU 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory*, that will require companies to account for the income tax effects of intercompany transfers of assets other than inventory (e.g., intangible assets) when the transfer occurs. The guidance is effective for annual periods beginning after December 15, 2018 and interim periods within annual periods beginning after December 15, 2019. Early adoption is permitted as of the beginning of an annual period (i.e., early adoption is permitted only in the first interim period). The Company early adopted ASU 2016-16 on January 1, 2018 and it did not have an effect on the Company's consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force)*, to clarify how entities should classify certain cash receipts and cash payments on the statement of cash flows. The new guidance also clarifies how the predominance principle should be applied when cash receipts and cash payments have aspects of more than one class of cash flows. The guidance will be applied retrospectively and is effective for the Company for the annual period beginning after December 15, 2018. Early adoption is permitted. The Company early adopted ASU 2016-15 on January 1, 2018 and it did not have an effect on the Company's consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers.* Subsequent to the issuance of Topic 606, the FASB clarified the guidance through several Accounting Standard Updates. This guidance represents a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which that company expects to be entitled to receive in exchange for those goods or services. This update sets forth a new five-step revenue recognition model which replaces the prior revenue recognition guidance in its entirety and is intended to eliminate numerous industry-specific pieces of revenue recognition guidance that have historically existed.

On January 1, 2018, the Company adopted Accounting Standards Codification ("ASC") 2014-09 and associated ASU's (collectively "Topic 606"), using the modified retrospective method, applied to all contracts not completed as of the date of adoption. This method requires the cumulative effect of the adoption to be recognized as an adjustment to opening retained earnings in the period of adoption.

The Company recorded a $5.0 million reduction to accumulated deficit as of January 1, 2018 due to the cumulative impact of adoption Topic 606. There is an acceleration of revenue for certain product sale arrangements which are designed to include profit share payments upon the customer's sell-through of certain products purchased from the Company. Previously under Topic 605, the Company deferred revenue until its customers sold the product through to their end customers, at which point the Company considered the profit share payments to be earned and collection reasonably assured. Under Topic 606, an estimate of the profit share payments is included in the transaction price as variable consideration and is recognized at the time the Company transfers control of the product to its customer. This change resulted in a cumulative-effect adjustment upon adoption of the ASU as of January 1, 2018 which was not material to the financial statements. In the second quarter of 2018, the Company made a correction to the cumulative impact adjustment as of January 1, 2018 by reducing accumulated deficit by $1.7 million. The Company does not believe that this adjustment is material to its financial statements and it had no impact on any prior periods. Refer to Note 4. Revenue Recognition for additional disclosures required by Topic 606.

Recently Issued Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 82): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which modifies the disclosure requirements on fair value measurement. The guidance is effective for annual periods beginning after December 15, 2019 and interim periods within those annual periods, and early adoption is permitted. The Company is currently evaluating the impact that the standard will have on its consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, *Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* that eliminates the requirement to calculate the implied fair value of goodwill (i.e., Step 2 of today's goodwill impairment test) to measure a goodwill impairment charge. Instead, entities will record an impairment charge based on the excess of a reporting unit's carrying amount over its fair value (i.e., measure the charge based on today's Step 1). The standard will be applied prospectively and is effective for the Company's annual and interim impairment tests performed in periods beginning after December 15, 2019. Early adoption is permitted for annual and interim goodwill impairment testing dates after January 1, 2017. The Company is evaluating the impact of this new guidance on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, guidance that changes the impairment model for most financial assets including trade receivables and certain other instruments that are not measured at fair value through net income. The standard will replace today's "incurred loss" approach with an "expected loss" model for instruments measured at amortized cost and require entities to record allowances for available-for-sale debt securities rather than reduce the carrying amount, as they do today under the other-than-temporary impairment model. It also simplifies the accounting model for purchased credit-impaired debt securities and loans. Entities will apply the standard's provisions as a cumulative effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. The guidance is effective for the Company for the annual period beginning after December 15, 2019. The Company is evaluating the impact of this new guidance on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* to improve financial reporting of leasing transactions. Topic 842 requires lessees to recognize most leases on their balance sheet, makes selected changes to lessor accounting and requires disclose of additional key information about leases. In July 2018, the FASB issued clarifying guidance to the topic in ASU No. 2018-11 and No. 2018-10, "Leases (Topic 842)," which defined several practical expedients for adoption and clarified new accounting methodologies. The standard is effective for annual and interim reporting periods beginning after December 15, 2018. The Company will adopt Topic 842 on a modified retrospective basis, applying the transition requirements as of January 1, 2019.

As part of the Company's impact assessment, it has performed an initial scoping exercise and preliminarily determined its lease population. A framework for the lease identification process has been developed and the Company is currently evaluating the lease population to determine its transition adjustment. Additionally, the Company is in the process of assessing any potential impacts on its internal controls and processes related to both the implementation and ongoing compliance of the new guidance. The Company is assessing the impact of the practical expedients, but anticipates electing to apply them. The Company plans to adopt the new guidance using a modified retrospective approach and upon adoption, there will be an increase to the Company's long-term assets and liabilities as a result of its minimum lease obligations.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments—Overall (Subtopic 825-10), Recognition and Measurement of Financial Assets and Financial Liabilities*, which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. The guidance is effective for annual periods and interim periods within those annual periods beginning after December 15, 2018, and early adoption is not permitted. The Company is currently evaluating the impact that the standard will have on its consolidated financial statements.

3. Acquisitions and Divestitures

Acquisitions

Impax Acquisition

On May 4, 2018, the Company completed the Combination, as described in Note 1. Nature of Operations and Basis of Presentation. For the nine months ended September 30, 2018, transaction costs associated with the Impax acquisition of $23.3 million were recorded in acquisition, transaction-related and integration expenses (none for the three months ended September 30, 2018).

The Impax acquisition was accounted for under the acquisition method of accounting, with Amneal as the accounting acquirer of Impax. Amneal was identified as the accounting acquirer because: (i) Amneal exchanged Amneal Common Units with the Company for the Company's interest in Impax, (ii) Holdings held a majority interest in the Company with an effective voting interest of approximately 75% on a fully diluted and as converted basis through their ownership of Class B Common Stock, and (iii) a majority of the directors on the Company's current board of directors were designated by Holdings. As such, the cost to acquire Impax was allocated to the respective assets acquired and liabilities assumed based on their estimated fair values as of the closing date of the Combination.

The measurement of the consideration transferred by Amneal for its interest in Impax is based on the fair value of the equity interest that Amneal would have had to issue to give the Impax shareholders the same percentage equity interest in the Company, which is equal to approximately 25% of Amneal, on May 4, 2018. However, the fair value of Impax's common stock was used to calculate the consideration for the Combination because Impax's common stock had a quoted market price and the Combination involved only the exchange of equity.

The purchase price, net of cash acquired, is calculated as follows (in thousands, except share amount and price per share):

Fully diluted Impax share number (1)	73,288,792
Closing quoted market price of an Impax common share on May 4, 2018	$ 18.30
Equity consideration—subtotal	$ 1,341,185
Add: Fair value of Impax stock options as of May 4, 2018 (2)	22,610
Total equity consideration	1,363,795
Add: Extinguishment of certain Impax obligations, including accrued and unpaid interest	320,290
Less: Cash acquired	(37,907)
Purchase price, net of cash acquired	$ 1,646,178

(1) Represents shares of Impax Common Stock issued and outstanding immediately prior to the Combination
(2) Represents the fair value of 3.0 million fully vested Impax stock options valued using the Black-Scholes options pricing model.

The following is a summary of the preliminary purchase price allocation for the Impax acquisition (in thousands):

	Preliminary Fair Values As of September 30, 2018
Trade accounts receivable, net	$ 206,749
Inventories	186,498
Prepaid expenses and other current assets	91,430
Property, plant and equipment	87,472
Goodwill	384,905
Intangible assets	1,584,488
Other	56,652
Total assets acquired	2,598,194
Accounts payable	47,912
Accrued expenses and other current liabilities	270,911
Long-term debt	599,400
Other long-term liabilities	33,793
Total liabilities assumed	952,016
Net assets acquired	$ 1,646,178

Intangible Assets

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

	Preliminary Fair Values	Weighted-Average Useful Life (Years)
Marketed product rights	$ 1,045,617	12.9

In addition to the amortizable intangible assets noted above, $538.9 million was allocated to IPR&D, which is currently not subject to amortization.

The estimated fair value of the in-process research and development 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 preliminary purchase price allocation and in determining the purchase price were based on management's best estimates as of the closing date of the Combination on May 4, 2018.

Some of the more significant assumptions inherent in the development of those asset valuations include the estimated net cash flows for each year for each asset or product (including net revenues, cost of sales, research and development costs, 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. No assurances can be given that the underlying assumptions used to prepare the discounted cash flow analysis will not change. For these and other reasons, actual results may vary significantly from estimated results.

Goodwill

Of the total goodwill acquired in connection with the Impax acquisition, approximately $360 million has been allocated to the Company's Specialty Pharma segment and approximately $25 million has been allocated to the Generic Segment. Goodwill is calculated as the excess of the consideration transferred over the net assets recognized and represents the expected revenue and cost synergies of the combined company. Factors that contributed to the Company's recognition of goodwill include the Company's intent to expand its generic and specialty product portfolios and to acquire certain benefits from the Impax product pipelines, in addition to the anticipated synergies that the Company expects to generate from the acquisition.

Gemini Laboratories, LLC Acquisition

On May 7, 2018, the Company acquired 98.0% of the outstanding equity interests in Gemini Laboratories, LLC ("Gemini") for total consideration of $119.5 million, net of $3.9 million cash acquired. At closing, the acquisition was funded by a $42.9 million up-front cash payment (including $2.9 million related to a preliminary working capital adjustment) from cash on hand and a $77.2 million unsecured promissory note. The note payable bears interest at 3% annually. The note payable and related accrued interest was paid on November 7, 2018, its maturity date. Additionally, the Company made a payment of $3.3 million in July 2018 related to the final working capital adjustment. In connection with the acquisition of Gemini, the Company recorded an amount representing the non-controlling interest of Gemini of $2.5 million.

Gemini is a pharmaceutical company with a portfolio that includes licensed and owned, niche and mature branded products, and a pipeline of 505(b)(2) products for niche therapeutic areas. Gemini was a related party of the Company; refer to Note 21. Related Party Transactions for further details.

For the nine months ended September 30, 2018, transaction costs associated with the Gemini acquisition of $0.4 million were recorded in acquisition, transaction-related and integration expenses (none for the three months ended September 30, 2018). The Gemini acquisition was accounted for under the acquisition method of accounting.

The following is a summary of the preliminary purchase price allocation for the Gemini acquisition (in thousands):

	Preliminary Fair Values As of September 30, 2018
Trade accounts receivable, net	$ 8,158
Inventories	1,851
Prepaid expenses and other current assets	3,795
Property, plant and equipment, net	11
Goodwill	1,500
Intangible assets	142,740
Other	324
Total assets acquired	158,379
Accounts payable	1,764
Accrued expenses and other current liabilities	14,644
License liability	20,000
Total liabilities assumed	36,408
Net assets acquired	$ 121,971

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

	Preliminary Fair Values	Weighted-Average Useful Life
Product rights for licensed / developed technology	$ 110,350	10 years
Product rights for developed technologies	5,500	9 years
Product rights for out-licensed generics royalty agreement	390	2 years
	$ 116,240	

In addition to the amortizable intangibles noted above, $26.5 million was allocated to IPR&D, which is currently not subject to amortization.

The goodwill recognized of $1.5 million is allocated to the Company's Specialty Pharma segment.

The Company makes an initial allocation of the purchase price at the date of acquisition based upon its understanding of the fair value of the acquired assets and assumed liabilities. The Company obtains this information during due diligence and through other sources. In the months after closing, as the Company obtains additional information about these assets and liabilities and learns more about the newly acquired business, it is able to refine the estimates of fair value and more accurately allocate the purchase price. Only items identified as of the acquisition date are considered for subsequent adjustment. The Company is continuing to evaluate certain pre-acquisition contingencies associated with its 2018 acquisitions. The Company will make appropriate adjustments to the purchase price allocation prior to completion of the measurement period, as required.

The Company's consolidated statements of operations for the three and nine months ended September 30, 2018 include the results of operations of Impax and Gemini subsequent to May 4, 2018 and May 7, 2018, respectively. For the three months ended September 30, 2018, Impax contributed net revenue of $177.5 million and estimated losses of $8.8 million and Gemini contributed net revenue of $13.4 million and estimated income of $3.0 million. For the periods from their respective acquisition dates to September 30, 2018, Impax contributed net revenue of $295.8 million and estimated losses of $64.7 million and Gemini contributed net revenue of $18.4 million and estimated income of $4.0 million. The unaudited pro forma combined results of operations for the three and nine months ended September 30, 2018 and 2017 (assuming the closing of the Combination occurred on January 1, 2017) are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net revenue	$ 476,487	$ 461,125	$ 1,341,555	$ 1,333,162
Net income (loss)	$ 17,465	$ (29,975)	$ (143,585)	$ (370,286)
Net income (loss) attributable to Amneal Pharmaceuticals, Inc.	$ 6,952	$ (3,374)	$ (21,502)	$ (145,065)

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 Combination taken place on January 1, 2017. Furthermore, the pro forma results do not purport to project the future results of operations of the Company.

The unaudited pro forma information reflects primarily the following non-recurring adjustments (all of which were adjusted for the applicable tax impact):

- Adjustments to costs of goods sold related to the inventory acquired; and
- Adjustments to selling, general and administrative expense related to transaction costs directly attributable to the transactions.

Divestitures

Australia Divestiture

On August 31, 2017, Amneal sold 100% of the equity of its Australian business, Amneal Pharma Pty Ltd, to Arrow Pharmaceuticals Pty Ltd (“Arrow”) for cash consideration of $9.9 million which was received in October 2017. The consideration received was subject to certain working capital adjustments. The carrying value of the net assets sold was $31.7 million, including intangible assets of $13.9 million and goodwill of $1.9 million. As a result of the sale, Amneal recognized a loss of $23.7 million, inclusive of divestiture costs of $1.5 million and a release of foreign currency translation adjustment loss of $0.4 million, within the loss on sale of certain international businesses for the three and nine months ended September 30, 2017.

As part of the disposition, Amneal agreed to indemnify Arrow for certain claims for up to 18 months from the closing date of the disposition. Additionally, Amneal will allow Arrow to use the Amneal trademark in Australia to enable Arrow to transfer the labeling and marketing authorizations from the Amneal name to the Arrow name for a period of three years. Amneal will supply Arrow with Linezolid for a period of three years and will further develop four other products for sale in Australia during the three years period. All terms of the sale were settled in 2018.

Spain/Nordics Divestitures

On September 30, 2017, Amneal sold 100% of the equity and certain marketing authorizations, including associated dossiers, of its Amneal Nordic ApS and Amneal Pharma Spain S.L. subsidiaries to Aristo Pharma GmbH (“Aristo”) for cash consideration of $8.4 million. Amneal received $6.5 million in October 2017 and the remainder was to be paid within 60 days of closing of the disposition based on the actual closing date net working capital of the entities sold. The carrying value of the net assets sold was $13.1 million, including intangible assets of $0.9 million and goodwill of $1.7 million. As a result of the sale, Amneal recognized a loss of $5.2 million, inclusive of a release of foreign currency translation adjustment loss of $0.5 million, within the loss on sale of certain international businesses for the three and nine months ended September 30, 2017.

Aristo was also required to make an additional payment within 12 months of the closing date of the disposition based on the actual inventory, transferred as part of the transaction, that the buyer sold over this period. Aristo has disputed the amounts owed for the working capital adjustment and the additional payment related to inventory.

4. Revenue Recognition

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 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 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.

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, 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 estimates its variable consideration using the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts, and represents the method that best predicts the amount of consideration to which the Company will be entitled to for transferring its products to its customers. 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 and historical chargeback rates. 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 and historical billback rates. 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 upon 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.

Concentration of Revenue

The Company's three largest customers account for approximately 83% of total gross sales of products for the three months ended September 30, 2018 and 82% for the nine months ended September 30, 2018. The Company's three largest customers account for approximately 79% of total gross sales of products for the three months ended September 30, 2017 and 79% of total gross sales of products for the nine months ended September 30, 2017.

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 research and development services over multiple periods. The Company's significant arrangements are discussed below.

Levothyroxine License and Supply 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"). The Company will be JSP's exclusive commercial partner in the U.S. market for a 10-year term commencing on March 22, 2019. The Company will be required to make a payment of $50.0 million to JSP upon the Company's first sale of Levothyroxine. The Company will be required to make an additional $20.0 million payment to JSP if the Food and Drug Administration ("FDA") has not given final approval to a third-party competitor's abbreviated new drug application for generic levothyroxine sodium tablets with an AB1, AB2, AB3 or AB4 designation by the first anniversary date of the Company's first sale of Levothyroxine. In addition, the agreement 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. For the three and nine months ended September 30, 2018, the Company has made no payments under this agreement.

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 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 $71.8 million. For the nine months ended September 30, 2018, the Company expensed a milestone payment of $0.5 million in research and development expense. There were no milestone payments expensed for the three months ended September 30, 2018.

License and Commercialization Agreement

On October 1, 2017, Amneal and Adello Biologics, LLC ("Adello"), a related party, entered into a license and commercialization agreement. Adello granted Amneal an exclusive license, under its New Drug Application, to distribute and sell two bio-similar products in the U.S. Adello 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.

In connection with the agreement, Amneal paid an upfront amount of $1.5 million in October 2017 for execution of the agreement which was expensed in research and development expenses. The agreement also provides for potential future milestone payments to Adello of (i) up to $21.0 million relating to regulatory approval, (ii) up to $43.0 million for successful delivery of commercial launch inventory, (iii) between $20.0 million and $50.0 million relating to number of competitors at launch for one product, and (iv) between $15 million and $67.5 million for the achievement of cumulative net sales for both products. The milestones are subject to certain performance conditions which may or may not be achieved, including FDA filing, FDA approval, launch activities and 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. The research and development expenses for payments made to Adello during the three and nine months ended September 30, 2018 and 2017 were immaterial.

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 provides 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 and through the quarter ended December 31, 2020. In the event the royalty reduction amounts exceed the royalty payments payable by Impax to AstraZeneca pursuant to the AZ Agreement in any given quarter, AstraZeneca will be 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 may be terminated, without penalty, under certain circumstances as set forth in the AZ Amendment. The Company recognizes the amounts received from AstraZeneca for the PREA Study as a reduction to research and development expense.

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. 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 is reduced by certain specified amounts beginning from the quarter ended June 30, 2016 and 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 sales for royalties under this agreement of $5.1 million and $8.1 million for the three and nine months ended September 30, 2018, respectively.

6. Restructuring and Other Charges

Restructuring Charges

During the second quarter of 2018, in connection with the Combination, the Company committed to a restructuring plan to achieve cost savings. The Company expects to integrate its operations and reduce its combined cost structure through workforce reductions that eliminate duplicative positions and the consolidation of certain administrative, manufacturing and research and development facilities. In connection with this plan, the Company announced on May 10, 2018 that it will close its Hayward, California based operations (the "Plan"). Employee separation charges include the cost of benefits provided pursuant to the Company's severance programs for employees at the Company's Hayward facility and other facilities.

The Company recorded a $2.2 million net benefit, primarily related to changes in estimates for certain employee-related separation liabilities, for the three months ended September 30, 2018. The Company recorded employee separation charges of $42.3 million for the nine months ended September 30, 2018. There were no restructuring charges in 2017.

The charges related to restructuring impacted segment earnings as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Generic	(2,885)	$ —	21,912	$ —
Specialty	(27)	—	2,394	—
Corporate	756	—	18,003	—
Total restructuring charges	$ (2,156)	$ —	$ 42,309	$ —

The following table shows the change in the employee separation-related liability associated with the Company's restructuring programs (in thousands):

	Employee Separation
Balance at December 31, 2017	$ —
Liabilities assumed in Impax acquisition	2,199
Charges to income	45,405
Change in estimated liability	(3,096)
Payments	(18,079)
Balance at September 30, 2018	$ 26,429

As of September 30, 2018, the Company currently estimates that it will incur additional aggregate cash expenditures of approximately $35.0 million to $45.0 million related to severance and other employee costs in connection with the Plan over the next 15 months. Since the Company is in the early stages of implementing the Plan, the amount and timing of any cash expenditures related to dismantling and asset removal and other site exit costs cannot be estimated at this time. As the Plan is implemented, the Company's management will reevaluate the estimated expenses and charges set forth above and may revise its estimates, as appropriate.

7. Acquisition, Transaction-Related and Integration Expenses

The following table sets forth the components of the Company's acquisition, transaction-related and integration expenses for the three and nine months ended September 30, 2018 and 2017.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Acquisition, transaction-related and integration expenses [1]	$ 2,231	$ 2,271	$ 30,374	$ 2,353
Profit Participation Units [2]	—	—	158,757	—
Transaction-related bonus [3]	—	—	27,742	—
Total	$ 2,231	$ 2,271	$ 216,873	$ 2,353

1 Acquisition, transaction-related and integration expenses include professional service fees (e.g. legal, investment banking and accounting), information technology systems conversions, and contract termination/renegotiation costs.

