**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**Form 10-Q**

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

**For the quarterly period ended September 30, 2019**

**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,** | **08807** |  |
| **Bridgewater, NJ** |  |
| **(Address of principal executive offices)** | **(Zip Code)** |  |
| **(908) 947-3120** |  |  |
| **(Registrant’s telephone number, including area code)** |  |  |
| **Not applicable** |  |  |

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

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

**Title of each class**

**Trading Symbol(s)**

**Name of each exchange on which registered**

Class A Common Stock, par value $0.01 per share

AMRX

New York Stock Exchange

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:

|  |  |  |  |
| --- | --- | --- | --- |
| 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, 2019, there were 134,095,850 shares of Class A common stock outstanding and 165,004,323 shares of Class B common stock outstanding, both with a par value of $0.01.



**Amneal Pharmaceuticals, Inc.**

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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** | | | | |  | **Nine Months Ended** | | | |  |
|  |  | **September 30,** | | | | |  | **September 30,** | | | |  |
|  |  | **2019** |  |  | **2018** |  |  | **2019** |  |  | **2018** |  |
| **Net revenue** | $ | 378,283 |  | $ | 476,487 |  | $ | 1,229,045 |  | $ | 1,165,463 |  |
| Cost of goods sold |  | 267,717 |  |  | 268,567 |  |  | 873,841 |  |  | 634,653 |  |
| Cost of goods sold impairment charges |  | 56,132 |  |  | 7,815 |  |  | 112,441 |  |  | 7,815 |  |
| **Gross profit** |  | 54,434 |  |  | 200,105 |  |  | 242,763 |  |  | 522,995 |  |
| Selling, general and administrative |  | 63,797 |  |  | 75,486 |  |  | 215,514 |  |  | 156,610 |  |
| Research and development |  | 38,125 |  |  | 42,349 |  |  | 139,999 |  |  | 136,893 |  |
| In-process research and development impairment charges |  | 23,382 |  |  | 650 |  |  | 46,169 |  |  | 650 |  |
| Charges (gains) related to legal matters, net |  | 14,750 |  |  | 2,589 |  |  | 14,750 |  |  | (411) |  |
| Intellectual property legal development expenses |  | 2,586 |  |  | 4,401 |  |  | 9,263 |  |  | 13,024 |  |
| Acquisition, transaction-related and integration expenses |  | 3,131 |  |  | 2,231 |  |  | 12,682 |  |  | 216,873 |  |
| Restructuring and other charges |  | 20,937 |  |  | (2,156) |  |  | 29,933 |  |  | 42,309 |  |
| **Operating (loss) income** |  | (112,274) |  |  | 74,555 |  |  | (225,547) |  |  | (42,953) |  |
| Other income (expense): |  |  |  |  |  |  |  |  |  |  |  |  |
| Interest expense, net |  | (42,209) |  |  | (43,018) |  |  | (129,376) |  |  | (100,691) |  |
| Foreign exchange loss, net |  | (12,531) |  |  | (5,137) |  |  | (9,684) |  |  | (22,518) |  |
| Loss on extinguishment of debt |  | — | |  | — | |  | — |  |  | (19,667) |  |
| (Loss) gain on sale of international businesses, net |  | — | |  | (2,812) |  |  | 6,930 |  |  | (2,812) |  |
| Gain from reduction of tax receivable agreement liability |  | 192,844 |  |  | — | |  | 192,844 |  |  | — |  |
| Other income (expense), net |  | 446 |  |  | (1,014) |  |  | 1,702 |  |  | 725 |  |
| **Total other income (expense), net** |  | 138,550 |  |  | (51,981) |  |  | 62,416 |  |  | (144,963) |  |
| Income (loss) before income taxes |  | 26,276 |  |  | 22,574 |  |  | (163,131) |  |  | (187,916) |  |
| Provision for (benefit from) income taxes |  | 389,668 |  |  | 5,109 |  |  | 375,539 |  |  | (6,943) |  |
| **Net (loss) income** |  | (363,392) |  |  | 17,465 |  |  | (538,670) |  |  | (180,973) |  |
| Less: Net loss attributable to Amneal Pharmaceuticals LLC pre- |  |  |  |  |  |  |  |  |  |  |  |  |
| Combination |  | — | |  | — | |  | — |  |  | 148,806 |  |
| Less: Net loss (income) attributable to non-controlling interests |  | 98,386 |  |  | (10,577) |  |  | 208,881 |  |  | 21,191 |  |
| Net (loss) income attributable to Amneal Pharmaceuticals, Inc. before |  |  |  |  |  |  |  |  |  |  |  |  |
| accretion of redeemable non-controlling interest |  | (265,006) |  |  | 6,888 |  |  | (329,789) |  |  | (10,976) |  |
| Accretion of redeemable non-controlling interest |  | — | |  | 64 |  |  | — |  |  | (1,176) |  |
| **Net (loss) income attributable to Amneal Pharmaceuticals, Inc.** | $ | (265,006) |  | $ | 6,952 |  | $ | (329,789) |  | $ | (12,152) |  |
| **Net (loss) income per share attributable to Amneal** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Pharmaceuticals, Inc.'s common stockholders:** |  |  |  |  |  |  |  |  |  |  |  |  |
| Class A and Class B-1 basic | $ | (2.03) |  | $ | 0.05 |  | $ | (2.56) | $ | | (0.10) |  |
| Class A and Class B-1 diluted | $ | (2.03) |  | $ | 0.05 |  | $ | (2.56) |  | $ | (0.10) |  |
| Weighted-average common shares outstanding: |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| Class A and Class B-1 basic |  | 130,729 |  |  | 127,247 |  |  | 128,822 |  |  | 127,196 |  |
| Class A and Class B-1 diluted |  | 130,729 |  |  | 128,222 |  |  | 128,822 |  |  | 127,196 |  |

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

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**Amneal Pharmaceuticals, Inc.**

**Consolidated Statements of Comprehensive (Loss) Income**

**(unaudited; in thousands)**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Three Months Ended** | | | | |  | **Nine Months Ended** | | | |
|  |  | **September 30,** | | | | |  | **September 30,** | | | |
|  |  | **2019** |  |  | **2018** |  |  | **2019** |  |  | **2018** |
| **Net (loss) income** | $ | (363,392) |  | $ | 17,465 |  | $ | (538,670) |  | $ | (180,973) |
| Less: Net loss attributable to Amneal Pharmaceuticals LLC pre- |  |  |  |  |  |  |  |  |  |  |  |
| Combination |  | — | |  | — | |  | — |  |  | 148,806 |
| Less: Net loss (income) attributable to non-controlling interests |  | 98,386 |  |  | (10,577) |  |  | 208,881 |  |  | 21,191 |
| Net (loss) income attributable to Amneal Pharmaceuticals, Inc. before |  |  |  |  |  |  |  |  |  |  |  |
| accretion of redeemable non-controlling interest |  | (265,006) |  |  | 6,888 |  |  | (329,789) |  |  | (10,976) |
| Accretion of redeemable non-controlling interest |  | — | |  | 64 |  |  | — |  |  | (1,176) |
| **Net (loss) income attributable to Amneal Pharmaceuticals, Inc.** |  | (265,006) |  |  | 6,952 |  |  | (329,789) |  |  | (12,152) |
| Other comprehensive income (loss): |  |  |  |  |  |  |  |  |  |  |  |
| Foreign currency translation adjustments |  |  |  |  |  |  |  |  |  |  |  |
| Foreign currency translation adjustments arising during the period |  | 4,997 |  |  | (7,939) |  |  | 4,014 |  |  | (8,964) |
| Less: Reclassification of foreign currency translation adjustment |  |  |  |  |  |  |  |  |  |  |  |
| included in net loss |  | — | |  | — | |  | 3,413 |  |  | — |
| Foreign currency translation adjustments, net |  | 4,997 |  |  | (7,939) |  |  | 7,427 |  |  | (8,964) |
| Less: Other comprehensive income attributable to Amneal |  |  |  |  |  |  |  |  |  |  |  |
| Pharmaceuticals LLC pre-Combination |  | — | |  | — | |  | — |  |  | (1,721) |
| Less: Other comprehensive (income) loss attributable to non-controlling |  |  |  |  |  |  |  |  |  |  |  |
| interests |  | (2,813) |  |  | 4,555 |  |  | (4,207) |  |  | 6,131 |
| Other comprehensive income (loss) attributable to Amneal |  |  |  |  |  |  |  |  |  |  |  |
| Pharmaceuticals, Inc. |  | 2,184 |  |  | (3,384) |  |  | 3,220 |  |  | (4,554) |
| **Comprehensive (loss) income attributable to Amneal** |  |  |  |  |  |  |  |  |  |  |  |
| **Pharmaceuticals, Inc.** | $ | (262,822) |  | $ | 3,568 |  | $ | (326,569) | $ | | (16,706) |
|  |  |  |  |  |  |  |  |  |  |  |  |

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

2



**Amneal Pharmaceuticals, Inc.**

**Consolidated Balance Sheets**

**(unaudited; in thousands)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **September 30, 2019** |  |  | **December 31, 2018** |
| **Assets** |  |  |  |  |  |  |
| Current assets: |  |  |  |  |  |  |
| Cash and cash equivalents | $ | | 212,738 | $ | | 213,394 |
| Restricted cash |  |  | 4,320 |  |  | 5,385 |
| Trade accounts receivable, net |  |  | 518,109 |  |  | 481,495 |
| Inventories |  |  | 401,827 |  |  | 457,219 |
| Prepaid expenses and other current assets |  |  | 66,699 |  |  | 128,321 |
| Related party receivables |  |  | 2,138 |  |  | 830 |
| Total current assets |  |  | 1,205,831 |  |  | 1,286,644 |
| Property, plant and equipment, net |  |  | 490,712 |  |  | 544,146 |
| Goodwill |  |  | 419,671 |  |  | 426,226 |
| Intangible assets, net |  |  | 1,435,801 |  |  | 1,654,969 |
| Deferred tax asset, net |  |  | — |  |  | 373,159 |
| Operating lease right-of-use assets |  |  | 56,455 |  |  | — |
| Operating lease right-of-use assets - related party |  |  | 14,930 |  |  | — |
| Financing lease right-of-use assets - related party |  |  | 61,936 |  |  | — |
| Other assets |  |  | 18,607 |  |  | 67,592 |
| Total assets | $ | | 3,703,943 | $ | | 4,352,736 |
| **Liabilities and Stockholders' Equity** |  |  |  |  |  |  |
| Current liabilities: |  |  |  |  |  |  |
| Accounts payable and accrued expenses | $ | | 495,857 | $ | | 514,440 |
| Current portion of long-term debt, net |  |  | 21,468 |  |  | 21,449 |
| Current portion of operating lease liabilities |  |  | 13,467 |  |  | — |
| Current portion of operating and financing lease liabilities - related party |  |  | 3,353 |  |  | — |
| Related party payables |  |  | 765 |  |  | 17,695 |
| Current portion of financing obligation - related party |  |  | — |  |  | 266 |
| Total current liabilities |  |  | 534,910 |  |  | 553,850 |
| Long-term debt, net |  |  | 2,614,412 |  |  | 2,630,598 |
| Deferred income taxes |  |  | — |  |  | 1,178 |
| Liabilities under tax receivable agreement |  |  | — |  |  | 192,884 |
| Operating lease liabilities |  |  | 44,375 |  |  | — |
| Operating lease liabilities - related party |  |  | 14,271 |  |  | — |
| Financing lease liabilities - related party |  |  | 61,719 |  |  | — |
| Financing obligation - related party |  |  | — |  |  | 39,083 |
| Other liabilities |  |  | 38,532 |  |  | 38,780 |
| Total long-term liabilities |  |  | 2,773,309 |  |  | 2,902,523 |
| Commitments and contingencies (Notes 5, 11 and 13) |  |  |  |  |  |  |
| **Stockholders' Equity** |  |  |  |  |  |  |
| Preferred stock, $0.01 par value, 2,000 shares authorized; none issued at both September 30, 2019 and December 31, |  |  |  |  |  |  |
| 2018 |  |  | — |  |  | — |
| Class A common stock, $0.01 par value, 900,000 shares authorized at both September 30, 2019 and December 31, 2018; |  |  |  |  |  |  |
| 134,090 and 115,047 shares issued at September 30, 2019 and December 31, 2018, respectively |  |  | 1,340 |  |  | 1,151 |
| Class B common stock, $0.01 par value, 300,000 shares authorized at both September 30, 2019 and December 31, 2018; |  |  |  |  |  |  |
| 165,005 and 171,261 shares issued at September 30, 2019 and December 31, 2018 respectively |  |  | 1,651 |  |  | 1,713 |
| Class B-1 common stock, $0.01 par value, 18,000 shares authorized at both September 30, 2019 and December 31, |  |  |  |  |  |  |
| 2018; no and 12,329 shares issued at September 30, 2019 and December 31, 2018, respectively |  |  | — |  |  | 123 |
| Additional paid-in capital |  |  | 565,641 |  |  | 530,438 |
| Stockholders' accumulated deficit |  |  | (345,752) |  |  | (20,920) |
| Accumulated other comprehensive loss |  |  | (4,879) |  |  | (7,755) |
| Total Amneal Pharmaceuticals, Inc. stockholders' equity |  |  | 218,001 |  |  | 504,750 |
| Non-controlling interests |  |  | 177,723 |  |  | 391,613 |
| Total stockholders' equity |  |  | 395,724 |  |  | 896,363 |
| Total liabilities and stockholders' equity | $ | | 3,703,943 | $ | | 4,352,736 |
|  |  |  |  |  |  |  |

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

3



**Amneal Pharmaceuticals, Inc.**

**Consolidated Statements of Cash Flows**

**(unaudited; in thousands)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Nine Months Ended September 30,** | | | |  |  |
|  |  | **2019** |  | **2018** | |  |  |
| **Cash flows from operating activities:** |  |  |  |  |  |  |  |
| Net loss | $ | | (538,670) | $ | | (180,973) |  |
| Adjustments to reconcile net loss to net cash used in operating activities: |  |  |  |  |  |  |  |
| Gain from reduction of tax receivable agreement liability |  |  | (192,884) |  |  | — |  |
| Depreciation and amortization |  |  | 152,932 |  |  | 89,910 |  |
| Amortization of Levothyroxine Transition Agreement asset |  |  | 36,393 |  |  | — |  |
| Unrealized foreign currency loss |  |  | 10,552 |  |  | 21,560 |  |
| Amortization of debt issuance costs |  |  | 4,849 |  |  | 4,220 |  |
| Loss on extinguishment of debt |  |  | — |  |  | 19,667 |  |
| (Gain) loss on sale of international businesses, net |  |  | (6,930) |  |  | 2,812 |  |
| Intangible asset impairment charges |  |  | 158,610 |  |  | 8,474 |  |
| Non-cash restructuring and asset-related charges |  |  | 11,923 |  |  | — |  |
| Deferred tax provision (benefit) |  |  | 371,683 |  |  | (9,111) |  |
| Stock-based compensation and PPU expense |  |  | 16,666 |  |  | 163,991 |  |
| Inventory provision |  |  | 67,844 |  |  | 20,755 |  |
| Other operating charges and credits, net |  |  | 5,945 |  |  | (1,955) |  |
| Changes in assets and liabilities: |  |  |  |  |  |  |  |
| Trade accounts receivable, net |  |  | (46,457) |  |  | (74,711) |  |
| Inventories |  |  | (25,906) |  |  | (53,708) |  |
| Prepaid expenses, other current assets and other assets |  |  | 41,256 |  |  | 9,803 |  |
| Related party receivables |  |  | (1,305) |  |  | 10,828 |  |
| Accounts payable, accrued expenses and other liabilities |  |  | (13,932) |  |  | (26,858) |  |
| Related party payables |  |  | 25 |  |  | (14,125) |  |
| Net cash provided by (used in) operating activities |  |  | 52,594 |  |  | (9,421) |  |
| **Cash flows from investing activities:** |  |  |  |  |  |  |  |
| Purchases of property, plant and equipment |  |  | (42,664) |  |  | (63,065) |  |
| Acquisition of product rights and licenses |  |  | (50,000) |  |  | (14,000) |  |
| Acquisitions, net of cash acquired |  |  | — |  |  | (324,634) |  |
| Proceeds from surrender of corporate owned life insurance |  |  | 43,017 |  |  | — |  |
| Proceeds from sale of international businesses, net of cash sold |  |  | 34,834 |  |  | — |  |
| Net cash used in investing activities |  |  | (14,813) |  |  | (401,699) |  |
| **Cash flows from financing activities:** |  |  |  |  |  |  |  |
| Payments of deferred financing costs and debt extinguishment costs |  |  | — |  |  | (54,955) |  |
| Proceeds from issuance of debt |  |  | — |  |  | 1,325,383 |  |
| Payments of principal on debt and capital leases |  |  | (20,250) |  |  | (610,482) |  |
| Net borrowings on revolving credit line |  |  | — |  |  | 25,000 |  |
| Proceeds from exercise of stock options |  |  | 1,385 |  |  | 3,162 |  |
| Employee payroll tax withholding on restricted stock unit vesting |  |  | (926) |  |  | — |  |
| Equity contributions |  |  | — |  |  | 27,742 |  |
| Capital contribution from non-controlling interest |  |  | — |  |  | 360 |  |
| Acquisition of non-controlling interest |  |  | (3,543) |  |  | (11,775) |  |
| Tax distribution to non-controlling interest |  |  | (13,494) |  |  | — |  |
| Distributions to members |  |  | — |  |  | (182,998) |  |
| Payments of principal on financing lease - related party |  |  | (1,707) |  |  | — |  |
| Repayment of related party note |  |  | — |  |  | (14,842) |  |
| Net cash (used in) provided by financing activities |  |  | (38,535) |  |  | 506,595 |  |
| Effect of foreign exchange rate on cash |  |  | (967) |  |  | (1,204) |  |
| Net (decrease) increase in cash, cash equivalents, and restricted cash |  |  | (1,721) |  |  | 94,271 |  |
| Cash, cash equivalents, and restricted cash - beginning of period |  |  | 218,779 |  |  | 77,922 |  |
| Cash, cash equivalents, and restricted cash - end of period |  | $ | 217,058 |  | $ | 172,193 |  |
| Cash and cash equivalents - end of period |  | $ | 212,738 |  | $ | 165,192 |  |
| Restricted cash - end of period |  |  | 4,320 |  |  | 7,001 |  |
| Cash, cash equivalents, and restricted cash - end of period |  | $ | 217,058 |  | $ | 172,193 |  |
| **Supplemental disclosure of cash flow information:** |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| Cash paid for interest | $ | | 121,872 | $ | | 89,075 |  |
| Cash received (paid) for income taxes, net | $ | | 11,857 | $ | | (5,379) |  |
| **Supplemental disclosure of non-cash investing and financing activity:** |  |  |  |  |  |  |  |
| Tax distribution to non-controlling interest | $ | | — | $ | | 35,543 |  |
| Distribution to members | $ | | — | $ | | 8,562 |  |

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

4



**Amneal Pharmaceuticals, Inc.**

**Consolidated Statement of Stockholders' Equity / Members’ Deficit**

**(unaudited; in thousands)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | **Accumulated** |  |  |  |  |  |  |  |
|  | **Class A Common** | | | | | **Class B Common** | | | | | **Additional** | | | **Stockholders'** | |  |  | **Other** |  |  | **Non-** | |  |  |  |
|  | **Stock** | | |  |  | **Stock** | | |  |  |  | **Paid-in** | | **Accumulated** | |  | **Comprehensive** | |  |  | **Controlling** | |  |  | **Total** |
|  | **Shares** |  |  | **Amount** |  | **Shares** | |  | **Amount** |  |  | **Capital** | |  | **Deficit** |  | **(Loss) Income** | |  |  | **Interests** | |  |  | **Equity** |
| **Balance at July 1, 2019** | 128,151 |  | $ | 1,281 |  | 170,941 |  | $ | 1,710 |  | $ | 544,161 |  | $ | (80,746) |  | $ | (6,750) |  | $ | 289,696 |  |  | $ | 749,352 |
| Net loss | — |  |  | — | | — | |  | — | |  | — | |  | (265,006) |  |  | — |  |  | (98,386) |  |  |  | (363,392) |
| Foreign currency translation adjustment | — |  |  | — | | — | |  | — | |  | — | |  | — |  |  | 2,184 |  |  | 2,813 |  |  |  | 4,997 |
| Stock-based compensation | — |  |  | — | | — | |  | — | |  | 6,095 |  |  | — |  |  | — |  |  | — | |  |  | 6,095 |
| Restricted stock unit vesting, net of shares withheld to |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| cover payroll taxes | 3 |  |  | — | | — | |  | — | |  | 4 |  |  | — |  |  | — |  |  | (9) |  |  |  | (5) |
| Redemption of Class B Common Stock | 5,936 |  |  | 59 |  | (5,936) |  |  | (59) |  |  | 16,481 |  |  | — |  |  | (313) |  |  | (16,391) |  |  |  | (223) |
| Other | — |  |  | — | | — | |  | — | |  | (1,100) |  |  | — |  |  | — |  |  | — | |  |  | (1,100) |
| **Balance at September 30, 2019** | 134,090 |  | $ | 1,340 |  | 165,005 |  | $ | 1,651 |  | $ | 565,641 |  | $ | (345,752) |  | $ | (4,879) |  | $ | 177,723 |  |  | $ | 395,724 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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

