AMAG PHARMACEUTICALS INC.
Form 10-Q
November 02, 2018

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

FORM 10-Q
(Mark
One)

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

For the quarterly period ended September 30, 2018
or

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

For the transition period from to
Commission file number 001-10865
AMAG Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Its Charter)

| | |
|---|---|
| Delaware | 04-2742593 |
| (State or Other Jurisdiction of Incorporation or Organization) | (I.R.S. Employer Identification No.) |
| 1100 Winter Street<br>Waltham, Massachusetts<br>(Address of Principal Executive Offices) | 02451<br>(Zip Code) |

(617) 498-3300
(Registrant’s Telephone Number, Including Area Code)

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 definition of “accelerated filer,” “large accelerated filer”, “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act. (Check one):

| | |
|---|---|
| Large accelerated filer | Accelerated filer |
| Non-accelerated filer | Smaller reporting company |
| | Emerging growth company |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of October 29, 2018, there were 34,535,659 shares of the registrant's Common Stock, par value $0.01 per share, outstanding.

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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements:

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AMAG PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)
(Unaudited)

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $287,166 | $162,855 |
| Marketable securities | 140,368 | 136,593 |
| Accounts receivable, net | 85,091 | 91,460 |
| Inventories | 27,953 | 34,443 |
| Prepaid and other current assets | 13,182 | 11,009 |
| Assets held for sale | — | 45,508 |
| Total current assets | 553,760 | 481,868 |
| Property and equipment, net | 7,047 | 7,904 |
| Goodwill | 422,513 | 422,513 |
| Intangible assets, net | 230,747 | 375,479 |
| Deferred tax assets | 1,185 | 47,120 |
| Restricted cash | 495 | 495 |
| Other long-term assets | 69 | 266 |
| Assets held for sale, net of current portion | — | 564,711 |
| Total assets | $1,215,816 | $1,900,356 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $30,331 | $7,717 |
| Accrued expenses | 141,753 | 166,732 |
| Current portion of convertible notes, net | 20,999 | — |
| Current portion of acquisition-related contingent consideration | 208 | 49,399 |
| Liabilities held for sale | — | 53,870 |
| Total current liabilities | 193,291 | 277,718 |
| Long-term liabilities: | | |
| Long-term debt, net | — | 466,291 |
| Convertible notes, net | 258,376 | 268,392 |
| Acquisition-related contingent consideration | 615 | 686 |
| Other long-term liabilities | 1,288 | 1,204 |
| Liabilities held for sale, net of current portion | — | 95,821 |
| Total liabilities | 453,570 | 1,110,112 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, par value $0.01 per share, 2,000,000 shares authorized; none issued | — | — |
| Common stock, par value $0.01 per share, 117,500,000 shares authorized; 34,522,957 and 34,083,112 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively | 345 | 341 |
| Additional paid-in capital | 1,286,227 | 1,271,628 |
| Accumulated other comprehensive loss | (4,161) | (3,908) |
| Accumulated deficit | (520,165) | (477,817) |
| Total stockholders' equity | 762,246 | 790,244 |
| Total liabilities and stockholders' equity | $1,215,816 | $1,900,356 |

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

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AMAG PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE DATA)
(Unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Revenues: | | | | |
| Product sales, net | $122,238 | $124,331 | $385,806 | $367,190 |
| Other revenues | — | — | 75 | 53 |
| Total revenues | 122,238 | 124,331 | 385,881 | 367,243 |
| Costs and expenses: | | | | |
| Cost of product sales | 46,489 | 31,085 | 187,176 | 90,761 |
| Research and development expenses | 10,133 | 16,274 | 32,635 | 63,021 |
| Acquired in-process research and development | 12,500 | — | 32,500 | 65,845 |
| Selling, general and administrative expenses | 72,451 | 11,962 | 161,780 | 119,482 |
| Impairment charges of intangible assets | — | 319,246 | — | 319,246 |
| Total costs and expenses | 141,573 | 378,567 | 414,091 | 658,355 |
| Operating loss | (19,335) | (254,236) | (28,210) | (291,112) |
| Other income (expense): | | | | |
| Interest expense | (13,366) | (16,847) | (45,400) | (52,403) |
| Loss on debt extinguishment | (35,922) | (314) | (35,922) | (9,830) |
| Interest and dividend income | 1,612 | 487 | 3,207 | 2,181 |
| Other expense | (19) | — | (63) | (43) |
| Total other expense, net | (47,695) | (16,674) | (78,178) | (60,095) |
| Loss from continuing operations before income taxes | (67,030) | (270,910) | (106,388) | (351,207) |
| Income tax (benefit) expense | (2,352) | (115,197) | 42,204 | (145,317) |
| Net loss from continuing operations | $(64,678) | $(155,713) | $(148,592) | $(205,890) |
| | | | | |
| Discontinued operations: | | | | |
| Income from discontinued operations | 5,838 | 4,506 | 18,873 | 4,998 |
| Gain on sale of CBR business | 89,581 | — | 89,581 | — |
| Income tax (benefit) expense | (98) | 854 | 3,346 | 1,796 |
| Net income from discontinued operations | $95,517 | $3,652 | $105,108 | $3,202 |
| | | | | |
| Net income (loss) | $30,839 | $(152,061) | $(43,484) | $(202,688) |
| | | | | |
| Basic and diluted net income (loss) per share: | | | | |
| Loss from continuing operations | $(1.88) | $(4.41) | $(4.33) | $(5.89) |
| Income from discontinued operations | 2.77 | 0.10 | 3.06 | 0.09 |
| Basic and diluted net income (loss) per share: | $0.89 | $(4.31) | $(1.27) | $(5.80) |
| | | | | |
| Weighted average shares outstanding used to compute net income (loss) per share (basic and diluted) | 34,492 | 35,311 | 34,339 | 34,948 |