2 Profit Participation Units expense relates to the accelerated vesting of certain of Amneal's profit participation units that occurred prior to the Closing of the Combination for current and former employees of Amneal for service prior to the Combination (see additional information in the paragraph below and Note 19. Stockholders' Equity/ Members' Deficit).

3 Transaction-related bonus is a cash bonus that was funded by Holdings for employees of Amneal for service prior to the closing of the Combination (see additional information in Note 19. Stockholders' Equity/ Members' Deficit).

Accelerated Vesting of Profit Participation Units

Amneal's historical capital structure included several classifications of membership and profit participation units. During the second quarter of 2018, the Board of Managers of Amneal Pharmaceuticals LLC approved a discretionary modification to certain profit participation units concurrent with the Combination that immediately caused the vesting of all profit participation units that were previously issued to certain current or former employees for service prior to the Combination. The modification entitled the holders to 6,886,140 shares of Class A Common Stock with a fair value of $126.0 million on the date of the Combination and $32.8 million of cash. The cash and shares were distributed by Holdings with no additional shares issued by the Company. As a result of this transaction, the Company recorded a charge in acquisition, transaction-related and integration expenses and a corresponding capital contribution of $158.8 million for the nine months ended September 30, 2018.

8. Income taxes

As a result of the Combination (refer to Note 1. Nature of Operations and Basis of Presentation), the Company became the sole managing member of Amneal, with Amneal being the predecessor for accounting purposes. The operations of Amneal are conducted through a limited liability company that is treated as a partnership for U.S. federal and for 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. Additionally, Amneal provides for income taxes in the various foreign jurisdictions in which it operates.

In connection with the Combination, the Company recorded a deferred tax asset for its outside basis difference in its investment in Amneal which was $305.4 million at May 4, 2018. Also, in connection with the Combination, the Company recorded a deferred tax asset of $52.0 million related to the net operating loss of Impax from January 1, 2018 through May 4, 2018 as well as certain federal and state credits of Impax that were attributable to the Company.

The Company records a valuation allowance against its deferred tax assets to reduce the net carrying value to an amount that it believes is more likely than not to be realized. As of September 30, 2018, the Company concluded, based on the weight of all available positive and negative evidence, those deferred tax assets recorded as part of the Combination are more likely than not to be realized. As such, no valuation allowance was recognized. The Company maintains a valuation allowance against Amneal's foreign jurisdiction tax attributes.

In connection with the Combination, the Company entered into a tax receivable agreement ("TRA") for which it is 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 the Company deemed to realize as a result of certain tax attributes of their Amneal 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 Units for shares of Class A common stock and (ii) tax benefits attributable to payments made under the tax receivable agreement (including imputed interest). In connection with the exchanges which occurred as part of the PIPE Investment and the Closing Date Redemption (Note 1. Nature of Operations and Basis of Presentation), the Company recorded a TRA liability of $195.8 million. Such amounts will be paid when such deferred tax assets are realized as a reduction to income taxes due or payable.

The Company's provision for (benefit from) income taxes and effective tax rates were $5.1 million and 22.6% and $(0.7) million and 2.8% for the three months ended September 30, 2018 and 2017, respectively. For the nine months ended September 30, 2018 and 2017, the Company's (benefit from) provision for income taxes and effective tax rates were $(6.9) million and 3.7% and $2.1 million and 1.9%, respectively.

The primary change in the (benefit from) provision is due to only certain limited liability company entity-level taxes and foreign taxes being recorded for Amneal prior to the Combination. Subsequent to May 4, 2018, federal income taxes were also provided related to the Company's allocable share of income (losses) from Amneal at the prevailing U.S. federal, state, and local corporate income tax rates.

On December 22, 2017, the Tax Cuts and Jobs Act was enacted in the United States, which significantly reforms U.S. tax legislation. In December 2017, the SEC staff issued Staff Accounting Bulletin ("SAB") 118, which provides a measurement period that should

not extend beyond one year from the enactment date for companies to complete the accounting for the effects of the Tax Cuts and Jobs Act. The Company will continue to evaluate the legislative changes during the measurement period allowed under SAB 118.

Given the complexity of the global intangible low-taxed income ("GILTI") provisions, the Company is still evaluating the effects of the GILTI provisions and has not yet determined its accounting policy. The Company's accounting policy election with respect to the new GILTI Tax rules will depend, in part, on analyzing global income to determine whether a reasonable estimate can be made. While the Company currently does not believe GILTI will have a material impact on its 2018 income tax provision, the Company has not completed its analysis and has not determined which method to elect. Adjustments related to the amount of GILTI tax recorded in the Company's consolidated financial statements may be required based on the outcome of this election.

9. Earnings per Share

Basic earnings per share of Class A Common Stock and Class B-1 Common Stock is computed by dividing net income (loss) attributable to Amneal Pharmaceuticals, Inc. by the weighted-average number of shares of Class A Common Stock and Class B-1 Common Stock outstanding during the period. Diluted earnings per share of Class A Common Stock and Class B-1 Common Stock is computed by dividing net income (loss) attributable to Amneal Pharmaceuticals, Inc. by the weighted-average number of shares of Class A Common Stock and Class B-1 Common Stock outstanding, 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 earnings per share of Class A Common Stock and Class B-1 Common Stock (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator:				
Net income (loss) attributable to Amneal Pharmaceuticals, Inc.	$ 6,952	$ —	$ (12,152)	$—
Denominator:				
Weighted-average shares of Class A Common Stock and Class B-1 Common Stock outstanding-basic	127,247		127,196	
Effect of dilutive securities:				
Stock options	661		—	
Restricted stock units	314		—	
Weighted-average shares of Class A Common Stock and Class B-1 Common Stock outstanding-diluted	128,222		127,196	
Net income (loss) per share attributable to Amneal Pharmaceuticals, Inc.'s common stockholders:				
Class A and Class B-1 basic	$ 0.05		$ (0.10)	
Class A and Class B-1 diluted	$ 0.05		$ (0.10)	

The allocation of net loss to the holders of shares of Class A Common Stock and Class B-1 Common Stock began following the closing of the Combination on May 4, 2018. 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 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 earnings per share of Class A Common Stock and Class B-1 Common Stock (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Stock options	965(1)	—	5,862(2)	—
Restricted stock units	—	—	1,324(2)	—
Shares of Class B Common Stock	171,261(3)	—	171,261(3)	—

(1) Excluded from the computation of diluted earnings per share of Class A Common Stock and Class B-1 Common Stock 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).

(2) Excluded from the computation of diluted earnings per share of Class A Common Stock and Class B-1 Common Stock because the effect of their inclusion would have been anti-dilutive since there was a net loss attributable to the Company for the nine months ended September 30, 2018.

(3) Shares of Class B Common Stock are considered potentially dilutive shares of Class A Common Stock and Class B-1 Common Stock. Shares of Class B Common Stock have been excluded from the computations of diluted earnings per share of Class A Common Stock and Class B-1 Common Stock because the effect of their inclusion would have been anti-dilutive under the if-converted method.

10. Trade Accounts Receivable, Net

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

	September 30, 2018	December 31, 2017
Gross accounts receivable	$ 1,298,867	$ 827,302
Allowance for doubtful accounts	(2,644)	(1,824)
Contract charge-backs and sales volume allowances	(625,518)	(453,703)
Cash discount allowances	(29,676)	(20,408)
Subtotal	(657,838)	(475,935)
Trade accounts receivable, net	$ 641,029	$ 351,367

Receivables from customers representing 10% or more of the Company’s gross trade accounts receivable reflected three customers at September 30, 2018, equal to 33%, 27%, and 26%, respectively. Receivables from customers representing 10% or more of the Company’s gross trade accounts receivable reflected three customers at December 31, 2017, equal to 36%, 27%, and 19%, respectively.

11. Inventories

Inventories, net of reserves, are comprised of the following (in thousands):

	September 30, 2018	December 31, 2017
Raw materials	$ 205,144	$ 140,051
Work in process	51,068	38,146
Finished goods	234,556	105,841
Inventories	$ 490,768	$ 284,038

12. Prepaid Expenses and Other Current Assets

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

	September 30, 2018	December 31, 2017
Deposits and advances	$ 1,617	$ 1,851
Prepaid insurance	7,069	3,154
Prepaid regulatory fees	701	5,926
Income tax receivable	74,782	—
Other current receivables	18,363	15,150
Other prepaid assets	23,854	16,315
Total prepaid expenses and other current assets	$ 126,386	$ 42,396

13. Property, Plant, and Equipment

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

	September 30, 2018	December 31, 2017
Land	$ 17,892	$ 5,275
Buildings	233,478	227,864
Leasehold improvements	100,322	70,354
Machinery and equipment	308,718	260,637
Furniture and fixtures	10,508	18,415
Vehicles	1,385	1,517
Computer equipment	34,599	26,831
Construction-in-progress	53,665	32,235
Total property, plant, and equipment	760,567	643,128
Less: Accumulated depreciation	(193,069)	(156,370)
Property, plant, and equipment, net	$ 567,498	$ 486,758

Depreciation recognized and interest capitalized and included in property, plant, and equipment by the Company is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Depreciation	$17,358	$10,680	$45,801	$30,043

Interest capitalized and included in property, plant, and equipment by the Company during the three months ended September 30, 2018 and 2017 was $0.1 million and $1.1 million, respectively. Interest capitalized and included in property, plant, and equipment by the Company during the nine months ended September 30, 2018 and 2017 was $0.5 million and $4.1 million, respectively.

14. Goodwill and Intangible Assets

The changes in goodwill for the nine months ended September 30, 2018 and for the year ended December 31, 2017 were as follows (in thousands):

	For the nine months ended September 30, 2018	For the year ended December 31, 2017
Balance, beginning of period	$ 26,444	$ 28,441
Goodwill acquired during the period	386,405	—
Goodwill divested during the period	—	(3,895)
Currency translation	(2,233)	1,898
Balance, end of period	$ 410,616	$ 26,444

As of September 30, 2018, $362 million and $49 million of goodwill was allocated to the Specialty Pharma and Generics segments, respectively. As of December 31, 2017, all goodwill was allocated to the Generics segment. For the nine months ended September 30, 2018 goodwill acquired was associated with the Impax and Gemini acquisitions.

Intangible assets at September 30, 2018 and December 31, 2017 is comprised of the following (in thousands):

		September 30, 2018			December 31, 2017		
	Weighted-Average Amortization Period (in years)	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Amortizing intangible assets:							
Product rights	12.2	$1,217,538	$ (59,831)	$1,157,707	$49,700	$ (17,210)	$32,490
Customer relationships	14.7	7,166	(1,911)	5,255	7,421	(1,072)	6,349
Marketing authorizations	2.9	74	(48)	26	76	(43)	33
Licenses	11.3	3,000	(750)	2,250	3,000	(600)	2,400
Trade names	14.7	2,606	(695)	1,911	2,699	(522)	2,177
Total		$1,230,384	$ (63,235)	$1,167,149	$62,896	$ (19,447)	$43,449
In-process research and development		565,871	—	565,871	1,150	—	1,150
Total intangible assets		$1,796,255	$ (63,235)	$1,733,020	$64,046	$ (19,447)	$44,599

For the three and nine months ended September 30, 2018, the Company recognized a total of $8.5 million of intangible asset impairment charges, of which $7.8 million was recognized in cost of goods sold and $0.7 million was recognized in research and development expense. The impairment charge was related to products in the Generics segment and almost entirely related to one product. The impairment charges were primarily the result of a loss of a customer for a marketed product during the third quarter of 2018, resulting in significantly lower expected future cash flows.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Amortization	$25,655	$1,278	$44,109	$3,051

The following table presents future amortization expense for the next five years and thereafter, excluding $565.9 million of IPR&D intangible assets (in thousands).

	Future Amortization
Remainder of 2018	$ 25,959
2019	115,347
2020	126,061
2021	141,879
2022	145,339
2023	124,238
Thereafter	488,326
Total	$ 1,167,149

15. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities are comprised of the following (in thousands):

	September 30, 2018	December 31, 2017
Accounts payable	$ 124,539	$ 70,013
Accrued returns allowance	139,698	45,175
Accrued compensation	72,624	23,954
Accrued Medicaid and commercial rebates	88,942	12,911
Accrued royalties	19,625	2,970
Estimated Teva and Allergan chargebacks and rebates [1]	13,537	—
Medicaid reimbursement accrual	15,000	15,000
Accrued professional fees	8,652	938
Accrued other	30,505	23,818
Total accounts payable and accrued expenses	$ 513,122	$ 194,779

1 In connection with Impax's August 2016 acquisition of certain assets from Teva Pharmaceuticals USA, Inc. ("Teva") and Allergan plc ("Allergan"), Impax agreed to manage the payment process for certain commercial chargebacks and rebates on behalf of Teva and Allergan related to products each of Teva and Allergan sold into the channel prior to Impax's acquisition of the products. On August 18, 2016, Impax received a payment totaling $42.4 million from Teva and Allergan, which represented their combined estimate of the amount of commercial chargebacks and rebates to be paid by Impax on their behalf to wholesalers who purchased products from Teva and Allergan prior to the closing. Pursuant to the agreed upon transition services, Teva and Allergan are obligated to reimburse Impax for additional payments related to chargebacks and rebates for products they sold into the channel prior to the closing and made on their behalf in excess of the $42.4 million. If the total payments made by Impax on behalf of Teva and Allergan are less than $42.4 million, Impax is obligated to refund the difference to Teva and/or Allergan. As of September 30, 2018, $13.5 million remained in accounts payable and accrued expenses.

16. Debt

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

	September 30, 2018	December 31, 2017
Senior Credit Facility – Term Loan due May 2025	$ 2,692,626	$ —
Senior Credit Facility – ABL	100,000	
Financing Obligations	39,411	40,298
Other	624	—
Senior Credit Facility – Term Loan	—	1,378,160
Senior Credit Facility – Revolver	—	75,000
Total debt and financing obligations	2,832,661	1,493,458
Less: debt issuance costs	(35,859)	(8,715)
Total debt and financing obligations, net of debt issuance costs	2,796,802	1,484,743
Less: current portion of long-term debt and financing obligations	(121,694)	(89,482)
Total long-term debt and financing obligations, net	$ 2,675,108	$ 1,395,261

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 credit facility ("ABL") under which loans and letters of credit up to a principal amount of $500.0 million are available (principal amount of up to $25 million is available for letters of credit) (collectively, the "Senior Secured Credit Facilities"). 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 LIBOR plus 3.5% at September 30, 2018. The ABL bears an annual interest rate of 5.75% at September 30, 2018 and matures on May 4, 2023. Beginning on September 30, 2018, the annual interest rate for the ABL may be reduced or increased by 0.25% based on step-downs and step-ups determined by the average historical excess availability. At September 30, 2018, the Company had $100.0 million of borrowings under the ABL. On November 5, 2018, the Company repaid $50 million of the borrowings under the ABL.

The proceeds from the Term Loan were used to finance, in part, the cost of the Combination and to pay off Amneal's debt and substantially all of Impax's debt at the close of the Combination. In connection with the refinancing of the Amneal and Impax debt, the Company recorded a loss on extinguishment of debt of $19.7 million for the nine months ended September 30, 2018.

The proceeds of any loans made under the Senior Secured 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 ABL at a rate based on average historical excess availability, between 0.25% and 0.375% per annum. At September 30, 2018, the ABL commitment fee rate is 0.375% per annum.

The Company incurred costs associated with the Term Loan of $38.1 million and the ABL of $4.6 million, which have been capitalized and are being are amortized over the life of the applicable debt agreement to interest expense. The Term Loan has been recorded in the balance sheet net of issuance costs. Costs associated with the ABL have been recorded in other assets because there were no borrowings outstanding on the effective date of the ABL. For the three and nine months ended September 30, 2018, amortization of deferred financing costs related to the Term Loan, ABL and historical Amneal debt was $1.6 million and $4.2 million, respectively. For the three and nine months ended September 30, 2017, amortization of deferred financing costs related to the historical Amneal debt was $1.4 million and $3.9 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 ABL Facility also includes a financial covenant whereby Amneal must maintain a minimum fixed charge coverage ratio if certain borrowing conditions are met. 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 September 30, 2018, Amneal was in compliance with all covenants.

The Company's Senior Secured Credit Facility requires payments of $6.8 million for the remainder of 2018, $27.0 million per year for the next five years and the balance thereafter.

On June 4, 2018, Impax completed a tender offer to repurchase all of Impax's 2.00% senior notes due 2022. Pursuant to the tender offer, $599.4 million aggregate principal amount of the senior notes was repurchased.

Financing Obligations

The Company has a non-cancelable lease agreement dated October 1, 2012, for two buildings located in Long Island, New York, that are used as an integrated manufacturing and office facility. Amneal was responsible for a portion of the renovation and construction costs, and is deemed, for accounting purposes, to be the owner of the building. As a result, the Company was required to record the property, plant, and equipment and a corresponding financing obligation. The financing obligation is reduced by rental payments through the end of the lease, June 30, 2043.

The remaining financing obligation was $39.4 million and $40.3 million as of September 30, 2018 and December 31, 2017, respectively. The current portion of the remaining financing obligation was $0.3 million as of both September 30, 2018 and December 31, 2017.

The monthly payments required under the terms of the non-cancelable lease agreement over the next five years and thereafter as follows (in thousands):

	Payments Due
Remainder of 2018	$ 1,300
2019	5,200
2020	5,200
2021	5,200
2022	5,200
2023	5,200
Thereafter	101,800
Total	$ 129,100

17. Fair Value Measurements of Financial Instruments

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 as of September 30, 2018 (in thousands) (there were no material assets or liabilities that were measured at fair value on a recurring basis as of December 31, 2017):

		Fair Value Measurement Based on		
	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Deferred Compensation Plan asset (1)	$44,099	$ —	$ 44,099	$ —
Liabilities				
Deferred Compensation Plan liabilities (1)	$33,882	$ —	$ 33,882	$ —

1 The deferred compensation plan liabilities are non-current liabilities 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 and is included in other long-term liabilities. The Company invests participant contributions in corporate-owned life insurance policies, for which the cash surrender value is included in other non-current assets.

There were no transfers between levels in the fair value hierarchy during the nine months ended September 30, 2018.

Assets and Liabilities Not Measured at Fair Value on a Recurring Basis

The carrying amounts of cash, accounts receivable, accounts payable and the ABL approximate their fair values due to the short-term maturity of these instruments.

The Company's Term Loan falls into 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 September 30, 2018 was approximately $2.73 billion.

As of December 31, 2017, Amneal's prior term loan (which was subsequently paid off at the closing of the Combination with the proceeds of the Term Loan) had a fair value of approximately $1.39 billion, which was based upon market data (Level 2).

Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

There were no non-recurring fair value measurements during the nine months ended September 30, 2018 and 2017.

18. Commitments and Contingencies

Contractual Obligations

The Company leases buildings and other tangible property. Rent expense under these leases was $5.6 million and $12.9 million for the three and nine months ended September 30, 2018, respectively. Rent expense under these leases was $4.4 million and $13.0 million for the three and nine months ended September 30, 2017, respectively. The table below reflects the future minimum lease payments, including reasonably assured renewals, due under these non-cancelable leases as of September 30, 2018 (in thousands):

	Operating Leases
Remainder of 2018	$ 6,051
2019	25,885
2020	12,071
2021	11,105
2022	10,329
2023	10,043
Thereafter	28,128
Total	$ 103,612

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.

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 the legal proceedings set forth below. While the Company believes it has valid claims and/or defenses to the matters described below, the nature of litigation is unpredictable and the outcome of the following 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 for a potential loss. 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 at this time unable to estimate the possible loss, if any, associated with such litigation.

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. Resolution of any or all claims, legal proceedings or investigations could have a material adverse effect on the Company's results of operations and/or cash flow in any given accounting period, or on the Company's overall financial condition.

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. See "Part II, Item IA. Risk Factors—The development, manufacture and sale of our products involves the risk of product liability and other claims by consumers and other third parties, and insurance against such potential claims is expensive and may be difficult to obtain" for more information.

Although the outcome and costs of the asserted and unasserted claims is difficult to predict, based on the information presently known to management, the Company does not currently expect the ultimate liability, if any, for such matters to have a material adverse effect on its business, financial condition, results of operations, or cash flows.

Medicaid Reimbursement Accrual

The Company is required to provide pricing information to state 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. Reserves are periodically established by the Company for any potential claims or settlements of overpayment. Although the Company intends to vigorously defend against any such claims, it had a reserve of approximately $15 million at both September 30, 2018 and December 31, 2017. The ultimate settlement of any potential liability for such claims may be higher or lower than estimated.