5



**Amneal Pharmaceuticals, Inc.**

**Consolidated Statement of Stockholders' Equity / Members’ Deficit**

**(unaudited; in thousands)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | **Accumulated** |  |  |  |  |  |  |
|  | **Class A Common** | | | | | **Class B Common** | | | | | **Class B-1 Common** | | | |  | **Additional** | | **Stockholders'** | | | |  | **Other** |  |  | **Non-** | |  |  |
|  | **Stock** | | |  |  | **Stock** | | |  |  | **Stock** | | |  |  |  | **Paid-in** |  | **Accumulated** | | | **Comprehensive** | |  | **Controlling** | | |  | **Total** |
|  | **Shares** |  | **Amount** | |  | **Shares** |  | **Amount** | |  | **Shares** | | **Amount** | |  |  | **Capital** |  |  | **Deficit** | | **(Loss) Income** | |  |  | **Interests** | |  | **Equity** |
| **Balance at January 1, 2019** | 115,047 |  | $ | 1,151 |  | 171,261 |  | $ | 1,713 |  | 12,329 |  | $ | 123 |  | $ | 530,438 |  | $ | (20,920) |  | $ | (7,755) |  | $ | 391,613 |  | $ | 896,363 |
| Net loss | — |  |  | — | | — |  |  | — | | — | |  | — |  |  | — |  |  | (329,789) |  |  | — |  |  | (208,881) |  |  | (538,670) |
| Cumulative-effective adjustment from adoption |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| of Topic 842 | — |  |  | — | | — |  |  | — | | — | |  | — |  |  | — |  |  | 4,957 |  |  | — |  |  | 8,604 |  |  | 13,561 |
| Foreign currency translation adjustment | — |  |  | — | | — |  |  | — | | — | |  | — |  |  | — |  |  | — | |  | 1,759 |  |  | 2,255 |  |  | 4,014 |
| Stock-based compensation | — |  |  | — | | — |  |  | — | | — | |  | — |  |  | 16,666 |  |  | — | |  | — |  |  | — | |  | 16,666 |
| Exercise of stock options | 205 |  |  | 2 |  | — |  |  | — | | — | |  | — |  |  | 922 |  |  | — | |  | (7) |  |  | 468 |  |  | 1,385 |
| Restricted stock unit vesting, net of shares |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| withheld to cover payroll taxes | 253 |  |  | 2 |  | — |  |  | — | | — | |  | — |  |  | 10 |  |  | — | |  | (5) |  |  | (933) |  |  | (926) |
| Redemption of Class B Common Stock | 6,256 |  |  | 62 |  | (6,256) |  |  | (62) |  |  |  |  |  |  |  | 17,605 |  |  | — | |  | (332) |  |  | (17,273) |  |  | — |
| Conversion of Class B-1 Common Stock | 12,329 |  |  | 123 |  | — |  |  | — | | (12,329) |  |  | (123) |  |  | — |  |  | — | |  | — |  |  | — | |  | — |
| Tax distribution | — |  |  | — | | — |  |  | — | | — | |  | — |  |  | — |  |  | — | |  | — |  |  | (82) |  |  | (82) |
| Reclassification of foreign currency translation |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| adjustment included in net loss | — |  |  | — | | — |  |  | — | | — | |  | — |  |  | — |  |  | — | |  | 1,461 |  |  | 1,952 |  |  | 3,413 |
| **Balance at September 30, 2019** | 134,090 |  | $ | 1,340 |  | 165,005 |  | $ | 1,651 |  | — |  | $ | — |  | $ | 565,641 |  | $ | (345,752) |  | $ | (4,879) |  | $ | 177,723 |  | $ | 395,724 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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

6



**Amneal Pharmaceuticals, Inc.**

**Consolidated Statement of Stockholders' Equity / Members’ Deficit**

**(unaudited; in thousands)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | **Accumulated** | | |  |  |  |  |  |  |  | **Redeemable** | | |
|  | **Class A Common** | | | | | **Class B Common** | | | | | **Class B-1** | | |  |  | **Additional** | | | **Stockholders'** | | |  | **Other** | |  | **Non-** |  |  |  |  |  |  |  | **Non-** |
|  | **Stock** | |  |  |  | **Stock** | |  |  |  | **Common Stock** | | |  |  |  | **Paid-in** | | **Accumulated** | | | **Comprehensive** | | | **Controlling** | |  |  | **Total** | |  |  | **Controlling** | |
|  | **Shares** | | **Amount** | |  | **Shares** | | **Amount** | |  | **Shares** |  | **Amount** | |  |  | **Capital** | |  | **Deficit** | |  | **Loss** | |  | **Interests** |  |  | **Equity** | |  |  |  | **Interest** |
| **Balance at July 1, 2018** | 114,859 |  | $ | 1,149 |  | 171,261 |  | $ | 1,713 |  | 12,329 |  | $ | 123 |  | $ | 517,122 |  | $ | (19,104) |  | $ | (6,502) |  | $ | 444,985 |  | $ | 939,486 |  |  |  | $ | 11,858 |
| Net income | — | |  | — | | — | |  | — | | — |  |  | — |  |  | — | |  | 6,888 |  |  | — | |  | 10,510 |  |  | 17,398 |  |  |  |  | 67 |
| Effect of the Combination | — | |  | — | | — | |  | — | | — |  |  | — |  |  | (2,329) |  |  | — | |  | — | |  | — |  |  | (2,329) |  |  |  |  | — |
| Foreign currency translation adjustment | — | |  | — | | — | |  | — | | — |  |  | — |  |  | — | |  | — | |  | (3,384) |  |  | (4,555) |  |  | (7,939) |  |  |  |  | — |
| Stock-based compensation | — | |  | — | | — | |  | — | | — |  |  | — |  |  | 3,590 |  |  | — | |  | — | |  | — |  |  | 3,590 |  |  |  |  | — |
| Exercise of stock options | 115 |  |  | 1 |  | — | |  | — | | — |  |  | — |  |  | 1,369 |  |  | — | |  | (3) |  |  | (182) |  |  | 1,185 |  |  |  |  | — |
| Reclassification of redeemable non- |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| controlling interest | — | |  | — | | — | |  | — | | — |  |  | — |  |  | — | |  | 64 |  |  | — | |  | 86 |  |  | 150 |  |  |  |  | (150) |
| Non-controlling interests from acquisition |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| of Gemini | — | |  | — | | — | |  | — | | — |  |  | — |  |  | — | |  | — | |  | — | |  | (531) |  |  | (531) |  |  |  |  | — |
| Acquisition of redeemable non-controlling |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| interest | — | |  | — | | — | |  | — | | — |  |  | — |  |  | — | |  | — | |  | — | |  | — |  |  | — | |  |  |  | (11,775) |
| Tax distribution | — | |  | — | | — | |  | — | | — |  |  | — |  |  | — | |  | — | |  | — | |  | (35,543) |  |  | (35,543) |  |  |  |  | — |
| Other | — | |  | — | | — | |  | — | | — |  |  | — |  |  | 408 |  |  | — | |  | — | |  | (556) |  |  | (148) |  |  |  |  | — |
| **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.

7



**Amneal Pharmaceuticals, Inc.**

**Consolidated Statement of Stockholders' Equity / Members’ Deficit**

**(unaudited; in thousands)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | **Accumulated** | |  |  |  |  |  |  |  | **Redeemable** | | |
|  |  |  |  | **Members'** | | | **Class A Common** | | | | | **Class B Common** | | | | | **Class B-1** | | |  |  | **Additional** | | | **Stockholders'** | |  |  | **Other** |  |  | **Non-** |  |  |  |  |  |  | **Non-** |
|  | **Members'** | | | **Accumulated** | | | **Stock** | |  |  |  | **Stock** | |  |  |  | **Common Stock** | | | |  |  | **Paid-in** | | **Accumulated** | | **Comprehensive** | | |  | **Controlling** | |  |  | **Total** |  |  | **Controlling** | |
|  |  | **Equity** | |  | **Deficit** | | **Shares** | | **Amount** | |  | **Shares** | | **Amount** | |  | **Shares** |  | **Amount** | |  |  | **Capital** | |  | **Deficit** |  | **(Loss) Income** | |  |  | **Interests** |  |  | **Equity** |  |  |  | **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) |  |  |  | 67 |
| 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) |  |  |  | 11,708 |
| Non-controlling interests |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| from |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| acquisition of Gemini |  | — | |  | — | | — | |  | — | | — | |  | — | | — |  |  | — |  |  | — | |  | — |  |  | — |  |  | 2,518 |  |  | 2,518 |  |  |  | — |
| Acquisition of redeemable |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| non- |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| controlling interest |  | — | |  | — | | — | |  | — | | — | |  | — | | — |  |  | — |  |  | — | |  | — |  |  | — |  |  | — |  |  | — |  |  |  | (11,775) |
| 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.

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**Amneal Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements**

**(unaudited)**

**1. Nature of Operations**

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

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 operates principally in the United States, Switzerland, India, and Ireland. Amneal divested its operations in the United Kingdom on March 30, 2019 and Germany on May 3, 2019. For additional information, refer to *Note 3. Acquisitions and Divestitures*. 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 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%.

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 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 (the "Amneal Group") upon the consummation of the Combination, PIPE Investment and Closing Date Redemption was approximately 57%. As of September 30, 2019 and December 31, 2018, the overall interest percentage held by non-controlling interest holders was approximately 55% and 57%, respectively.

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, 2019, Holdings did not hold any equity interest in Amneal or the Company.

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During the three months ended June 30, 2019, pursuant to the Company's certificate of incorporation, the Company converted all (12.3 million) of its issued and outstanding shares of Class B-1 Common Stock to Class A Common Stock and such shares of Class B-1 Common Stock have been retired and may not be reissued by the Company. The rights of Class A Common Stock and Class B-1 Common Stock are identical, except that the Class B-1 Common Stock had certain director appointment rights and the Class B-1 Common Stock had no voting rights (other than with respect to its director appointment right and as otherwise required by law).

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The accompanying unaudited consolidated financial statements, which are prepared in accordance with generally accepted accounting principles in the United States of America, should be read in conjunction with Amneal’s annual audited financial statements for the year ended December 31, 2018 included in the Company’s 2018 Annual Report on Form 10-K. Certain information and footnote disclosures normally included in annual financial statements have been omitted from the accompanying unaudited consolidated financial statements. In the opinion of management, the accompanying unaudited consolidated financial statements contain all adjustments, consisting of only normal recurring adjustments, necessary for a fair statement of the Company's financial position as of September 30, 2019, cash flows for the nine months ended September 30, 2019 and 2018 and the results of its operations, its comprehensive loss and changes in stockholders' equity for the three and nine months ended September 30, 2019 and 2018. The consolidated balance sheet data at December 31, 2018 was derived from the Company's audited annual financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America.

The accounting policies of the Company are set forth in *Note 2. Summary of Significant Accounting Policies* contained in the Company’s 2018 Annual Report on Form 10-K, except for the impact of the adoption of new accounting standards discussed under *Recently Adopted Accounting Pronouncements*.

***Use of Estimates***

The preparation of financial statements requires the Company's management to make estimates and assumptions that affect the reported financial position at the date of the financial statements and the reported results of operations during the reporting period. Such estimates and assumptions affect the reported amounts of assets, liabilities, revenues and expenses, and disclosure of contingent assets and liabilities in the consolidated financial statements and accompanying notes. The following are some, but not all, of such estimates: the determination of chargebacks, sales returns, rebates, billbacks, allowances for accounts receivable, accrued liabilities, stock-based compensation, valuation of inventory balances, the determination of useful lives for product rights, allowances for deferred tax assets 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.

***Reclassifications***

Certain prior period balances have been reclassified to conform to the current period presentation.

***Recently Adopted Accounting Pronouncements***

***Leases***

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-02, *Leases,* which was subsequently supplemented by clarifying guidance (collectively, "Topic 842") to improve financial reporting of leasing transactions. Topic 842 requires a lessee to recognize most leases, including those classified as operating, on its balance sheets as right of use ("ROU") assets and lease liabilities and requires disclose of additional key information about leases.

The Company elected to apply the modified retrospective transition provisions of Topic 842 on January 1, 2019, the date of adoption. In addition, the Company elected the package of practical expedients permitted under the transition guidance within the new standard. This allowed the Company to carry forward historical lease classifications. Adoption of this standard resulted in the recording of operating lease ROU assets and operating lease liabilities of $85 million and $86 million, respectively.

The transition guidance of Topic 842 also required the Company to de-recognize the build to suit accounting associated with a related party lease for integrated manufacturing and office space and recognize that transaction as a financing lease as of January 1, 2019. The resulting de-recognition reduced leasehold improvements and a financing obligation by $24 million and $39 million, respectively, and increased non-controlling interests and stockholders' accumulated deficit, net of income taxes, by $9 million and $5 million, respectively. The arrangement was then recognized as a financing lease with an ROU asset and lease liability of $64 million on January 1, 2019. Leases with related parties, the details of which are described in *Note 15. Related Party* *Transactions,* are presented separately in the Company's balance sheets.

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The adoption of Topic 842 did not have a material impact on the Company's consolidated statements of operations. ROU assets and lease liabilities for reporting periods beginning on or after January 1, 2019 are presented under the new guidance, while prior periods amounts were not adjusted and continue to be reported in accordance with previous guidance.

All significant lease arrangements after January 1, 2019 are recognized as ROU assets and lease liabilities at lease commencement. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at the commencement date based on the present value of the future lease payments using the Company's incremental borrowing rate, which is assessed quarterly.

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

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

For further details regarding the Company's leases, refer to *Note 11. Leases*.

***Financial Instruments***

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 Companyadopted ASU 2016-01 as of January 1, 2019 and it did not have a material impact on the Company's consolidated financial statements.

***Goodwill***

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. The Company adopted ASU 2017-04 as of April 1, 2019 on a prospective basis and it did not have a material impact on the Company's consolidated financial statements.

***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 afterDecember 15, 2019 and interim periods within those annual periods, and early adoption is permitted. 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.

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**3. Acquisitions and Divestitures**

***Impax Acquisition Unaudited Pro Forma Information***

On May 4, 2018, the Company completed the Combination, as described in *Note 1. Nature of Operations*. The unaudited pro forma combined results of operations for the nine months ended September 30, 2018 (assuming the closing of the Combination occurred on January 1, 2017) are as follows (in thousands):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  | **Nine Months Ended** |  |
|  |  |  | **September 30, 2018** |  |
| Net revenue |  | $ | 1,341,555 |  |
| Net loss |  | |  |  |
|  | $ | (143,585) |  |
| Net loss attributable to Amneal Pharmaceuticals, Inc. |  | $ | (21,502) |  |
|  |  |  |  |  |

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.

***UK Divestiture***

On March 30, 2019, the Company sold 100% of the stock of its Creo Pharma Holding Limited subsidiary, which comprised substantially all of the Company's operations in the United Kingdom, to AI Sirona (Luxembourg) Acquisition S.a.r.l ("AI Sirona") for net cash consideration of approximately $32 million which was received in April 2019. The carrying value of the net assets sold was $22 million, including intangible assets of $7 million and goodwill of $5 million. As a result of the sale, the Company recognized a pre-tax gain of $9 million, inclusive of transaction costs and the recognition of accumulated foreign currency translation adjustment losses of $3 million, within (loss) gain on sale of international business for the nine months ended September 30, 2019. As part of the disposition, the Company entered into a supply and license agreement with AI Sirona to supply certain products for a period of up to two years.

***Germany Divestiture***

On May 3, 2019, the Company sold 100% of the stock of its Amneal Deutschland GmbH subsidiary, which comprised substantially all of the Company's operations in Germany, to EVER Pharma Holding Ges.m.b.H. (“EVER”) for net cash consideration of approximately $3 million which was received in May 2019. The carrying value of the net assets sold was $7 million, including goodwill of $0.5 million. As a result of the sale, the Company recognized a pre-tax loss of $2 million, inclusive of transaction costs and the recognition of accumulated foreign currency translation adjustment losses, within (loss) gain on sale of international business for the nine months ended September 30, 2019. As part of the disposition, the Company also entered into a license and supply agreement with EVER to supply certain products for an 18 month period.

1. **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.

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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 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.

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***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 accounted for approximately 81% and 80% of total gross sales of products for the three and nine months ended September 30, 2019, respectively. The Company's three largest customers accounted for approximately 83% and 82% of total gross sales of products for the three and nine months ended September 30, 2018, respectively.

***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, 2019 and 2018 are set forth below (in thousands, except for percentages):

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Segment** | | **Product Family** |  | **Three Months Ended September 30,** | | | | |  |  |
|  |  |  | **2019** | | |  |  |  |
|  |  |  |  |  | **$** |  |  |  | **%** |  |  |
|  | Generics | | Levothyroxine Sodium |  | $ | 39,767 |  |  | 11% |  |  |
|  | Specialty | | Rytary® |  |  | 33,710 |  |  | 9% |  |  |
|  | Generics | | Epinephrine Auto-Injector (generic Adrenaclick®) |  |  | 22,687 |  |  | 6% |  |  |
|  | Generics | | Diclofenac Sodium Gel |  |  | 19,264 |  |  | 5% |  |  |
|  | Specialty (1) | | Oxymorphone | $ | | 17,142 |  |  | 5% |  |  |
|  |  |  | 14 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |



|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Segment** | | **Product Family** |  | **Three Months Ended September 30,** | | | | |  |
|  |  | **2018** | | |  |  |
|  |  |  |  | **$** |  |  |  | **%** |  |
| Generics | | Yuvafem-Estradiol |  | $ | 48,466 |  |  | 10% |  |
| Specialty | | Rytary® |  |  | 33,073 |  |  | 7% |  |
| Generics | | Epinephrine Auto-Injector (generic Adrenaclick®) |  |  | 30,259 |  |  | 6% |  |
| Generics | | Diclofenac Sodium Gel |  |  | 26,455 |  |  | 6% |  |
| Generics | | Aspirin; Dipyridamole ER Capsule | $ | | 22,777 |  |  | 5% |  |
| **Segment** | | **Product Family** |  | **Nine Months Ended September 30, 2019** | | | | |  |
|  |  |  |  | **$** |  |  |  | **%** |  |
| Generics | | Levothyroxine Sodium |  | $ | 135,220 |  |  | 11% |  |
| Specialty | | Rytary® |  |  | 95,538 |  |  | 8% |  |
| Generics | | Diclofenac Sodium Gel |  |  | 67,741 |  |  | 6% |  |
| Generics | | Epinephrine Auto-Injector (generic Adrenaclick®) |  |  | 53,841 |  |  | 4% |  |
| Specialty (1) | | Oxymorphone | $ | | 45,191 |  |  | 4% |  |

1. For the six months ended June 30, 2019 Oxymorphone net revenue was recorded in the Generics segment.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **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 Capsule |  |  | 67,718 |  | 6% |
| Specialty | | Rytary® |  |  | 53,593 |  | 5% |
| Generics | | Epinephrine Auto-Injector (generic Adrenaclick®) | $ | | 49,425 |  | 4% |

A rollforward of the major categories of sales-related deductions for the nine months ended September 30, 2019 is as follows (in thousands):

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **Contract** |  |  |  |  |  |  |  |  |  |  |
|  | **Charge- backs** | | |  |  |  |  |  |  |  |  |  | **Accrued** |
|  |  |  | **and Sales** |  |  |  |  |  | **Accrued** | | **Medicaid and** | | |
|  |  |  | **Volume** | **Cash Discount** | | |  |  | **Returns** | |  | **Commercial** | |
|  |  |  | **Allowances** |  |  | **Allowances** |  |  | **Allowance** | |  |  | **Rebates** |
| Balance at December 31, 2018 |  | $ | 829,596 |  | $ | 36,157 |  | $ | 154,503 |  |  | $ | 74,202 |
| Provision related to sales recorded in the period |  |  | 3,413,718 |  |  | 101,285 |  |  | 71,126 |  |  |  | 143,145 |
| Credits/payments issued during the period |  |  | (3,444,048) |  |  | (109,309) |  |  | (85,666) |  |  |  | (110,319) |
| Balance at September 30, 2019 |  | $ | 799,266 |  | $ | 28,133 |  | $ | 139,963 |  |  | $ | 107,028 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**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; Transition Agreement***

On August 16, 2018, the Company entered into a license and supply agreement with Jerome Stevens Pharmaceuticals, Inc. ("JSP") for levothyroxine sodium tablets ("Levothyroxine"). This agreement designated the Company as JSP's exclusive commercial partner for Levothyroxine in the U.S. market for a 10 -year term commencing on March 22, 2019. Under this license and supply agreement with JSP, the Company accrued the up-front license payment of $50 million on March 22, 2019, which was paid in April 2019. The agreement also provides for the Company to pay a profit share to JSP based on net profits of the Company's sales of Levothyroxine, after considering product costs.

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On November 9, 2018, the Company entered into a transition agreement ("Transition Agreement") with Lannett Company (“Lannett”) and JSP. Under the terms of the Transition Agreement, the Company assumed the distribution and marketing of Levothyroxine from Lannett beginning December 1, 2018 through March 22, 2019, ahead of the commencement date of the license and supply agreement with JSP described above.

In accordance with the terms of the Transition Agreement, the Company made $47 million of non-refundable payments to Lannett. For the nine months ended September 30, 2019 and the year ended December 31, 2018, $37 million and $10 million, respectively, were expensed to cost of goods sold, as the Company sold Levothyroxine (none in the three months ended September 30, 2019). As of December 31, 2018 , the Company had a $4 million transition contract liability, which was fully settled in February 2019.

***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 development and regulatory milestone payments as well as commercial milestone payments on reaching pre-agreed sales targets in the market to Mabxience, up to $72 million. For the nine months ended September 30, 2019 the Company expensed a milestone payment of $1 million (none for the three months ended September 30, 2019), to research and development. For the nine months ended September 30, 2018, the Company expensed a milestone payment of $0.5 million to research and development (none for the three months ended September 30, 2018).

***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 million to be received in quarterly amounts specified in the AZ 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 million. The Company recorded cost of sales for royalties under this agreement of $5 million and $14 million for the three and nine months ended September 30, 2019 , respectively, and $5 million and $8 million for the three and nine months ended September 30, 2018, respectively.

***Adello 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 $2 million in October 2017 for execution of the agreement which was expensed in research and development. 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,

1. between $20 million and $50 million relating to number of competitors at launch for one product, and (iv) between $15 million and $68 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 for the three and nine months ended September 30, 2019 and 2018 were immaterial.

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**6. Restructuring and Other Charges**

During the three months ended June 30, 2018, in connection with the Combination, the Company committed to a restructuring plan to achieve cost savings. The Company expected 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 intended to close its Hayward, California based operations.