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

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AMAG PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(IN THOUSANDS)
(Unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Net income (loss) | $30,839 | $(152,061) | $(43,484) | $(202,688) |
| Other comprehensive (loss) income: | | | | |
| Holding gains (losses) arising during period, net of tax | 134 | (4) | (253) | 201 |
| Total comprehensive income (loss) | $30,973 | $(152,065) | $(43,737) | $(202,487) |

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

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AMAG PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)
(Unaudited)

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2018 | 2017 |
| Cash flows from operating activities: | | |
| Net loss | $(43,484) | $(202,688) |
| Adjustments to reconcile net loss to net cash provided by operating activities: | | |
| Depreciation and amortization | 158,002 | 88,941 |
| Impairment of intangible assets | — | 319,246 |
| Provision for bad debt expense | 754 | 3,503 |
| Amortization of premium/discount on purchased securities | 96 | 218 |
| Gain on disposal of fixed assets | (99) | — |
| Non-cash equity-based compensation expense | 14,599 | 18,058 |
| Non-cash IPR&D expense | — | 945 |
| Loss on debt extinguishment | 35,922 | 9,830 |
| Amortization of debt discount and debt issuance costs | 11,824 | 10,600 |
| Gains on marketable securities, net | (1) | (255) |
| Change in fair value of contingent consideration | (49,175) | (47,142) |
| Deferred income taxes | 43,747 | (146,682) |
| Gain on sale of the CBR business | (89,581) | — |
| Transaction costs | (14,111) | — |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | 7,175 | (8,889) |
| Inventories | 3,587 | (600) |
| Prepaid and other current assets | 1,101 | (1,409) |
| Accounts payable and accrued expenses | (4,280) | 29,977 |
| Deferred revenues | 8,658 | 14,134 |
| Other assets and liabilities | 159 | (1,139) |
| Net cash provided by operating activities | 84,893 | 86,648 |
| Cash flows from investing activities: | | |
| Proceeds from sales or maturities of marketable securities | 60,146 | 279,526 |
| Purchase of marketable securities | (64,400) | (110,894) |
| Acquisition of Intrarosa intangible asset | — | (55,800) |
| Proceeds from the sale of the CBR business | 519,303 | — |
| Capital expenditures | (1,913) | (6,573) |
| Net cash provided by investing activities | 513,136 | 106,259 |
| Cash flows from financing activities: | | |
| Long-term debt principal payments | (475,000) | (328,125) |
| Proceeds from 2022 Convertible Notes | — | 320,000 |
| Payment to repurchase 2019 Convertible Notes | — | (191,480) |
| Payment of premium on debt extinguishment | (28,054) | — |
| Proceeds to settle warrants | — | 323 |
| Payment of convertible debt issuance costs | — | (9,553) |
| Payments of contingent consideration | (87) | (165) |
| Proceeds from the exercise of common stock options | 2,635 | 2,350 |
| Payments of employee tax withholding related to equity-based compensation | (2,632) | (2,588) |

| | | |
|---|---|---|
| Net cash used in financing activities | (503,138 ) | (209,238 ) |
| Net increase (decrease) in cash, cash equivalents, and restricted cash | 94,891 | (16,331 ) |
| Cash, cash equivalents, and restricted cash related to discontinued operations | — | (50,017 ) |
| Cash, cash equivalents, and restricted cash at beginning of the period | 192,770 | 276,898 |
| Cash, cash equivalents, and restricted cash at end of the period | $287,661 | $210,550 |
| Supplemental data for cash flow information: | | |
| Cash paid for taxes | $5,041 | $3,565 |
| Cash paid for interest | $43,546 | $50,892 |
| Non-cash investing and financing activities: | | |
| Fair value of common stock issued in connection with the acquisition of the Intrarosa intangible asset | $— | $12,555 |
| Contingent consideration accrued for the acquisition of the Intrarosa intangible asset | $— | $9,300 |