Legal Settlement Gain

In July 2017, Amneal entered into a settlement agreement regarding one of its generic pharmaceutical products, Buprenorphine and Naloxone, pursuant to which Amneal received a settlement payment of $25 million, resulting in a net gain of $21.5 million after legal fees. Amneal filed a claim against the innovator of Suboxone, a combination of active pharmaceutical ingredients Buprenorphine and Naloxone, alleging anti-competitive conduct resulting in lost profits during the time period in which Amneal was restricted from entering the market to sell its generic version of Suboxone.

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 days period, the FDA can review and approve the ANDA, but 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 generic products division 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. Likewise, the Company's branded products division is currently involved in patent infringement litigation against generic drug manufacturers who have filed Paragraph IV certifications to market their generic drugs prior to expiration of the Company's patents at issue in the litigation.

The uncertainties inherent in patent litigation make the outcome of such litigation difficult to predict. For the Company's generic products division, 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 is found to infringe a valid, enforceable patent. For the Company's branded products division, 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 Matters

Merck Sharp & Dohme Corp. v. Amneal Pharmaceuticals LLC (Mometasone furoate)

In March 2015, Merck Sharp & Dohme Corp filed suit against Amneal in the U.S. District Court for the District of Delaware alleging patent infringement based on the filing of the Amneal's ANDA for a generic alternative to Merck's Nasonex® product. The District Court trial was completed on June 22, 2016. The court issued an opinion finding that Amneal's proposed generic product did not infringe the asserted patent. Merck filed an appeal of that decision with the Court of Appeals for the Federal Circuit. The Federal Circuit affirmed the District Court's opinion, denied Merck's request for rehearing, and issued the mandate on May 11, 2018. Amneal launched its generic version of the product on April 5, 2017, prior to the appellate court decision, and continues to sell the product as of September 30, 2018.

Otsuka Pharmaceutical Co. Ltd. v. Amneal Pharmaceuticals LLC, et. al. (Aripiprazole)

In March 2015, Otsuka Pharmaceutical Co. Ltd. filed suit against Amneal in the U.S. District Court for the District of New Jersey alleging patent infringement based on the filing of Amneal's ANDA for a generic alternative to Otsuka's Abilify® tablet product. The District Court has not yet set a trial date for the remaining patents-in-suit. Amneal, like a number of other generic manufacturers, has launched its generic version of Otsuka's Abilify® "at-risk," prior to the rendering of an appellate court decision, and continues to sell the product as of September 30, 2018.

Patent Infringement Matters

Impax Laboratories, LLC, et al. v. Lannett Holdings, Inc. and Lannett Company (Zomig®)

In July 2014, Impax filed suit against Lannett Holdings, Inc. and Lannett Company (collectively, "Lannett") in the United States District Court for the District of Delaware, alleging patent infringement based on the filing of the Lannett ANDA relating to Zolmitriptan Nasal Spray, 5mg, generic to Zomig® Nasal Spray. The case went to trial in September 2016. On March 29, 2017, the District Court issued a Trial Opinion finding the asserted patents valid and infringed. On April 17, 2017, the District Court entered a Final Judgment and Injunction that, *inter alia*, bars FDA approval of Lannett's proposed generic product prior to May 29, 2021. On May 12, 2017, Lannett filed a Notice of Appeal with the United States Court of Appeals for the Federal Circuit. The Federal Circuit affirmed the District Court's decision in full, and later denied Lannett's motion for rehearing.

Impax Laboratories, LLC, et al. v. Par Pharmaceutical, Inc. (Zomig®)

On September 23, 2016, Impax filed suit against Par Pharmaceutical, Inc. ("Par") in the United States District Court for the District of Delaware, alleging patent infringement based on the filing of the Par ANDA relating to Zolmitriptan Nasal Spray, 2.5 mg and 5 mg, generic to Zomig® Nasal Spray. On October 12, 2016, the parties stipulated to stay the case pending the outcome of the related case, *Impax Laboratories, LLC, et al. v. Lannett* matter described above. On April 24, 2017, the parties stipulated that the stay shall remain in effect until the *Impax Laboratories, LLC, et al. v. Lannett* matter is fully resolved. On July 10, 2018, Par notified Impax that it had converted its Paragraph IV certification with respect to the sole patent-in-suit to a Paragraph III certification, and requested that Impax dismiss the lawsuit. The stipulation of dismissal was entered into and the lawsuit was dismissed on August 7, 2018.

Impax Laboratories, LLC., et al. v. Actavis Laboratories FL, Inc. and Actavis Pharma Inc. (Rytary®)

In September 2015, Impax filed suit against Actavis Laboratories FL, Inc. and Actavis Pharma Inc. (collectively, "Actavis") in the United States District Court for the District of New Jersey, alleging patent infringement of U.S. Patent Nos. 7,094,427; 8,377,474; 8,454,998; 8,557,283; 9,089,607; 9,089,608, based on the filing of the Actavis ANDA relating to carbidopa and levodopa extended release capsules, generic to Rytary®. Impax filed related actions alleging infringement of later-issued U.S. Patent No. 9,463,246 in December 2016 and of later-issued U.S. Patent No. 9,533,046 in May 2017. Both related actions were consolidated with the lead action. On December 15, 2017, the Patent and Trademark Office issued an Ex Parte Reexamination Certificate canceling all claims of the '427 patent; the parties subsequently stipulated to dismiss with prejudice all claims and counterclaims relating to the '427 patent. Fact discovery and claim construction briefing have concluded and a claim construction hearing was held on April 26, 2017. On May 9, 2017, the District Court issued a decision interpreting certain claim terms in dispute in the litigation. Subject to reservation of all rights to appeal the Court's May 9, 2017 decision, the parties stipulated to dismiss without prejudice all claims and counterclaims relating to the '474, '998, and '607 patents, and the Court entered an order recognizing this stipulation on June 8, 2017. The parties have completed expert discovery and Actavis filed a summary judgment motion on October 23, 2017. On March 8, 2018, the Court issued an Opinion and Order, granting in part Actavis's motion for summary judgment. A four day trial was held in May 14, 2018. The parties reached a settlement agreement in June 2018, before post-trial briefing was complete. The case has been dismissed.

Impax Laboratories, LLC. v. Sandoz Inc. (Rytary®)

On March 31, 2017, Impax filed suit against Sandoz Inc. in the United States District Court for the District of New Jersey, alleging infringement of U.S. Patent Nos. 7,094,427; 8,377,474; 8,454,998; 8,557,283; 9,089,607; 9,089,608; 9,463,246; and 9,533,046, based on the filing of Sandoz's ANDA relating to carbidopa and levodopa extended release capsules, generic to Rytary®. Sandoz answered the complaint on February 28, 2018. Fact discovery has not yet commenced.

Impax Laboratories, LLC. v. Zydus Pharmaceuticals USA, Inc. and Cadila Healthcare Ltd. (Rytary®)

On December 21, 2017, Impax filed suit against Zydus Pharmaceuticals USA, Inc. and Cadila Healthcare Ltd. (collectively, "Zydus") in the United States District Court for the District of New Jersey, alleging infringement of U.S. Patent No. 9,089,608, based on the filing of Zydus's ANDA relating to carbidopa and levodopa extended release capsules, generic to Rytary®. Zydus answered the complaint on April 27, 2018, asserting counterclaims of non-infringement and invalidity of U.S. Pat. Nos. 7,094,427; 8,377,474; 8,454,998; 8,557,283; and 9,089,607. Impax answered Zydus's counterclaims on June 1, 2018. A case schedule has been set with trial anticipated in February 2020.

Other Litigation Related to the Company's Business

Solodyn® Antitrust Class Actions

From July 2013 to January 2016, 18 complaints were filed as class actions on behalf of direct and indirect purchasers, as well as by certain direct purchasers, against manufacturers of the brand drug Solodyn® and its generic equivalents, including Impax.

On July 22, 2013, Plaintiff United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On July 23, 2013, Plaintiff Rochester Drug Co-Operative, Inc., a direct purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On August 1, 2013, Plaintiff International Union of Operating Engineers Local 132 Health and Welfare Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Northern District of California on behalf of itself and others similarly situated. On August 29, 2013, this Plaintiff withdrew its complaint from the United States District Court for the Northern District of California, and on August 30, 2013, re-filed the same complaint in the United States Court for the Eastern District of Pennsylvania, on behalf of itself and others similarly situated.

On August 9, 2013, Plaintiff Local 274 Health & Welfare Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On August 12, 2013, Plaintiff Sheet Metal Workers Local No. 25 Health & Welfare Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On August 27, 2013, Plaintiff Fraternal Order of Police, Fort Lauderdale Lodge 31, Insurance Trust Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On August 29, 2013, Plaintiff Heather Morgan, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On August 30, 2013, Plaintiff Plumbers & Pipefitters Local 178 Health & Welfare Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On September 9, 2013, Plaintiff Ahold USA, Inc., a direct purchaser, filed a class action complaint in the United States District Court for the District of Massachusetts on behalf of itself and others similarly situated.

On September 24, 2013, Plaintiff City of Providence, Rhode Island, an indirect purchaser, filed a class action complaint in the United States District Court for the District of Arizona on behalf of itself and others similarly situated.

On October 2, 2013, Plaintiff International Union of Operating Engineers Stationary Engineers Local 39 Health & Welfare Trust Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the District of Massachusetts on behalf of itself and others similarly situated.

On October 7, 2013, Painters District Council No. 30 Health and Welfare Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the District of Massachusetts on behalf of itself and others similarly situated.

On October 25, 2013, Plaintiff Man-U Service Contract Trust Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On March 13, 2014, Plaintiff Allied Services Division Welfare Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the District of Massachusetts on behalf of itself and others similarly situated.

On March 19, 2014, Plaintiff NECA-IBEW Welfare Trust Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the District of Massachusetts on behalf of itself and others similarly situated.

On February 25, 2014, the United States Judicial Panel on Multidistrict Litigation ordered the pending actions transferred to the District of Massachusetts for coordinated pretrial proceedings, as In Re Solodyn (Minocycline Hydrochloride) Antitrust Litigation.

On March 26, 2015, Walgreen Co., The Kruger Co., Safeway Inc., HEB Grocery Company L.P., Albertson’s LLC, direct purchasers, filed a separate complaint in the United States District Court for the Middle District of Pennsylvania. On April 8, 2015, the Judicial Panel on Multi-District Litigation ordered the action be transferred to the District of Massachusetts, to be coordinated or consolidated with the coordinated proceedings. The original complaint filed by the plaintiffs asserted claims only against defendant Medicis. On October 5, 2015, the plaintiffs filed an amended complaint asserting claims against Impax and the other generic defendants.

On April 16, 2015, Rite Aid Corporation and Rite Aid Hdqtrs. Corp, direct purchasers, filed a separate complaint in the United States District Court for the Middle District of Pennsylvania. On May 1, 2015, the Judicial Panel on Multi-District Litigation ordered the action be transferred to the District of Massachusetts, to be coordinated or consolidated with the coordinated proceedings. The original complaint filed by the plaintiffs asserted claims only against defendant Medicis. On October 5, 2015, the plaintiffs filed an amended complaint asserting claims against Impax and the other generic defendants.

On January 25, 2016, CVS Pharmacy, Inc., a direct purchaser, filed a separate complaint in the United States District Court for the Middle District of Pennsylvania. On February 11, 2016, the Judicial Panel on Multi-District Litigation ordered the action to be transferred to the District of Massachusetts to be coordinated or consolidated with the coordinated proceedings.

The consolidated amended complaints allege that Medicis engaged in anticompetitive schemes by, among other things, filing frivolous patent litigation lawsuits, submitting frivolous Citizen Petitions, and entering into anticompetitive settlement agreements with several generic manufacturers, including Impax, to delay generic competition of Solodyn® and in violation of state and federal antitrust laws. Plaintiffs seek, among other things, unspecified monetary damages and equitable relief, including disgorgement and restitution. On August 14, 2015, the District Court granted in part and denied in part defendants' motion to dismiss the consolidated amended complaints. On October 16, 2017, the Court certified the Direct Purchaser Plaintiffs' and End-Payor Plaintiffs' classes. Trial began on March 12, 2018. During March 2018, Impax separately settled all claims with the direct purchaser plaintiff class, retailer plaintiffs and the end payor plaintiff class for a total settlement amount of $84.5 million prior to the Combination and the cases were dismissed. The settlements with the class plaintiffs are subject to court approval. The settlement with the direct purchaser plaintiff class was preliminarily approved by the Court on March 12, 2018, and the settlement with the end payor plaintiff class was preliminarily approved by the Court on April 5, 2018. Both class settlements were granted final Court approval on July 18, 2018.

Opana ER® FTC Antitrust Suit

On February 25, 2014, Impax received a Civil Investigative Demand ("CID") from the 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, 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 co-promotion and development agreement and a June 2010 settlement agreement that resolved patent litigation in connection with the submission of Impax's ANDA for generic original Opana® ER. In July 2016, the defendants filed a motion to dismiss the complaint, and a motion to sever the claims regarding Opana® ER from claims with respect to a separate settlement agreement that was challenged by the FTC. On October 20, 2016, the Court granted the motion to sever, formally terminating the suit against Impax, with an order that the FTC re-file no later than November 3, 2016 and dismissed the motion to dismiss as moot. On October 25, 2016, the FTC filed a notice of voluntary dismissal. On January 19, 2017, the FTC filed a Part 3 Administrative complaint against Impax with similar allegations regarding Impax's June 2010 settlement agreement with Endo that resolved patent litigation in connection with the submission of Impax's ANDA for generic original Opana® ER. Impax filed its answer to the Administrative Complaint on February 7, 2017. Trial concluded on November 15, 2017. On May 11, 2018, the Administrative Law Judge ruled in favor of Impax and dismissed the case in its entirety. The government has appealed this ruling to the five Federal Trade Commissioners, who will review the case *de novo.* Briefing on the appeal to the Federal Trade Commission concluded on August 24, 2018. Oral arguments were heard on October 11, 2018, and a decision is expected within 100 days.

Opana ER® Antitrust Class Actions

From June 2014 to April 2015, 14 complaints were filed as class actions on behalf of direct and end-payor (indirect) purchasers, as well as by certain direct purchasers, against the manufacturer of the brand drug Opana ER® and Impax.

On June 4, 2014, Plaintiff Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On June 4, 2014, Plaintiff Rochester Drug Co-Operative, Inc., a direct purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated. On June 6, 2018, Plaintiff Rochester Drug Co-Operative, Inc. filed a motion to voluntarily dismiss its complaint with prejudice. The court granted that motion on June 11, 2018.

On June 6, 2014, Plaintiff Value Drug Company, a direct purchaser, filed a class action complaint in the United States District Court for the Northern District of California on behalf of itself and others similarly situated. On June 26, 2014, this Plaintiff withdrew its complaint from the United States District Court for the Northern District of California, and on July 16, 2014, re-filed the same complaint in the United States District Court for the Northern District of Illinois, on behalf of itself and others similarly situated.

On June 19, 2014, Plaintiff Wisconsin Masons' Health Care Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Northern District of Illinois on behalf of itself and others similarly situated.

On July 17, 2014, Plaintiff Massachusetts Bricklayers, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On August 11, 2014, Plaintiff Pennsylvania Employees Benefit Trust Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Northern District of Illinois on behalf of itself and others similarly situated.

On September 19, 2014, Plaintiff Meijer Inc., a direct purchaser, filed a class action complaint in the United States District Court for the Northern District of Illinois on behalf of itself and others similarly situated.

On October 3, 2014, Plaintiff International Union of Operating Engineers, Local 138 Welfare Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Northern District of Illinois on behalf of itself and others similarly situated.

On November 17, 2014, Louisiana Health Service & Indemnity Company d/b/a Blue Cross and Blue Shield of Louisiana, an indirect purchaser, filed a class action complaint in the United States District Court for the Middle District of Louisiana on behalf of itself and others similarly situated.

On December 12, 2014, the United States Judicial Panel on Multidistrict Litigation ordered the pending actions transferred to the Northern District of Illinois for coordinated pretrial proceedings, as In Re Opana ER Antitrust Litigation.

On December 19, 2014, Plaintiff Kim Mahaffay, an indirect purchaser, filed a class action complaint in the Superior Court of the State of California, Alameda County, on behalf of herself and others similarly situated. On January 27, 2015, the Defendants removed the action to the United States District Court for the Northern District of California.

On January 12, 2015, Plaintiff Plumbers & Pipefitters Local 178 Health & Welfare Trust Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Northern District of Illinois on behalf of itself and others similarly situated.

On March 26, 2015 Walgreen Co., The Kruger Co., Safeway Inc., HEB Grocery Company L.P., Albertson's LLC, direct purchasers, filed a separate complaint in the United States District Court for the Northern District of Illinois.

On April 23, 2015, Rite Aid Corporation and Rite Aid Hdqtrs. Corp, direct purchasers, filed a separate complaint in the United States District Court for the Northern District of Illinois.

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. Consolidated amended complaints were filed on May 4, 2015 by direct purchaser plaintiffs and end-payor (indirect) purchaser plaintiffs.

On July 3, 2015, defendants filed motions to dismiss the consolidated amended complaints, as well as the complaints of the "Opt-Out Plaintiffs" (Walgreen Co., The Kruger Co., Safeway Inc., HEB Grocery Company L.P., Albertson's LLC, Rite Aid Corporation and Rite Aid Hdqtrs. Corp.).

On February 1, 2016, CVS Pharmacy, Inc. filed a complaint in the United States District Court for the Northern District of Illinois. The parties agreed that CVS Pharmacy, Inc. would be bound by the Court's ruling on the defendants' motion to dismiss the Opt-Out Plaintiffs' complaints.

On February 10, 2016, the court granted in part and denied in part defendants' motion to dismiss the end-payor purchaser plaintiffs' consolidated amended complaint, and denied defendants' motion to dismiss the direct purchaser plaintiffs' consolidated amended complaint. The end-payor purchaser plaintiffs filed a second consolidated amended complaint and Impax moved to dismiss certain state law claims. On August 11, 2016, the court granted in part and denied in part defendants' motion to dismiss the end-payor purchaser plaintiffs' second consolidated amended complaint. Impax has filed its answer. On September 15, 2018, the claims of Mary Davenport were voluntarily dismissed from the end-payor action.

On February 25, 2016, the court granted defendants' motion to dismiss the Opt-Out Plaintiffs' complaints, with leave to amend. The Opt-Out Plaintiffs and CVS Pharmacy, Inc. have filed amended complaints and Impax has filed its answer.

Discovery is ongoing. No trial date has been scheduled.

Sergeants Benevolent Association Health & Welfare Fund v. Actavis, PLC, et. al.

In August 2015, a complaint was filed against Amneal in the U.S. District Court for the Southern District of New York involving patent litigation settlement agreements between Amneal and Forest Laboratories. Amneal was one of a number of pharmaceutical companies named in the lawsuit. The settlement agreement at issue settled the patent litigation between Forest Laboratories and Amneal regarding Namenda© immediate release tablets. On September 13, 2016, the court denied the defendants' motion to dismiss with respect to the federal claims and stayed the state law claims pending against Amneal and the other generic pharmaceutical company defendants until the federal claims are resolved. The court denied the defendants' motion to dismiss with respect to the state law claims without prejudice to renew the motion after the federal claims have been resolved. The court cited the interests of judicial economy and the myriad state antitrust and unfair business practices laws as the basis for severing the state law claims and placing them on the court's inactive docket. The court's decision places the entirety of the claims pending against Amneal and the other generic pharmaceutical companies on the court's inactive docket, which effectively stays the litigation as to Amneal until the federal claims are resolved or until the court removes those claims from its inactive docket. On September 10, 2018, the Court lifted the stay, referred the case to the assigned Magistrate Judge for supervision of supplemental, non-duplicative discovery, and turned its attention to motions to dismiss filed on behalf of Amneal and the other IPP defendants (which had been pending when the claims were stayed). Supplemental discovery, as well as supplemental motion-to-dismiss briefing, are now underway.

United States Department of Justice Investigations

Previously 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 Justice Department (the "Justice Department"). In connection with this same investigation, on March 13, 2015, Impax received a grand jury subpoena from the Justice Department requesting the production of information and documents regarding the sales, marketing, and pricing of certain generic prescription medications. In particular, the Justice Department's investigation currently focuses on four generic medications: digoxin tablets, terbutaline sulfate tablets, prilocaine/lidocaine cream, and calcipotriene topical solution. The Company has been cooperating and intends to continue cooperating with the investigation. 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 Justice Department (the "Civil Division"). The CID requests the production of information and documents regarding the pricing and sale of Impax's pharmaceuticals and Impax's interactions with other generic pharmaceutical manufacturers. According to the CID, the investigation concerns allegations that generic pharmaceutical manufacturers, including Impax, engaged in market allocation and price-fixing agreements, paid illegal remuneration, and caused false claims to be submitted to the Federal government. The Company has been cooperating and intends to continue cooperating with the Civil Division's investigation. However, no assurance can be given as to the timing or outcome of the investigation.