In addition to the actions noted above, on July 10, 2019, the Company announced a plan to restructure its operations that is intended to reduce costs and optimize its organizational and manufacturing infrastructure. Pursuant to the restructuring plan as revised, the Company expects to reduce its headcount by approximately 300 to 350 employees, primarily by closing its manufacturing facility located in Hauppauge, NY. As a result of the restructuring plan, the Company estimates that it will incur a pre-tax restructuring charge of approximately $6 to $8 million of cash expenditures related to severance benefits.

Other cash expenditures associated with this restructuring plan, including decommissioning and dismantling the sites and other third party costs cannot be estimated at this time (collectively these actions comprise the "Plans").

The following table sets forth the components of the Company's restructuring and other charges (in thousands):

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **Three Months Ended** | | | |  |  | **Nine Months Ended** | | | |
|  |  |  | **September 30,** | | | |  |  | **September 30,** | | | |
|  |  |  | **2019** |  |  | **2018** |  |  | **2019** |  |  | **2018** |
| Employee restructuring separation charges (1) |  | $ | 6,187 |  | $ | (2,156) |  | $ | 8,607 |  | $ | 42,309 |
| Asset-related charges (2) |  |  | 10,609 |  |  | — |  |  | 11,923 |  |  | — |
| Total employee and asset-related restructuring charges |  |  | 16,796 |  |  | (2,156) |  |  | 20,530 |  |  | 42,309 |
| Other employee severance charges (3) |  |  | 4,141 |  |  | — |  |  | 9,403 |  |  | — |
| **Total restructuring and other charges** |  | $ | 20,937 |  | $ | (2,156) |  | $ | 29,933 |  | $ | 42,309 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

1. Employee restructuring separation charges include the cost of benefits provided pursuant to the Company's severance programs for employees impacted by the Plans at the Company's Hauppauge, NY, Hayward, CA and other facilities.
2. Asset-related charges are primarily associated with the impairment of property, plant and equipment and right of use asset associated with the Company's Hauppauge, NY facility.
3. For the three months ended September 30, 2019, other employee severance charges are primarily associated with the resignation of the Company’s former Chief Executive Officer. For the nine months ended September 30, 2019, other employee severance charges are primarily associated with the resignation of the Company’s former Chief Executive Officer and other former senior executives.

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Three Months Ended** | | | |  |  | **Nine Months Ended** | | | | |
|  |  | **September 30,** | | | |  |  | **September 30,** | | | | |
|  |  | **2019** |  |  | **2018** |  |  | **2019** |  |  |  | **2018** |
| Generics | $ | 14,888 |  | $ | (2,885) |  | $ | 17,201 |  |  | $ | 21,912 |
| Specialty |  | 213 |  |  | (27) |  |  | 391 |  |  |  | 2,394 |
| Corporate |  | 1,695 |  |  | 756 |  |  | 2,938 |  |  |  | 18,003 |
| Total employee and asset-related restructuring charges | $ | 16,796 |  | $ | (2,156) |  | $ | 20,530 |  |  | $ | 42,309 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

The following table shows the change in the employee separation-related liability associated with the Plans, which is included in accounts payable and accrued expenses (in thousands):

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | **Employee** |  |  |
|  |  |  | **Restructuring** | |  |  |
|  | Balance at December 31, 2018 |  | $ | 22,112 |  |  |
|  | Charges to income |  |  | 8,607 |  |  |
|  | Payments |  |  | (28,422) |  |  |
| Balance at September 30, 2019 | |  | $ | 2,297 |  |  |
|  |  | 17 |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |  |



**7. (Loss) Earnings per Share**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **Three Months Ended** | | | |  |  | **Nine Months Ended** | | | |
|  |  |  | **September 30,** | | | |  |  | **September 30,** | | | |
|  |  |  | **2019** |  |  | **2018** |  |  | **2019** |  |  | **2018** |
| Numerator: |  |  |  |  |  |  |  |  |  |  |  |  |
| Net (loss) income attributable to Amneal Pharmaceuticals, Inc. | $ | | (265,006) | $ | | 6,952 | $ | | (329,789) | $ | | (12,152) |
| Denominator: |  |  |  |  |  |  |  |  |  |  |  |  |
| Weighted-average shares of Class A Common Stock and Class B-1 |  |  |  |  |  |  |  |  |  |  |  |  |
| Common Stock outstanding - basic |  |  | 130,729 |  |  | 127,247 |  |  | 128,822 |  |  | 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 |  |  | 130,729 |  |  | 128,222 |  |  | 128,822 |  |  | 127,196 |
| Net (loss) earnings per share attributable to Amneal Pharmaceuticals, |  |  |  |  |  |  |  |  |  |  |  |  |
| Inc.'s common stockholders: |  |  |  |  |  |  |  |  |  |  |  |  |
| Class A and Class B-1 basic | $ | | (2.03) | $ | | 0.05 | $ | | (2.56) | $ | | (0.10) |
| Class A and Class B-1 diluted |  | $ | (2.03) |  | $ | 0.05 |  | $ | (2.56) |  | $ | (0.10) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

The allocation of net (loss) earnings 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** | | | |  |  | **Nine Months Ended** | | | |  |  |
|  | **September 30,** | | | |  |  | **September 30,** | | | |  |  |
|  | **2019** |  |  | **2018** |  |  | **2019** |  |  | **2018** |  |  |
| Stock options | 7,973 | (1) | | 965 | (2) | | 7,973 | (1) | | 5,862 | (1) | |
| Restricted stock units | 2,915 | (1) | | — |  |  | 2,915 | (1) | | 1,324 | (1) | |
| Performance stock units | 357 | (1) | | — |  |  | 357 | (1) | | — |  |  |
| Shares of Class B Common Stock | 165,004 | (3) | | 171,261 | (3) | | 165,004 | (3) | | 171,261 | (3) | |

1. Excluded from the computation of diluted loss 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 during the period.
2. 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).
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.

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**8. Income Taxes**

As a result of the Combination (refer to *Note 1. Nature of Operations*), the Company became the sole managing member of Amneal, with Amneal being the accounting predecessor for accounting purposes. Amneal is a limited liability company that is treated as a partnership for U.S. federal and most applicable state and local income tax purposes. As a partnership, Amneal is not subject to U.S. federal and certain state and local income taxes. Any taxable income or loss generated by Amneal is passed through to and included in the taxable income or loss of its members, including the Company, on a pro rata basis subject to applicable tax regulations. The Company is subject to U.S. federal income taxes, in addition to state and local income taxes with respect to its allocable share of any taxable income or loss of Amneal, as well as any stand-alone income or loss generated by the Company. Amneal provides for income taxes in the various foreign jurisdictions in which it operates.

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

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

In assessing the need for a valuation allowance in the third quarter of fiscal 2019, the Company considered all available objective and verifiable evidence both positive and negative, including historical levels of pre-tax income (loss) both on a consolidated basis and tax reporting entity basis, legislative developments, expectations and risks associated with estimates of future pre-tax income, and prudent and feasible tax planning strategies. The Company currently estimates that as of September 30, 2019 it will have generated a cumulative consolidated three year pre-tax loss. As a result of this analysis, the Company determined that it is more likely than not that it will not realize the benefits of its gross DTAs and therefore has recorded a valuation allowance of $372 million for the three months ended September 30, 2019 to reduce the carrying value of these gross DTAs, net of the impact of the reversal of taxable temporary differences, to zero.

In connection with the Combination, the Company entered into a tax receivable agreement (“TRA”) for which it is generally required to pay the other holders of Amneal Common Units 85% of the applicable tax savings, if any, in U.S. federal and state income tax that it is deemed to realize as a result of certain tax attributes of their Amneal Common Units sold to the Company (or exchanged in a taxable sale) and that are created as a result of (i) the sales of their Amneal Common Units for shares of Class A Common Stock and (ii) tax benefits attributable to payments made under the TRA (including imputed interest). In conjunction with the valuation allowance recorded on the DTAs, the Company reversed the accrued TRA liability of $193 million, which resulted in a gain recorded as a component of Other income (expense), net.

The projection of future taxable income involves significant judgment. Actual taxable income may differ from our estimates, which could significantly impact the liability under the TRA. As noted above, we have determined it is more-likely-than-not we will be unable to utilize all of our DTAs subject to TRA; therefore, we have reversed the liability under the TRA related to the tax savings we may realize from common units sold or exchanged through September 30, 2019. If utilization of these DTAs becomes more-likely- than-not in the future, at such time, we will record liabilities under the TRA of up to an additional $193 million as a result of basis adjustments under Internal Revenue Code Section 754, which will be recorded through charges to our consolidated statement of operations. However, if the tax attributes are not utilized in future years, it is reasonably possible no amounts would be paid under the TRA. Should we determine that a DTA with a valuation allowance is realizable in a subsequent period, the related valuation allowance will be released and if a resulting TRA payment is determined to be probable, a corresponding TRA liability will be recorded.

For the three months ended September 30, 2019 and 2018, the Company's provision for income taxes and effective tax rates were $390 million and 1483.0% and $5 million and 22.6%, respectively. The change in provision for income taxes is primarily associated with the charge to record the valuation allowance against the Company’s DTAs.

For the nine months ended September 30, 2019, the Company’s provision for income taxes and effective tax rate were $376 million and (230.2%) For the nine months ended September 30, 2018, the Company’s benefit from income taxes and effective tax rate were $7 million and 3.7% The change in income taxes was primarily due to the provision to record the valuation allowance against the Company’s DTAs. The change is also due to the change in the Company's legal structure subsequent to the Combination. Prior to the Combination, as a limited liability company, income taxes were only provided for the international subsidiaries as all domestic taxes flowed to the members. Subsequent to May 4, 2018, domestic income taxes were also provided for the Company's allocable share of income or losses from Amneal at the prevailing U.S. federal, state, and local corporate income tax rates.

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The Company and its subsidiaries file income tax returns in the U.S. federal, and various state, local and foreign jurisdictions. The Company is not currently under income tax audit in any jurisdiction, and it will file its first income tax returns for the period ended December 31, 2018. Impax's federal tax filings for the 2015, 2016 and 2017 tax years are currently under audit and these are the only tax years open under the IRS statute of limitations for Impax. If there were adjustments to the attributes of Impax, they could impact the carryforward losses at the Company, which is the successor in interest to Impax. The Amneal partnership was audited for the tax year ended December 31, 2015 without any adjustments to taxable income. Income tax returns are generally subject to examination for a period of 3 years in the U.S. The statute of limitations for the 2016 and 2017 tax years will, therefore, expire no earlier than 2020. However, any adjustments to the 2016 or 2017 tax years would be pre-transaction when the Company had no ownership interest in Amneal. Under the partnership income tax regulations and audit guidelines, the Company is not responsible for any hypothetical pre-transaction income tax liabilities which pass through to the owners as of the year of any potential income tax adjustment. Neither the Company nor any of its other affiliates is currently under audit for state income tax.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **9. Trade Accounts Receivable, Net** | |  |  |  |  |  |  |
| Trade accounts receivable, net is comprised of the following (in thousands): | |  |  |  |  |  |  |
|  |  |  | **September 30,** | | | **December 31,** | |
|  |  |  |  | **2019** |  |  | **2018** |
|  | Gross accounts receivable |  | $ | 1,347,401 |  | $ | 1,349,588 |
|  | Allowance for doubtful accounts |  |  | (1,893) |  |  | (2,340) |
|  | Contract charge-backs and sales volume allowances |  |  | (799,266) |  |  | (829,596) |
|  | Cash discount allowances |  |  | (28,133) |  |  | (36,157) |
|  | Subtotal |  |  | (829,292) |  |  | (868,093) |
| Trade accounts receivable, net | |  | $ | 518,109 |  | $ | 481,495 |
|  |  |  |  |  |  |  |  |

Receivables from customers representing 10% or more of the Company’s gross trade accounts receivable reflected three customers at September 30, 2019, equal to 35%, 25%, and 25%, respectively. Receivables from customers representing 10% or more of the Company’s gross trade accounts receivable reflected three customers at December 31, 2018, equal to 30%, 28%, and 24%, respectively.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **10. Inventories** | |  |  |  |  |  |  |
| Inventories, net of reserves, are comprised of the following (in thousands): | |  |  |  |  |  |  |
|  |  | **September 30,** | | |  | **December 31,** | |
|  |  |  | **2019** |  |  |  | **2018** |
|  | Raw materials | $ | 182,828 |  |  | $ | 181,654 |
|  | Work in process |  | 50,763 |  |  |  | 54,152 |
|  | Finished goods |  | 168,236 |  |  |  | 221,413 |
|  | Total inventories | $ | 401,827 |  |  | $ | 457,219 |
|  |  |  |  |  |  |  |  |

**11. Leases**

The majority of the Company's operating and financing lease portfolio consists of corporate offices, manufacturing sites, warehouse space, research and development facilities and manufacturing equipment. The Company's leases have remaining lease terms of 1 year to 25 years. Rent expense for the three and nine months ended September 30, 2019 was $7 million and $19 million, respectively. Rent expense for the three and nine months ended September 30, 2018 was $6 million and $13 million, respectively. The Company recorded a $2 million impairment charge for the right of use asset associated with its Hauppauge, NY facility during the three and nine months ended September 30, 2019 because the Company’s latest forecast does not support recoverability of that asset. For further details, see *Note 6. Restructuring and Other Charges.*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| The components of total lease costs were as follows (in thousands): | |  |  |  |  |  |  |  |  |
|  |  |  |  | **Three Months Ended** |  |  | **Nine Months Ended** |  |  |
|  |  |  |  | **September 30, 2019** |  |  | **September 30, 2019** |  |  |
|  | Operating lease cost (1) |  | $ | 5,960 |  | $ | 16,850 |  |  |
|  | Finance lease cost: |  |  |  |  |  |  |  |  |
|  | Amortization of right-of-use assets |  |  | 652 |  |  | 1,956 |  |  |
|  | Interest on lease liabilities |  |  | 1,115 |  |  | 3,358 |  |  |
|  | Total finance lease cost |  |  | 1,767 |  |  | 5,314 |  |  |
| **Total lease cost** | |  | $ | 7,727 |  | $ | 22,164 |  |  |
|  |  | 20 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |



|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| (1) Includes variable and short-term lease costs. | |  |  |  |  |
| Supplemental balance sheet information related to the Company's leases was as follows (in thousands): | |  |  |  |  |
| **Operating leases** | |  | **September 30, 2019** | |  |
|  | Operating lease right-of-use assets |  | $ | 56,455 |  |
|  | Operating lease right-of-use assets - related party |  |  | 14,930 |  |
|  | Total operating lease right-of-use assets |  | $ | 71,385 |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| Operating lease liabilities | $ | | 44,375 |  |
|  | Operating lease liabilities - related party |  |  | 14,271 |  |
|  | Current portion of operating lease liabilities |  |  | 13,467 |  |
|  | Current portion of operating and financing lease liabilities - related party |  |  | 2,299 |  |
|  | Total operating lease liabilities |  | $ | 74,412 |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| **Financing leases** |  |  |  |  |
|  | Financing lease right of use assets - related party | $ | | 61,936 |  |
|  |  |  |  |  |  |
| Financing lease liabilities - related party | $ | | 61,719 |  |
|  | Current portion of operating and financing lease liabilities - related party |  |  | 1,054 |  |
| Total financing lease liabilities | |  | $ | 62,773 |  |
|  |  |  |  |  |  |

At September 30, 2019 financing right of use assets of $3 million, financing short-term liabilities of $1 million and financing long-term liabilities of $2 million associated with our auto fleet are recorded in Other assets, Accounts payable and accrued expenses and Other liabilities, respectively.

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

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | **Three Months Ended** |  |  | **Nine Months Ended** |  |
|  |  |  |  | **September 30, 2019** |  |  | **September 30, 2019** |  |
|  | **Cash paid for amounts included in the measurement of lease** |  |  |  |  |  |  |  |
|  | **liabilities:** |  |  |  |  |  |  |  |
|  | Operating cash flows from finance leases | $ | | 1,117 | $ | | 2,987 |  |
|  | Operating cash flows from operating leases |  |  | 4,964 |  |  | 14,968 |  |
|  | Financing cash flows from finance leases |  |  | 252 |  |  | 1,118 |  |
|  | **Non-cash activity:** |  |  |  |  |  |  |  |
|  | Right-of-use assets obtained in exchange for new operating lease |  |  |  |  |  |  |  |
| liabilities | | $ | | — | $ | | 360 |  |
| 21 | |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |



The table below reflects the weighted average remaining lease term and weighted average discount rate for the Company's operating and finance leases as of September 30, 2019.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  | **September 30, 2019** |
|  | Weighted average remaining lease term - operating leases |  |  |  |  |  | 6 years |
|  | Weighted average remaining lease term - finance leases |  |  |  |  |  | 23 years |
|  | Weighted average discount rate - operating leases |  |  |  |  |  | 6.1% |
|  | Weighted average discount rate - finance leases |  |  |  |  |  | 7.0% |
| Maturities of lease liabilities as of September 30, 2019 were as follows (in thousands): | | | |  |  |  |  |
|  |  |  |  | **Operating** |  |  | **Financing** |
|  |  |  |  | **Leases** |  |  | **Leases** |
|  | 2019 (1) |  | $ | 4,999 |  | $ | 1,368 |
|  | 2020 |  |  | 19,812 |  |  | 5,474 |
|  | 2021 |  |  | 16,173 |  |  | 5,474 |
|  | 2022 |  |  | 12,327 |  |  | 5,474 |
|  | 2023 |  |  | 10,038 |  |  | 5,474 |
|  | Thereafter |  |  | 26,930 |  |  | 106,740 |
|  | Total lease payments |  |  | 90,279 |  |  | 130,004 |
|  | Less: Imputed interest |  |  | (15,867) |  |  | (67,231) |
|  | Total |  | $ | 74,412 |  | $ | 62,773 |
|  |  |  |  |  |  |  |  |

(1) Excludes the nine months ended September 30, 2019.

As disclosed in the Company's 2018 Annual Report on Form 10-K, under the previous lease accounting standard, the table below reflects the future minimum lease payments, including reasonably assured renewals, due under non-cancelable leases and a financing obligation as of December 31, 2018 (in thousands):

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **Operating** |  |  |  | **Financing** |
|  |  |  | **Leases** |  |  |  | **Obligation** |
|  | 2019 |  | $ | 25,885 |  | $ | 5,474 |
|  | 2020 |  |  | 12,071 |  |  | 5,474 |
|  | 2021 |  |  | 11,105 |  |  | 5,474 |
|  | 2022 |  |  | 10,329 |  |  | 5,474 |
|  | 2023 |  |  | 10,043 |  |  | 5,474 |
|  | Thereafter |  |  | 28,128 |  |  | 107,196 |
|  | Total lease payments |  |  | 97,561 |  |  | 134,566 |
|  | Less: Imputed interest |  |  | — |  |  | (95,217) |
|  | Total |  | $ | 97,561 |  | $ | 39,349 |
|  |  |  |  |  |  |  |  |

For additional information regarding lease transactions between related parties, refer to *Note 15. Related Party Transactions.*

**12. 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 assetsand 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.

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*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, 2019 and December 31, 2018 (in thousands):

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  | **Fair Value Measurement Based on** | | | | | | |
|  |  |  |  |  |  |  |  | **Quoted** |  |  | **Significant** |  |  |  |
|  |  |  |  |  |  |  |  | **Prices in** |  |  | **Other** |  |  | **Significant** |
|  |  |  |  |  |  |  |  | **Active** |  | **Observable** | |  | **Unobservable** | |
|  |  |  |  |  |  |  |  | **Markets** |  |  | **Inputs** |  |  | **Inputs** |
| **September 30, 2019** | | |  |  | **Total** |  |  | **(Level 1)** |  |  | **(Level 2)** |  |  | **(Level 3)** |
|  | **Liabilities** | |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Deferred Compensation Plan liabilities (1) | | $ | | 21,637 | $ | | — | $ | | 21,637 | $ | | — |
|  | **December 31, 2018** |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Assets | |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Deferred Compensation Plan asset (1) | | $ | | 40,101 | $ | | — | $ | | 40,101 | $ | | — |
|  | **Liabilities** | |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Deferred Compensation Plan liabilities (1) | | $ | | 27,978 | $ | | — | $ | | 27,978 | $ | | — |

1. As of September 30, 2019, deferred compensation plan liabilities of $8 million and $14 million were recorded in current and non-current liabilities, respectively. As of December 31, 2018, deferred compensation plan liabilities were recorded in non-current liabilities. They are recorded at the value of the amount owed to the plan participants, with changes in value recognized as compensation expense. The calculation of the deferred compensation plan obligation is derived from observable market data by reference to hypothetical investments selected by the participants and is included in other long-term liabilities. The Company invested participant contributions in corporate-owned life insurance policies, for which the cash surrender value was included in Other non-current assets as of December 31, 2018. In July 2019, the Company surrendered all corporate-owned life insurance for approximately $43 million in cash proceeds.

There were no transfers between levels in the fair value hierarchy during the nine months ended September 30, 2019.

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

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

The $2.7 billion term loan under the Company’s senior credit agreement entered into on May 4, 2018 (the "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, 2019 and December 31, 2018 was approximately $2.3 billion and $2.5 billion, respectively.

***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, 2019 and 2018.

**13. Commitments and Contingencies**

***Commitments***

*Commercial Manufacturing, Collaboration, License, and Distribution Agreements*

The Company continues to seek to enhance its product line and develop a balanced portfolio of differentiated products through product acquisitions and in-licensing. Accordingly, the Company, in certain instances, may be contractually obligated to make potential future development, regulatory, and commercial milestone, royalty and/or profit sharing payments in conjunction with collaborative agreements or acquisitions that the Company has entered into with third parties. The Company has also licensed certain technologies or intellectual property from various third parties. The Company is generally required to make upfront payments as well as other payments upon successful completion of regulatory or sales milestones. The agreements generally permit the Company to terminate the agreement with no significant continuing obligation. The Company could be required to make significant payments pursuant to these arrangements. These payments are contingent upon the occurrence of certain future events and, given the nature of these events, it is unclear when, if ever, the Company may be required to pay such amounts. Further, the timing of any future payment is not reasonably estimable.

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***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. Additionally, the Company is subject to legal proceedings that are not 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. For the three and nine months ended September 30, 2019, the Company recorded a net charge of $15 million for the commercial and governmental legal proceedings and claims. The ultimate resolution of any or all claims, legal proceedings or investigations could differ materially from our estimate and 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. As of September 30, 2019 and December 31, 2018, the Company had liabilities for commercial and governmental legal proceedings and claims of $30 million and $15 million, respectively.

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.

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 and Price Reporting Matters*

The Company is required to provide pricing information to state agencies, including agencies that administer federal Medicaid programs. Certain state agencies have alleged that manufacturers have reported improper pricing information, which allegedly caused them to overpay reimbursement costs. Other agencies have alleged that manufacturers have failed to timely file required reports concerning pricing information. Reserves are periodically established by the Company for any potential claims or settlements of overpayment. The Company intends to vigorously defend against any such claims. The ultimate settlement of any potential liability for such claims may be higher or lower than estimated.

*Patent Litigation*

There is substantial litigation in the pharmaceutical, biological, and biotechnology industries with respect to the manufacture, use, and sale of new products which are the subject of conflicting patent and intellectual property claims. One or more patents often cover the brand name products for which the Company is developing generic versions and the Company typically has patent rights covering the Company’s branded products.

Under federal law, when a drug developer files an Abbreviated New Drug Application ("ANDA") for a generic drug seeking approval before expiration of a patent which has been listed with the FDA as covering the brand name product, the developer must certify its product will not infringe the listed patent(s) and/or the listed patent is invalid or unenforceable (commonly referred to as a "Paragraph IV" certification). Notices of such certification must be provided to the patent holder, who may file a suit for patent infringement within 45 days of the patent holder’s receipt of such notice. If the patent holder files suit within the 45-day period, the FDA can review and tentatively approve the ANDA, but generally is prevented from granting final marketing approval of the product until a final judgment in the action has been rendered in favor of the generic drug developer, or 30 months from the date the notice was received, whichever is sooner. The Company’s Generics segment is typically subject to patent infringement litigation brought by branded pharmaceutical manufacturers in connection with the Company’s Paragraph IV certifications seeking an order delaying the approval of the Company’s ANDA until expiration of the patent(s) at issue in the litigation. Likewise, the Company’s Specialty segment is currently involved in patent infringement litigation against generic drug manufacturers that 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 Generics segment, the potential consequences in the event of an unfavorable outcome in such litigation include delaying launch of its generic products until patent expiration. If the Company were to launch its generic product prior to successful resolution of a patent litigation, the Company could be liable for potential damages measured by the profits lost by the branded product manufacturer rather than the profits earned by the Company if it is found to infringe a valid, enforceable patent, or enhanced treble damages in cases of willful infringement. For the Company’s Specialty segment, an unfavorable outcome may significantly accelerate generic competition ahead of expiration of the patents covering the Company’s branded products. All such litigation typically involves significant expense.

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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 Infringement Matter***

*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. Zydus filed a motion for judgment on the pleadings regarding its counterclaims. On November 29, 2018, the Court granted Zydus’s motion for judgment as to its counterclaims. A case schedule has been set with trial anticipated in February 2020.

***Other Litigation Related to the Company’s Business***

*Opana ER® FTC Antitrust Litigation*

On February 25, 2014, Impax received a Civil Investigative Demand (“CID”) from the Federal Trade Commission (“FTC”) concerning its investigation into the drug Opana® ER and its generic equivalents. On March 30, 2016, the FTC filed a complaint against Impax, Endo Pharmaceuticals Inc. ("Endo"), and others in the United States District Court for the Eastern District of Pennsylvania, alleging that Impax and Endo violated antitrust laws when they entered into a June 2010 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 appealed this ruling to the FTC. On March 28, 2019, the FTC issued an Opinion & Order reversing the Administrative Law Judge’s initial dismissal decision. The FTC found that Impax had violated Section 5 of the FTC Act by engaging in an unfair method of competition, and accordingly entered an order enjoining Impax from entering into anticompetitive reverse patent settlements (or agreements with other generic original Opana® ER manufacturers) and requiring Impax to maintain an antitrust compliance program. On June 6, 2019, the Company filed a Petition for Review of the FTC’s Opinion & Order with the United States Court of Appeals for the Fifth Circuit. The Company filed its opening appellate brief with the Fifth Circuit on October 3, 2019.

On July 12, 2019, the Company received a CID from the FTC concerning an August 2017 settlement agreement between Impax and Endo, which resolved a dispute between the parties regarding, and amended, the above-referenced June 2010 settlement agreement related to Opana® ER. The Company has been cooperating and intends to continue cooperating with the FTC regarding the CID. However, no assurance can be given as to the timing or outcome of the FTC’s underlying investigation.

*Opana ER® Antitrust Litigation*

From June 2014 to April 2015, 14 complaints styled as class actions on behalf of direct purchasers and indirect purchasers (also known as end-payors) and several separate individual complaints on behalf of certain direct purchasers (the “opt-out plaintiffs”) were filed against the manufacturer of the brand drug Opana ER® and Impax.

The direct purchaser plaintiffs comprise Value Drug Company and Meijer Inc. The end-payor plaintiffs comprise the Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund; Wisconsin Masons’ Health Care Fund; Massachusetts Bricklayers; Pennsylvania Employees Benefit Trust Fund; International Union of Operating Engineers, Local 138 Welfare Fund; Louisiana Health Service & Indemnity Company d/b/a Blue Cross and Blue Shield of Louisiana; Kim Mahaffay; and Plumbers & Pipefitters Local 178 Health & Welfare Trust Fund. The opt-out plaintiffs comprise Walgreen Co.; The Kroger Co.; Safeway, Inc.; HEB Grocery Company L.P.; Albertson’s LLC; Rite Aid Corporation; Rite Aid Hdqtrs. Corp.; and CVS Pharmacy, Inc.

On December 12, 2014, the United States Judicial Panel on Multidistrict Litigation (the "JPML") ordered the pending class actions transferred to the United States District Court for the Northern District of Illinois (“N.D. Ill.”) for coordinated pretrial proceedings, as In Re: Opana ER Antitrust Litigation (MDL No. 2580). (Actions subsequently filed in other jurisdictions also were transferred by the JPML to the N.D. Ill. to be coordinated or consolidated with the coordinated proceedings, and the District Court likewise has consolidated the opt-out plaintiffs’ actions with the direct purchaser class actions for pretrial purposes.)

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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. Discovery, including expert discovery, is ongoing. On March 25, 2019, plaintiffs filed motions for class certification and served opening expert reports. Defendants’ oppositions to class certification and rebuttal expert reports were filed and served on August 29, 2019. No trial date has been scheduled.

The Company believes it has substantial meritorious defenses to the claims asserted with respect to the litigation. However, any adverse outcome could negatively affect the Company and could have a material adverse effect on the Company's results of operations, cash flows and/or overall financial condition.

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

In August 2015, a complaint styled as a class action was filed against Forest Laboratories (a subsidiary of Actavis plc) and numerous generic drug manufacturers, including Amneal, in the United States District Court for the Southern District of New York involving patent litigation settlement agreements between Forest Laboratories and the generic drug manufacturers concerning generic versions of Forest’s Namenda IR product. The complaint (as amended on February 12, 2016) asserts federal and state antitrust claims on behalf of indirect purchasers, who allege in relevant part that during the class period they indirectly purchased Namenda® IR or its generic equivalents in various states at higher prices than they would have absent the defendants’ allegedly unlawful anticompetitive conduct. Plaintiffs seek, among other things, unspecified monetary damages and equitable relief, including disgorgement and restitution. On September 13, 2016, the Court stayed the indirect purchaser plaintiffs’ claims pending factual development or resolution of claims brought in a separate, related complaint by direct purchasers (in which the Company is not a defendant). On September 10, 2018, the Court lifted the stay, referred the case to the assigned Magistrate Judge for supervision of supplemental, non-duplicative discovery in advance of mediation to be scheduled in 2019. The parties thereafter participated in supplemental discovery, as well as supplemental motion-to-dismiss briefing. On December 26, 2018, the Court granted in part and denied in part motions to dismiss the indirect purchaser plaintiffs’ claims. On January 7, 2019, Amneal, its relevant co-defendants, and the indirect purchaser plaintiffs informed the Magistrate Judge that they had agreed to mediation, which occurred in April 2019. In June 2019, the Company reached a settlement with plaintiffs, subject to Court approval. On September 10, 2019, the Court entered an order preliminarily approving the settlement and indefinitely staying the case as to the settling defendants (including the Company). The amount of the settlement is not material to the Company's consolidated financial statements.

*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. However, no assurance can be given as to the timing or outcome of this investigation.

*United States Department of Justice Investigations*

On November 6, 2014, Impax disclosed that one of its sales representatives received a grand jury subpoena from the Antitrust Division of the United States Department of Justice (the "DOJ"). In connection with this same investigation, on March 13, 2015, Impax received a grand jury subpoena from the DOJ requesting the production of information and documents regarding the sales, marketing, and pricing of certain generic prescription medications. In particular, the DOJ’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 DOJ (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.

*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 million in alleged overpayments. After analyzing the Texas AG’s demand, Amneal

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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. In March 2019, the Texas AG provided Amneal with a re-calculation of the alleged overpayment, and in October 2019, Amneal reached an agreement in principle with the Texas AG to settle the matter.

*In Re Generic Pharmaceuticals Pricing Antitrust Litigation*

Between March 2016 and January 2019, numerous complaints styled as antitrust class actions on behalf of direct purchasers and indirect purchasers (or end-payors) and several separate individual complaints on behalf of certain direct and indirect purchasers (the “opt-out plaintiffs”) have been filed against manufacturers of generic digoxin, lidocaine/prilocaine, glyburide-metformin, and metronidazole, including Impax.

The end-payor plaintiffs comprise Plaintiff International Union of Operating Engineers Local 30 Benefits Fund; Tulsa Firefighters Health and Welfare Trust; NECA-IBEW Welfare Trust Fund; Pipe Trade Services MN; Edward Carpinelli; Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund; Nina Diamond; UFCW Local 1500 Welfare Fund; Minnesota Laborers Health and Welfare Fund; The City of Providence, Rhode Island; Philadelphia Federation of Teachers Health and Welfare Fund; United Food & Commercial Workers and Employers Arizona Health and Welfare Trust; Ottis McCrary; Plumbers & Pipefitters Local 33 Health and Welfare Fund; Plumbers & Pipefitters Local 178 Health and Welfare Trust Fund; Unite Here Health; Valerie Velardi; and Louisiana Health Service Indemnity Company. The direct purchaser plaintiffs comprise KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc.; Rochester Drug Co-Operative, Inc.; César Castillo, Inc.; Ahold USA, Inc.; and FWK Holdings, L.L.C. The opt-out plaintiffs comprise The Kroger Co.; Albertsons Companies, LLC; H.E. Butt Grocery Company L.P.; Humana Inc.; and United Healthcare Services, Inc.

On April 6, 2017, the JPML ordered the consolidation of all civil actions involving allegations of antitrust conspiracies in the generic pharmaceutical industry regarding 18 generic drugs in the United States District Court for the Eastern District of Pennsylvania (“E.D. Pa.”), as In Re: Generic Pharmaceuticals Pricing Antitrust Litigation (MDL No. 2724). Consolidated class action complaints were filed on August 15, 2017 for each of the 18 drugs; Impax is named as a defendant in the 2 complaints respecting digoxin and lidocaine-prilocaine. Impax also is a defendant in the class action complaint filed with the MDL court on June 22, 2018 by certain direct purchasers of glyburide-metformin and metronidazole.

Each of the various complaints alleges a conspiracy to fix, maintain, stabilize, and/or raise prices, rig bids, and allocate markets or customers for the particular drug products at issue. Plaintiffs seek, among other things, unspecified monetary damages and equitable relief, including disgorgement and restitution. On October 16, 2018, the Court denied Impax and its co-defendants’ motion to dismiss the digoxin complaint. On February 15, 2019, the Court granted in part and denied in part defendants’ motions to dismiss various state antitrust, consumer protection, and unjust enrichment claims brought by two classes of indirect purchasers in the digoxin action. The Court dismissed seven state law claims in the end-payor plaintiffs’ complaint and six state law claims in the indirect reseller plaintiffs’ complaint. Motions to dismiss the glyburide-metformin and metronidazole complaint, as well as 2 of the complaints filed by certain opt-out plaintiffs, were filed February 21, 2019. On March 11, 2019, the Court issued an order approving a stipulation withdrawing the direct purchaser plaintiffs’ glyburide-metformin claims against Impax. Document discovery otherwise is proceeding.

On May 10, 2019, the Company was named in a civil lawsuit filed by the Attorneys General of 43 States and the Commonwealth of Puerto Rico in the United States District Court for the District of Connecticut against numerous generic pharmaceutical manufacturers, as well as certain of their current or former sales and marketing executives, regarding an alleged conspiracy to fix prices and allocate or divide customers or markets for various products, including, with respect to the Company, bethanechol chloride tablets, norethindrone acetate, and ranitidine HCL tablets, in violation of federal and state antitrust and consumer protection laws. Plaintiff States seek, among other things, unspecified monetary damages (including treble damages and civil penalties), as well as equitable relief, including disgorgement and restitution. On June 4, 2019, the JPML transferred the lawsuit to the E.D. Pa. for coordination and consolidation with MDL No. 2724. On November 1, 2019, the State Attorneys General filed an Amended Complaint in their lawsuit, bringing claims on behalf of 9 additional states and territories against several defendants; the relief sought and allegations concerning the Company (including the products allegedly at issue) are unchanged from the original complaint.

On July 31, 2019, the Company and Impax were served with a Praecipe to Issue Writ of Summons and Writ of Summons filed in the Philadelphia County Court of Common Pleas by 87 health insurance companies and managed health care providers (America’s 1st Choice of South Carolina, Inc., et al. v. Actavis Elizabeth, LLC, et al., No. 190702094), naming as defendants in the putative action the same generic pharmaceutical manufacturers and individuals named in the above-referenced State Attorneys General lawsuit. However, to date, no complaint has been filed or served in this action, and in October 2019, the parties stipulated that the case will be placed in deferred status pending further developments in MDL No. 2724.

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On October 11, 2019, opt-out plaintiff United Healthcare Services, Inc. filed a second complaint, in the United States District Court for the District of Minnesota (United Healthcare Services, Inc. v. Teva Pharmaceuticals USA, Inc., et al., No. 0:19-cv-02696), following on and supplementing its original action, asserting antitrust claims against the Company and other generic pharmaceutical manufacturers arising from the facts alleged in the above-referenced State Attorneys General lawsuit. Plaintiff seeks, among other things, unspecified monetary damages and equitable relief, including disgorgement and restitution. The parties anticipate that the lawsuit will be transferred by the JPML to the E.D. Pa. for coordination and consolidation with MDL No. 2724.

On October 18, 2019, opt-out plaintiff Humana, Inc. also filed a second complaint, likewise following on supplementing its original action to assert antitrust claims against the Company and other generic pharmaceuticals manufacturers arising from the facts alleged in the above-referenced State Attorneys General lawsuit, and similarly seeking, among other things, unspecified monetary damages and equitable relief, including disgorgement and restitution. The lawsuit was filed in the E.D. Pa. (Humana Inc. v. Actavis Elizabeth, LLC, et al., No. 2:19-cv 04862), and likely will be incorporated into MDL No. 2724 for coordinated pretrial proceedings.

The Company believes it has substantial meritorious defenses to the claims asserted with respect to the litigation. However, any adverse outcome could negatively affect the Company and could have a material adverse effect on the Company's results of operations, cash flows and/or overall financial condition.

*Prescription Opioid Litigation*

The Company and certain of its affiliates have been named as defendants 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 and 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 intends to continue to vigorously defend these cases. In light of 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 a 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. The complaint 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. 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. The complaint does not include any specific damage amounts. Gemini filed a general denial and, on June 28, 2018, it joined the other pharmaceutical company defendants in moving to dismiss plaintiffs’ complaint. On January 29, 2019, the Court granted without prejudice Gemini’s motion to dismiss and dismissed Gemini from the litigation on March 22, 2019.

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, Amneal Pharmaceuticals of New York, LLC, Impax, 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. The complaint seeks compensatory and punitive damages, but plaintiff’s complaint does not include any allegation of specific damage amounts. 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.

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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.

On July 9, 2018, the Muscogee (Creek) Nation filed a First Amended Complaint in its case pending in the MDL against the Company and 55 other defendants consisting of pharmaceutical companies, wholesalers, distributors, and pharmacies. Plaintiff alleges it has been damaged by the Company and the other pharmaceutical company defendants as a result of 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. 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 opposed these motions. Additionally, on September 28, 2018, plaintiff filed a motion to add Amneal 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 April 1, 2019, the MDL court's designated magistrate judge issued a Report and Recommendation as to the Company’s motion to dismiss, recommending dismissal of plaintiff’s Lanham Act claims and state-law claims based on an alleged duty to correct alleged misrepresentations of brand-name manufacturers, but recommending denial of relief as to all other claims. On April 12, 2019, the magistrate judge overruled the Company’s objection to adding Amneal and Amneal Pharmaceuticals of New York, LLC, but dismissed the Company. Amneal and Amneal Pharmaceuticals of New York, LLC, filed an objection to the magistrate’s Report and Recommendation as to the Company’s motion to dismiss on April 29, 2019. On June 13, 2019, the MDL court denied the objections and subsequently ordered the defendants to file Answers to the First Amended Complaint. On August 16, 2019, Amneal and Amneal Pharmaceuticals of New York, LLC filed their respective answers.

On July 18, 2018, the County of Webb, Texas requested waivers of service from Amneal and Amneal Pharmaceuticals of New York, LLC, in its case pending in the MDL. Plaintiff’s Amended Complaint, filed against Amneal and forty-one other defendants consisting of pharmaceutical companies, wholesalers, distributors, and pharmacy benefit managers, 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. Amneal and Amneal Pharmaceuticals of New York, LLC have returned the requested waivers. 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. 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. 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 filed a notice of removal on October 29, 2018. Plaintiff filed an Emergency Motion to Remand on October 30, 2018. On December 19, 2018, the Court granted plaintiff’s motion and remanded the case to the Superior Court of Pima County, Arizona. On February 13, 2019, the Company again filed a motion to dismiss the complaint. The defendants (including the Company) also moved for a discovery stay pending resolution of their motions to dismiss. The Court entered an order on April 8, 2019 staying discovery until the earlier of June 25, 2019 or when the Court rules on the defendants’ separate motions to dismiss. On June 12, 13, and 14, 2019, the Court held hearings on all pending motions to dismiss. Immediately prior to the hearing on Amneal’s Motion to Dismiss, plaintiff agreed to a voluntary dismissal without prejudice of Amneal, which the parties then entered on the record. The co-defendants removed the case to federal court, but the federal court re-remanded the case to state court. Plaintiff is attempting to amend its complaint in state court and will attempt to add Amneal as a defendant.

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On October 4, 2018, the City of Martinsville, Virginia, filed a complaint in Virginia state court, naming the Company, Amneal, Amneal Pharmaceuticals of New York, LLC, Impax, and 45 other pharmaceutical companies and other entities as defendants. Plaintiff alleges that the defendants are liable for the economic and non-economic injuries allegedly suffered by resident doctors, health care payors, and opioid-addicted individuals, as well as for the costs incurred in addressing the opioid epidemic. Plaintiff requests an unspecified amount of damages against the defendants. The case was removed to federal court on December 13, 2018 and was conditionally transferred to the MDL on December 27, 2018. Plaintiff opposed the transfer to the MDL and moved to remand the case to Virginia state court. On February 14, 2019, the Western District of Virginia, Roanoke Division, remanded the case to the Martinsville Circuit Court in Martinsville, Virginia. Nine other Virginia municipalities have filed identical complaints naming the same defendants, but none have been served on the Company or its affiliates. The unserved Virginia cases have been removed and are in federal court, though plaintiffs have filed motions to remand and are opposing transfer of those cases to the MDL court. On April 24, 2019, the Court in Martinsville, Virginia, stayed this case until it is determined whether the other Virginia cases that were removed to federal court will be remanded, or until the parties or the court may determine whether consolidation of this case with others is possible in Virginia state court.

In October and November 2018, the SouthEast Alaska Regional Health Consortium, the Kodiak Area Native Association, and the Norton Sound Health Corporation requested that the Company execute waivers of service in their cases pending in the MDL. Plaintiffs’ complaints name the Company and 37 other entities as defendants. Plaintiffs allege damages and seek injunctive relief, compensatory and statutory damages, “as well as the means to abate the epidemic” that they allege was “created by Defendants’ wrongful and/or unlawful conduct.” All activity in these cases is stayed by order of the MDL court.

On December 3, 2018, Appalachian Regional Healthcare, Inc., filed a complaint in Kentucky state court, naming Amneal and 32 other pharmaceutical companies and other entities as defendants. Plaintiff alleges that the defendants are liable for the economic and non-economic injuries allegedly suffered by Kentucky’s hospitals and others. Plaintiff requested an unspecified amount of damages against the defendants. The case has now been removed to federal court, and all activity in these cases is stayed by order of the MDL court.

On January 23, 2019, Indian Health Council, Inc., requested that the Company execute a waiver of service in its case pending in the MDL. Plaintiff’s complaint names the Company and 18 other pharmaceutical companies and other entities as defendants. Plaintiff, an intertribal health organization which provides healthcare services to its consortium’s member tribes, alleges that the defendants are liable for the economic injuries it allegedly suffered as a result of its role in responding to an alleged “epidemic of opioid abuse”. Plaintiff requests an unspecified amount of damages against the defendants. The case has been transferred to the MDL. All activity in the case is stayed by order of the MDL court.

On February 7, 2019, Kentucky River District Health Department requested that the Company execute a waiver of service in its case pending in the MDL. Plaintiff’s putative class action complaint names Amneal and 20 other pharmaceutical companies and other entities as defendants. Plaintiff alleges that the defendants are liable for the economic injuries it suffered, on behalf of itself and similarly situated Kentucky health departments, as a result of their role in responding to an alleged “opioid epidemic.” Plaintiff requests an unspecified amount of damages against the defendants. All activity in the case is stayed by order of the MDL court.