Attorney General of the State of Connecticut Interrogatories and Subpoena Duces Tecum

On July 14, 2014, Impax received a subpoena and interrogatories (the "Subpoena") from the State of Connecticut Attorney General ("Connecticut AG") concerning its investigation into sales of Impax's generic product, digoxin. According to the Connecticut AG, the investigation is to determine whether anyone engaged in a contract, combination or conspiracy in restraint of trade or commerce which has the effect of (i) fixing, controlling or maintaining prices or (ii) allocating or dividing customers or territories relating to the sale of digoxin in violation of Connecticut state antitrust law. The Company has produced documents and information in response to the Subpoena. To the knowledge of the Company, no proceedings by the Connecticut AG have been initiated against the Company at this time; however, no assurance can be given as to the timing or outcome of this investigation.

Texas State Attorney General Civil Investigative Demand

On May 27, 2014, a CID was served on Amneal by the Office of the Attorney General for the state of Texas (the "Texas AG") relating to products distributed by Amneal under a specific Amneal labeler code. Shortly thereafter, Amneal received a second CID with respect to the same products sold by Interpharm Holding, Inc. ("Interpharm"), the assets of which had been acquired by Amneal in June 2008. Amneal completed its production of the direct and indirect sales transaction data in connection with the products at issue and provided this information to the Texas AG in November 2015. In May 2016, the Texas AG delivered two settlement demands to Amneal in connection with alleged overpayments made by the State of Texas for such products under its Medicaid programs. For the Amneal and Interpharm products at issue, the Texas AG's initial demand was for an aggregate total of $36 million based on $16.2 million in alleged overpayments. After analyzing the Texas AG's demand, Amneal raised certain questions regarding the methodology used in the Texas AG's overpayment calculations, including the fact that the calculations treated all pharmacy claims after 2012 for the products at issue as claims for over-the-counter ("OTC") drugs, even though the products were prescription pharmaceuticals. This had the effect of increasing the alleged overpayment because the dispensing fee for OTC drugs was lower than that for prescription drugs. Therefore, the Texas AG's calculations were derived by subtracting a lower (and incorrect) OTC dispensing fee from the higher (and correct) prescription dispensing fee. The Texas AG later acknowledged this discrepancy and is in the process of re-calculating the alleged overpayment.

In re Generic Pharmaceuticals Pricing Antitrust Litigation

From March 2016 to April 2017, 22 complaints were filed as class actions on behalf of direct and indirect purchasers against manufacturers of generic digoxin and doxycycline and Impax alleging a conspiracy to fix, maintain and/or stabilize prices of these generic products. From January 2017 to April 2017, three complaints were filed on behalf of indirect purchasers against manufacturers of generic lidocaine/prilocaine and Impax alleging a conspiracy to fix, maintain and/or stabilize prices of these generic products.

On March 2, 2016, Plaintiff International Union of Operating Engineers Local 30 Benefits Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated. The plaintiff filed an amended complaint on June 9, 2016.

On March 25, 2016, Plaintiff Tulsa Firefighters Health and Welfare Trust, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On March 25, 2016, Plaintiff NECA-IBEW Welfare Trust Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On April 4, 2016, Plaintiff Pipe Trade Services MN, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On April 25, 2016, Plaintiff Edward Carpinelli, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On April 27, 2016, Plaintiff Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On May 2, 2016, Plaintiff Nina Diamond, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On May 5, 2016, Plaintiff UFCW Local 1500 Welfare Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On May 6, 2016, Plaintiff Minnesota Laborers Health and Welfare Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On May 12, 2016, Plaintiff The City of Providence, Rhode Island, an indirect purchaser, filed a class action complaint in the United States District Court for the District of Rhode Island on behalf of itself and others similarly situated.

On May 18, 2016, Plaintiff KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc., a direct purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On May 19, 2016, Plaintiff Philadelphia Federation of Teachers Health and Welfare Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On June 8, 2016, Plaintiff United Food & Commercial Workers and Employers Arizona Health and Welfare Trust, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On June 17, 2016, Plaintiff Ottis McCrary, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On June 20, 2016, Plaintiff Rochester Drug Co-Operative, Inc., a direct purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On June 27, 2016, Plaintiff César Castillo, Inc., a direct purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On June 29, 2016, Plaintiff Plumbers & Pipefitters Local 33 Health and Welfare Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On July 1, 2016, Plaintiff Plumbers & Pipefitters Local 178 Health and Welfare Trust Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On July 15, 2016, Plaintiff Ahold USA, Inc., a direct purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On September 7, 2016, Plaintiff United Here Health, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On September 20, 2016, Plaintiff Valerie Velardi, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated.

On January 13, 2017, Plaintiff International Union of Operating Engineers Local 30 Benefits Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated against manufacturers of generic lidocaine/prilocaine and the Company alleging a conspiracy to fix, maintain and/or stabilize prices of this generic drug.

On April 17, 2017, Plaintiff UFCW Local 1500 Welfare Fund, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated against manufacturers of generic lidocaine/prilocaine and Impax alleging a conspiracy to fix, maintain and/or stabilize prices of this generic drug.

On April 25, 2017, Plaintiff Louisiana Health Service Indemnity Company, an indirect purchaser, filed a class action complaint in the United States District Court for the Eastern District of Pennsylvania on behalf of itself and others similarly situated against manufacturers of generic lidocaine/prilocaine and Impax alleging a conspiracy to fix, maintain and/or stabilize prices of this generic drug.

On May 19, 2016, several indirect purchaser plaintiffs filed a motion with the Judicial Panel on Multidistrict Litigation to transfer and consolidate the actions in the United States District Court for the Eastern District of Pennsylvania. The Judicial Panel ordered the actions consolidated in the Eastern District of Pennsylvania and ordered that the actions be renamed “In *re Generic Digoxin and Doxycycline Antitrust Litigation*.”

On January 27, 2017, plaintiffs filed two consolidated class action complaints.

On April 6, 2017, the Judicial Panel on Multidistrict Litigation ordered the consolidation of all civil actions involving allegations of antitrust conspiracies in the generic pharmaceutical industry regarding 18 generic drugs to the Eastern District of Pennsylvania. The consolidated actions have been renamed *In re Generic Pharmaceuticals Pricing Antitrust Litigation.* Consolidated class action complaints for each of the 18 drugs were filed on August 15, 2017. Direct purchaser plaintiffs, end-payer plaintiffs, and indirect reseller plaintiffs filed consolidated class complaints against Impax for two products, digoxin and lidocaine-prilocaine.

On October 6, 2017, Impax filed a motion to dismiss the digoxin complaint. On February 9, 2018, the Court issued an order denying the discovery stay and allowing certain fact discovery to proceed. On October 16, 2018, the Court denied the motion to dismiss the digoxin complaint.

On January 19, 2018, Plaintiffs The Kroger Co., Albertsons Companies, LLC, and H.E. Butt Grocery Company L.P., opt-outs, filed a complaint in the United States District Court for the Eastern District of Pennsylvania against 35 companies, including Impax, alleging a conspiracy to fix, maintain and/or stabilize prices of 30 drugs and specifically digoxin and lidocaine/prilocaine with respect to Impax. No schedule has been set.

On June 22, 2018, Plaintiffs Ahold USA, Inc., César Castillo, Inc., FWK Holdings, L.L.C., KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc., and Rochester Drug Co-Operative, Inc. filed a complaint on behalf of themselves and all others similarly situated against 23 companies, including Impax, and one individual, alleging a conspiracy to fix, maintain, stabilize, and/or raise prices, rig bids, and allocate markets or customers for various drugs, specifically glyburide-metformin and metronidazole with respect to Impax. No schedule has been set.

On June 27, 2018, Plaintiffs Marion Diagnostic Center, LLC and Marion Healthcare, LLC filed a motion seeking leave to file a complaint in the United States District Court for the Eastern District of Pennsylvania against seven named defendants, alleging a horizontal and vertical distributor conspiracy to fix prices and allocate sales of lidocaine products. On September 7, 2018, the Court denied the Marion Plaintiffs' motion without prejudice. On September 25, 2018, the Marion Plaintiffs filed a new civil action in the Eastern District of Pennsylvania regarding other generic drugs that does not name Impax as a defendant.

On August 3, 2018, Plaintiff Humana Inc. filed a complaint against 37 companies, including the Company, as the successor to Impax, alleging a conspiracy to fix, maintain, stabilize, and/or raise prices, rig bids, and allocate markets or customers for various drugs, specifically digoxin and lidocaine-prilocaine with respect to Impax. No schedule has been set.

Prescription Opioid Litigation.

The Company or certain of its affiliates have been named as a defendant in various matters relating to the promotion and sale of prescription opioid pain relievers. The Company is aware that other individuals and states and political subdivisions are filing comparable actions against, among others, manufacturers and parties that have promoted and sold prescription opioid pain relievers, and additional suits may be filed.

The complaints, asserting claims under provisions of different state law and, in one case, Federal law, generally contend that the defendants allegedly engaged in improper marketing of opioids, and seek a variety of remedies, including restitution, civil penalties, disgorgement of profits, treble damages, attorneys' fees and injunctive relief. None of the complaints specifies the exact amount of damages at issue. The Company and its affiliates that are defendants in the various lawsuits deny all allegations asserted in these complaints and have filed or intend to file motions to dismiss where possible. Each of the opioid-related matters described below is in its early stages. The Company is cooperating with the investigations relating to these matters, which are ongoing, and intends to continue to vigorously defend these cases. In light of those facts and the inherent uncertainties of civil litigation, the Company is not in a position to predict the likelihood of an unfavorable outcome or provide an estimate of the amount or range of potential loss in the event of an unfavorable outcome in any of these matters.

On August 17, 2017, plaintiff Linda Hughes, as the mother of Nathan Hughes, decedent, filed her complaint in Missouri state court naming Amneal Pharmaceuticals of New York LLC, Impax, five other pharmaceutical company defendants, and three healthcare provider defendants. Plaintiff alleges that use of defendants' opioid medications caused the death of her son, Nathan Hughes. In her original complaint, plaintiff requested damages against the defendants and certification of a class action. Plaintiff abandoned her request for a class action in her December 22, 2017, amended complaint. In her amended complaint, plaintiff alleges causes of action against Amneal and Impax for strict product liability, negligent product liability, violation of Missouri Merchandising Practices Act and fraudulent misrepresentation. The case was removed to federal court on September 18, 2017. It was transferred to the United States District Court for the Northern District of Ohio on February 2, 2018, and is part of the multidistrict litigation pending as *In Re: National Prescription Opiate Litigation*, MDL No. 2804 (the "MDL"). Plaintiff has filed a motion to remand the case to Missouri state court. That motion remains pending before the MDL court. All activity in the case is stayed by order of the MDL court.

On March 15, 2018, plaintiff Scott Ellington, purporting to represent the State of Arkansas, more than sixty counties and a dozen cities, filed a complaint in Arkansas state court naming Gemini Laboratories, LLC and fifty-one other pharmaceutical companies as defendants. Plaintiffs allege that Gemini and the other pharmaceutical company defendants improperly marketed, sold, and distributed opioid medications and failed to adequately warn about the risks of those medications. The complaint also includes claims against distributors and retailers of opioid medications. Plaintiffs allege causes of actions against Gemini and the other pharmaceutical company defendants for negligence and nuisance and alleged violations of multiple Arkansas statutes. Plaintiffs request past damages and restitution for monies allegedly spent by the State of Arkansas and the county and city plaintiffs for "extraordinary and additional services" for responding to what plaintiffs term the "Arkansas Opioid Epidemic." Plaintiffs also seek prospective damages to allow them to "comprehensively intervene in the Arkansas Opioid Epidemic," punitive and treble damages as provided by law, and their costs and fees. Plaintiffs' complaint does not include any specific damage amounts. Gemini has filed a general denial and, on June 28, 2018, it joined the other pharmaceutical company defendants in moving to dismiss plaintiffs' complaint.

On March 27, 2018, plaintiff American Resources Insurance Company, Inc. filed a complaint in the United States District Court for the Southern District of Alabama against Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, LLC, Impax, the Impax Generics Division, and thirty-five other pharmaceutical company defendants. Plaintiff seeks certification of a class of insurers that since January 1, 2010, allegedly have been wrongfully required to: (i) reimburse for prescription opioids that allegedly were promoted, sold, and distributed illegally and improperly by the pharmaceutical company defendants; and (ii) incur costs for treatment of overdoses of opioid medications, misuse of those medications, or addiction to them. Plaintiff's complaint also includes claims against distributors of opioid medications. Plaintiff alleges causes of action against Amneal, Impax and the other defendants for negligence, recklessness and gross negligence, unjust enrichment, subrogation, fraud, and violations of federal RICO statutes. Plaintiff demands compensatory and punitive damages, but plaintiff's complaint does not include any allegation of specific damage amounts. On April 18, 2018, the Judicial Panel on Multidistrict Litigation conditionally transferred the case to the MDL. On or about May 2, 2018, the case was transferred to the MDL. All activity in the case is stayed by order of the MDL court.

On May 30, 2018, plaintiff William J. Comstock filed a complaint in Washington state court against Amneal Pharmaceuticals of New York, LLC, and four other pharmaceutical company defendants. Plaintiff alleges he became addicted to opioid medications manufactured and sold by the pharmaceutical company defendants, which plaintiff contends caused him to experience opioid-induced psychosis, prolonged hospitalizations, pain, and suffering. Plaintiff asserts causes of action against Amneal and the other pharmaceutical company defendants for negligence, fraudulent misrepresentation, and violations of the Washington Consumer Protection Act. On July 12, 2018, Amneal and other defendants removed the case to the United States District Court for the Eastern District of Washington. On August 17, 2018, the case was transferred to the MDL. All activity in the case is stayed by order of the MDL court.

On June 18, 2018, a Subpoena and CID issued by the Office of the Attorney General of Kentucky, Office of Consumer Protection was served on Amneal. The CID contains eleven requests for production of documents pertaining to opioid medications manufactured and/or sold by Amneal, or for which Amneal holds an Abbreviated New Drug Application. The Company is evaluating the CID and has been in communication with the Office of the Attorney General about the scope of the CID, the response to the CID, and the timing of the response. It is unknown if the Office of the Attorney General will pursue any claim or file a lawsuit against Amneal. The Attorney General has filed six lawsuits against manufacturers and distributors of opioid medications asserting that those companies engaged in improper marketing, sales and distribution of opioid medications and failed to adequately warn about the risks of opioid medications. In those lawsuits, the Attorney General has demanded injunctive relief, civil penalties, restitution, compensatory damages, treble damages, punitive damages, and awards of attorney's fees. If the Attorney General files a lawsuit, the Company intends to vigorously defend the lawsuit. The Company's investigation relative to the CID is ongoing and there is no case or claim to evaluate at this time. Accordingly, the Company is not in a position to predict the likelihood of an unfavorable outcome or provide an estimate of the amount or range of potential loss in the event of an unfavorable outcome if the Attorney General files a lawsuit.

On July 9, 2018, the Muscogee (Creek) Nation filed a First Amended Complaint in its case pending in the National Prescription Opiate Litigation Multidistrict Litigation (The Muscogee (Creek) Nation v. Purdue Pharma, L.P., et al., U.S. District Court, Northern District of Ohio, MDL No. 2804 (In Re: National Prescription Opiate Litigation), Member Case No. 1:18-op-45459-DAP) against the Company and 55 other defendants consisting of pharmaceutical companies, wholesalers, distributors, and pharmacies. Plaintiff describes itself in the First Amended Complaint as a federally recognized Indian tribe with a membership of 83,570 citizens. Plaintiff alleges it exercises sovereign governmental authority over its citizens and within its territory, which it describes as covering 4,867 square miles within the state of Oklahoma. Plaintiff alleges it has been damaged by the Company and the other pharmaceutical company defendants alleged improper marketing, including off-label marketing, failure to adequately warn of the risks of opioid medications, and failure to properly monitor and control diversion of opioid medications within the

Nation. The case has been designated as a bellwether motion to dismiss case for the MDL, meaning it is a test case for arguments directed at the complaints filed by Indian tribes in the MDL cases. It is not a bellwether or test case at this juncture for any other purpose. On August 31, 2018, the Company moved to dismiss the First Amended Complaint, and also joined in separate motions to dismiss filed by different defense subgroups. Plaintiff has opposed these motions. Additionally, on September 28, 2018, plaintiff filed a motion to add Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals of New York, LLC, and to dismiss the Company from the complaint. The Company opposed that motion, and plaintiff filed a reply on October 19, 2018.

On July 18, 2018, the County of Webb Texas requested waivers of service pursuant to Fed. R. Civ. P. 4 and the MDL Court's CMOs from Amneal and Amneal Pharmaceuticals of New York, LLC, in its case pending in the National Prescription Opiate Litigation Multidistrict Litigation (County of Webb, Texas v. Purdue Pharma, L.P., et al., U.S. District Court, Northern District of Ohio, MDL No. 2804 (In Re: National Prescription Opiate Litigation), Member Case No. 1:18-op-45175-DAP). Plaintiff's Amended Complaint filed against Amneal and forty-one other defendants consisting of pharmaceutical companies, wholesalers, distributors, and pharmacy benefit managers, contains allegations that plaintiff is a county created under the authority of the State of Texas located in southern Texas with approximately 272,000 residents. Plaintiff alleges damages as a result of Amneal's and the pharmaceutical company defendants' improper marketing, failure to adequately warn of the risks of opioid medications, and failure to properly monitor and control diversion of opioid medications in or affecting Webb County. Plaintiff alleges causes of action against Amneal and other pharmaceutical company defendants for negligence, negligence per se, nuisance, gross negligence, fraud, civil conspiracy, violation of Texas consumer protection and deceptive trade practice acts (Tex. Bus. & Comm. Code § 17.41, et. seq.), unjust enrichment, and violations of federal RICO statutes. All activity in the case is stayed by order of the MDL court.

On August 24, 2018, the Tucson Medical Center filed a complaint against the Company and 18 other defendants consisting of pharmaceutical companies, distributors, and unidentified John Doe defendants, in the Superior Court of the State of Arizona, Pima County. Plaintiff alleges damages as a result of Amneal's and the pharmaceutical company defendants' improper marketing, failure to adequately warn of the risks of opioid medications, and failure to properly monitor and control diversion of opioid medications. Plaintiff seeks economic damages related to its purchase of opioid medications and for the costs of unreimbursed healthcare it has provided as a result of the opioid epidemic over and above ordinary healthcare services. Plaintiff further contends that between April 1, 2016, and September 30, 2017, it treated approximately 22,000 patients with an opioid-related condition. In addition, Plaintiff seeks compensatory damages, treble damages, punitive damages, awards of attorney's fees, and abatement of the alleged public nuisance, as provided by law. Plaintiff purports to assert eleven causes of action against all defendants, including: (1) Violation of RICO, A.R.S. § 13-2314.04—Opioid False Narrative Enterprise; (2) Violation of Arizona's Consumer Fraud Act (A.R.S. § 44-1522); (3) Negligence; (4) Wanton Negligence; (5) Negligence Per Se; (6) Negligent Marketing; (7) Negligent Distribution; (8) Nuisance; (9) Unjust Enrichment; (10) Fraud and Deceit; and (11) Civil Conspiracy to Commit Fraud and Maintain a Nuisance. On September 24, 2018, the distributor defendants removed the case to the United States District Court for the District of Arizona. Plaintiff filed a motion to remand on September 25, 2018, which the distributor defendants opposed. The Company filed a motion to dismiss on October 1, 2018. On October 8, 2018, following the Court's denial of its remand motion, Plaintiff voluntarily dismissed its Complaint without prejudice. Plaintiff re-filed its Complaint on October 9, 2018, in the Superior Court of the State of Arizona, Pima County, along with a motion to designate the case as "complex." The distributor defendants intend to once again remove the case to federal court.

AWP Litigation

On December 30, 2015, Plumbers' Local Union No. 690 Health Plan and others similarly situated filed a class action against several generic drug manufacturers, including Impax, in the Court of Common Pleas of Philadelphia County, First Judicial District of Pennsylvania, Civil Trial Division, alleging that Impax and others violated the law, including the Pennsylvania Unfair Trade Practices and Consumer Protection law, by inflating the Average Wholesale Price ("AWP") of certain generic drugs. The case has since been removed to federal court in the United States District Court for the Eastern District of Pennsylvania. By virtue of an amended complaint filed on March 29, 2016, the suit has been amended to comprise a nationwide class of third party payors that allegedly reimbursed or purchased certain generic drugs based on AWP and to assert causes of action under the laws of other states in addition to Pennsylvania. On May 17, 2016, this case was stayed. On January 18, 2017, Impax, along with the other defendants, filed a joint motion to dismiss the complaint. On September 15, 2017, the Court dismissed the complaint with prejudice. The time period to file an appeal has lapsed.

On February 5, 2016, Delaware Valley Health Care Coalition filed a lawsuit based on substantially similar allegations in the Court of Common Pleas of Philadelphia County, First Judicial District of Pennsylvania, Civil Trial Division that seeks declaratory judgment. On May 20, 2016, this case was stayed pending resolution of the federal court action described above.