In February and March 2019, the Aleutian Pribilof Islands Association and Alaska Native Tribal Health Consortium requested that the Company execute waivers of service in their cases pending in the MDL. Plaintiffs’ complaints name the Company and 37 other entities as defendants. Plaintiffs allege damages and seek injunctive relief, compensatory and statutory damages, “as well as the means to abate the epidemic” that they allege was “created by Defendants’ wrongful and/or unlawful conduct.” All activity in these cases is stayed by order of the MDL court.

In March 2019, Glynn County, Georgia, requested waivers of service from the Company and Amneal in its case pending in the MDL. Plaintiff’s second amended short-form complaint, filed against Amneal and 39 other defendants consisting of pharmaceutical companies, wholesalers, retailers, and distributors, alleges damages as a result of defendants’ alleged improper marketing, fraud, including RICO violations, failure to adequately warn of the risks of opioid medications, failure to properly monitor and control diversion of opioid medications in or affecting Glynn County, negligence, public nuisance, and unjust enrichment. All activity in the case is stayed by order of the MDL court.

On March 14, 2019, the City of Concord, New Hampshire, filed a short-form amendment to its Second Amended Complaint in the MDL court adding the Company, Amneal, and Impax, to 31 other defendants, including pharmaceutical companies, corporate officers of certain brand manufacturer pharmaceutical companies, and distributors. As to the Company, Amneal, and Impax, plaintiff asserts claims for violation of the New Hampshire Consumer Protection Act, public nuisance, unjust enrichment, and violation of RICO. Plaintiff alleges that defendants are liable for economic injuries experienced by plaintiff, including unspecified restitution, civil penalties, disgorgement of unjust enrichment and attorneys’ fees, as well as for injunctive relief as to defendants’ further false or misleading statements as to opioids, and for exemplary damages. Amneal was served on April 25, 2019. All activity in the case is stayed by order of the MDL court.

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On March 15, 2019, the International Union of Painters and Allied Trades, District Council No. 21 Welfare Fund, and, separately, the International Brotherhood of Electrical Workers Local 98 Health & Welfare Fund, and International Brotherhood of Electrical Workers Local 98 Sound and Communications Health and Welfare Fund, filed complaints in the Philadelphia County Common Pleas Court, naming Amneal, Impax, Amneal Pharmaceuticals of New York, LLC, and 29 other pharmaceutical companies as defendants. In each, plaintiffs allege that the defendants are liable for economic injuries allegedly suffered by the respective funds to the extent those funds paid for long term treatment of their benefit members with opioids, and for the costs incurred in addressing an alleged “opioid epidemic.” Plaintiffs request an unspecified amount of damages against the defendants. On April 17, 2019, Amneal and Amneal Pharmaceuticals of New York, LLC were served with both complaints. Both cases have been transferred to Delaware County, Pennsylvania, where numerous other opioid cases currently are pending. The cases are now stayed by order of the Delaware County court.

In March 2019, the State of New Mexico filed a Second Amended Complaint in its case pending against numerous generic drug manufacturers and distributors in the First District Court of Santa Fe County, naming as defendants Amneal and Amneal Pharmaceuticals of New York, LLC. Plaintiff seeks unspecified damages, and injunctive relief, “to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance in [the state], and to recoup State monies that have been spent” on account of defendants’ alleged “false, deceptive and unfair marketing and/or unlawful diversion of prescription opioids.” On July 17, 2019, the Amneal entities moved to dismiss for lack of personal jurisdiction and failure to state a claim upon which relief can be granted. On October 15, 2019, the court entered an order dismissing the plaintiff’s negligence per se claims, but declining to dismiss the Amneal entities for lack of personal jurisdiction. Responsive pleadings are presently due to be filed on November 29, 2019.

In April 2019, several Virginia municipalities (the County Board of Arlington, Dinwiddie County, and Mecklenburg County) filed Complaints in their respective local circuit courts against the Company, Amneal, Amneal Pharmaceuticals of New York, LLC, and Impax along with numerous additional generic drug manufacturers, distributors, and pharmacies. In each Complaint, plaintiffs seek unspecified damages and equitable relief, alleging that defendants were negligent and/or grossly negligent in flooding the relevant municipalities with prescription opioid medications and engaged in civil conspiracies to do so. Each case had been removed to the United States District Court for the Eastern District of Virginia, but all three since have been remanded back to Virginia state court. The Company was nonsuited (dismissed) from the Arlington case. Amended Complaints are expected to be filed in the Dinwiddie and Mecklenburg cases before the end of November 2019. There are no deadlines presently in those cases, and no responsive pleadings are due until after the Amended Complaints are filed.

On June 10, 2019, in their cases currently pending in the MDL, West Virginia municipal-entity plaintiffs Cabell County Commission and the City of Huntington were granted leave to file, then filed, a Joint and Third Amended Complaint naming approximately 20 additional defendants, including the Company, Amneal, Amneal Pharmaceuticals of New York, LLC, and Impax. The plaintiff municipalities, seek unspecified actual, treble, and punitive damages and disgorgement “to eliminate the hazard to public health and safety, to abate the public nuisance caused by the opioid epidemic in the City and County and to compensate both for abatement measures undertaken or underway and damages sustained as a result of the opioid epidemic” they allege the defendants “proximately caused.” These actions have been designated “Track Two” bellwether cases by the MDL court (intended to be adjudicated following the “Track One” cases for which bellwether trials had been scheduled for October 2019). On December 31, 2018, the MDL court entered an Order directing the then-parties in these Track Two actions to work with one of the MDL court's appointed Special Masters to prepare case management deadlines. On May 12, 2019, the Special Master entered an Order acknowledging that the press of issues surrounding ongoing litigation of the Track One cases had prevented both the parties and the MDL court from acting on the directives of the prior Track Two Order, and setting deadlines of June 10, 2019 for plaintiffs to amend their complaints, and June 14, 2019 for the submission of proposals for case management by the then-parties to the cases (the Amneal entities were not served with plaintiffs’ Third Amended Complaints until June 25, 2019). However, to date, none of the existing parties to the cases have filed or submitted any case management proposals to the Special Master. Accordingly, the case management aspect of these Track Two cases remains pending.

In October 2019, the Company, Amneal, Amneal Pharmaceuticals of New York, LLC, and Impax were served with a putative class action complaint, which also names as defendants numerous manufacturers of opioid products (and certain corporate officers thereof), filed in the United States District Court for the Middle District of Tennessee by several individuals who allegedly purchased prescription opioid medication in cash and/or with an insurance co-payment (Rhodes, et al., v. Rhodes Technologies, Inc., et al., No. 3:19-cv-00885). Plaintiffs claim that they would not have purchased these prescription opioid products had defendants not allegedly misrepresented the products’ “addiction propensities,” and thereby suffered economic loss. Plaintiffs purport to represent a nationwide class of all individuals who directly or indirectly purchased prescription opioid medication from January 2008 to the present in 31 different states, allege causes of action for violations of those states’ antitrust laws and consumer protection statutes (and unjust enrichment), and seek, in addition to class certification, unspecified monetary damages (including actual, statutory, and punitive or treble damages) and equitable relief, including declaratory judgment and restitution. Responsive pleadings are not yet due to be filed.

Including the above-referenced cases, the Company and certain of its affiliates recently have been named in approximately 800 cases now pending in the

MDL court or in various state and territorial courts, including cases brought by:

* Political subdivision / municipal entity plaintiffs from the states of Alabama, Arkansas, Arizona, California, Colorado, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Puerto Rico, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming;

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* Third-party payor plaintiffs;
* Indian tribe plaintiffs; and
* Hospital / healthcare provider plaintiffs.

Requests for waivers for service of process have been transmitted by plaintiffs’ counsel to defense counsel in relation to the Company and certain of its affiliates in most of these cases. In each case where service on the Company or its affiliates has been perfected, and the case is not stayed, responsive pleadings or pre-answer motions have been filed.

The Company believes it has substantial meritorious defenses to the claims asserted with respect to the litigation. However, any adverse outcome could negatively affect the Company and could have a material adverse effect on the Company's results of operations, cash flows and/or overall financial condition.

*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 and four current or former Impax officers alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5. Plaintiff asserts claims regarding alleged misrepresentations about three generic drugs. Its principal claim alleges that Impax concealed that it colluded with competitor Lannett Corp. to fix the price of generic drug digoxin, and that its digoxin profits stemmed from this collusive pricing. Plaintiff also alleges that Impax concealed from the market anticipated erosion in the price of generic drug diclofenac and that Impax overstated the value of budesonide, a generic drug that it acquired from Teva. On June 1, 2017, Impax filed its motion to dismiss the amended complaint. On September 7, 2018, the Court granted Impax’s motion, dismissing plaintiff’s claims without prejudice and with leave to amend the complaint. Plaintiff filed a second amended complaint October 26, 2018. Impax filed a motion to dismiss the second amended complaint on December 6, 2018; plaintiffs’ opposition thereto was filed on January 17, 2019; and Impax’s reply in support of its motion to dismiss was filed on February 7, 2019. A hearing before the Court on the motion to dismiss took place on May 2, 2019. On August 12, 2019, the Court entered an order granting Impax’s motion, dismissing plaintiff’s second amended complaint with prejudice. On September 5, 2019, plaintiff filed a notice of appeal from both dismissal orders with the United States Court of Appeals for the Ninth Circuit.

*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 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 (and therefore that Impax is liable to Teva for the amounts it paid to settle those litigations). Impax filed a Motion to Disqualify Teva’s counsel related to the matter, and on August 23, 2017, the trial court denied Impax's motion. Following the trial court’s order, Teva filed its complaint. On September 6, 2017, Impax appealed the trial court’s decision to the Pennsylvania Superior Court. On September 20, 2017, the Superior Court stayed the trial court action pending the outcome of Impax’s appeal. On November 2, 2018, the Superior Court affirmed the trial court’s decision. On November 16, 2018, Impax filed an application for reargument with the Superior Court, which was denied on December 28, 2018. On February 13, 2019, the Superior Court remitted the record to the trial court. On February 15, 2019, Impax filed its answer with new matter to Teva’s complaint. On February 19, 2019, the trial court issued a revised case management order providing that, absent any extensions or amendments thereto, discovery was to have closed on July 1, 2019 and the case is expected to be ready for trial by February 3, 2020. On or about March 4, 2019, Teva filed a motion for judgment on the pleadings. Impax filed its answer and brief in opposition to Teva’s motion for judgment on the pleadings on March 25, 2019. On April 4, 2019, the trial court denied Teva’s motion. On April 16, 2019, Impax filed a motion to stay the proceedings and compel Teva to arbitrate the dispute pursuant to an Indemnification Release Agreement negotiated and executed by the parties in 2012. Teva’s opposition to the motion was filed on May 7, 2019. On June 11, 2019, the trial court denied Impax’s motion. On June 24, 2019, Impax noticed its intent to appeal to the Superior Court the trial court’s denial of the motion to compel arbitration, and moved both to stay the trial court proceedings pending that appeal and for an extension of case management deadlines. On July 12, 2019, the trial court denied both motions. On July 24, 2019, Impax moved the Superior Court to stay all trial court proceedings pending the outcome of Impax’s appeal of the trial court’s denial of the motion to compel arbitration and, on August 13, 2019, the Superior Court granted Impax’s motion. Impax filed its opening appellate brief with the Superior Court on September 3, 2019 and Teva filed its response brief on October 3, 2019. In October 2019, the parties reached an agreement in principle to resolve the matter, subject to finalized documentation.

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*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, and seeking, among other things, declaratory judgment, restitution of allegedly unpaid wages, and disgorgement. 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. 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. Plaintiff filed her opening appellate brief on February 22, 2019; Impax’s brief in response was filed on April 18, 2019; plaintiff filed her reply brief on May 7, 2019; and Impax filed a surreply on May 22, 2019. The appeal has now been fully submitted on the briefs.

*United States Department of Justice / Drug Enforcement Administration Subpoenas*

On July 7, 2017, Amneal Pharmaceuticals of New York, LLC received an administrative subpoena issued by the Long Island, NY District Office of the Drug Enforcement Administration (the “DEA”) requesting information related to compliance with certain recordkeeping and reporting requirements pursuant to regulations promulgated by the DEA. The Company is cooperating with this request for information and has provided relevant information responsive to the request. The Company and the U.S. Attorney for the Eastern District of New York (“E.D.N.Y.”) have entered into a tolling agreement with respect to the investigation. The material provisions of the tolling agreement provide that the investigation is ongoing, that the U.S. Attorney will not file a claim against the Company on or before December 19, 2019, and requests that the Company agree that the applicable statute(s) of limitations be tolled during the period from January 19, 2018 through December 20, 2019. The Company cannot predict at this time whether the U.S. Attorney will file a lawsuit or other claims against the Company with respect to the investigation.

On March 14, 2019, Amneal received a subpoena (the “Subpoena”) from an Assistant U.S. Attorney (“AUSA”) for the Southern District of Florida. The Subpoena requests information and documents generally related to the marketing, sale, and distribution of oxymorphone. The Company intends to cooperate with the AUSA regarding the Subpoena. However, no assurance can be given as to the timing or outcome of its underlying investigation.

On May 28, 2019, Amneal received a subpoena (the “Subpoena”) from an AUSA for the E.D.N.Y. requesting information and documents generally related to the Company’s compliance with Controlled Substances Act regulations. The Company intends to cooperate with the AUSA regarding the Subpoena. The Company and the U.S. Attorney for the E.D.N.Y. have entered into a tolling agreement with respect to the investigation. The material provisions of the tolling agreement provide that the E.D.N.Y. has made no decision as yet as to the appropriate resolution of its pending investigation, that the Company’s time to present evidence and arguments to the E.D.N.Y. concerning the investigation is extended to November 12, 2019, and that the Company agrees that the applicable statute(s) of limitations are tolled during the period from April 12, 2019 through November 12, 2019. The Company cannot predict at this time whether the U.S. Attorney will file a lawsuit or other claims against the Company with respect to the investigation.

**14. Segment Information**

The Company has two reportable segments, Generics and Specialty. Generics 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.

Specialty 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. The Company's 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.

Specialty 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.

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  | **Corporate** |  |  |  | **Total** |
| **Three Months Ended September 30, 2019** |  | **Generics (1)** | |  | **Specialty (1)** | |  |  | **and Other** |  |  |  | **Company** |
| **Net revenue** |  | $ | 291,021 |  | $ | 87,262 |  | $ | — |  |  | $ | 378,283 |
| Cost of goods sold |  |  | 217,773 |  |  | 49,944 |  |  | — |  |  |  | 267,717 |
| Cost of goods sold impairment charges |  |  | 49,115 |  |  | 7,017 |  |  | — |  |  |  | 56,132 |
| **Gross profit** |  |  | 24,133 |  |  | 30,301 |  |  | — |  |  |  | 54,434 |
| Selling, general and administrative |  |  | 14,256 |  |  | 20,228 |  |  | 29,313 |  |  |  | 63,797 |
| Research and development |  |  | 34,316 |  |  | 3,809 |  |  | — |  |  |  | 38,125 |
| In-process research and development impairment charges |  |  | 23,382 |  |  | — |  |  | — |  |  |  | 23,382 |
| Charges (gains) related to legal matters, net |  |  | 14,750 |  |  | — |  |  | — |  |  |  | 14,750 |
| Intellectual property legal development expenses |  |  | 2,586 |  |  | — |  |  | — |  |  |  | 2,586 |
| Acquisition, transaction-related and integration expenses |  |  | 502 |  |  | 2,455 |  |  | 174 |  |  |  | 3,131 |
| Restructuring and other charges |  |  | 14,702 |  |  | 213 |  |  | 6,022 |  |  |  | 20,937 |
| **Operating (loss) income** |  | $ | (80,361) |  | $ | 3,596 |  | $ | (35,509) |  |  | $ | (112,274) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  | **Corporate** |  |  |  | **Total** |
| **Nine Months Ended September 30, 2019** |  | **Generics (1)** | |  | **Specialty (1)** | |  |  | **and Other** |  |  |  | **Company** |
| **Net revenue** |  | $ | 1,008,562 |  | $ | 220,483 |  | $ | — |  | | $ | 1,229,045 |
| Cost of goods sold |  |  | 760,074 |  |  | 113,767 |  |  | — |  |  |  | 873,841 |
| Cost of goods sold impairment charges |  |  | 105,424 |  |  | 7,017 |  |  | — |  |  |  | 112,441 |
| **Gross profit** |  |  | 143,064 |  |  | 99,699 |  |  | — |  |  |  | 242,763 |
| Selling, general and administrative |  |  | 52,783 |  |  | 57,705 |  |  | 105,026 |  |  |  | 215,514 |
| Research and development |  |  | 129,915 |  |  | 10,084 |  |  | — |  |  |  | 139,999 |
| In-process research and development impairment charges |  |  | 46,169 |  |  | — |  |  | — |  |  |  | 46,169 |
| Charges (gains) related to legal matters, net |  |  | 14,750 |  |  | — |  |  | — |  |  |  | 14,750 |
| Intellectual property legal development expenses |  |  | 8,218 |  |  | 1,045 |  |  | — |  |  |  | 9,263 |
| Acquisition, transaction-related and integration expenses |  |  | 4,086 |  |  | 5,705 |  |  | 2,891 |  |  |  | 12,682 |
| Restructuring and other charges |  |  | 17,201 |  |  | 391 |  |  | 12,341 |  |  |  | 29,933 |
| **Operating (loss) income** |  | $ | (130,058) |  | $ | 24,769 |  | $ | (120,258) |  | | $ | (225,547) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |

1. For the quarter ended September 30, 2019, operating results for Oxymorphone were reclassified from the Generics to the Specialty, where it is sold as a non-promoted product. Prior period results have not been restated to reflect the reclassification.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  | **Corporate** |  |  | **Total** |  |  |
|  | **Three Months Ended September 30, 2018** |  |  |  | **Generics** |  |  | **Specialty** |  |  | **and Other** |  |  | **Company** |  |  |
|  | **Net revenue** |  |  | $ | 391,175 |  | $ | 85,312 |  | $ | — |  | $ | 476,487 |  |  |
|  | Cost of goods sold |  |  |  | 230,051 |  |  | 38,516 |  |  | — |  |  | 268,567 |  |  |
|  | Cost of goods sold impairment charges |  |  |  | 7,815 |  |  | — |  |  | — |  |  | 7,815 |  |  |
|  | **Gross profit** |  |  |  | 153,309 |  |  | 46,796 |  |  | — |  |  | 200,105 |  |  |
|  | Selling, general and administrative |  |  |  | 21,030 |  |  | 19,716 |  |  | 34,740 |  |  | 75,486 |  |  |
|  | Research and development |  |  |  | 38,347 |  |  | 4,002 |  |  | — |  |  | 42,349 |  |  |
|  | In-process research and development impairment charges |  |  |  | 650 |  |  | — |  |  | — |  |  | 650 |  |  |
|  | Intellectual property legal development expenses |  |  |  | 3,929 |  |  | 472 |  |  | — |  |  | 4,401 |  |  |
|  | Acquisition, transaction-related and integration expenses |  |  |  | — |  |  | — |  |  | 2,231 |  |  | 2,231 |  |  |
|  | Restructuring and other charges |  |  |  | (2,885) |  |  | (27) |  |  | 756 |  |  | (2,156) |  |  |
|  | Charges (gains) related to legal matters, net |  |  |  | — |  |  | — |  |  | 2,589 |  |  | 2,589 |  |  |
|  | **Operating income (loss)** |  |  | $ | 92,238 |  | $ | 22,633 |  | $ | (40,316) |  | $ | 74,555 |  |  |
|  |  | 34 | |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |



|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  | **Corporate** | |  |  | **Total** |
| **Nine Months Ended September 30, 2018** |  |  | **Generics** |  |  | **Specialty** |  |  | **and Other** | |  |  | **Company** |
| **Net revenue** |  | $ | 1,028,134 |  | $ | 137,329 |  | $ | — |  |  | $ | 1,165,463 |
| Cost of goods sold |  |  | 572,179 |  |  | 62,474 |  |  | — | |  |  | 634,653 |
| Cost of goods sold impairment charges |  |  | 7,815 |  |  | — |  |  | — | |  |  | 7,815 |
| **Gross profit** |  |  | 448,140 |  |  | 74,855 |  |  | — |  |  |  | 522,995 |
| Selling, general and administrative |  |  | 51,854 |  |  | 33,265 |  |  | 71,491 |  |  |  | 156,610 |
| Research and development |  |  | 129,762 |  |  | 7,131 |  |  | — | |  |  | 136,893 |
| In-process research and development impairment charges |  |  | 650 |  |  | — |  |  | — | |  |  | 650 |
| Intellectual property legal development expenses |  |  | 12,509 |  |  | 515 |  |  | — | |  |  | 13,024 |
| Acquisition, transaction-related and integration expenses |  |  | 114,622 |  |  | — |  |  | 102,251 |  |  |  | 216,873 |
| Restructuring and other charges |  |  | 21,912 |  |  | 2,394 |  |  | 18,003 |  |  |  | 42,309 |
| Charges (gains) related to legal matters, net |  |  | (3,000) |  |  | — |  |  | 2,589 |  |  |  | (411) |
| **Operating income (loss)** |  | $ | 119,831 |  | $ | 31,550 |  | $ | (194,334) |  |  | $ | (42,953) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**15. 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 in the respective reporting periods are described below.

*Financing Lease/Financing Obligation - Related Party*

The Company has a financing lease for two buildings located in Long Island, New York, that are used as an integrated manufacturing and office facility. For annual payments required under the terms of the non-cancelable lease agreement over the next five years and thereafter, refer to *Note 11. Leases*.

*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 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, 2019 and 2018 was $0.5 million. Rent expense paid to the related party for both of the nine months ended September 30, 2019 and 2018 was $1.5 million.

*Asana Biosciences, LLC*

Asana Biosciences, LLC (“Asana”) is an early stage drug discovery and research and development 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, 2019 was nil and $1.4 million, respectively. The total amount of income earned from this arrangement for both the three and nine months ended September 30, 2018 was $0.2 million. At September 30, 2019, receivables of approximately $1 million were due from the related party for research and development related services.