Impax Laboratories, LLC. v. Turing Pharmaceuticals AG

On May 2, 2016, Impax filed suit against Turing in the United States District Court for the Southern District of New York alleging breach of the terms of the contract by which Turing purchased from Impax the right to sell the drug Daraprim®, as well as the right to sell certain Daraprim® inventory (the "Purchase Agreement"). Specifically, Impax seeks (i) a declaratory judgment that Impax may revoke Turing's right to sell Daraprim® under Impax's labeler code and national drug codes; (ii) specific performance to require Turing to comply with its obligations under the Purchase Agreement for past due reports and for reports going forward; and (iii) money damages to remedy Turing's failure to reimburse Impax for chargebacks and Medicaid rebate liability when due, currently in excess of $40.9 million and for future amounts that may be due. Turing has filed its answer and a counterclaim against Impax alleging breach of contract and breach of the duty of good faith and fair dealing. Discovery is closed. On October 14, 2016, Impax filed a motion for summary judgment. The District Court issued its order on September 29, 2017. The Court found that Turing breached the Purchase Agreement by failing to reimburse Impax for Medicaid rebate liability, however, the Court also found that Impax breached the Purchase Agreement by not filing a restatement with the Centers for Medicare and Medicaid Services at Turing's request. Therefore, Impax was not entitled to damages. On October 13, 2017, Impax filed a Motion for Clarification/Reconsideration of the Summary Judgment Order. On May 29, 2018, Impax filed a letter with the Court informing it of Impax's submission of a restatement of its Average Manufacturer Price for Daraprim for the third quarter of fiscal year 2015 and the fourth quarter of fiscal year 2015 and again requesting an order granting its Motion for Summary Judgment. On August 21, 2018, the Court entered an order granting in part Impax's reconsideration motion, and granting Impax's summary judgment claim for breach of contract for Medicaid rebate liability with respect to the time period beginning January 1, 2016.

Telephone Consumer Protection Act Cases

On January 31, 2017, Plaintiff Family Medicine Pharmacy LLC filed a class action complaint in the United States District Court for the Southern District of Alabama on behalf of itself and others similarly situated against Impax alleging violation of the Telephone Consumer Protection Act, as amended by the Junk Fax Prevention Act of 2005 (the "Telephone Consumer Protection Act"). On March 27, 2017, Impax filed a motion to dismiss the complaint and plaintiff filed an amended complaint on April 10, 2017. On July 18, 2017, the parties reached an agreement in principle regarding the class settlement. On September 29, 2017, the District Court preliminarily approved the proposed class settlement. The Court held a hearing on March 6, 2018 and issued an order with final approval of the proposed class settlement.

On February 14, 2017, Plaintiff Medicine To Go Pharmacies, Inc. filed a class action complaint in the United States District Court for the District of New Jersey on behalf of itself and others similarly situated against Impax alleging violation of the Telephone Consumer Protection Act. On April 17, 2017, Impax filed a motion to dismiss, transfer, or stay this case in light of the first-filed case described above. This case was transferred to the Southern District of Alabama. On September 15, 2017, the Court stayed this matter pending the final approval of the class settlement described above. In October 2018, the Company settled with the individual plaintiff (whose class claims were subsumed by and released in connection with the settlement reached in the earlier-filed Alabama action discussed above) for a nominal amount.

Securities Class Action

On April 17, 2017, Lead Plaintiff New York Hotel Trades Council & Hotel Association of New York City, Inc. Pension Fund filed an amended class action complaint in the United States District Court for the Northern District of California on behalf of itself and others similarly situated against Impax alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5. On June 1, 2017, Impax filed its motion to dismiss the amended complaint. On September 7, 2018, the Court granted Impax's motion, dismissing plaintiffs' claims without prejudice and with leave to amend their complaint. On September 18, 2018, the Court entered a Scheduling Order, providing that: plaintiffs' second amended complaint is due to be filed October 26, 2018; Impax's motion to dismiss is due December 6, 2018; plaintiffs' opposition thereto is due January 17, 2019; and Impax's reply in support of its motion to dismiss is due February 7, 2019.

Shareholder Derivative Action

On February 22, 2017, Plaintiff Ed Lippman filed a shareholder derivative complaint in the Superior Court for the State of California in the County of Alameda on behalf of Impax against former executives, a current executive, and certain current members of the board of directors alleging breach of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, and corporate waste. This matter has been stayed pending the securities class action referenced above.

Securities Class Actions related to the Combination

On December 12, 2017 and December 14, 2017, Plaintiffs Susan Vana and David Stone, respectively, filed class action complaints in the United States District Court for the Northern District of California on behalf of themselves and others similarly situated against Amneal and Impax alleging violations of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934 generally alleging that the Registration Statement on Form S-4 related to the Combination contains false and misleading statements and/or omissions concerning the financial projections of Impax, Amneal, and the combined company; Morgan Stanley & Co. LLC's valuation analyses and Fairness Opinions relating to Impax and Amneal; potential conflicts of interest associated with one of Impax's financial advisors and the Combination with Amneal; and background information of the proposed business combination, including confidentiality agreements entered into by Impax in connection with the Combination. On April 4, 2018, plaintiffs filed a Stipulation and Proposed Order voluntarily dismissing the actions and on April 5, 2018, the court issued an order to dismiss the actions. Plaintiffs did not file any petition for an award of attorneys' fees and expenses by the court-ordered deadline of June 1, 2018. The Court has now terminated the case on its docket.

Teva v. Impax Laboratories, LLC.

On February 15, 2017, Plaintiffs Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Curacao N.V. ("Teva") filed a Praecipe to Issue Writ of Summons and Writ of Summons (precursor to a complaint) in the Philadelphia County Court of Common Pleas against Impax alleging that Impax breached the Strategic Alliance Agreement between the parties by not indemnifying Teva in its two litigations with GlaxoSmithKline LLC regarding Wellbutrin® XL. Impax filed a Motion to Disqualify Teva's counsel related to the matter, and on August 23, 2017, the Court denied Impax's motion. Following the Court's order, Teva filed its complaint. Impax filed an appeal regarding the disqualification order, and a decision is pending. The matter is currently stayed pending an appellate decision on the disqualification order.

California Wage and Hour Class Action

On August 3, 2017, Plaintiff Emielou Williams filed a class action complaint in the Superior Court for the State of California in the County of Alameda on behalf of herself and others similarly situated against Impax alleging violation of California Business and Professions Code section 17200 by violating various California wage and hour laws. On October 10, 2017, Impax filed a Demurrer and Motion to Strike Class Allegations. On December 12, 2017, the Court overruled Impax's Demurrer to Plaintiff's individual claims, however, it struck all of Plaintiff's class allegations. On March 13, 2018, Plaintiff filed her First Amended Complaint once again including the same class allegations. The Company filed a Demurrer and Motion to Strike Class Allegations on April 12, 2018, and oral argument concerning the motion was heard on August 24, 2018. On September 20, 2018, the Court again struck Plaintiff's class allegations; Plaintiff has appealed this most recent order to the California State Court of Appeal.

19. Stockholders' Equity/ Members' Deficit

Members' Deficit Prior to the Combination

As of December 31, 2017, Amneal had 189 million units authorized, issued, and outstanding.

During 2018, the board of managers of Amneal approved a discretionary modification to the profit participation units be concurrent with the Combination that caused the vesting of all PPUs that were previously issued to certain current or former employees for service prior to the Combination. The modification entitled the holders to 6.9 million shares of Class A Common Stock with a fair value of $126.0 million on the date of the Combination and $32.8 million of cash. In July 2018, Holdings distributed the shares it received in the Redemption to settle the PPUs with no additional shares issued by the Company. Additionally, during 2018, Holdings distributed $27.7 million of cash bonuses to employees of Amneal for service prior to the Combination. As a result of these transactions, the Company recorded charges aggregating $186.5 million to acquisition, integration and transaction-related expenses during the nine months ended September 30, 2018, and corresponding capital contributions of $158.8 million related to the vesting of the PPUs and $27.7 million related to the cash bonus in members' accumulated deficit. During the nine months ended September 30, 2018, Amneal made distributions of $183.0 million to its members.

Pursuant to the BCA, Amneal's units prior to the Combination were canceled and the Amneal Common Units were distributed as discussed in further detail in the paragraph below.

Stockholders' Equity Subsequent to the Combination

Amended Certificate of Incorporation

In connection with the closing of the Combination, on May 4, 2018, the Company amended and restated its certificate of incorporation ("Charter") to, among other things, reflect the change of its name from Atlas Holdings, Inc. to Amneal Pharmaceuticals, Inc. and provide for the authorization of (i) 900 million shares of Class A Common Stock with a par value of $0.01 per share; (ii) 300 million shares of Class B Common Stock with a par value of $0.01 per share; (iii) 18 million shares of Class B-1 Common Stock with a par value of $0.01 per share; and (iv) 2 million shares of undesignated preferred stock with a par value of $0.01 per share.

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 and except in connection with the election of the Class B-1 director, holders of Class B-1 Common Stock are not entitled to vote on any matter. 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 and Class B-1 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, Class B Common Stock and Class B-1 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, Holdings will have the right to purchase its *pro rata* share of such securities, based on the number of shares of common stock owned by Holdings 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 Holdings and its 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 and Class B-1 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 or Class B-1 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 Units directly with the holder. Additionally, the Company may elect to settle any such redemption or exchange in shares of Class A Common stock, Class B-1 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 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 Charter, the Company's Board of Directors has the authority to issue preferred stock and set its rights and preferences. As of September 30, 2018, no preferred stock had been issued.

Common Stock Issued

In connection with the Combination, the Company issued 73.3 million shares of Class A Common Stock to the holders of Impax Common Stock and 225 million shares of Class B Common Stock to Holdings. In connection with the PIPE, Holdings redeemed 46.8 million shares of Class B Common Stock and an equal number of Amneal units for 34.5 million shares of unregistered Class A Common Stock and 12.3 million shares of unregistered Class B-1 Common Stock. In connection with the Redemption, Holdings redeemed an additional 6.9 million shares of Class B Common Stock and an equal number of Amneal Units for 6.9 million shares of Class A Common Stock for distribution to members of Holdings to whom PPUs were previously issued. No cash was received by the Company with respect to issuances of common stock. The Combination, the PIPE and the Redemption are more fully described in Note 1. Nature of Operations and Basis of Presentation.

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 the Limited Liability Company Agreement, Amneal is obligated to make tax distributions to its members. For the three and nine months ended September 30, 2018, a tax distribution of $35.5 million was recorded as a reduction of non-controlling interests. As of September 30, 2018, a liability of $35.5 million was included in related-party payables for the tax distribution.

Redeemable Non-Controlling Interest

During July 2018, a non-controlling interest holder in one of Amneal's non-public subsidiaries notified the Company of its intent to redeem its remaining ownership interest based on the terms of an agreement. During the second quarter of 2018, the Company reclassified the redeemable non-controlling interest and in September 2018, the Company made an $11.8 million cash purchase of the redeemable non-controlling interest. The Company recorded charges to stockholders' accumulated deficit and non-controlling interests of $1.2 million and $1.6 million, respectively, during the nine months ended September 30, 2018, to accrete the redeemable non-controlling interest to contract value. At September 30, 2018, no redeemable non-controlling interest remained outstanding.

20. 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 and restricted stock unit award grants are made in accordance with the Company's 2018 Plan and are subject to forfeiture if the vesting conditions are not met.

The aggregate number of shares of Class A Common Stock authorized for issuance pursuant to the Company's 2018 Plan is 23 million shares. As of September 30, 2018, the Company had 18,335,646 shares available for issuance under the 2018 Plan.

Exchanged Impax Options

As a result of the acquisition of Impax, on May 4, 2018, each Impax stock option outstanding immediately prior to the closing of the Combination became fully vested and exchanged for a fully vested and exercisable option to purchase an equal number of shares of Class A Common Stock of the Company with the same exercise price per share as the replaced options and otherwise subject to the same terms and conditions as the replaced options. Consequently, at the Closing, the Company issued 3.0 million fully vested stock options in exchange for the outstanding Impax options.

The Company recognizes the grant date fair value of each option and share of restricted stock unit over its vesting period. Stock options and restricted stock unit awards are granted under the Company's 2018 Plan and generally vest over a four 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 current year through September 30, 2018:

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, 2017	—	$ —		
Conversion of Impax stock options outstanding on May 4, 2018	3,002,669	18.90		
Options granted	3,462,780	16.58		
Options exercised	(278,302)	11.36		
Options forfeited	(325,048)	23.86		
Outstanding at September 30, 2018	5,862,099	$ 17.61	8.2	$ 34.2
Options exercisable at September 30, 2018	2,521,662	$ 19.04	6.2	$ 15.3

The intrinsic value of options exercised during the nine months ended September 30, 2018 was $2.6 million.

The following table summarizes all of the Company's restricted stock unit activity for the current year through September 30, 2018:

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, 2017	—	$ —		
Granted	1,371,672	17.23		
Vested	—	—		
Forfeited	(47,755)	18.64		
Non-vested at September 30, 2018	1,323,917	$ 17.18	3.5	$ 29.4

As of September 30, 2018, the Company had total unrecognized stock-based compensation expense of $44.5 million related to all of its stock-based awards, which is expected to be recognized over a weighted average period of 3.5 years.

The Company estimated the fair value of each stock option award on the grant date using the Black-Scholes option pricing model, wherein expected volatility is based on historical volatility of the publicly traded common stock of a peer group of companies. The expected term calculation is based on the "simplified" method described in SAB No. 107, Share-Based Payment, and SAB No. 110, Share-Based Payment, as the result of the simplified method provides a reasonable estimate in comparison to actual experience. The risk-free interest rate is based on the U.S. Treasury yield at the date of grant for an instrument with a maturity that is commensurate with the expected term of the stock options. The dividend yield of zero is based on the fact that the Company has never paid cash dividends on its common stock, and has no present intention to pay cash dividends. Options granted under each of the above plans generally vest over four years and have a term of 10 years. The following table presents the weighted-average assumptions used in the option pricing model for options granted under the 2018 Plan.

	September 30, 2018
Volatility	46.5%
Risk-free interest rate	2.9%
Dividend yield	— %
Weighted-average expected life (years)	6.25
Weighted average grant date fair value	$ 8.11

The amount of stock-based compensation expense recognized by the Company is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of goods sold	$ 400	$ —	$ 515	$ —
Selling, general and administrative	2,836	—	4,259	—
Research and development	354	—	460	—
Total	$ 3,590	$ —	$ 5,234	$ —

21. 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 related party relationships that generated income and or expense and in the respective reporting period are described below.

Kanan, LLC

Kanan, LLC ("Kanan") is an independent real estate company which 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. 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. Rent expense paid to the related party for both of the three months ended September 30, 2018 and 2017 was $0.5 million. Rent expense paid to the related party for both of the nine months ended September 30, 2018 and 2017 was $1.5 million.

AE Companies, LLC

AE Companies, LLC ("AE LLC") is an independent company which provides certain shared services and corporate type functions to a number of independent entities with respect to which, from time to time, Amneal conducts business. Amneal has ongoing professional service agreements with AE LLC for administrative and research and development services. The total amount of income earned from these agreements for the three months ended September 30, 2017 was $0.4 million (none in 2018). The total amount of income earned from these agreements for the nine months ended September 30, 2017 was $0.6 million (none in 2018).

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. Amneal provided research and development services to Asana under a development

and manufacturing agreement. The total amount of income earned from this arrangement for the three and nine months ended September 30, 2018 was $0.2 million (none in 2017). At September 30, 2018, receivables of $0.2 million were due from the related party.

Industrial Real Estate Holdings NY, LLC

Industrial Real Estate Holdings NY, LLC ("IRE") is an independent real estate management entity which, among other activities, is the landlord of Amneal's leased manufacturing facilities located at 75 and 85 Adams Avenue, Hauppauge, New York. The lease at 85 Adams Avenue expired in March 2017 while the lease for 75 Adams Avenue expires in March 2021. Rent expense paid to the related party for the three months ended September 30, 2018 and 2017 was $0.5 million and $0.3 million, respectively. Rent expense paid to the related party for the nine months ended September 30, 2018 and 2017 was $1.0 million and $0.9 million, respectively.

Kashiv Pharmaceuticals LLC

Kashiv Pharmaceuticals 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. In May 2013, Amneal entered into a sublease agreement with Kashiv for a portion of one of its research and development facilities. The sublease automatically renews annually if not terminated and has an annual base rent of $1.8 million. Rental income from the related party sublease for the three months ending September 30, 2017 was $0.5 million (none in 2018). Rental income from the related party sublease for the nine months ended September 30, 2018 and 2017 was $0.4 million and $1.5 million, respectively. On January 15, 2018, Amneal and Kashiv entered into an Assignment and Assumption of Lease Agreement. The lease was assigned to Kashiv, and Amneal was relieved of all obligations. At September 30, 2018 and December 31, 2017, $0.6 million and $10.4 million of receivables were due, respectively.

Amneal has also entered into various development and commercialization arrangements with Kashiv to collaborate on the development and commercialization of certain generic pharmaceutical products. Kashiv receives a percentage of net profits with respect to Amneal's sales of these products. The total profit share paid to Kashiv for the three months ended September 30, 2018 and 2017 was $0.8 million and $0.3 million, respectively. The total profit share paid to Kashiv for the nine months ended September 30, 2018 and 2017 was $2.8 million and $9.6 million, respectively. In addition, Amneal provided development services to Kashiv in the amount of $1.1 million for the nine months ended September 30, 2018 (none in the three months ended September 30, 2018). At September 30, 2018 and December 31, 2017 payables of $0.8 million and $0.6 million, respectively, were due to the related party for royalty-related transactions.

In June 2017, Amneal and Kashiv entered a product acquisition and royalty stream purchase agreement. The aggregate purchase price was $25 million on the closing, which has been paid, plus two potential future $5 million earn outs related to the Estradiol Product. The contingent earn outs will be recorded in the period in which they are earned. The first and second $5 million earn outs were recognized in March 2018 and June 2018, respectively, as an increase to the cost of the Estradiol product intangible asset and will be amortized on a straight-line basis over the remaining life of the Estradiol intangible asset. The first earn out was paid in July 2018 and the second earn out was paid in September 2018.

Pursuant to a product development agreement, Amneal and Kashiv agreed to collaborate on the development and commercialization of Oxycodone HCI ER Oral Tablets. Under the agreement, this product is owned by Kashiv, with Amneal acting as the exclusive marketing partner and as Kashiv's agent for filing the product ANDA. Under the agreement, Amneal was also responsible for assuming control of and managing all aspects of the patent litigation arising from the filing of the ANDA, including selecting counsel and settling such proceeding (subject to Kashiv's consent). In December 2017, Amneal and Kashiv terminated the product development agreement and pursuant to the termination and settlement of the agreement, Kashiv agreed to pay Amneal $7.8 million, an amount equal to the legal costs incurred by Amneal related to the defense of the ANDA. The $7.8 million settlement was recorded within general and administrative expenses for the year ended December 31, 2017 and related-party receivables as of December 31, 2017. The cash payment was received in February 2018.

Adello Biologics, LLC

Adello is an independent clinical stage company engaged in the development of biosimilar pharmaceutical products. Amneal and Adello are parties to a master services agreement pursuant to which, from time to time, Amneal provides human resources and product quality assurance services on behalf of Adello. The parties are also party to a license agreement for parking spaces in Piscataway, NJ. The total amount of net expense paid to Adello from these agreements for both of the three months ended September 30, 2018 and 2017 was less than $0.1 million. The total amount of net expense paid to Adello from these agreements for both of the nine months ended September 30, 2018 and 2017 was $0.1 million.

In March 2017, Amneal entered into a product development agreement with Adello. The collaboration extended the remaining development process to Adello for a complex generic product, while Amneal retained its commercial rights upon approval. Pursuant to the agreement, Adello paid Amneal $10 million for reimbursement of past development costs, which Amneal deferred as a liability and will pay royalties upon commercialization.

In October 2017, Amneal and Adello terminated their product development agreement pursuant to which Amneal and Adello had been collaborating to develop and commercialize Glatiramer Acetate products. Pursuant to the termination agreement, Amneal owed Adello $10.5 million for the up-front payment plus interest. This amount was paid in January 2018 and recognized as a related party payable in the Consolidated Balance Sheet as of December 31, 2017.

On October 1, 2017, Amneal and Adello entered into a license and commercialization agreement pursuant to which the parties have agreed to cooperate with respect to certain development activities in connection with two biologic pharmaceutical products. In addition, under the agreement, Adello has appointed Amneal as its exclusive marketing partner for such products in the United States. In connection with the agreement, Amneal paid an upfront amount of $1.5 million in October 2017 which was recorded within research and development expenses in the Consolidated Statement of Income. The agreement also provides for potential future milestone payments to Adello.