*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 facility located at 75 Adams Avenue, Hauppauge, New York. The lease expires in March 2021. Rent expense paid to the related party for the three months ended September 30, 2019 and 2018 was $0.3 million and $0.5 million, respectively. Rent expense paid for the related party for the nine months ended September 30, 2019 and 2018 was $0.8 million and $1.0 million, respectively.

*Kashiv BioSciences LLC*

Kashiv BioSciences, LLC ("Kashiv") is an independent contract development organization focused primarily on the development of 505(b) (2) NDA products. Amneal has various business agreements with Kashiv.

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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 $2 million. 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. Rental expense from the related party sublease for the nine months ended September 30, 2018 was $0.4 million (none for both the three months ended September 30, 2019 and 2018 and nine months ended September 30, 2019).

Amneal has also entered into various development and commercialization arrangements with Kashiv to collaborate on the development and commercialization of certain generic pharmaceutical products. The total reimbursable expenses associated with these arrangements for the nine months ended September 30, 2019 was $1 million, (none for the three months ended September 30, 2019 and for the three and nine months ended September 30, 2018). 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, 2019 and 2018 was $0.6 million and $0.8 million, respectively. The total profit share paid to Kashiv for the nine months ended September 30, 2019 and 2018 were $2 million and $3 million, respectively. At September 30, 2019 and December 31, 2018 payables of approximately $0.6 million and $0.8 million, respectively, were due to the related party for royalty-related transactions. Additionally, as of September 30, 2019 a receivable of $0.7 million was due from the related party.

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 were to 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 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 $8 million, an amount equal to the legal costs incurred by Amneal related to the defense of the ANDA. The cash payment was received in February 2018.

Pursuant to a product development agreement, Amneal and Kashiv agreed to collaborate on the development and commercialization of Levothyroxine Sodium. Under the agreement, the IP and ANDA for this product is owned by Amneal and Kashiv is to receive a profit share for all sales of the product made by Amneal. Amneal is precluded from selling the product made by Kashiv during the term of the license and supply agreement with JSP. Under the terms of the amended agreement with Kashiv, Amneal paid $2 million in July 2019 and may be required to pay up to an additional $18 million upon certain regulatory milestones being met. For the nine months ended September 30, 2019, the Company recorded a $2 million as research and development expense to compensate Kashiv for costs incurred to develop the product.

*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 income received from Adello from these agreements was less than $0.1 million for both the three and nine months ended September 30, 2019. The total amount of net expense paid to Adello from these agreements for both the three and nine months ended September 30, 2018 was less than $0.1 million. At September 30, 2019, a receivable of approximately $0.1 million was due from the related party.

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 $11 million for the up-front payment plus interest. This amount was paid in January 2018.

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 $2 million in October 2017 which was recorded within research and development expenses. The agreement also provides for potential future milestone payments to Adello.

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In October 2017, Amneal purchased a building from Adello in Ireland to further support its inhalation dosage form. Amneal issued a promissory note for 13 million euros ($15 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. Refer to *Note 5. Alliance and Collaboration* for further information on collaboration agreements with Adello.

*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, 2019 and 2018 was $0.3 million and $0.2 million, respectively. The total amount of income earned from these agreements for the nine months ended September 30, 2019 and 2018 was $0.9 million and $0.5 million, respectively. At September 30, 2019 and December 31, 2018 receivables of $0.3 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, Amneal and Gemini were parties to various agreements. Total gross profit earned from the sale of inventory to Gemini for the nine months ended September 30, 2018 (through the acquisition date) was $0.1 million. The total profit share paid by Gemini for the nine months ended September 30, 2018 (through the acquisition date) was $5 million.

*Fosun International Limited*

Fosun International Limited (“Fosun”) is a Chinese international conglomerate and investment company that is a shareholder of the Company. On June 6, 2019, the Company entered into a license and supply agreement with a subsidiary of Fosun, which is a Chinese pharmaceutical company. Under the terms of the agreement, the Company will hold the imported drug license required for pharmaceutical products manufactured outside of China and will supply Fosun with finished, packaged products for Fosun to then sell in the China market. Fosun will be responsible for obtaining regulatory approval in China and for shipping the product from Amneal’s facility to Fosun’s customers in China. In consideration for access to the Company's U.S. regulatory filings to support its China regulatory filings and for the supply of product, Fosun paid the Company a $1 million non-refundable fee, net of tax, in July 2019 and will be required to pay the Company $0.3 million for each of 8 products upon the first commercial sale of each in China in addition to a supply price and a profit share. For the three and nine months ended September 30, 2019, the Company has not recognized any revenue from this agreement.

*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* contained in the Company's 2018 Annual Report on Form 10-K.

*Non-Controlling Interests*

During December 2018, the Company acquired the non-controlling interests in one of Amneal's non-public subsidiaries for approximately $3 million. As of December 31, 2018, the Company recorded a $3 million related party payable for this transaction which was paid in full as of September 30, 2019.

**16. Goodwill and Intangible Assets**

The changes in goodwill for the nine months ended September 30, 2019 and for the year ended December 31, 2018 were as follows (in thousands):

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **September 30,** | | | **December 31,** | |  |  |
|  |  |  |  | **2019** |  |  | **2018** |  |  |
|  | Balance, beginning of period |  | $ | 426,226 |  | $ | 26,444 |  |  |
|  | Impax acquisition adjustment |  |  | (1,255) |  |  | — |  |  |
|  | Goodwill acquired during the period |  |  | — | |  | 401,488 |  |  |
|  | Goodwill divested during the period |  |  | (5,175) |  |  | — |  |  |
|  | Currency translation |  |  | (125) |  |  | (1,706) |  |  |
| Balance, end of period | |  | $ | 419,671 |  | $ | 426,226 |  |  |
|  |  | 37 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |



As of September 30, 2019, $361 million and $59 million of goodwill was allocated to the Specialty and Generics segment, respectively. As of December 31, 2018, $360 million and $66 million of goodwill was allocated to the Specialty and Generics segment, respectively. For the nine months ended September 30, 2019, goodwill divested was associated with the sale of the Company's operations in the United Kingdom and Germany. For the year ended December 31, 2018, goodwill acquired was associated with the Impax and Gemini acquisitions. Refer to *Note 3. Acquisitions and Divestitures* for additional information about the acquisition of Impax and the divestiture of the Company's operations in the United Kingdom and Germany.

*Interim Goodwill Impairment Test*

In light of the continued decline in the Company’s share price and financial performance, the Company performed an interim goodwill impairment test during the three months ended September 30, 2019 by evaluating its two reporting units, which are the same as the Company’s two reportable segments. The fair values of the reporting units were determined by combining both the income and market approaches. In performing this test, the Company utilized long-term growth rates for its reporting units ranging from no growth to 1.0% and discount rates ranging from 9.0% to 11.5% in its estimation of fair value. The assumptions used in evaluating goodwill for impairment are subject to change and are tracked against historical performance by management.

Based on the results of the interim test performed as of August 31, 2019 and updated on September 30, 2019, the Company determined that the estimated fair values of the Generics and Specialty reporting units exceeded their respective carrying amounts; therefore, the Company did not record a goodwill impairment charge during the three months ended September 30, 2019. The Generics reporting unit was in excess of its carrying value by approximately 15% and the Specialty reporting unit was in excess of its carrying value by approximately 9%.

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

Intangible assets at September 30, 2019 and December 31, 2018 are comprised of the following (in thousands):

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **September 30, 2019** | | | | | |  |  |  |  |  | **December 31, 2018** | | | | |  |  |  |
|  | **Weighted-Average** | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | **Amortization Period** | |  |  |  | **Accumulated** | | |  |  |  |  |  |  |  | **Accumulated** | | |  |  |  |
|  | **(in years)** | |  | **Cost** | | **Amortization** | | |  | **Net** | |  | **Cost** |  | **Amortization** | | | |  |  | **Net** |
| Amortizing intangible assets: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Product rights | 9.9 |  | $ | 1,213,195 |  | $ | (161,969) |  | $ | 1,051,226 |  | $ | 1,282,011 | $ | | | (88,081) |  | $ | | 1,193,930 |
| Customer relationships |  |  |  | — | |  | — | |  | — | |  | 7,005 |  |  |  | (1,955) |  |  |  | 5,050 |
| Other intangible assets | 10.3 |  |  | 3,000 |  |  | (950) |  |  | 2,050 |  |  | 5,620 |  |  |  | (1,561) |  |  |  | 4,059 |
| **Total** |  |  | $ | 1,216,195 |  | $ | (162,919) |  | $ | 1,053,276 |  | $ | 1,294,636 |  |  | $ | (91,597) |  |  | $ | 1,203,039 |
| In-process research and |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| development |  |  |  | 382,525 |  |  | — | |  | 382,525 |  |  | 451,930 |  |  |  | — | |  |  | 451,930 |
| **Total intangible assets** |  |  | $ | 1,598,720 |  | $ | (162,919) |  | $ | 1,435,801 |  | $ | 1,746,566 |  |  | $ | (91,597) |  |  | $ | 1,654,969 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

The Company evaluated assets for potential impairment by comparing estimated future undiscounted net cash flows to the carrying amount of the asset. For the three months ended September 30, 2019, the Company recognized a total of $79 million of intangible asset impairment charges, of which $56 million was recognized in cost of goods sold impairment charges and $23 million was recognized in in-process research and development impairment charges. For the nine months ended September 30, 2019, the Company recognized a total of $158 million of intangible asset impairment charges, of which $112 million was recognized in cost of goods sold impairment charges and $46 million was recognized in in-process research and development expense.

The impairment charges for the three months ended September 30, 2019 are primarily related to 4 currently marketed products and 4 IPR&D products, all acquired as part of the Combination. For the currently marketed products, the impairment charges were the result of significant price erosion during the three months ended September 30, 2019, without an offsetting increase in customer demand, resulting in significantly lower than expected future cash flows. For the IPR&D products, the impairment charges were the result of expected significant price erosion for the products resulting in significantly lower than expected future cash flows.

The impairment charges for the nine months ended September 30, 2019 are primarily related to twelve products, six of which are currently marketed products and six of which are IPR&D products, all acquired as part of the Combination. For the currently marketed products, the impairment charges were the result of significant price erosion during 2019, without an offsetting increase in customer demand, resulting in significantly lower than expected future cash flows. For one IPR&D product, the impairment charge was the result of increased competition at launch resulting in significantly lower than expected future cash flows. For one IPR&D product, the impairment charge was the result of a strategic decision to no longer pursue approval of the product. For the other four IPR&D products, the impairment charges were the result of expected significant price erosion for the products resulting in significantly lower than expected future cash flows.

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During the nine months ended September 30, 2019, the Company recognized a $50 million product rights intangible asset for the exclusive rights to sell Levothyroxine in the U.S. market under a license and supply agreement with JSP. Refer to *Note 5. Alliance and Collaboration* for additional information.

For the nine months ended September 30, 2019, included in the Company's divested United Kingdom operations were a net customer relationship intangible asset and a net trade name intangible asset of $5 million and $2 million, respectively. Refer to *Note 3. Acquisitions and Divestitures* for additional information.

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Three Months Ended** | | | |  |  | **Nine Months Ended** | | | | |
|  |  | **September 30,** | | | |  |  | **September 30,** | | | | |
|  |  | **2019** |  |  | **2018** |  |  | **2019** |  |  |  | **2018** |
| Amortization | $ | 38,015 |  | $ | 25,655 |  | $ | 103,774 |  |  | $ | 44,109 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

The following table presents future amortization expense for the next five years and thereafter, excluding $383 million of IPR&D intangible assets (in thousands):

|  |  |  |
| --- | --- | --- |
|  |  | **Future** |
|  | **Amortization** | |
| Remainder of 2019 | $ | 40,163 |
| 2020 |  | 147,242 |
| 2021 |  | 150,941 |
| 2022 |  | 140,971 |
| 2023 |  | 131,778 |
| 2024 |  | 127,107 |
| Thereafter |  | 315,074 |
| Total | $ | 1,053,276 |
|  |  |  |

**17. 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, 2019 and 2018 (in thousands):

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Three Months Ended** | | | |  |  | **Nine Months Ended** | | | | |
|  |  | **September 30,** | | | |  |  | **September 30,** | | | | |
|  |  | **2019** |  |  | **2018** |  |  | **2019** |  |  |  | **2018** |
| Acquisition, transaction-related and integration expenses (1) | $ | 3,131 |  | $ | 2,231 |  | $ | 12,682 |  |  | $ | 30,374 |
| Profit participation units (2) |  | — |  |  | — |  |  | — | |  |  | 158,757 |
| Transaction-related bonus (3) |  | — |  |  | — |  |  | — | |  |  | 27,742 |
| Total | $ | 3,131 |  | $ | 2,231 |  | $ | 12,682 |  |  | $ | 216,873 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

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. These costs for the three and nine months ended September 30, 2019 primarily consist of integration 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 in the Company's 2018 Annual Report on Form 10-K* ).
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 in the Company's 2018 Annual Report on Form 10-K* ).

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***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 million on the date of the Combination and $33 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 $159 million for the three and nine months ended September 30, 2018.

***Impax Acquisition***

On May 4, 2018, the Company completed the Combination, as described in *Note 1. Nature of Operations*. For the nine months ended September 30, 2018, transaction costs associated with the Impax acquisition were $23 million (none for the three months ended September 30, 2018) were recorded in acquisition, transaction-related and integration expenses (none in 2019).

**18. Subsequent Events**

*Financial Instrument*s

Effective October 31 2019, the Company entered into an interest rate lock agreement for a total notional amount of $1.3 billion, with a maturity date of May 2025. The hedge will be accounted for as a cash flow hedge.

*Option Repricing*

On October 10, 2019, the Compensation Committee of the Board of Directors of the Company, subject to the approval of the stockholders of the Company, approved a one-time stock option repricing (the “Option Repricing”). Pursuant to the Option Repricing, the exercise price of each relevant option will be amended to reduce such exercise price to the closing price of a share of the Company’s Class A Common Stock as reported on the New York Stock Exchange on or around November 13, 2019. The Company does not expect that the Option Repricing will have a material impact on its statement of operations.

*Related Party Licensing Agreement*

The Company has entered into a definitive licensing agreement with Kashiv for the development and commercialization of Kashiv’s orphan drug K127 (pyridostigmine) for the treatment of Myasthenia Gravis. Through this agreement, the Company has an exclusive license within the United States to market and sell the K127 product under a New Drug Application (“NDA”).

Under the terms of the agreement, Kashiv will be responsible for all development and clinical work required to secure Food and Drug Administration (“FDA”) approval and Amneal will be responsible for filing the NDA and commercializing the product. Kashiv will receive an upfront payment of approximately $2 million and is eligible to receive development and regulatory milestones totaling approximately $17 million. Kashiv is also eligible to receive tiered royalties from the low double-digits to mid-teens on net sales of K127.

*Voluntary Recall*

On September 13, 2019, the FDA announced that ranitidine may potentially contain NDMA, which is classified as a probable human carcinogen. As a precautionary measure, the Company immediately halted shipments of ranitidine-based products and began evaluation of its externally sourced ranitidine active pharmaceutical ingredient. Based on the FDA’s November 1, 2019 statement summarizing their NDMA results to date for numerous ranitidine products on the market, the Company has made the decision to conduct a voluntary recall of its ranitidine-based products. As of September 30, 2019, the Company had approximately $6 million of ranitidine-based product inventory. The Company is currently testing the impacted inventory and is unable to estimate the possible loss, if any, at this time.

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

Amneal Pharmaceuticals, Inc. (the "Company," "we," "us," or "our") 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 (the "Combination") of Impax Laboratories, Inc. ("Impax") and Amneal Pharmaceuticals LLC ("Amneal"), which closed on May 4, 2018.

The following discussion and analysis for the three and nine months ended September 30, 2019 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 for the year ended December 31, 2018 included in our 2018 Annual Report on Form 10-K.

Our Specialty segment is engaged in the development, promotion, sale and distribution of proprietary branded pharmaceutical products, with a focus on products addressing central nervous system ("CNS") disorders, including migraine and Parkinson’s disease. Our portfolio of products includes Rytary®, an extended release oral capsule formulation of carbidopa-levodopa for the treatment of Parkinson’s disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication. In addition to Rytary®, our promoted Specialty portfolio includes Zomig® (zolmitriptan) products, for the treatment of migraine headaches, which is sold under a license agreement with AstraZeneca UK Limited, Emverm® (mebendazole) 100 mg chewable tablets, for the treatment of pinworm, whipworm, common roundworm, common hookworm and American hookworm in single or mixed infections, and Unithroid® (levothyroxine sodium), for the treatment of hypothyroidism, which is sold under a license and distribution agreement with JSP.

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

The Company’s Generics segment includes over 200 product families covering an extensive range of dosage forms and delivery systems, including both immediate and extended release oral solids, powders, liquids, sterile injectables, nasal sprays, inhalation and respiratory products, ophthalmics (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 resulting from complex drug formulations or manufacturing, or legal or regulatory challenges. Generic products, particularly in the U.S., generally contribute most significantly to revenues and gross margins at the time of their launch, and even more so in periods of market exclusivity, or in periods of limited generic competition. As such, the timing of new product introductions can have a significant impact on the Company’s financial results. The entrance into the market of additional competition generally has a negative impact on the volume and pricing of the affected products. Additionally, pricing is often affected by factors outside of the Company’s control.

The pharmaceutical industry is highly competitive and highly regulated. As a result, we face a number of industry-specific factors and challenges, which can significantly impact our results. For a more detailed explanation of our business and its risks, refer to our *2018 Annual Report on Form 10-K.*

In 2019, our Generics segment has experienced both industry-wide and company-specific challenges that resulted in our financial performance falling short of our expectations since the beginning of the year. Such challenges include increased competition on certain key generic products, the uncertainty of supply of epinephrine auto-injector (generic Adrenaclick®) from our third-party supplier, and delays in key product approvals and launches, including generic NuvaRing®. We expect these challenges and others to persist at least for the remainder of 2019.

To address these challenges, we have, among other things, conducted an in depth, company wide review of our organizational structures, operational budgets, current and future capital projects and existing capability and infrastructure alignments, resulting in the comprehensive restructuring plan we announced in July 2019. The revised restructuring plan is designed to reduce costs, optimize our organizational and manufacturing infrastructure, which we expect to reduce costs by approximately $40 million per year once the plan has been executed. For additional information, refer to *Note 6, Restructuring and Other* *Charges*, to the unaudited financial statements in Part I, Item 1 of this report.

Our current year results continue to be impacted by our Combination with Impax as a result of our continued actions to adjust our operations and cost structure. The historical financial results of the Company for the periods prior the May 4, 2018 closing of the Combination are the historical financial results of Amneal, and thus the current period results, and balances, may not be comparable to prior years as the current year includes the results of Impax from May 4, 2018.

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**Results of Operations**

***Consolidated Results***

The following table sets forth our summarized, consolidated results of operations for the three and nine months ended September 30, 2019 and 2018 (in thousands):

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **Three Months Ended** | | | |  |  | **Nine Months Ended** | | | | |
|  |  |  | **September 30,** | | | |  |  | **September 30,** | | | | |
|  |  |  | **2019** |  |  | **2018** |  |  | **2019** |  |  |  | **2018** |
| **Net revenue** |  | $ | 378,283 |  | $ | 476,487 |  | $ | 1,229,045 |  |  | $ | 1,165,463 |
| Cost of goods sold |  |  | 267,717 |  |  | 268,567 |  |  | 873,841 |  |  |  | 634,653 |
| Cost of goods sold impairment charges |  |  | 56,132 |  |  | 7,815 |  |  | 112,441 |  |  |  | 7,815 |
| **Gross profit** |  |  | 54,434 |  |  | 200,105 |  |  | 242,763 |  |  |  | 522,995 |
| Selling, general and administrative |  |  | 63,797 |  |  | 75,486 |  |  | 215,514 |  |  |  | 156,610 |
| Research and development |  |  | 38,125 |  |  | 42,349 |  |  | 139,999 |  |  |  | 136,893 |
| In-process research and development impairment charges |  |  | 23,382 |  |  | 650 |  |  | 46,169 |  |  |  | 650 |
| Charges (gains) related to legal matters, net |  |  | 14,750 |  |  | 2,589 |  |  | 14,750 |  |  |  | (411) |
| Intellectual property legal development expenses |  |  | 2,586 |  |  | 4,401 |  |  | 9,263 |  |  |  | 13,024 |
| Acquisition, transaction-related and integration expenses |  |  | 3,131 |  |  | 2,231 |  |  | 12,682 |  |  |  | 216,873 |
| Restructuring and other charges |  |  | 20,937 |  |  | (2,156) |  |  | 29,933 |  |  |  | 42,309 |
| **Operating (loss) income** |  |  | (112,274) |  |  | 74,555 |  |  | (225,547) |  |  |  | (42,953) |
| Gain from reduction of tax receivable agreement liability |  |  | 192,844 |  |  | — |  |  | 192,844 |  |  |  | — |
| Other expense, net |  |  | (54,294) |  |  | (51,981) |  |  | (130,428) |  |  |  | (144,963) |
| Total other income (expense), net |  |  | 138,550 |  |  | (51,981) |  |  | 62,416 |  |  |  | (144,963) |
| Income (loss) before income taxes |  |  | 26,276 |  |  | 22,574 |  |  | (163,131) |  |  |  | (187,916) |
| Provision for (benefit from) income taxes |  |  | 389,668 |  |  | 5,109 |  |  | 375,539 |  |  |  | (6,943) |
| **Net (loss) income** |  | $ | (363,392) |  | $ | 17,465 |  | $ | (538,670) |  |  | $ | (180,973) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |

Net Revenue

Net revenue for the three months ended September 30, 2019 decreased by 21%, or $98 million, to $378 million compared to $476 million for the three months ended September 30, 2018. The decrease is primarily attributable to price and volume erosion of $132 million mainly in our Generics segment, $12 million in divestitures of our international businesses and $15 million in the loss of exclusivity on Albenza in our Specialty segment which were partially offset by a $40 million contribution from Levothyroxine sodium tablets ("Levothyroxine") which launched in the fourth quarter 2018, and $19 million from new product launches in our Generics segment.