In October 2017, Amneal purchased a building from Adello in Ireland to further support its inhalation dosage form. Amneal issued a promissory note for 12.5 million euros ($14.7 million based on exchange rate as of December 31, 2017) which accrues interest at a rate of 2% per annum, due on or before July 1, 2019. The promissory note was paid in full in the second quarter of 2018.

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. Currently PharmaSophia is actively developing two injectable products. PharmaSophia and Nava are parties to a research and development agreement pursuant to which Nava provides research and development services to PharmaSophia. Nava subcontracted this obligation to Amneal, entering into a subcontract research and development services agreement pursuant to which Amneal provides research and development services to Nava in connection with the products being developed by PharmaSophia. The total amount of income earned from these agreements for the three months ended September 30, 2018 and 2017 was $0.2 million and $0.1 million, respectively. The total amount of income earned from these agreements for the nine months ended September 30, 2018 and 2017 was $0.5 million and $0.2 million, respectively. At September 30, 2018 and December 31, 2017 receivables of $0.1 million and $0.1 million, respectively, were due from the related party.

Gemini Laboratories, LLC

Prior to the Company’s acquisition of Gemini in May 2018 as described in Note 3. Acquisitions and Divestitures, Amneal and Gemini were parties to various agreements. Total gross profit earned from the sale of inventory to Gemini for the three months ended September 30, 2017 was $1.3 million. Total gross profit earned from the sale of inventory to Gemini for the nine months ended September 30, 2018 (through the acquisition date) and 2017 was $0.1 million and $2.2 million, respectively. The total profit share paid by Gemini for the three months ended September 30, 2017 was $2.4 million. The total profit share paid by Gemini for the nine months ended September 30, 2018 (through the acquisition date) and 2017 was $4.8 million and $8.5 million, respectively. At December 31, 2017, receivables of $5.6 million were due from the related party.

At September 30, 2018, the Company has a note payable owed to the sellers of Gemini in the amount of $78.1 million, which includes $77.2 million of principal and $0.9 million of accrued interest. The Company has incurred interest expense related to the note payable of $0.6 million and $0.9 million for the three and nine months ended September 30, 2018, respectively.

APHC Holdings, LLC (formerly, Amneal Holdings, LLC)

APHC Holdings, LLC (formerly, Amneal Holdings, LLC) was the ultimate parent of Amneal prior to the Combination. In connection with the Combination, Amneal is required to reimburse transaction-related costs incurred by APHC Holdings. As of September 30, 2018, no amounts were due to APHC Holdings.

Tax Distributions

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 19. Stockholders' Equity/ Members' Deficit.

22. 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 three months ended September 30, 2018 and 2017, the Company made matching contributions of $2.3 million and $0.7 million, respectively. For the nine months ended September 30, 2018 and 2017, the Company made matching contributions of $6.6 million and $1.9 million, respectively.

The Company also has a deferred compensation plan for certain former executives of Impax. 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 other long-term liabilities. The Company invests participant contributions in corporate-owned life insurance policies, for which the cash surrender value is included in other non-current assets. Matching contributions for the three and nine months ended September 30, 2018 were immaterial.

23. Segment Information

The Company has two reportable segments, the Generics business and the Specialty Pharma business. The Generics business develops, manufactures and commercializes complex oral solids, injectables, ophthalmics, liquids, topicals, softgels, inhalation products and transdermals across a broad range of therapeutic categories. The Company's retail and institutional portfolio contains approximately 200 product families, many of which represent difficult-to-manufacture products or products that have a high barrier-to-entry, such as oncologics, anti-infectives and supportive care products for healthcare providers.

The Specialty Pharma business delivers proprietary medicines to the U.S. market. The Company offers a growing portfolio in core therapeutic categories including central nervous system disorders, endocrinology, parasitic infections and other therapeutic areas. 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.

The Specialty Pharma business also has a number of product candidates that are in varying stages of development.

The Company's chief operating decision maker evaluates the financial performance of the Company's segments based upon segment operating income (loss). Items below income (loss) from operations 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 maker.

The tables below present segment information reconciled to total Company financial results, with segment operating income or loss including gross profit less direct research and development expenses and direct selling expenses as well as any litigation settlements, to the extent specifically identified by segment (in thousands):

Three Months Ended September 30, 2018	Generics	Specialty Pharma	Corporate and Other	Total Company
Net revenue	$391,175	$ 85,312	$ —	$476,487
Cost of goods sold	237,866	38,516	—	276,382
Gross profit	153,309	46,796	—	200,105
Selling, general and administrative	21,030	19,716	37,329	78,075
Research and development	38,997	4,002	—	42,999
Intellectual property legal development expenses	3,929	472	—	4,401
Acquisition, transaction-related and integration expenses	—	—	2,231	2,231
Restructuring expenses	(2,885)	(27)	756	(2,156)
Operating income (loss)	$ 92,238	$ 22,633	$ (40,316)	$ 74,555

Nine Months Ended September 30, 2018	Generics	Specialty Pharma	Corporate and Other	Total Company
Net revenue	$1,028,134	$137,329	$ —	$1,165,463
Cost of goods sold	579,994	62,474	—	642,468
Gross profit	448,140	74,855	—	522,995
Selling, general and administrative	48,854	33,265	74,080	156,199
Research and development	130,412	7,131	—	137,543
Intellectual property legal development expenses	12,509	515	—	13,024
Acquisition, transaction-related and integration expenses	114,622	—	102,251	216,873
Restructuring expenses	21,912	2,394	18,003	42,309
Operating income (loss)	$ 119,831	$ 31,550	$(194,334)	$ (42,953)

Three Months Ended September 30, 2017	Generics	Specialty Pharma	Corporate and Other	Total Company
Net revenue	$254,733	$ —	$ —	$254,733
Cost of goods sold	119,720	—	—	119,720
Gross profit	135,013	—	—	135,013
Selling, general and administrative	15,030	—	12,410	27,440
Research and development	41,323	—	—	41,323
Intellectual property legal development expenses	6,693	—	—	6,693
Legal settlement gain	(21,467)	—	—	(21,467)
Acquisition and transaction-related expenses	—	—	2,271	2,271
Operating income (loss)	$ 93,434	$ —	$(14,681)	$ 78,753

Nine Months Ended September 30, 2017	Generics	Specialty Pharma	Corporate and Other	Total Company
Net revenue	$740,285	$ —	$ —	$740,285
Cost of goods sold	365,523	—	—	365,523
Gross profit	374,762	—	—	374,762
Selling, general and administrative	44,838	—	37,242	82,080
Research and development	127,926	—	—	127,926
Intellectual property legal development expenses	17,786	—	—	17,786
Legal settlement gain	(21,467)	—	—	(21,467)
Acquisition and transaction-related expenses	—	—	2,353	2,353
Operating income (loss)	$205,679	$ —	$(39,595)	$166,084

Significant Products

The Company generally consolidates net revenue by "product family," meaning that it consolidates net revenue from products containing the same active ingredient(s) irrespective of dosage strength, delivery method or packaging size. The Company's significant product families, as determined based on net revenue, and their percentage of the Company's consolidated net revenue for each of the three and nine months ended September 30, 2018 and 2017 are set forth below (in thousands, except for percentages):

Segment	Product Family	Three Months Ended September 30, 2018	
		$	%
Generics	Yuvafem-Estradiol	$ 48,466	10%
Specialty Pharma	Rytary® family	$ 33,073	7%
Generics	Epinephrine Auto-Injector family (generic Adrenaclick®)	$ 30,259	6%
Generics	Diclofenac Sodium Gel	$ 26,455	6%
Generics	Aspirin; Dipyridamole ER Capsul	$ 22,777	5%

Segment	Product Family	Three Months Ended September 30, 2017	
		$	%
Generics	Aspirin; Dipyridamole ER Capsul	$ 29,539	12%
Generics	Yuvafem-Estradiol	$ 29,317	12%
Generics	Diclofenac Sodium Gel	$ 23,903	9%
Generics	Oseltamivir	$ 19,383	8%
Generics	Lidocaine	$ 8,685	3%

Segment	Product Family	Nine Months Ended September 30, 2018	
		$	%
Generics	Yuvafem-Estradiol	$ 106,477	9%
Generics	Diclofenac Sodium Gel	$ 78,551	7%
Generics	Aspirin; Dipyridamole ER Capsul	$ 67,718	6%
Specialty Pharma	Rytary® family	$ 53,593	5%
Generics	Epinephrine Auto-Injector family (generic Adrenaclick®)	$49,425	4%

Segment	Product Family	Nine Months Ended September 30, 2017	
		$	%
Generics	Yuvafem-Estradiol	$ 100,094	14%
Generics	Diclofenac Sodium Gel	$ 66,023	9%
Generics	Aspirin; Dipyridamole ER Capsul	$ 45,133	6%
Generics	Lidocaine	$ 24,563	3%
Generics	Atovaquone	$ 23,198	3%

Item 2. Management's Discussion and Analysis of Results of Operations and Financial Condition

The following discussion and analysis summarizes the significant factors affecting the results of operations, financial condition and liquidity position of the Company as of and for the three and nine months ended September 30, 2018 and should be read in conjunction with the consolidated financial statements and related notes of thereto included elsewhere in this Quarterly Report on Form 10-Q and with our audited consolidated financial statements included in our Registration Statement on Form S-1, as amended, filed with the Securities and Exchange Commission on May 7, 2018.

The following discussion and analysis contains forward-looking statements that reflect Amneal Pharmaceuticals, Inc.'s plans, estimates and beliefs. Actual results could differ materially from those discussed in the forward-looking statements. Statements included in this Quarterly Report on Form 10-Q that do not relate to present or historical conditions are "forward-looking statements." Such forward-looking statements involve risks and uncertainties that could cause results or outcomes to differ materially from those expressed in the forward-looking statements. Forward-looking statements may include statements relating to our plans, strategies, objectives, expectations and intentions. Words such as "believes," "forecasts," "intends," "possible," "estimates," "anticipates," and "plans" and similar expressions are intended to identify forward-looking statements. Our ability to predict results or the effect of events on our operating results is inherently uncertain. Such risks and uncertainties include, but are not limited to: the impact of global economic conditions; our ability to integrate the operations of Amneal Pharmaceuticals LLC and Impax Laboratories, LLC pursuant to the business combination completed on May 4, 2018, and our ability to realize the anticipated synergies and other benefits of the combination; our ability to successfully develop and commercialize new products; our ability to obtain exclusive marketing rights for our products and to introduce 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 manage our growth; the illegal distribution and sale by third parties of counterfeit versions of our products or of stolen products; market perceptions of us and the safety and quality of our products; our dependence on the sales of a limited number of products for a substantial portion of our total revenues; our ability to develop, license or acquire and introduce new products on a timely basis; the ability of our approved products to achieve expected levels of market acceptance; the risk that we may discontinue the manufacture and distribution of certain existing products; the impact of manufacturing or quality control problems; 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 United States federal and state laws related to healthcare fraud abuse and health information privacy and security and changes in such laws; changes to FDA product approval requirements; risks related to federal regulation of arrangements between manufacturers of branded and generic products; the impact of healthcare reform and changes in coverage and reimbursement levels by governmental authorities and other third-party payers; our dependence on a few locations that produce a majority of our products; relationships with our major customers; the continuing trend of consolidation of certain customer groups; our reliance on certain licenses to proprietary technologies from time to time; our dependence on third party suppliers and distributors for raw materials for our products and certain finished goods; the time necessary to develop generic and branded drug products; our dependence on third parties for testing required for regulatory approval of our products; our dependence on third party agreements for a portion of our product offerings; our ability to make acquisitions of or investments in complementary businesses and products on advantageous terms; regulatory oversight related to our international operations; our increased exposure to tax liabilities due to our international operations and the impact of recent U.S. tax legislation; payments required by our Tax Receivable Agreement; our involvement in various legal proceedings, including those brought by third parties alleging infringement of their intellectual property rights; legal, regulatory and legislative efforts by our brand competitors to deter competition from our generic alternatives; the significant amount of resources we expend on research and development; 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; risks inherent in conducting clinical trials; our reporting and payment obligations under the Medicaid rebate program and other government purchase and rebate programs; quarterly fluctuations in our operating results; adjustments to our reserves based on price adjustments and sales allowances; investigations and litigation concerning the calculation of average wholesale prices; the high concentration of ownership of our Class A Common Stock and the fact that we are controlled by the Amneal Group; and such other factors as may be set forth elsewhere in this Quarterly Report, particularly in the section entitled "*Risk Factors*" and our public filings with the SEC.

Overview

Amneal Pharmaceuticals, Inc. is a pharmaceutical company specializing in developing, manufacturing, marketing and distributing high-value generic pharmaceutical products across a broad array of dosage forms and therapeutic areas, as well as branded products. We were formed on October 4, 2017, under the name Atlas Holdings, Inc. for the purpose of facilitating the combination of Impax Laboratories, Inc. ("Impax") and Amneal Pharmaceuticals LLC ("Amneal"), which closed on May 4, 2018. Refer to "Item 1. Financial Statements—Notes to Consolidated Financial Statements—Note 1. Nature of Operations and Basis of Presentation" for further information related to the Combination. Prior to the consummation of the Combination, Amneal and Impax operated separately as independent companies. We operate in two segments, referred to as the Generics business and the Specialty Pharma business. The Generics business concentrates its efforts on generic products, which are the pharmaceutical and therapeutic equivalents of brand-name drug products and are usually marketed under their established nonproprietary drug names rather than a brand name. The Specialty Pharma business utilizes its specialty sales force to market proprietary branded pharmaceutical products for the treatment of CNS disorders and other select specialty segments.

The Generics business specializes in developing, manufacturing, marketing and distributing high-value generic pharmaceutical products across a broad array of dosage forms and therapeutic areas. We currently market over 200 product families in the United States and our marketed and pipeline generics portfolios cover an extensive range of dosage forms and delivery systems, including both immediate and extended release oral solids such as tablets, capsules and powders, liquids, sterile injectables, nasal sprays, inhalation and respiratory products, ophthalmics (which are sterile pharmaceutical preparations administered for ocular conditions), films, transdermal patches and topicals (which are creams or gels designed to administer pharmaceuticals locally through the skin). We focus on developing products with substantial barriers-to-entry as a result of complex drug formulations or manufacturing, legal and/or regulatory challenges. We believe that focusing on these opportunities allows us to offer first-to-file ("FTF"), first-to-market ("FTM") and other "high-value" products, which we define as products with zero to three generic competitors at time of launch. These products tend to be more profitable and often have longer life cycles than other generic pharmaceuticals. As of September 30, 2018, we had 156 products approved but not yet launched or pending FDA approval and another 123 products in various stages of clinical development. Over 58% of our total generic pipeline consists of potential FTF, FTM and high-value products. We believe that as of the date of this report we are leading the U.S. generics market in product approvals and launches in 2018, with 56 of our products receiving final approval, 10 receiving tentative approval and 39 product launches.

The Specialty Pharma business is comprised of the Impax Specialty business acquired on May 4, 2018 and the Gemini business acquired on May 7, 2018. Refer to "Item 1. Financial Statements—Notes to Interim Consolidated Financial Statements—Note 3. Acquisitions and Divestitures" for further information related to the Combination and the Gemini acquisition. Prior to these two transactions, we did not have a specialty business. The Specialty Pharma business is engaged in the development, promotion, sale and distribution of proprietary branded pharmaceutical products that we believe represent improvements to already-approved pharmaceutical products addressing CNS disorders, including migraine, multiple sclerosis, Parkinson's disease and post-herpetic neuralgia, and branded pharmaceutical products in other select specialty segments. We believe that we have the research, development and formulation expertise to develop branded products that will deliver significant improvements over existing therapies.

Our branded pharmaceutical product portfolio currently consists of commercial CNS and other select specialty products, including its internally developed branded product, Rytary® (IPX066), 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 and/or manganese intoxication, which was approved by the FDA on January 7, 2015 and which Impax began marketing in the United States in April 2015. Impax received marketing authorization from the European Commission for Numient® (the brand name of IPX066 outside of the United States) during the fourth quarter of fiscal year 2015. In addition to Rytary®, the Amneal Specialty Pharma division is also currently engaged in the sale and distribution of four other branded products; the more significant include Zomig® (zolmitriptan) products, indicated for the treatment of migraine headaches, under the terms of a Distribution, License, Development and Supply Agreement with AstraZeneca UK Limited ("AstraZeneca") in the United States and in certain U.S. territories, and Emverm® (mebendazole) 100 mg chewable tablets, indicated for the treatment of pinworm, whipworm, common roundworm, common hookworm, and American hookworm in single or mixed infections.

Results of Operations

Overview

The following table sets forth our summarized, consolidated results of operations for the three and nine months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net revenue	476,487	254,733	1,165,463	740,285
Gross profit	200,105	135,013	522,995	374,762
Operating income (loss)	74,555	78,753	(42,953)	166,084
Income (loss) before income taxes	22,574	26,384	(187,916)	109,248
Provision for (benefit from) income taxes	5,109	(738)	(6,943)	2,117
Net income (loss)	17,465	27,122	(180,973)	107,131

Consolidated net revenues for the three months ended September 30, 2018 increased by 87%, or $221.8 million, to $476.5 million compared to $254.7 million for the three months ended September 30, 2017. Consolidated net revenues for the nine months ended September 30, 2018 increased by 57%, or $425.2 million, to $1,165.5 million compared to $740.3 million for the nine months ended September 30, 2017. The increases were primarily attributable to the acquisitions of Impax on May 4, 2018 and Gemini on May 7, 2018, as well as new product launches in the period in our Generics business.

We recognized net income of $17.5 million for the three months ended September 30, 2018 and a net loss of $181.0 million for the nine months ended September 30, 2018. We recognized net income of $27.1 million and $107.1 million for the three and nine months ended September 30, 2017, respectively. Our results for the three months ended September 30, 2018 are impacted by the May 4, 2018 combination with Impax, including approximately $24.0 million of incremental interest expense. Our results for the nine months ended September 30, 2018 are impacted by the May 4, 2018 combination with Impax, including second quarter charges of $158.8 million for the vesting of profit participation units, $28.0 million for special employee payments, $30.4 million for acquisition, transaction-related and integration expenses, $42.3 million for restructuring, primarily related to severance, and $19.7 million for a loss on extinguishment of debt, as well as approximately $49.6 million of incremental interest expense.

Generics Business

The following table sets forth results of operations for our Generics segment for the three and nine months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net revenue	$ 391,175	$ 254,733	$ 1,028,134	$ 740,285
Cost of goods sold	237,866	119,720	579,994	365,523
Gross profit	153,309	135,013	448,140	374,762
Selling, general and administrative	21,030	15,030	48,854	44,838
Research and development	38,997	41,323	130,412	127,926
Intellectual property legal development expenses	3,929	6,693	12,509	17,786
Legal settlement gain	—	(21,467)	—	(21,467)
Acquisition, transaction-related and integration expenses	—	—	114,622	—
Restructuring expenses	(2,885)	—	21,912	—
Operating income	$ 92,238	$ 93,434	$ 119,831	$ 205,679

Revenues

Net revenues for the Generics business increased by 54% and 39% for the three and nine months ended September 30, 2018, respectively, when compared with the same period in 2017. The increase in net revenues in the three month period as compared to the prior year period is primarily attributable to strong 2018 launches, including Methylphenidate Hydrochloride extended release tablets, Phytonadione tablets and Potassium Chloride oral solution, higher demand for Yuvafem, Diflofenac Sodium gel 1% and Spironoctalone cream, and the combination with Impax. These increases are offset by lower demand for Oseltamivir, Diclofenac Sodium gel 3%, and Epinephrine auto-injector due to supply constraints.

The increase in net revenues for the nine month period as compared to the prior year period is primarily attributable to strong new launches, including Methylphenidate Hydrochloride extended release tablets, Phytonadione tablets and Erythromycin instant release tablets, higher demand for Aspirin Dipyridamole extended release capsules, Oseltamivir and Triamcinolone Acetonide injectable suspension, and the combination with Impax. These increases are offset by lower demand for Lidocaine gel, Diclofenac Sodium gel and Diclofenac tables as well as supply constraints on Epinephrine auto injector.

Cost of Goods Sold and Gross Profit

Cost of goods sold for the three months ended September 30, 2018 was $237.9 million, an increase of $118.1 million compared to the prior year period. The increase in cost of goods sold was primarily attributable to new product launches and higher product sales due to the combination with Impax. Additional increases to cost of goods sold were driven by $39.3 million of inventory related expenses, including $20.9 million for purchase accounting adjustments related to amortization of intangible assets and inventory, $10.2 million of excess capacity charges associated with the wind-down of our Hayward, CA manufacturing plant, and an impairment of product intangible assets of $7.8 million.

Cost of goods sold for the nine months ended September 30, 2018 was $580.0 million, an increase of $214.5 million compared to the prior year period. The increase in cost of goods sold was primarily attributable to new product launches and higher product sales due to the combination with Impax. Additional increases to cost of goods sold were driven by $74.8 million of inventory related expenses, including $39.0 million for purchase accounting adjustments related to amortization of intangible assets and inventory, $15.2 million of excess capacity charges associated with the wind-down of our Hayward, CA manufacturing plant, an impairment of product intangible assets of $7.8 million and write-offs of pre-launch inventory of approximately $8.0 million.

Accordingly, gross profit for the three and nine months ended September 30, 2018 was $153.3 million (39.2% of total revenues) and $448.1 million (43.6% of total revenues), respectively, as compared to gross profit of $135.0 million (53.0% of total revenues) and $374.8 million (50.6% of total revenues) for the comparable prior year periods. Our gross profit as a percentage of sales declined compared to both prior year periods primarily as a result of higher cost of sales due to incremental amortization and inventory acquisition accounting adjustments, inventory related charges, impairment of product intangible assets and lower margin products in the Impax portfolio.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses for the three months ended September 30, 2018 were $21.0 million, as compared to $15.0 million for the three months ended September 30, 2017. The $6.0 million increase from the prior period was primarily due to the combination with Impax.

Selling, general, and administrative expenses for the nine month period ended September 30, 2018 were $48.9 million, as compared to $44.8 million for the nine month period ended September 30, 2017. The $4.0 million increase from the prior period was primarily due to the combination with Impax, partially offset by savings generated from prior year divestitures of several international business.

Research and Development Expenses

Research and development expenses for the three month period ended September 30, 2018 were $39.0 million, as compared to $41.3 million for the three months ended September 30, 2017. The decrease from the prior year was primarily due to lower usage of materials and lower external development costs due to timing, slightly offset by an increase in spending on projects acquired in the combination with Impax.

Research and development expenses for the nine month period ended September 30, 2018 were $130.4 million, as compared to $127.9 million for the nine month period ended September 30, 2017. The $2.5 million increase from the prior year period was primarily due to an increase in spending from the first quarter for increased external development costs and higher GDUFA filing fees.

Intellectual Property Legal Development Expense

Intellectual property legal development expenses for the three and nine months ended September 30, 2018 were $3.9 million and $12.5 million, respectively, as compared to $6.7 million and $17.8 million for the prior year periods. The $2.8 million decrease for the three months ended September 30, 2018 and $5.3 million decrease for the nine months ended September 30, 2018 was primarily due to reduced expenses related to trials on patent challenges during 2018. These costs include, but are not limited to, formulation assessments, patent challenge opinions and strategy, and litigation expenses to defend the intellectual property.

Legal Settlement Gain

We recognized a legal settlement gain of $21.5 million for the three and nine month periods ended September 30, 2017. In July 2017, we settled an anti-competitive claim against the innovator of Suboxone, a combination of active pharmaceutical ingredients Buprenorphine and Naloxone.

Acquisition, Transaction-related and Integration Expenses

We recognized approximately $114.6 million of acquisition, transaction-related and integration expenses for the nine month period ended September 30, 2018 with no comparable charges in 2017. This cost primarily represents a $98.2 million charge for the vesting of profit participation units and a $16.4 million charge for special employee bonuses during the second quarter.

Restructuring

We recorded an approximate $2.9 million net benefit, primarily related to changes in estimates for certain employee-related separation liabilities for the three months ended September 30, 2018. The changes in estimates were primarily associated with employees who exited early.

We recorded an approximate $21.9 million restructuring charge for the nine month period ended September 30, 2018 with no comparable charge in 2017. This severance charge primarily relates to a reduction in workforce resulting from the combination with Impax.

Specialty Pharma Business

The following table sets forth results of operations for our Specialty Pharma business for the three and nine months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net revenue	$ 85,312	$ —	$137,329	$—
Cost of goods sold	38,516	—	62,474	—
Gross profit	46,796	—	74,855	—
Selling, general and administrative	19,716	—	33,265	—
Research and development	4,002	—	7,131	—
Intellectual property legal development expenses	472	—	515	—
Acquisition, transaction-related and integration expenses	—	—	—	—
Restructuring expenses	(27)	—	2,394	—
Operating income	$ 22,633	$ —	$ 31,550	$—

Our Specialty Pharma business is comprised of the Impax Specialty business acquired on May 4, 2018 and the Gemini Laboratories, LLC business acquired on May 7, 2018. Prior to these two transactions, we did not have a specialty business. Refer to "Item 1. Financial Statements - Notes to Financial Statements - Note 3. Acquisitions and Divestitures" for further information related to these two transactions.

Corporate and Other

The following table sets forth corporate general and administrative expenses, as well as other items of income and expense presented below income or loss from operations for the three and nine month periods ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net revenue	$ —	$ —	$ —	$ —
Cost of goods sold	—	—	—	—
Gross profit	—	—	—	—
General and administrative	37,329	12,410	74,080	37,242
Research and development	—	—	—	—
Intellectual property legal development expenses	—	—	—	—
Acquisition, transaction-related and integration expenses	2,231	2,271	102,251	2,353
Restructuring expenses	756	—	18,003	—
Operating loss	$(40,316)	$(14,681)	$(194,334)	$(39,595)
Other expense, net	$(51,981)	$(52,369)	$(144,963)	$(56,836)

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2018 were $37.3 million, as compared to $12.4 million for the three months ended September 30, 2017. The $24.9 million increase compared to the prior year period was primarily due to general and administrative expenses of the Impax organization since combination, which includes certain public company costs that will remain on a go-forward basis. The increase is also attributable to stock-based compensation.

General and administrative expenses for the nine months ended September 30, 2018 were $74.1 million, as compared to $37.2 million for the nine months ended September 30, 2017. The $36.8 million increase compared to the prior year period was primarily due to general and administrative expenses of the Impax organization since combination, which includes certain public company costs that will remain on a go-forward basis. The increase is also attributable to stock-based compensation.

Acquisition, Transaction-related and Integration Expenses

We recognized $2.2 million of acquisition, transaction-related and integration expenses for the three months ended September 30, 2018, as compared to $2.3 million for the three month period ended September 30, 2017.

We recognized approximately $102.3 million of acquisition, transaction-related and integration expenses for the nine months ended September 30, 2018, as compared to $2.4 million for the nine month period ended September 30, 2017. This cost primarily represents a $60.6 million charge for the vesting of profit participation units, a $12.2 million charge for special employee bonuses at the closing of the Combination and $29.5 million of advisor and other third party costs associated with the Combination and integration.

Restructuring

We recorded a $18.0 million restructuring charge in the nine months ended September 30, 2018 with no comparable charge in 2017. This severance charge primarily relates to a reduction in workforce resulting from the combination with Impax.

Other Income (Expense)

We recognized approximately $52.0 million and $145.0 million of other expense for the three and nine months ended September 30, 2018, respectively. For the three and nine months ended September 30, 2017, the Company recognized $52.4 million and $56.8 million of other expense, respectively. The increase of approximately $88.1 million for the nine months ended September 30, 2018 is caused by $43.0 million of additional interest expense associated with an increase in long-term debt, $48.3 million increase in foreign exchange loss caused by fluctuation in the Swiss Franc and Indian Rupee, a $19.7 million loss on extinguishment of debt arising from the debt refinancing executed in connection with the Impax combination and is offset by a $26.1 million reduction in loss on sale of certain international businesses.

Liquidity and Capital Resources

Our primary source of liquidity is cash generated from operations, available cash and borrowings under debt financing arrangements, including $400 million of available additional capacity on the ABL. 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.

Our primary uses of capital resources are to fund operating activities, including research and development expenses associated with new product filings, and pharmaceutical product manufacturing expenses, license payments, and spending on production facility expansions and capital equipment items.

On November 7, 2018, we made a payment to settle a $77.2 million note payable and related interest associated with the purchase of Gemini, as described above under Item 1. Financial Statements—Notes to Consolidated Financial Statements—Note 3. Acquisitions and Divestitures. Over the next 12 months, we will also make substantial payments for monthly interest and quarterly principal amounts due on our Senior Secured Credit Facilities, severance, and capital expenditures. We will also be required to make a $50 million payment to JSP upon our first sale of Levothyroxine pursuant to the terms of a license and supply agreement, as described above under Item 1. Financial Statements—Notes to Consolidated Financial Statements—Note 5. Alliance and Collaboration. Given the magnitude of projected expenditures, we may require additional funds from our ABL to meet these increased cash needs in the next year.

As of September 30, 2018, we had total cash and cash equivalents of $165.2 million, compared to $74.2 million of cash and cash equivalents as of December 31, 2017. The increase of $91.0 million during the nine months ended September 30, 2018 resulted primarily from net cash provided by financing activities of $506.6 million, partially offset by net cash used in investing activities of $401.7 million and net cash used in operating activities of $9.4 million.

Significant financing activities for the nine months ended September 30, 2018 include $684.9 million of net new borrowings and $27.7 million of equity contributions, partially offset by $183.0 million of distributions to members, repayment of a related party note payable of $14.8 million, and payment of $11.8 million for the acquisition of a redeemable non-controlling interest in one of Amneal’s subsidiaries.

Net cash used in investing activities for the nine months ended September 30, 2018 includes payments for acquisitions, net of cash acquired, of $282.3 million for the acquisition of Impax and $42.3 million for the acquisition of Gemini, and $10 million for the acquisition of Estradiol product rights from Kashiv.

At September 30, 2018, our cash and cash equivalents consist of cash on deposit and highly liquid investments. A portion of our cash flows are derived outside the United States. 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 (FDIC). 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

Our net cash used in operating activities was $9.4 million for the nine months ended September 30, 2018, as compared to cash provided by operating activities of $168.9 million for the nine months ended September 30, 2017. The decrease of $178.3 million in net cash provided by operating activities was primarily attributed to increased transaction and integration costs in connection with the acquisitions of Impax and Gemini, increased purchases of inventory to support the combined company, timing of collections of trade accounts receivable, a decrease in accounts payable and accrued expenses and increased interest due to additional debt of the combined company.

Our net cash used in investing activities was $401.7 million for the nine months ended September 30, 2018, as compared to $89.7 million for the nine months ended September 30, 2017. The increase in cash used in investing activities of $312.0 million was primarily attributed to the acquisitions of Impax and Gemini, partially offset by lower capital expenditures and acquisitions of product rights and licenses.

Our net cash provided by financing activities was $506.6 million for the nine months ended September 30, 2018, as compared to cash used in financing activities of $95.5 million for the nine months ended September 30, 2017. The increase of $602.1 million was primarily related to an increase in net new borrowings, equity contributions, and lower distributions to members, partially offset by payment of a related party note and the acquisition of a redeemable non-controlling interest in one of Amneal's subsidiaries.

Term Loan and Revolving Credit Agreements

On May 4, 2018 we 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 credit facility ("ABL") under which loans and letters of credit up to a principal amount of $500.0 million are available (principal amount of up to $25 million is available for letters of credit) (collectively, the "Senior Secured Credit Facilities"). The term loan is repayable in equal quarterly installments at a rate of 1.00% or 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 LIBOR plus 3.5% at September 30, 2018. The ABL bears an annual interest rate of 1.5% at September 30, 2018 and matures on May 4, 2023. Beginning on September 30, 2018, the annual interest rate for the ABL may be reduced or increased by 0.25% based on step-downs and step-ups determined by the average historical excess availability. At September 30, 2018, the Company had $100.0 million of borrowings under the ABL. On November 5, 2018, the Company repaid $50 million of the borrowings under the ABL.

The proceeds of any loans made under the Senior Secured Credit Facility can be used for capital expenditures, acquisitions, working capital needs and other general purposes, subject to covenants as described below. We pay a commitment fee based on the average daily unused amount of the ABL at a rate based on average historical excess availability, between 0.25% and 0.375% per annum. At September 30, 2018, the ABL commitment fee rate is 0.375% per annum.

JSP License and Supply 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"). The Company will be JSP's exclusive commercial partner in the U.S. market for a 10-year term commencing on March 22, 2019. The Company will be required to make a payment of $50.0 million to JSP upon the Company's first sale of Levothyroxine. Additionally, the Company will be required to make an additional $20.0 million payment to JSP if the Food and Drug Administration ("FDA") has not given final approval a third-party competitor's abbreviated new drug application for generic levothyroxine sodium tablets with an AB1, AB2, AB3 or AB4 designation by the first anniversary date of the Company's first sale of Levothyroxine. In addition, the agreement provides for the Company to pay a share of the net profits of the Company's sales of Levothyroxine, after considering product costs.

Adello License and Commercialization Agreement

On October 1, 2017, Amneal and Adello entered into a license and commercialization agreement. Adello granted Amneal an exclusive license, under Adello's NDA, to distribute and sell two bio-similar products in the United States. Adello 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 applicable product's launch date.

In connection with the agreement, Amneal paid an upfront amount of $1.5 million in October 2017 for execution of the agreement. The agreement also provides for potential future milestone payments to Adello of (i) up to $21 million relating to regulatory approval, (ii) up to $43 million for successful delivery of commercial launch inventory, (iii) between $20 million and $50 million relating to number of competitors at launch for one product, and (iv) between $15 million and $67.5 million for the achievement of cumulative net sales for both products. The milestones are subject to certain performance conditions, which may or may not be achieved, including FDA filing, FDA approval, launch activities and 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.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of September 30, 2018.

Critical Accounting Policies

Our significant accounting policies are described in Item 1. Financial Statements—Notes to Consolidated Financial Statements—Note 2. Summary of Significant Accounting Policies.

Recently Issued Accounting Standards

Recently issued accounting standards are discussed in Item 1. Financial Statements—Notes to Consolidated Financial Statements—Note 2. Summary of Significant Accounting Policies.

Item 3. 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 September 30, 2018 or December 31, 2017.

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 above under Term Loan and Revolving Credit Agreement, we are party to a Term Loan with a principal amount of $2.7 billion and an ABL under which loans and letters of credit up to a principal amount of $500.0 million are available (principal amount of up to $25 million is available for letters of credit) pursuant to the Senior Secured Credit Facilities. The proceeds for any loans made under our Senior Secured 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 the 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, our foreign currency risk is diversified. Principal drivers of this diversified foreign exchange exposure include the European Euro, British Pound, 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 consolidated statements of income. Such foreign currency transaction gains and losses include fluctuations related to long term intercompany loans that are payable in the foreseeable future.

Inflation has not had a significant impact on our revenues or operations to date and we do not believe that inflation will have a significant impact on our revenues or operations for the remainder of 2018 or 2019.

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 our 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 September 30, 2018, we had $100.0 million of fixed rate debt and $2.7 billion of variable rate debt. Increases or decreases in interest rates would affect our annual interest expense. We may enter into interest rate swaps to manage the impact of interest rate changes. There were no outstanding interest rate swap agreements as of September 30, 2018 or 2017.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) of 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 Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer 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 Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Exchange Act, were effective as of September 30, 2018 at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2018, there were no changes in the Company's internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) which materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Limitations on the Effectiveness of Controls

Systems of disclosure controls and internal controls over financial reporting and their associated policies and procedures, no matter how well conceived and operated, are designed to provide a reasonable, but not an absolute, level of assurance that the objectives of the system of control are achieved. Further, the design of a control system must be balanced against resource constraints, and therefore the benefits of controls must be considered relative to their costs. Given the inherent limitations in all systems of controls, no evaluation of controls can provide absolute assurance all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Accordingly, given the inherent limitations in a cost-effective system of internal control, financial statement misstatements due to error or fraud may occur and may not be detected. Our disclosure controls and procedures are designed to provide a reasonable assurance of achieving their objectives. We conduct periodic evaluations of our systems of controls to enhance, where necessary, our control policies and procedures.

Part II - Other Information

ITEM 1. LEGAL PROCEEDINGS

Information pertaining to legal proceedings can be found in Item 1. Financial Statements - Notes to Consolidated Financial Statements - Note 18. Commitments and Contingencies and is incorporated by reference herein.

Item 1A. Risk Factors

Global economic conditions could harm us.

While global economic conditions have been fairly stable as a whole in recent years, 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 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.

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. 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. In addition, the currencies of some countries may depreciate against the U.S. dollar substantially and if we are unable to offset the impact of such depreciation, our financial performance within such countries could be adversely affected.

We may be unable to integrate operations successfully and realize the anticipated synergies and other benefits of the Combination

The business combination of Impax and Amneal involves the combination of two companies that operated as independent companies prior to the closing of the Combination. The integration of the businesses may be more time consuming and require more resources than initially estimated and we may fail to realize some or all of the anticipated benefits of the Combination if the integration process takes longer than expected or is more costly than expected. The integration process could also result in the diversion of management's attention, the disruption or interruption of, or the loss of momentum in, the businesses of Impax and Amneal or inconsistencies in standards, control, procedures and policies, any of which could adversely affect the Company's ability to maintain relationships with customers, partners and employees or its ability to achieve the anticipated benefits of the Combination, or could reduce the earnings or otherwise adversely affect our business and financial results.

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 any of our products presently under development, if and when fully developed and tested, will not perform as expected;
- 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 active pharmaceutical ingredients ("APIs") and other key ingredients necessary to the development of our generic drug products; and
- Our ability to scale-up manufacturing methods to successfully manufacture commercial quantities of generic drug product in compliance with regulatory requirements.

As a result of these and other difficulties, our products currently 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. 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 or marketing products will be recouped, even if we are successful in commercializing those products.

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 Federal Food, Drug, and Cosmetic Act (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 (described further below), 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. 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. No assurances can be given 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 United States and European Union exempts generic products from costly and time-consuming clinical trials to demonstrate their safety and efficacy and rely 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, that a pharmacist 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 expires or because our patent protection is not sufficiently broad or enforceable.

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;
- 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 us. Consequently, some of our competitors may be able to develop products and/or processes competitive with, or superior to, our products. 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 technological 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 pharmaceutical market, where we primarily compete, are Teva Pharmaceutical Industries Limited, Sandoz (a division of Novartis AG) (“Sandoz”), Endo International plc (Par) (“Endo”), Mylan N.V. (“Mylan”) and Fresenius Medical Care AG & Co. KGaA /Akorn, Inc. 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 first-to-file or first-to-market products. There can be no 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 for our own branded drug. 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 first-to-file 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 are unable to manage our growth, our business will suffer.

We have experienced rapid growth in the past several years, and anticipate continued rapid expansion in the future. This growth has required us to expand, upgrade, and improve our administrative, operational, and management systems, internal controls and resources. Although we cannot assure you that we will, in fact, grow as we expect, if we fail to manage growth effectively or to develop a successful marketing approach, our business and financial results will be materially harmed. We may also 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 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 have 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.

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. 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 active pharmaceutical ingredient or no active pharmaceutical ingredients 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. 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, there has been increasing U.S. federal and state legislative and enforcement interest with respect to drug pricing. For instance, the United States Department of Justice issued subpoenas to pharmaceutical companies, including to the Company, seeking information about the sales, marketing and pricing of certain generic drugs. 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 three and nine months ended September 30, 2018, our significant product families accounted for 34% and 31% of our consolidated net revenue, respectively. 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 growth is dependent on our ability to continue to successfully develop and commercialize new products in a timely manner.

Our financial results will depend upon our ability to introduce and commercialize additional generic and branded products in a timely manner. In the generic pharmaceutical products market, revenue from newly launched generic products is typically relatively high during the period immediately following launch and can be expected generally to decline over time. Revenue from generic drugs in general, including prices of generic products that have generic alternatives on the market, can generally be expected to decline over time. Revenue from branded pharmaceutical products can be expected to decline as the result of entry of new competitors, particularly of companies producing generic versions of the branded products. Our growth is therefore dependent upon our ability to successfully introduce and commercialize new generic and branded products.

Our ability to develop or license, or otherwise acquire, and introduce new products on a timely basis in relation to our competitors' product introductions involves inherent risks and uncertainties.

Product development is inherently risky, especially for new drugs for which safety and efficacy have not been established and the market is not yet proven. Likewise, 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. The development and commercialization process, particularly with regard to new drugs, also requires substantial time, effort and financial resources. The process of obtaining FDA approval to manufacture and market new pharmaceutical products is rigorous, time consuming, costly and largely unpredictable. We, or a partner, may not be successful in obtaining FDA approval or in commercializing any of the products that we are developing or licensing.

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, Impax or Amneal. 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 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 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 United States or elsewhere, with the FDA as well as regulators outside the United States, and our products must be made in a manner consistent with current good manufacturing practices (“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 and other agencies periodically inspect our manufacturing facilities. Following an inspection, an agency may 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 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 development, manufacture and sale of our products involves the risk of product liability and other claims by consumers and other third parties, and insurance against such potential claims is expensive and may be difficult to obtain.

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, 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, 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 Drug Enforcement Administration (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. 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. See “Item 1. Financial Statements—Notes to Consolidated Financial Statements—Note 18. Commitments and Contingencies” 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 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) 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 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 information in certain circumstances, such as the requirements under the European Union General Data Protection Regulation which became effective in May 2018, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Violations of 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. 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 Generic Drug Fee User Amendments of 2012 ("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.