Net revenue for the nine months ended September 30, 2019 increased by 5%, or $64 million, to $1,229 million compared to $1,165 million for the nine months ended September 30, 2018. The increase over the prior year period is primarily attributable to a $211 million timing impact from the Combination and the acquisition of Gemini, a $135 million contribution from Levothyroxine, and $36 million from new product launches in our Generics segment which were partially offset by price and volume erosion of $240 million mainly in our Generics segment, $38 million from the loss of exclusivity on Albenza in our Specialty segment and $27 million from the divestitures of our international businesses in the UK and Germany.

Cost of Goods Sold and Gross Profit

Cost of goods sold, including impairment charges, increased 17%, or $47 million, to $324 million for the three months ended September 30, 2019 as compared to $276 million for the three months ended September 30, 2018. The increase in cost of goods sold was primarily attributable to $48 million of impairment charges on intangible assets primarily in our Generics segment, $14 million in inventory charges, and $13 million in amortization of intangible assets, partially offset by a year over year decline in Generics volume.

Accordingly, gross profit for the three months ended September 30, 2019 was $54 million (14% of total revenues) as compared to gross profit of $200 million (42% of total revenues) for the three months ended September 30, 2018. Our gross profit as a percentage of sales declined compared to the prior year period primarily as a result of the impairment charges as well as price and volume erosion in the Generics segment.

Cost of goods sold, including impairment charges, increased 54%, or $344 million, to $986 million for the nine months ended September 30, 2019 as compared to $642 million for the nine months ended September 30, 2018. The increase in cost of goods sold was primarily attributable to higher product sales due to the Combination and Gemini acquisition, $105 million in intangible impairment mainly in our Generics segment, incremental expenses related to the Combination and the acquisition of Gemini, including amortization of intangible assets of $61 million and royalties of $22 million, $47 million of inventory charges in our Generics segment and $36 million of expenses related to the Levothyroxine transition agreement with Lannett Company ("Lannett").

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Accordingly, gross profit for the nine months ended September 30, 2019 was $243 million (20% of total revenues) as compared to gross profit of $523 million (45% of total revenues) for the nine months ended September 30, 2018. Our gross profit as a percentage of sales declined compared to the prior year period primarily as a result of the impairment charges, increased inventory related charges, and price erosion in our Generics segment as well as other factors described above.

Selling, General, and Administrative

Selling, general, and administrative ("SG&A") expenses for the three months ended September 30, 2019 were $64 million, as compared to $75 million for the three months ended September 30, 2018. The $11 million decrease from the prior year period was primarily due to post Combination synergies.

SG&A expenses for the nine months ended September 30, 2019 were $216 million, as compared to $157 million for the nine months ended September 30, 2018. The $59 million increase from the prior year was primarily due to the timing of the Combination and Gemini acquisition, including selling expenses associated with our Specialty segment, stock-based compensation and higher Corporate functions spend including public company costs that did not exist prior to the Combination. These increases were partially offset by post Combination synergies.

Research and Development

Research and development expenses for the three months ended September 30, 2019 were $38 million as compared to $42 million for the three months ended September 30, 2018. The $4 million decrease is primarily attributable to post Combination synergies.

Research and development expenses for the nine months ended September 30, 2019 were $140 million, as compared to $137 million for the nine months ended September 30, 2018. The $3 million increase compared to the prior year is primarily attributable to the timing of the Combination and increased milestone payments in our Generics segment partially offset by post Combination synergies.

In-Process Research and Development Impairment Charges

For the three months ended September 30, 2019, we recognized in-process research and development (“IPR&D”) impairment charges of $23 million associated with four intangible assets that were acquired as part of the Combination. The impairment charges were the result of expected significant price erosion for the products resulting in significantly lower than expected future cash flows. IPR&D impairment charges for the three months ended September 30, 2018 were less than $1 million.

We recognized IPR&D impairment charges of $46 million for the nine months ended September 30, 2019. The charges are primarily associated with six products in our Generics segment that were acquired as part of the Combination. The impairment charges were the result of expected significant price erosion for the products resulting in significantly lower than expected future cash flows. IPR&D impairment charges for nine months ended September 30, 2018 were less than $1 million.

Intellectual Property Legal Development Expense

Intellectual property legal development expenses for the three months ended September 30, 2019 were $3 million as compared to $4 million for the three months ended September 30, 2018. Intellectual property legal development expenses for the nine months ended September 30, 2019 were $9 million as compared to $13 million for the nine months ended September 30, 2018. These costs include, but are not limited to, formulation assessments, patent challenge opinions and strategy, and litigation expenses to defend the intellectual property.

Charges (Gains) Related to Legal Matters, Net

For the three and nine months ended September 30, 2019, the Company recorded a net charge of $15 million primarily associated with an agreement in principle with Teva Pharmaceuticals. For further details, see *Note 13. Commitments and Contingencies.*

Acquisition, Transaction-Related and Integration Expenses

We recognized approximately $3 million of acquisition, transaction-related and integration expenses for the three months ended September 30, 2019 as compared to $2 million for the three months ended September 30, 2018. We recognized approximately $13 million of acquisition, transaction-related and integration expenses for the nine months ended September 30, 2019 as compared to $217 million for the nine months ended September 30, 2018.

Expenses for the three and nine months ended September 30, 2019 were related to the ongoing integration and site closure expenses associated with Impax and Gemini. During the prior year period, expenses were primarily for transaction-related costs associated with pre and post Combination activities.

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Restructuring and Other Charges

On July 10, 2019, the Company announced a plan to restructure its operations that is intended to reduce costs and optimize its organizational and manufacturing infrastructure. Pursuant to the restructuring plan as revised, the Company expects to reduce its headcount by approximately 300 to 350, primarily by closing its manufacturing facility located in Hauppauge, NY. As a result of the restructuring plan, the Company estimates that it will incur a pre-tax restructuring charge of approximately $6 to $8 million of cash expenditures related to severance benefits.

We recorded $21 million of restructuring and other charges for the three months ended September 30, 2019, which primarily consisted of $11 million of property plant and equipment and right of use asset impairment charges in connection with the planned closure of the Company’s Hauppauge, NY facility. Restructuring and other charges also consisted of employee restructuring separation charges of approximately $6 million for severance provided pursuant to our severance programs for employees at our Hauppauge, NY, Hayward, CA and other facilities and approximately $4 million of other employee severance charges. The restructuring and other charges for the three months ended September 30, 2018 were a benefit of $2 million, which was primarily related to changes in estimates for certain employee-related separation liabilities associated with employees who exited early.

We recorded $30 million of restructuring and other charges for the nine months ended September 30, 2019, which primarily consisted of $11 million of property plant and equipment and right of use asset impairment charges in connection with the planned closure of the Company’s Hauppauge, NY facility. Restructuring and other charges also consisted of employee restructuring separation charges of approximately $9 million for severance provided pursuant to our severance programs for employees at our Hauppauge, NY, Hayward, CA and other facilities and $9 million of other employee severance charges. The restructuring and other charges for the nine months ended September 30, 2018 were $42 million, which were primarily associated with a reduction in workforce resulting from the Combination.

Gain From Reduction in Tax Receivable Agreement Liability

In connection with the Combination, the Company entered into a tax receivable agreement (“TRA”) for which it is generally required to pay the other holders of Amneal Common Units 85% of the applicable tax savings, if any, in U.S. federal and state income tax that it is deemed to realize as a result of certain tax attributes of their Amneal Common Units sold to the Company (or exchanged in a taxable sale) and that are created as a result of (i) the sales of their Amneal Common Units for shares of Class A Common Stock and (ii) tax benefits attributable to payments made under the TRA (including imputed interest).

During the three months and nine months ended September 30, 2019, we recorded a $372 million valuation allowance to reduce our deferred tax assets (“DTAs”). For further discussion, see Provision For (Benefit From) Income Taxes below. In conjunction with the valuation allowance of our DTAs, we reversed the accrued TRA liability, which resulted in a $193 million gain to our statement of operations.

Other Expense, Net

Other expense, net was $54 million for the quarter ended September 30, 2019, as compared to $52 million for the quarter ended September 30, 2018. The increase of $2 million was primarily attributable to $7 million of additional expense from the change in foreign exchange rates, primarily as a result of the impact of fluctuations in the Swiss Franc, Indian Rupee and Euro on intercompany loans, partially offset by $3 million decline in loss on the sale of international businesses and a $1 million savings on interest expense.

Other expense, net was $130 million for the nine months ended September 30, 2019, as compared to $145 million for the nine months ended September 30, 2018. The decrease of $15 million was primarily attributable to a $20 million decline in loss from extinguishment of debt, a $13 million benefit from the change in foreign exchange rates, primarily as a result of the impact of fluctuations in the Swiss Franc, Indian Rupee and Euro on intercompany loans and a $10 million beneficial impact from the divestitures of our international businesses. These decreases were partially offset by $29 million of additional interest expense associated with an increase in long-term debt related to the Combination and the acquisition of Gemini.

Provision For (Benefit From) Income Taxes

The provision for income taxes was $390 million for the three months ended September 30, 2019 as compared to the provision for income taxes of $5 million for the three months ended September 30, 2018. The provision for income taxes was $376 million for the nine months ended September 30, 2019, as compared to the benefit from income taxes of $7 million for the nine months ended September 30, 2018.

The change in income tax provision for the three and nine months ended September 30, 2019 is primarily impacted by a $372 million valuation allowance against our DTAs. We recorded valuation allowances against our various DTAs on a jurisdictional basis after it was determined that it is more likely than not that our deferred tax assets will not be realized. The provision for the nine months ended September 30, 2019 compared to the prior year period was also impacted by the company structure. Prior to the Combination, as a limited liability company, income taxes were only provided for the international subsidiaries as all domestic taxes flowed to the members. Subsequent to May 4, 2018, domestic income taxes were also provided for our allocable share of income or losses from Amneal at the prevailing U.S. federal, state, and local corporate income tax rates.

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Net (Loss) Income

We recognized a net loss for the three months ended September 30, 2019 of $363 million as compared to net income of $17 million for the three months ended September 30, 2018. For the three months ended September 30, 2019, we recorded a $98 million decline in net revenues from the prior year period, a tax provision of $390 million, impairment charges of $79 million on intangible assets, $21 million in restructuring and other charges and $15 million in charges for legal matters, which were partially offset by $193 million from the gain in reduction of TRA liability.

We recognized a net loss for the nine months ended September 30, 2019 of $539 million as compared to net loss of $181 million for the nine months ended September 30, 2018. The year over year increase of $358 million is primarily attributable to a $382 million unfavorable impact from income tax expense, a $150 million of intangible asset impairment charges, a $15 million unfavorable impact on legal matters and incremental expenses related to the Combination and acquisition of Gemini. These increases were partially offset by a $204 million decline in acquisition, transaction related and integration expenses associated with the Combination and Gemini acquisition, a $20 million decline in loss on extinguishment of debt, a $13 million benefit from the change in foreign exchange rates, primarily as a result of the impact of fluctuations in the Swiss Franc, Indian Rupee and Euro on intercompany loans and a $12 million decline in restructuring and other charges.

***Generics***

The following table sets forth results of operations for our Generics segment for the three and nine months ended September 30, 2019 and 2018 (in thousands):

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **Three Months Ended** | | | |  |  | **Nine Months Ended** | | | |
|  |  |  | **September 30,** | | | |  |  | **September 30,** | | | |
|  |  |  | **2019** |  |  | **2018** |  |  | **2019** |  |  | **2018** |
| **Net revenue** |  | $ | 291,021 |  | $ | 391,175 |  | $ | 1,008,562 |  | $ | 1,028,134 |
| Cost of goods sold |  |  | 217,773 |  |  | 230,051 |  |  | 760,074 |  |  | 572,179 |
| Cost of goods sold impairment charges |  |  | 49,115 |  |  | 7,815 |  |  | 105,424 |  |  | 7,815 |
| **Gross profit** |  |  | 24,133 |  |  | 153,309 |  |  | 143,064 |  |  | 448,140 |
| Selling, general and administrative |  |  | 14,256 |  |  | 21,030 |  |  | 52,783 |  |  | 51,854 |
| Research and development |  |  | 34,316 |  |  | 38,347 |  |  | 129,915 |  |  | 129,762 |
| In-process research and development impairment charges |  |  | 23,382 |  |  | 650 |  |  | 46,169 |  |  | 650 |
| Charges (gains) related to legal matters, net |  |  | 14,750 |  |  | — |  |  | 14,750 |  |  | (3,000) |
| Intellectual property legal development expenses |  |  | 2,586 |  |  | 3,929 |  |  | 8,218 |  |  | 12,509 |
| Other operating expense (income) |  |  | 15,204 |  |  | (2,885) |  |  | 21,287 |  |  | 136,534 |
| **Operating (loss) income** |  | $ | (80,361) |  | $ | 92,238 |  | $ | (130,058) |  | $ | 119,831 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

Net Revenue

Generics net revenue was $291 million for the three months ended September 30, 2019, a decrease of $100 million or 26% when compared with the same period in 2018. Volume and pricing erosion of $132 million in our existing business as well as a $17 million decline from the reclassification of Oxymorphone to the Specialty segment (where it is sold as a non-promoted product), and a $12 million decline in international revenues from divestitures were partially offset by $40 million in sales of Levothyroxine which launched in the fourth quarter 2018 and $19 million from new product launches. Favorable volume growth increased revenue in Levothyroxine, Abiraterone Acetate, Chlorpromazine HCI, Guanfacine and Hydroxyprogesterone Caproate Injection, which was partially offset by price and volume declines in revenue of Yuvafem, Diclofenac Gel and Aspirin Dipyridamole ER Capsules.

Generics net revenue was $1,009 million for the nine months ended September 30, 2019, a decrease of $20 million or 2% when compared with the same period in 2018. The year over year decrease was primarily driven by price and volume declines of $249 million in our existing business primarily in Yuvafem, Aspirin Dipyridamole ER Capsules, Diclofenac Gel (price only) and Oseltamavir, a $27 million decline in international revenues from divestitures and $17 million from the reclassification of Oxymorphone, partially offset by $135 million in sales of Levothyroxine, a $113 million impact from the timing of the Combination, and $36 million from new product launches.

Cost of Goods Sold and Gross Profit

Generics cost of goods sold, including impairment charges, for the three months ended September 30, 2019 was $267 million, an increase of 12% or $29 million compared to the three months ended September 30, 2018. The year over year increase is primarily associated with $41 million of impairment charges, $14 million in inventory charges, amortization of intangible assets of $5 million and $5 million of royalties partially offset by a $16 million decline of purchase accounting adjustments, a $7 million decline in acquisition and site closure expenses and a year over year decline in volume. The impairment charges are associated with four products that experienced significant price erosion during the three months ended September 2019, without an offsetting increase in customer demand, resulting in significantly lower than expected future cash flows.

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Generics gross profit for the three months ended September 30, 2019 was $24 million (8% of total revenues) as compared to gross profit of $153 million (39% of total revenues) for the three months ended September 30, 2018. Our Generics gross profit as a percentage of sales declined compared to the prior year period primarily as a result of $41 million of incremental impairment charges and price erosion in addition to the other factors noted above.

Generics cost of goods sold, including impairment charges, for the nine months ended September 30, 2019 was $865 million, an increase of 49% or $286 million compared to the nine months ended September 30, 2018. The year over year increase is primarily associated with sales of Impax products added to portfolio with the Combination, $98 million in impairment charges primarily associated with six marketed products acquired as part of the Combination and $47 million in inventory charges. The impairment charges are associated with six products that experienced significant price erosion during 2019, without an offsetting increase in customer demand, resulting in significantly lower than expected future cash flows. Cost of goods sold was also unfavorably impacted by $36 million of expenses related to the Levothyroxine transition agreement with Lannett and incremental expenses related to the Combination, including amortization of intangible assets of $22 million, royalties of $17 million and site closure costs of $5 million. These increases were partially offset by a $29 million decrease in purchase accounting adjustments.

Generics gross profit for the nine months ended September 30, 2019 was $143 million (14% of total revenue) as compared to gross profit of $448 million (44% of total revenue) for the nine months ended September 30, 2018. Our Generics gross profit as a percentage of sales declined compared to the prior year period primarily as a result of the $98 million of incremental impairment charges, price erosion and other factors described above.

Selling, General, and Administrative

Generics SG&A expenses for the three months ended September 30, 2019 were $14 million, as compared to $21 million for the three months ended September 30, 2018. The $7 million decrease from the prior year period was primarily due to post Combination synergies and the divesting of our UK and Germany businesses.

Generics SG&A expense for the nine months ended September 30, 2019 were $53 million, as compared to $52 million for the nine months ended September 30, 2018. The impact from the timing of the Combination was offset by post Combination synergies and the divesting of our UK and Germany businesses.

Research and Development

Generics research and development expenses for the three months ended September 30, 2019 were $34 million as compared to $38 million for the three months ended September 30, 2018. The year over year decrease is primarily attributable to post Combination synergies.

Generics research and development expenses remained consistent for the nine months ended September 30, 2019 and 2018 at $130 million. The impact from the timing of the Combination was offset by post Combination synergies.

In-Process Research and Development Impairment Charges

For the three months ended September 30, 2019, we recognized IPR&D impairment charges of $23 million associated with four intangible assets that were partially impaired and one intangible asset that was fully impaired.

For the nine months ended September 30, 2019, we recognized IPR&D impairment charges of $46 million in the Generics segment. The impairment charges are primarily related to six products, all acquired as part of the Combination. For one IPR&D product, the impairment charge was the result of increased competition at launch resulting in significantly lower than expected future cash flows. For one IPR&D product, the impairment charge was the result of a strategic decision to no longer pursue approval of the product. For the other four IPR&D products, the impairment charges were the result of expected significant price erosion for the products resulting in significantly lower than expected future cash flows.

The IPR&D charges for the three and nine months ended September 30, 2018 were less than $1 million.

Charges (Gains) Related to Legal Matters, Net

For the three and nine months ended September 30, 2019, the Company recorded a net charge of $15 million primarily associated with an agreement in principle with Teva Pharmaceuticals. For further details, see *Note 13. Commitments and Contingencies.*

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Gains for legal matters of $3 million for the nine months ended September 30, 2018 were primarily related to settlements with several innovators of branded pharmaceutical products (none for the three months ended September 30, 2018).

Intellectual Property Legal Development Expenses

Generics intellectual property legal development expenses for the three months ended September 30, 2019 were $3 million as compared to $4 million for the prior year period. Generics intellectual property legal development expenses for the nine months ended September 30, 2019 were $8 million as compared to $13 million for the prior year period. For both the three and nine month periods, these costs include, but are not limited to, formulation assessments, patent challenge opinions and strategy, and litigation expenses to defend the intellectual property.

Other Operating Expenses (Income)

For the three and nine months ended September 30, 2019, we recorded other expenses of $15 million and $21 million, respectively. These charges were primarily attributable to restructuring, severance, and integration expenses associated with the Combination.

For the three and nine months ended September 30, 2018, we recorded $3 million of other operating income and $137 million of other operating expenses, respectively. For the three months ended September 30, 2018, the $3 million of other operating income was a result of changes in estimates on restructuring charges. For the nine months ended September 30, 2018, the charges were primarily attributable to acquisition, integration and restructuring expenses associated with the Combination.

***Specialty***

The following table sets forth results of operations for our Specialty segment for the three and nine months ended September 30, 2019 and 2018 (in thousands):

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **Three Months Ended** | | | |  |  | **Nine Months Ended** | | | |
|  |  |  | **September 30,** | | | |  |  | **September 30,** | | | |
|  |  |  | **2019** |  |  | **2018** |  |  | **2019** |  |  | **2018** |
| **Net revenue** |  | $ | 87,262 |  | $ | 85,312 |  | $ | 220,483 |  | $ | 137,329 |
| Cost of goods sold |  |  | 49,944 |  |  | 38,516 |  |  | 113,767 |  |  | 62,474 |
| Cost of goods sold impairment charges |  |  | 7,017 |  |  | — |  |  | 7,017 |  |  | — |
| **Gross profit** |  |  | 30,301 |  |  | 46,796 |  |  | 99,699 |  |  | 74,855 |
| Selling, general and administrative |  |  | 20,228 |  |  | 19,716 |  |  | 57,705 |  |  | 33,265 |
| Research and development |  |  | 3,809 |  |  | 4,002 |  |  | 10,084 |  |  | 7,131 |
| Intellectual property legal development expenses |  |  | — |  |  | 472 |  |  | 1,045 |  |  | 515 |
| Other operating expense (income) |  |  | 2,668 |  |  | (27) |  |  | 6,096 |  |  | 2,394 |
| **Operating income** |  | $ | 3,596 |  | $ | 22,633 |  | $ | 24,769 |  | $ | 31,550 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

Our Specialty segment is comprised of the Impax Specialty business acquired on May 4, 2018 and the Gemini business acquired on May 7, 2018. Prior to these two transactions, we did not have a Specialty segment. Refer to *Note 3. Acquisitions and Divestitures* in our 2018 Annual Report on Form 10-K and in this Quarterly Report on Form 10-Q for further information related to these two transactions.

Net Revenue

Specialty net revenue for the three months ended September 30, 2019 was $87 million, an increase of 2% or $2 million compared to the three months ended September 30, 2018. The increase from the prior year period was primarily due to $17 million from the reclassification of Oxymorphone from the Generics segment to the Specialty segment (where it is sold as a non-promoted product), which was partially offset by a $15 million decline in our existing business primarily associated with the loss of exclusivity on Albenza.

Specialty net revenue for the nine months ended September 30, 2019 was $220 million, an increase of 61% or $83 million compared to the nine months ended September 30, 2018. The increase from the prior year period was primarily due to a $99 million timing impact from the Combination and Gemini acquisition, and $17 million from the reclassification of Oxymorphone, which was partially offset by a $29 million decline in our existing business primarily associated with the loss of exclusivity on Albenza.

Cost of Goods Sold and Gross Profit

Specialty cost of goods sold, including impairment charges, for the three months ended September 30, 2019 was $57 million, an increase of 48% or $19 million compared to the three months ended September 30, 2018. The increase from the prior year period was primarily due to $8 million of amortization expense and $7 million of impairment charges associated with one marketed product.

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Accordingly, Specialty gross profit for the three months ended September 30, 2019 was $30 million (35% of total revenues) as compared to gross profit of $47 million (55% of total revenues) for the three months ended September 30, 2018.

Specialty cost of goods sold, including impairment charges, for the nine months ended September 30, 2019 was $121 million, an increase of $58 million or 93% compared to the nine months ended September 30, 2018. The increase from the prior year period was primarily due to $37 million of amortization expense, increased volume associated with the timing of the Combination and Gemini acquisition and $7 million of impairment charges associated with one marketed product.

Accordingly, Specialty gross profit for the nine months ended September 30, 2019 was $100 million (45% of total revenue) as compared to gross profit of $75 million (55% of total revenues) for the nine months ended September 30, 2018.

Selling, General, and Administrative

Specialty SG&A expenses remained consistent for the three months ended September 30, 2019 at $20 million compared to the prior year period.

Specialty SG&A expense for the nine months ended September 30, 2019 was $58 million, as compared to $33 million for the nine months ended September 30, 2018. The $25 million increase from the prior period was primarily due to the timing of the Combination partially offset by post-Combination operating synergies.

Research and Development

Specialty research and development expenses remained consistent for the three month period ended September 30, 2019 at $4 million when compared to the prior year period of $4 million.

Specialty research and development expenses for the nine months ended September 30, 2019 were $10 million, as compared to $7 million for the nine months ended September 30, 2018. The $3 million increase from the prior year period was primarily due to clinical costs associated with our bio studies.

Other Operating Expenses

For the three months ended September 30, 2019, we recognized other operating expenses of $3 million in the Specialty segment compared to none for the three months ended September 30, 2018. For the nine months ended September 30, 2019, we recognized other operating expenses of $6 million in the Specialty segment compared to $2 million for the nine months ended September 30, 2018. For the three and nine month periods, these expenses were primarily attributable to acquisition, site closure and integration expenses associated with the Combination.

**Liquidity and Capital Resources**

Our primary source of liquidity is cash generated from operations, available cash and borrowings under debt financing arrangements, including $433 million of available additional capacity on our asset backed revolving credit facility ("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. However, our ability to satisfy our working capital requirements and debt obligations will depend upon economic conditions and demand for our products, which are factors that may be out of our control.

Our primary uses of capital resources are to fund operating activities, including 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.

Over the next 12 months, we will make substantial payments for monthly interest and quarterly principal amounts due on our term loan under our senior secured credit facility (the "Term Loan"), any future borrowings under the ABL, severance and capital expenditures. We made a $50 million payment to JSP on April 22, 2019 pursuant to the terms of a license and supply agreement, as described in *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.

We are party to a tax receivable agreement that requires us to make cash payments to APHC Holdings LLC (formerly known as Amneal Holdings LLC) ("Holdings") in respect of certain tax benefits that we may realize or may be deemed to realize as a result of redemptions or exchanges of Amneal common units by Holdings. The tax receivable agreement also requires that we make an accelerated payment to Holdings equal to the present value of all future payments due under the agreement upon certain change of control and similar transactions. The timing of any payments under the tax receivable agreement will vary depending upon a number of factors, but payments could be substantial, and could be in excess of the tax savings that we ultimately realize. Because of the foregoing, our obligations under the tax receivable agreement could have a substantial negative impact on our liquidity. For further details, see *Item 1A.* *Risk Factors* and *Note 8. Income Taxes* in our 2018 Annual Report on Form 10-K.

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In addition, pursuant to the limited liability operating agreement of Amneal, in connection with any tax period, Amneal will be required to make distributions to its members, on a pro rata basis in proportion to the number of Amneal Common Units held by each member, of cash until each member (other than the Company) has received an amount at least equal to its assumed tax liability and the Company has received an amount sufficient to enable it to timely satisfy all of its U.S. federal, state and local and non-U.S. tax liabilities, and meet its obligations pursuant to the tax receivable agreement. For the nine months ended September 30, 2019, Amneal made an aggregate of $13 million in tax distributions to Holdings (none for the three months ended September 30, 2019). The amount due to Holdings as of September 30, 2019 is immaterial.

At September 30, 2019, 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***

*(in thousands)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | **Nine Months Ended** | | | |
|  |  | **September 30,** | | | |
|  |  | **2019** |  |  | **2018** |
| Cash provided by (used in): |  |  |  |  |  |
| Operating activities | $ | 52,594 |  | $ | (9,421) |
| Investing activities |  | (14,813) |  |  | (401,699) |
| Financing activities |  | (38,535) |  |  | 506,595 |
| Effect of exchange rate changes on cash |  | (967) |  |  | (1,204) |
| Net (decrease) increase in cash, cash equivalents, and restricted cash | $ | (1,721) |  | $ | 94,271 |
|  |  |  |  |  |  |

*Cash Flows from Operating Activities*

Net cash provided by operating activities was $53 million for the nine months ended September 30, 2019 compared to net cash used in operating activities of $9 million for the nine months ended September 30, 2018. The change was primarily attributed to favorable timing of collections of trade accounts receivable and decreased transaction and integration costs partially offset by increased interest due to additional debt of the combined company and an increase in restructuring and severance related payments.

*Cash Flows from Investing Activities*

The decrease in cash used in investing activities of $387 million for the nine months ended September 30, 2019 compared to the nine months ended September 30, 2018, was primarily related to a decrease in cash paid for acquisitions, an increase in proceeds from corporate owned life insurance and an increase in the proceeds received on the sale of international businesses.

*Cash Flows from Financing Activities*

Net cash used in financing activities was $39 million for the nine months ended September 30, 2019 compared to net cash provided by financing activities of $507 million for the nine months September 30, 2018. The change was primarily attributable to a decrease in net proceeds from our Term Loan and an increase in tax distributions to non-controlling interests partially offset by a decrease in distributions to members.

***UK Divestiture***

On March 30, 2019, Amneal sold 100% of the stock of its Creo Pharma Holding Limited subsidiary, which comprised substantially all of our operations in the United Kingdom, to AI Sirona (Luxembourg) Acquisition S.a.r.l for net cash consideration of approximately $32 million which was received in April 2019.

***Germany Divestiture***

On May 3, 2019, the Company sold 100% of the stock of its Amneal Deutschland GmbH subsidiary, which compromised substantially all of our operations in Germany, to EVER Pharma Holding Ges.m.b.H. for net cash consideration of approximately $3 million which was received in May 2019.

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**Commitments and Contractual Obligations**

The contractual obligations of the Company are set forth in *Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations* contained in the Company’s 2018 Annual Report on Form 10-K. We include herein certain updates to those obligations. The $50 million Levothyroxine license and supply contract liability outstanding at March 31, 2019 was paid in April 2019.

***Levothyroxine License and Supply Agreement; Transition Agreement***

On August 16, 2018, the Company entered into a license and supply agreement with Jerome Stevens Pharmaceuticals, Inc. ("JSP") for Levothyroxine. This agreement designated the Company as JSP's exclusive commercial partner for Levothyroxine in the U.S. market for a 10-year term commencing on March 22, 2019. Under this license and supply agreement with JSP, the Company accrued the up-front license payment of $50 million on March 22, 2019, which was paid in April 2019. The agreement also provides for the Company to pay a profit share to JSP based on net profits of the Company's sales of Levothyroxine, after considering product costs.

On November 9, 201 8, the Company entered into a transition agreement ("Transition Agreement") with Lannett and JSP. Under the terms of the Transition Agreement, the Company assumed the distribution and marketing of Levothyroxine from Lannett beginning December 1, 2018 through March 22, 2019, ahead of the commencement date of the license and supply agreement with JSP described above.

In accordance with the terms of the Transition Agreement, the Company made $47 million of non-refundable payments to Lannett. For the nine months ended September 30, 2019 and the year ended December 31, 2018, $37 million and $ 10 million, respectively, were expensed to cost of goods sold, as the Company sold Levothyroxine. As of December 31, 2018, the Company had a $4 million transition contract liability, which was fully settled in February 2019.

**Outstanding Debt Obligations**

***Term Loan and Revolving Credit Agreements***

On May 4, 2018 we entered into a senior credit agreement that provided the Term Loan with a principal amount of $2.7 billion and the ABL under which loans and letters of credit up to a principal amount of $500 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 one-month LIBOR plus 3.5% at September 30, 2019. The ABL bears an annual interest rate of one-month LIBOR plus 1.5% at September 30, 2019 and matures on May 4, 2023. As of September 30, 2019, 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, 2019, we had no outstanding 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, 2019, the ABL commitment fee rate is 0.375% per annum.

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 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, 2019, Amneal was in compliance with all covenants under the Senior Secured Credit Facilities.

**Off-Balance Sheet Arrangements**

We did not have any off-balance sheet arrangements as of September 30, 2019.

**Critical Accounting Policies**

For a discussion of the Company’s critical accounting policies, see *Item 7. Management’s Discussion and Analysis of Financial Condition and Results of* *Operations* in our 2018 Annual Report on Form 10-K. Other than as set forth below, there have been no material changes to the disclosure presented in our2018 Annual Report on Form 10-K.

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***Impairment of Goodwill***

In January 2017, the Financial Accounting Standards Board 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) tomeasure a goodwill impairment charge. We adopted ASU 2017-04 as of April 1, 2019 on a prospective basis and have updated our critical accounting policy accordingly.

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

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

Goodwill is allocated and evaluated for impairment at the reporting unit level, which is defined as an operating segment or one level below an operating segment. We have two reportable segments, Generics and Specialty, which are the same as the respective operating segments and reporting units. As of September 30, 2019, $361 million and $59 million of goodwill was allocated to our Specialty and Generics segments, respectively.

*Interim Goodwill Impairment Test*

In light of the decline in our share price and financial performance, we performed an interim goodwill impairment test during the three months ended September 30, 2019 by evaluating our two reporting units, which are the same as our two reportable segments. The fair values of each of our reporting units were determined by combining both the income and market approaches. In performing this test, the Company utilized long-term growth rates for its reporting units ranging from no growth to 1.0% and discount rates ranging from 9.0% to 11.5% in its estimation of fair value. The assumptions used in evaluating goodwill for impairment are subject to change and are tracked against historical performance by management.

Based on the results of the interim test performed as of August 31, 2019 and updated on September 30, 2019, we determined that the estimated fair values of the Generics and Specialty reporting units exceeded their respective carrying amounts; therefore, the Company did not record a goodwill impairment charge for the three months ended September 30, 2019. The Generics reporting unit was in excess of its carrying value by approximately 15% and the Specialty reporting unit was in excess of its carrying value by approximately 9%.

A 50-basis point increase in the assumed discount rates utilized in each test would have not created a goodwill impairment charge in our Generics reporting unit or our Specialty reporting unit.

Significant judgment is employed in determining the assumptions utilized as of the acquisition date and for each subsequent measurement period.

Accordingly, changes in assumptions described above, could have a material impact on our consolidated results of operations.

For each of our reporting units, there are a number of future events and factors that may impact future results and the outcome of subsequent goodwill impairment testing. For a list of these factors, see *Item 1A. Risk Factors.*

**Recently Issued Accounting Standards**

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

**Item 3.** **Quantitative and Qualitative Disclosures About Market Risk**

For a discussion of the Company’s quantitative and qualitative disclosures about market risks, see *Item 7A. Quantitative and Qualitative Disclosures About* *Market Risk* , in our 2018 Annual Report on Form 10-K.

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**Item 4.** **Controls and Procedures**

**Disclosure Controls and Procedures**

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

Our management, with the participation of our Co-Chief Executive Officers and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Co-Chief Executive Officers 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, 2019 at the reasonable assurance level.

**Changes in Internal Control over Financial Reporting**

During the quarter ended September 30, 2019, 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.

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**Part II – OTHER INFORMATION**

**Item 1.** **Legal Proceedings**

Information pertaining to legal proceedings can be found in *Note 13. Commitments and Contingencies* and is incorporated by reference herein.

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

Other than as set forth below, there have been no material changes to the disclosure presented in our 2018 Annual Report on Form 10-K under *Item 1A. Risk* *Factors.*

***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, 2019, the group of shareholders who owned Amneal prior to the Combination (the "Amneal Group") controlled approximately 55% of the voting power of all of our outstanding shares of common stock.

Through its control of a majority of our voting power and the provisions set forth in our charter, bylaws and the Second Amended and Restated Stockholders Agreement dated December 16, 2017 (the "Stockholders Agreement"), the Amneal Group has the ability to designate and elect and has designated and elected a majority of our board of directors. 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.

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

***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. On August 5, 2019, we announced that President and Chief Executive Officer Robert A. Stewart was leaving the Company and resigning as a director, effective immediately, and would be replaced by Amneal’s co-founders Chirag Patel, who will serve as President and Co-Chief Executive Officer, and Chintu Patel, who will serve as Co-Chief Executive Officer. Each of Chirag Patel and Chintu Patel is a member of the Amneal Group. In connection with this transition, among other changes to the Company's board of directors, Executive Chairman Paul M. Bisaro also resigned from the Company and the board and was replaced on the board by Paul Meister, who will serve as non-executive Chairman of the Board. Any change in senior management involves significant inherent risk, and any failure to effect a smooth transition process could hinder our strategic planning, execution and future performance. While we endeavor to minimize any negative impact associated with changes such as these, there may be uncertainty among investors, employees and others regarding our future direction and performance. Any disruption in our operations, uncertainty regarding our future or negative public perception regarding the change could have a material adverse effect on our business, financial condition, operating results and cash flows.

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.

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***If we determine that our goodwill has become impaired, we may record significant impairment charges, which would adversely affect our financial condition and results of operations.***

Goodwill represents 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 may increase as a result of future acquisitions. We review our goodwill and indefinite lived intangible assets at least annually for impairment. Impairment may result from, among other things, deterioration in the performance of acquired businesses, adverse market conditions and adverse changes in applicable laws or regulations, including changes that restrict the activities of an acquired business.

Generic pharmaceuticals have faced regular and increasing price erosion each year, placing even greater importance on our ability to continually introduce new products. If these trends continue or worsen, or if we experience further difficulty in this market or the Specialty market, this may continue to adversely affect our revenues and profits in our Generics and Specialty segments. Furthermore, during the first three quarters of 2019, the Company's market capitalization decreased significantly. Additional decline in our market capitalization, even if due to macroeconomic or industry-wide factors, could put pressure on the carrying value of our goodwill in both our Generics and Specialty segments and cause the Company to conduct an interim impairment test. A determination that all or a portion of our goodwill is impaired, although a non-cash charge against earnings, could have a material adverse effect on our results of operations and financial condition.

***If we determine in the future that we will not be able to fully utilize all or part of our deferred tax assets, we would record a valuation allowance through earnings in the period the determination was made, which could have an adverse effect on our results of operations and earnings.***

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

In assessing the need for a valuation allowance in the third quarter of fiscal 2019, we considered all available objective and verifiable evidence both positive and negative, including historical levels of pre-tax income (loss) both on a consolidated basis and tax reporting entity basis, legislative developments, expectations and risks associated with estimates of future pre-tax income, and prudent and feasible tax planning strategies. We currently estimate that as of September 30, 2019 we will have generated a cumulative consolidated three-year pre-tax loss. As a result of this analysis, we considered it more likely than not that we will not realize the benefits of our gross DTAs and therefore, for the three and nine months ended September 30, 2019, we have recorded a valuation allowance of $372 million to reduce the carrying value of these gross DTAs, net of the impact of the reversal of taxable temporary differences, to zero.

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

None.

**Item 3.** **Defaults Upon Senior Securities**

None.

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

Not applicable.

**Item 5.** **Other Information**

None.

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**Item 6.** **Exhibits**

**Exhibit No.** **Description of Document**



10.1 [Separation Agreement between Robert Stewart, Amneal Pharmaceuticals, Inc. and Amneal Pharmaceuticals LLC, dated as of August 2,](http://www.sec.gov/Archives/edgar/data/1723128/000172312819000111/amrx-06x30x2019xex104.htm)

[2019 (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, filed August 5, 2019) †](http://www.sec.gov/Archives/edgar/data/1723128/000172312819000111/amrx-06x30x2019xex104.htm)

10.2 [Amendment No. 1, dated as of August 2, 2019, to Second Amended and Restated Stockholders Agreement, by and among Amneal](http://www.sec.gov/Archives/edgar/data/1723128/000172312819000111/amrx-06x30x2019xex105.htm) [Pharmaceuticals Holding Company, LLC, a Delaware limited liability company, AP Class D Member, LLC, a Delaware limited liability](http://www.sec.gov/Archives/edgar/data/1723128/000172312819000111/amrx-06x30x2019xex105.htm) [company, AP Class E Member, LLC, a Delaware limited liability company, AH PPU Management, LLC, a Delaware limited liability](http://www.sec.gov/Archives/edgar/data/1723128/000172312819000111/amrx-06x30x2019xex105.htm) [company, and Amneal Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q,](http://www.sec.gov/Archives/edgar/data/1723128/000172312819000111/amrx-06x30x2019xex105.htm) [filed August 5, 2019)](http://www.sec.gov/Archives/edgar/data/1723128/000172312819000111/amrx-06x30x2019xex105.htm)

31.1 Certification of the Co - Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2 Certification of the Co - Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.3 Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1 Certification of the Co - Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*\*

32.2 Certification of the Co - Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*\*

32.3 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.\*\*

* 1. The following materials from the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Statements of Operations for each of the three and nine months ended September 30, 2019 and 2018, (ii) Consolidated Statements of Comprehensive Loss/Income for each of the three and nine months ended September 30, 2019 and 2018, (iii) Consolidated Balance Sheets as of September 30, 2019 and December 31, 2018, (iv) Consolidated Statements of Cash Flows for each of the nine months ended September 30, 2019 and 2018, (v) Consolidated Statements of Stockholders' Equity/ Members' Deficit for each the three and nine months ended September 30, 2019 and 2018 and (vi) Notes to Consolidated Financial Statements. \*
* 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.
* Denotes management compensatory plan or arrangement.

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**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 6, 2019 | **Amneal Pharmaceuticals, Inc.** | |
|  |  | (Registrant) |
|  | *By:* /s/ Chirag Patel | |
|  |  | Chirag Patel |
|  |  | President and Co-Chief Executive Officer |
|  |  | (Co-Principal Executive Officer) |
|  | *By:* /s/ Chintu Patel | |
|  |  | Chintu Patel |
|  |  | Co-Chief Executive Officer |
|  |  | (Co-Principal Executive Officer) |
|  | *By:* /s/ Todd P. Branning | |
|  |  | Todd P. Branning |
|  |  | Senior Vice President and Chief Financial Officer |
|  |  | (Principal Financial and Accounting Officer) |
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**Exhibit 31.1**

**CERTIFICATION PURSUANT TO**

**SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Chirag Patel, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2019 of Amneal Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   1. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   2. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   3. Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   4. Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
   1. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
   2. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

|  |  |  |
| --- | --- | --- |
| November 6, 2019 | By: /s/ Chirag Patel | |
|  |  | Chirag Patel |
|  |  | President and Co-Chief Executive Officer |
|  |  | (Co-Principal Executive Officer) |

**Exhibit 31.2**

**CERTIFICATION PURSUANT TO**

**SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Chintu Patel, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2019 of Amneal Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   1. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   2. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   3. Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   4. Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
   1. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
   2. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

|  |  |  |
| --- | --- | --- |
| November 6, 2019 | By: /s/ Chintu Patel | |
|  |  | Chintu Patel |
|  |  | Co-Chief Executive Officer |
|  |  | (Co-Principal Executive Officer) |

**Exhibit 31.3**

**CERTIFICATION PURSUANT TO**

**SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Todd P. Branning, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2019 of Amneal Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   1. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   2. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   3. Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   4. Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
   1. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
   2. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

|  |  |  |
| --- | --- | --- |
| November 6, 2019 | By: /s/ Todd P. Branning | |
|  |  | Todd P. Branning |
|  |  | Senior Vice President and Chief Financial Officer |
|  |  | (Principal Financial and Accounting Officer) |

**Exhibit 32.1**

**CERTIFICATION PURSUANT TO**

**18 U.S.C. SECTION 1350**

**AS ADOPTED PURSUANT TO**

**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Amneal Pharmaceuticals, Inc. (the “Company”) for the fiscal quarter ended September 30, 2019 (the “Report”), Chirag Patel, President and Co-Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

|  |  |  |
| --- | --- | --- |
| November 6, 2019 | By:/s/ Chirag Patel | |
|  |  | Chirag Patel |
|  |  | President and Co-Chief Executive Officer |
|  |  | (Co-Principal Executive Officer) |

A signed original of this written statement required by Section 906 has been provided to Amneal Pharmaceuticals, Inc. and will be retained by Amneal Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

**Exhibit 32.2**

**CERTIFICATION PURSUANT TO**

**18 U.S.C. SECTION 1350**

**AS ADOPTED PURSUANT TO**

**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Amneal Pharmaceuticals, Inc. (the “Company”) for the fiscal quarter ended September 30, 2019 (the “Report”), Chintu Patel, Co-Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

|  |  |  |
| --- | --- | --- |
| November 6, 2019 | By:/s/ Chintu Patel | |
|  |  | Chintu Patel |
|  |  | Co-Chief Executive Officer |
|  |  | (Co-Principal Executive Officer) |

A signed original of this written statement required by Section 906 has been provided to Amneal Pharmaceuticals, Inc. and will be retained by Amneal Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

**Exhibit 32.3**

**CERTIFICATION PURSUANT TO**

**18 U.S.C. SECTION 1350**

**AS ADOPTED PURSUANT TO**

**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Amneal Pharmaceuticals, Inc. (the “Company”) for the fiscal quarter ended September 30, 2019 (the “Report”), Todd P. Branning, Senior Vice President and Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

|  |  |  |
| --- | --- | --- |
| November 6, 2019 | By:/s/ Todd P. Branning | |
|  |  | Todd P. Branning |
|  |  | Senior Vice President and Chief Financial Officer |
|  |  | (Principal Financial and Accounting Officer) |

A signed original of this written statement required by Section 906 has been provided to Amneal Pharmaceuticals, Inc. and will be retained by Amneal Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.