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 it challenges the validity or enforceability of innovator companies' listed patents and/or their applicability to its generic pharmaceutical products, as well as patent infringement litigation in which generic companies challenge the validity or enforceability of our patents and/or their applicability to their generic 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 pharmaceutical companies related to the manufacture, marketing and sale of generic versions of branded drugs for their review. The FTC has publicly stated that, in its view, some of the brand-generic settlement agreements violate the antitrust laws and has brought actions against some brand and generic companies that have entered into such agreements. In June 2013, the U.S. Supreme Court in its decision in *FTC v. Actavis* determined that "reverse payment" settlement agreements between brand and generic companies could violate 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." It is currently uncertain the effect the Supreme Court's decision will have on our existing settlement agreements or its impact on its ability to enter into such settlement agreements in the future or the terms thereof. The Supreme Court's decision may result in heightened scrutiny from the FTC of such settlement agreements and we may 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, may also become more active in bringing private litigation claims against us and other brand and generic pharmaceutical companies alleging that such settlement agreements violate 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, or others, such as customers, may commence an action against us alleging violations of the antitrust laws. Such settlement agreements may further expose us to claims by purchasers of the products for unlawfully inhibiting competition. We have been involved in private antitrust actions involving certain settlement agreements as described in "Item 1. Financial Statements—Notes to Consolidated Financial Statements—Note 18. Commitments and Contingencies".

Antitrust investigation 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 products, further legislation and the potential for private-party lawsuits associated with such arrangements could adversely affect our business.

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 50% 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 Centers for Medicare & Medicaid Services ("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. 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 rulemaking, reform or repeal of healthcare laws.

The majority of our products are produced at a few locations and a business interruption at one or more of these locations 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, California, and India, as well as at certain third party suppliers. A significant disruption at any of these facilities, even on a short-term basis, could impair our ability to produce and ship products to the market on a timely basis, 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.

We currently have over 200 customers, some of which are part of large purchasing groups. Our three largest customers accounted for approximately 83% and 82% of our total gross sales of products for the three and nine months, ended September 30, 2018, respectively, and our three largest customers accounted for approximately 79% and 79% of our total gross sales for products for the three and nine months ended September 30, 2017, 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.

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.

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.

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.

The bulk of the raw materials essential to our manufacturing business are purchased from third parties. If we experience supply interruptions or delays, 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. Any significant supply interruption could have a material adverse effect on our business, condition (financial and otherwise), prospects and results of operations. To date, 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 and branded 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.

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 research and development, 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 research and development process of new products, there is a significant risk that funds invested in research and development 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.

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.

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.

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, may require additional debt or equity financing, which could increase our leverage and dilute equity holders.

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 choose to enter into such transactions at any time. Nonetheless, we cannot provide assurance that we will be able to identify suitable acquisition or investment candidates. To the extent that we do identify candidates that we believe to be suitable, we cannot provide assurance that we will be able to reach an agreement with the selling party or parties, that the terms we may agree to will be commercially advantageous to us, or that we will be able to successfully consummate such investments or acquisitions even after definitive documents have been signed. 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 owners. If we require financing, we cannot provide assurance that we will be able to obtain required financing when needed on acceptable terms or at all.

Our operations in, and anticipated expansion into additional, international markets subjects us to increased regulatory oversight both in those international markets and domestically and 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 assets and operations located in foreign jurisdictions, including our operations in India, Germany and the United Kingdom. We may also in the future expand our international business and operations into jurisdictions in which we have limited operating experience, including with respect to seeking regulatory approvals, marketing or selling products.

Our operations in these jurisdictions may be adversely affected by general economic conditions and economic and fiscal policy, including changes in exchange rates and controls, interest rates and taxation policies, increased government regulation, and, with respect to India, any reversal of India's recent economic liberalization and deregulation policies, as well as social stability and 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, or armed hostilities 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, anti-bribery and anti-corruption laws may conflict with some local customs and practices in foreign jurisdictions. Our international operations may subject us to heightened scrutiny under the Foreign Corrupt Practices Act ("FCPA"), the UK Bribery Act and similar anti-bribery laws, and could subject us to liability under such laws despite our best efforts to comply with such laws. As a result of our policy to comply with the FCPA, the UK Bribery Act and similar anti-bribery laws, we may be at a competitive disadvantage to competitors that are not subject to, or do not comply with, such laws.

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

As a U.S. company with subsidiaries in, among other countries, India, Germany, Switzerland and England, we are subject to, or potentially subject to, income taxes as well as non-income based 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 significantly 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 research and development activities and manufacturing. Tax authorities in various jurisdictions may disagree with, and subsequently challenge, the amount of profits taxed in such jurisdictions; such challenges may result in increased tax liability, including accrued interest and penalties, which would cause our tax expense to increase and which may have a material adverse effect on our business, financial position and results of operations and our ability to satisfy our debt obligations.

Recent U.S. tax legislation may materially adversely affect our financial condition, results of operations and cash flows.

Recently enacted U.S. tax legislation has significantly changed the U.S. federal income taxation of U.S. and multinational businesses, including by reducing the U.S. corporate income tax rate, limiting interest deductions, permitting immediate expensing of certain capital expenditures, modifying or repealing many business deductions and credits (including certain foreign tax credits), adopting elements of a territorial tax system, imposing a one-time transition tax (or "repatriation tax") on all undistributed earnings and profits of certain U.S.-owned foreign corporations, broadening the categories of income earned by certain U.S.-owned foreign corporations that may be subject to current US taxation, revising the rules governing net operating losses, repealing the deduction of certain performance-based compensation paid to an expanded group of executive officers and introducing new anti-base erosion provisions, such as the base erosion and anti-abuse tax. Many of these changes are effective immediately, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and IRS, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities.

Our analysis and interpretation of this legislation is preliminary and ongoing and there may be material adverse effects resulting from the legislation that we have not yet identified. While some of the changes made by the tax legislation may adversely affect us, other changes may be beneficial. We continue to work with our tax advisors and auditors to determine the full impact that the recent tax legislation as a whole will have on us. We urge our investors to consult with their legal and tax advisors with respect to such legislation and its potential effect on an investment in our common stock.

Our Tax Receivable Agreement with Holdings dated May 4, 2018 (the "Tax Receivable Agreement") requires us to make cash payments to them 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 the Tax Receivable Agreement with Amneal Holdings LLC (now APHC Holdings, LLC), which we refer to as "Holdings". Under the Tax Receivable Agreement, we will be required to make cash payments to Holdings and its 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 by Holdings and its permitted transferees as set forth in the agreement. We expect that the amount of the cash payments that we will be required to make under the Tax Receivable Agreement will be significant. Any payments made by us to Holdings or its permitted transferees under the Tax Receivable Agreement will generally reduce the amount of overall cash flow that might have otherwise been available to us.

The actual amount and timing of any payments under the Tax Receivable Agreement, will vary depending upon a number of factors, including the timing of redemptions or exchanges by the holders of Amneal common units, the amount of gain recognized by such holders, the amount and timing of the taxable income we generate in the future, and the federal tax rates then applicable.

In certain cases, payments under the Tax Receivable Agreement to Holdings or its permitted transferees may be accelerated or significantly exceed the actual benefits we realize in respect of the tax attributes subject to the Tax Receivable Agreement.

The Tax Receivable Agreement 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 Tax Receivable Agreement, then our obligations under the Tax Receivable Agreement to make payments thereunder 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 Tax Receivable Agreement.

As a result of the foregoing, we could be required to make payments under the Tax Receivable Agreement that (i) are greater than the actual benefits we may ultimately realize in respect of the tax benefits that are subject to the Tax Receivable Agreement and (ii) are based on the present value of the anticipated future tax benefits that are the subject of the Tax Receivable Agreement, 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 Tax Receivable Agreement 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 Tax Receivable Agreement.

We will not be reimbursed for any payments made to Holdings or its permitted transferees under the Tax Receivable Agreement in the event that any tax benefits are disallowed.

Payments under the Tax Receivable Agreement will be based on the tax reporting positions that we determine, and the Internal Revenue Service (the "IRS") 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 Tax Receivable Agreement, then we will not be permitted to settle or fail to contest such challenge without the consent of Holdings. We will not be reimbursed for any cash payments previously made to Holdings or its permitted transferees under the Tax Receivable Agreement in the event that any tax benefits initially claimed by us and for which payment has been made to Holdings or its permitted transferees are subsequently challenged by a taxing authority and are ultimately disallowed. Instead, any excess cash payments made by us to Holdings or its 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 Tax Receivable Agreement. However, we might not determine that we have effectively made an excess cash payment to Holdings or its permitted transferees for a number of years following the initial time of such payment. As a result, payments could be made under the Tax Receivable Agreement in excess of the tax savings that we ultimately realize in respect of the tax attributes with respect to Holdings or its permitted transferees.

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 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. Litigation often involves significant expense and can delay or prevent introduction or sale of our generic 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, which can be significantly higher than the profits we make from selling the generic version of the product. We could be liable for substantial damages from adverse court decisions in such matters. We may also be harmed by the loss of any value of such inventory that we are unable to market or sell.

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

We are or may become a party to litigation in the ordinary course of our business, including, among others, matters alleging product liability, other intellectual property rights infringement, violations of securities laws, employment discrimination or breach of commercial contract. In general, litigation claims can be expensive and time consuming to bring or defend against and could result in settlements or damages that could have a material adverse effect on our business, results of operations and financial condition.

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 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.

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 at the same time that we introduce a generic equivalent of that product, directly or through agreement with a generic competitor;
- 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.

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 research and development 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 research and development 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 research and development efforts in the industry, particularly with respect to new drugs, our research and development expenditures may not result in the successful introduction of FDA-approved pharmaceutical products. Additionally, after we or our development partners submit an ANDA, the FDA may request that additional studies be conducted. As a result, we may be unable to reasonably determine the total research and development 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 research and development 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 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 Combination, during the nine months ended September 30, 2018, we borrowed $2.7 billion in an aggregate principal amount of new senior secured term loans and entered into a new senior secured asset based revolving credit facility with borrowing capacity of up to $500 million, under which $100.0 million was drawn and outstanding as of September 30, 2018. The net proceeds from the new term loans were used to finance in part the Combination, 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, see “Item 1. Financial Statements—Notes to Consolidated Financial Statements—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 interest rate fluctuations 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.

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 September 30, 2018, we had approximately $2.8 billion of indebtedness, with an annual interest expense of approximately $170 million to $180 million and an annual debt payments of approximately $27 million on our Term Loan.

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 money; and
- we could be forced into bankruptcy or liquidation.

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, there is no assurance that such regulatory authorities will not subject marketing of such products to certain limits on indicated use.

Failure can occur at any time during the clinical trial process and, 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 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.

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. As described in “Item 1. Financial Statements—Notes to Consolidated Financial Statements—Note 18. Commitments and Contingencies”, we and other pharmaceutical companies are defendants in a number of suits filed by state attorneys general and have been notified of an investigation by the DOJ with respect to Medicaid reimbursement and rebates. 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.

Our operating results are affected by many factors and may fluctuate significantly on a quarterly basis.

Our operating results may vary substantially from quarter to quarter and may be greater or less than those achieved in the immediately preceding period or in the comparable period of the prior year. Factors that may cause quarterly results to vary include, but are not limited to, the following:

- the number of new product introductions by us;
- losses related to inventory write-offs;
- marketing exclusivity, if any, which may be obtained on certain new products;
- the level of competition in the marketplace for certain products;
- our ability to create demand in the marketplace for our products;
- availability of raw materials and finished products from suppliers;
- our ability to manufacture products at our manufacturing facilities;
- the scope and outcome of governmental regulatory actions;
- our dependence on a small number of products for a significant portion of net revenue or income;
- legal actions against our generic products brought by brand competitors, and legal challenges to our intellectual property rights by generic competitors;
- price erosion and customer consolidation; and
- significant payments (such as milestones) payable by us under collaboration, licensing, and development agreements to our partners before the related product has received FDA approval.

The profitability of our product sales is also dependent upon the prices we are able to charge for our products, the costs to purchase products from third parties, and our ability to manufacture our products in a cost effective manner. If our revenues decline or do not grow as anticipated, we may not be able to reduce our operating expenses to offset such declines. Failure to achieve anticipated levels of revenues could, therefore, significantly harm our operating results for a particular fiscal period.

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. Because the entry of a competitive generic product following the expiration of any exclusivity period is unpredictable, we do not establish reserves for such potential adjustments, and therefore the full effect of such adjustments are not reflected in our operating results until such adjustments actually occur. 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. Any impairment of goodwill or other intangible assets would result in a non-cash charge against earnings, which would adversely affect our results of operations.

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 AWPs 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. We, for example, are subject to a civil investigative demand issued by the Texas State Attorney General alleging certain overpayments to us by the Texas Medicaid system as further described in "Item 1. Financial Statements—Notes to Consolidated Financial Statements—Note 18. Commitments and Contingencies." 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.

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. We have also 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, and may be susceptible to intentional or accidental physical damage to the infrastructure maintained by us or by third parties. Maintaining the secrecy of confidential, proprietary, and/or trade secret information is important to our competitive business position. While we have taken steps to protect such information and have invested in systems and infrastructures to do so, there can be no guarantee that our efforts will 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 research and development 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.

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.

There are inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with GAAP. Any future changes in estimates, judgments and assumptions used or necessary revisions to prior estimates, judgments or assumptions could lead to a restatement of our results.

The consolidated financial statements included in this report are prepared in accordance with GAAP. This involves making estimates, judgments and assumptions that affect reported amounts of assets (including intangible assets), liabilities, revenues, expenses and income. Estimates, judgments and assumptions are inherently subject to change in the future and any necessary revisions to prior estimates, judgments or assumptions could lead to a restatement. Any such changes could result in corresponding changes to the amounts of assets (including goodwill and other intangible assets), liabilities, revenues, expenses and income.

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. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and attestations of the effectiveness of 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 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 internal control material weaknesses may result in current and potential stockholders and alliance and collaboration agreements' 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 agreements' partners.

In addition, the existence of material weaknesses in our internal control over financial reporting may affect our ability to timely file periodic reports under the Exchange Act. An internal control material weakness may develop in the future and affect our ability to timely file our periodic reports. The inability to timely file periodic reports under the Exchange Act could result in the SEC revoking the registration of our common stock, which would prohibit us from listing or having our stock quoted on any public market. This would have an adverse effect on our business and stock price by limiting the publicly available information regarding us and greatly reducing the ability of our stockholders to sell or trade our common stock.

Terrorist attacks and other acts of violence or war may adversely affect our business.

Terrorist attacks at or nearby our facilities may negatively affect our operations. While we do not believe that we are more susceptible to such attacks than other companies, such attacks could directly affect our physical facilities or those of our suppliers or customers and could make the transportation of our products more difficult and more expensive and ultimately affect our sales.

We carry insurance coverage on our facilities of types and in amounts that we believe are in line with coverage customarily obtained by owners of similar properties. We continue to monitor the state of the insurance market in general and the scope and cost of coverage for acts of terrorism in particular, but we cannot anticipate what coverage will be available on commercially reasonable terms in future policy years. Currently, we carry terrorism insurance as part of our property and casualty and business interruption coverage. If we experience a loss that is uninsured or that exceeds policy limits, we could lose the capital invested in the damaged facilities, as well as the anticipated future net sales from those facilities.

The expansion of social media platforms present new risks and challenges, which could cause a material adverse effect on our business, results of operations and financial condition.

The inappropriate use of certain media vehicles could cause brand damage or information leakage or could lead to legal implications from the improper collection and/or dissemination of personally identifiable information. In addition, negative posts or comments about us on any social networking website could seriously damage our reputation. Further, the disclosure of non-public company sensitive information through external media channels could lead to information loss as there might not be structured processes in place to secure and protect information. If our non-public sensitive information is disclosed or if our reputation is seriously damaged through social media, it could have a material adverse effect on our business, results of operations and financial condition.

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.

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.

Risks Related to Our Class A Common Stock

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

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, including Impax. As a result, 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.

The Class A Common Stock price is expected to be volatile, and the market price of Class A Common Stock may decline.

The market price of our Class A Common Stock could be subject to significant fluctuations. Market prices for securities of pharmaceutical, biotechnology, and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of Class A Common Stock to fluctuate include:

- our ability to obtain regulatory approvals for product candidates, and delays or failures to obtain such approvals;
- the failure of any of our product candidates, if approved for marketing and commercialization, to achieve commercial success;
- issues in manufacturing our approved products or product candidates;
- the entry into, or termination of, key agreements, including key licensing or collaboration agreements;
- the initiation of material developments in, or conclusion of, litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others;
- announcements by commercial partners or competitors of new commercial products, clinical progress (or the lack thereof), significant contracts, commercial relationships, or capital commitments;
- adverse publicity relating to our markets, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies competing with our products or our potential products;
- the loss of talented employees;
- changes in estimates or recommendations by securities analysts, if any, who cover the Class A Common Stock;
- general and industry-specific economic conditions potentially affecting our research and development expenditures;
- changes in the structure of health care payment systems;
- period-to-period fluctuations in our financial results;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislators, regulators, and the investment community;
- adverse regulatory decisions;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- sales of the Class A Common Stock by us or our stockholders in the future;
- trading volume of the Class A Common Stock; and
- period-to-period fluctuations in our financial results

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies or the biotechnology sector. These broad market fluctuations may also adversely affect the trading price of our Class A Common Stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management's attention and resources, which could significantly harm the Company's profitability and reputation.

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

If our stockholders sell, or indicate an intention to sell, substantial amounts of Class A Common Stock in the public market after the expiration of the lock-up period as described below and the other applicable legal restrictions on resale lapse, the trading price of Class A Common Stock could decline.

The Company's Second Amended and Restated Stockholders Agreement, dated December 16, 2017 (the "Stockholders' Agreement"), includes certain lock-up provisions limiting the ability of Holdings and its permitted transferees to transfer shares of our common stock held by such members for a period of 180 days from the closing of the Combination. Upon the expiration of the lock-up restrictions, the 171,260,707 shares of Class A Common Stock subject to outstanding Amneal common units held by Holdings and its permitted transferees will become eligible for sale or transfer (subject to certain continuing restrictions). If these shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of the Class A Common Stock could decline.

If the ownership of the Class A Common Stock is highly concentrated, it may prevent other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause the Class A Common Stock's stock price to decline.

As of September 30, 2018, our executive officers and directors, and affiliates of our executive officers and directors, beneficially owned or controlled approximately 60% of the outstanding shares of our common stock. Accordingly, these executive officers, directors, and their affiliates, acting as a group, have 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. The significant concentration of stock ownership may adversely affect the trading price of Class A Common Stock due to investors' perception that conflicts of interest may exist or arise.

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

As of September 30, 2018, the Amneal Group possessed approximately 60% of the voting power of all of our outstanding shares of common stock.

Through its ownership of a majority of our voting power and the provisions set forth in our charter, bylaws and the Stockholders Agreement, the Amneal Group has the ability to designate and elect a majority of our board of directors. As of September 30, 2018, seven out of thirteen members of our board of directors, as well as one observer, 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 such interests.

Among other things, the Amneal Group's control could delay, defer, or prevent a sale of the Company that the Company's other stockholders support, or, conversely, this control could result in the consummation of such a transaction that our other stockholders do not support. 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.

In addition, members of the Amneal Group could pledge Amneal Common Units or shares of Class B Common Stock or both to secure borrowings. The forced sale of these units or shares pursuant to a margin call could cause our stock price to decline and negatively impact our business.

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 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 its business, results of operations, and financial condition.

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. 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.

The current expectation is 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, if any, for the foreseeable future.

If securities or industry analysts change their recommendations regarding our Class A Common Stock adversely, the Class A Common Stock price and trading volume could decline.

The trading market for Class A Common Stock will be influenced by what industry or securities analysts publish in their research and reports about us, our business, our market or our competitors. Analysts that cover us may make adverse recommendations regarding our Class A Common Stock, adversely change their recommendations from time to time, and/or provide more favorable relative recommendations about our competitors. If any analyst who covers us were to cease coverage of the Company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the stock price or trading volume of the Class A Common Stock to decline.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Recent Sale of Unregistered Securities

There were no sales of unregistered securities during the quarter ended September 30, 2018.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

There were no purchases of equity securities during the quarter ended September 30, 2018.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

Exhibit No.	Description of Document
31.1	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.* **
32.2	Certification of the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.* **
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of September 30, 2018 and December 31, 2017, (ii) Consolidated Statements of Operations for each of the three and nine months ended September 30, 2018 and 2017, (iii) Consolidated Statements of Comprehensive Income (Loss) for each of the three and nine months ended September 30, 2018 and 2017, (iv) Consolidated Statements of Cash Flows for each of the nine months ended September 30, 2018 and 2017 and (v) Notes to Interim Consolidated Financial Statements.*

* 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 7, 2018

Amneal Pharmaceuticals, Inc.
(Registrant)

By: /s/ Robert Stewart
Robert Stewart
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Bryan M. Reasons
Bryan M. Reasons
Chief Financial Officer and
Senior Vice President, Finance
(Principal Financial and Accounting Officer)