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

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AMAG PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

A. DESCRIPTION OF BUSINESS

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a pharmaceutical company focused on bringing innovative products to patients with unmet medical needs. We do this by leveraging our development and commercial expertise to invest in and grow our pharmaceutical products across a range of therapeutic areas, including women's health. Our currently marketed products support the health of patients in the areas of maternal and women's health, anemia management and cancer supportive care, including Makena® (hydroxyprogesterone caproate injection), Intrarosa® (prasterone) vaginal inserts, Feraheme® (ferumoxytol injection) for intravenous ("IV") use, and MuGard® Mucoadhesive Oral Wound Rinse. In addition to our marketed products, our portfolio includes two product candidates, Vyleesi™ (bremelanotide), which is being developed for the treatment of hypoactive sexual desire disorder ("HSDD") in pre-menopausal women and digoxin immune Fab (ovine) (now referred to as AMAG-423), which is being studied for the treatment of severe preeclampsia.

Since August 2015, we had provided services related to the preservation of umbilical cord blood stem cell and cord tissue units operated through Cord Blood Registry® ("CBR"). On August 6, 2018, we completed the sale of our wholly-owned subsidiary, CBR Acquisition Holdings Corp, and the CBR business to GI Chill Acquisition LLC, an affiliate of GI Partners, a private equity investment firm (together "GI") pursuant to the June 14, 2018 Stock Purchase Agreement (the "CBR Purchase Agreement") between us and GI. We received $519.3 million in cash at closing and recognized a gain of $89.6 million on the sale during the three and nine months ended September 30, 2018. For additional information, see Note C "Discontinued Operations and Held for Sale".

Throughout this Quarterly Report on Form 10-Q, AMAG Pharmaceuticals, Inc. and our consolidated subsidiaries are collectively referred to as "the Company," "AMAG," "we," "us," or "our."

B. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

These condensed consolidated financial statements are unaudited and, in the opinion of management, include all adjustments necessary for a fair statement of the financial position and results of operations of the Company for the interim periods presented. Such adjustments consisted only of normal recurring items. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America ("GAAP").

In accordance with GAAP for interim financial reports and the instructions for Form 10-Q and the rules of the Securities and Exchange Commission, certain information and footnote disclosures normally included in annual financial statements have been condensed or omitted. Our accounting policies are described in the Notes to the Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2017 (our "Annual Report"). Interim results are not necessarily indicative of the results of operations for the full year. These interim financial statements should be read in conjunction with our Annual Report.

As of June 30, 2018, our CBR business met all of the conditions to be classified as held for sale and represented a discontinued operation, as we considered the disposal of the CBR business to be a strategic shift that would have a major effect on our operations and financial results. All assets and liabilities associated with CBR were therefore classified as assets and liabilities held for sale in our condensed consolidated balance sheets for the historical period presented. Further, all historical operating results for CBR are reflected within discontinued operations in the condensed consolidated statements of operations for all periods presented. For additional information, see Note C, "Discontinued Operations and Held for Sale."

Principles of Consolidation

The accompanying condensed consolidated financial statements include our accounts and the accounts of our wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates and Assumptions

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. The most significant estimates and assumptions are used to determine amounts and values of, but are not limited to: revenue recognition related to product sales revenue; product sales allowances and

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accruals; allowance for doubtful accounts; marketable securities; inventory; acquisition date fair value and subsequent fair value estimates used to assess impairment of long-lived assets, including goodwill, in-process research and development ("IPR&D") and other intangible assets; contingent consideration; debt obligations; certain accrued liabilities, including clinical trial accruals; income taxes, inclusive of valuation allowances; and equity-based compensation expense. Actual results could differ materially from those estimates.

Restricted Cash

We classified $0.5 million of our cash as restricted cash, a non-current asset on the balance sheet, as of September 30, 2018 and December 31, 2017. This amount represented the security deposit delivered to the landlord of our Waltham, Massachusetts headquarters in the form of an irrevocable letter of credit.

Concentrations and Significant Customer Information

Financial instruments which potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents, marketable securities, and accounts receivable. We currently hold our excess cash primarily in institutional money market funds, corporate debt securities, U.S. treasury and government agency securities, commercial paper and certificates of deposit. As of September 30, 2018, we did not have a material concentration in any single investment.

Our operations are located entirely within the U.S. We focus primarily on developing, manufacturing, and commercializing our products and product candidates. We perform ongoing credit evaluations of our customers and generally do not require collateral. The following table sets forth customers who represented 10% or more of our total revenues for the three and nine months ended September 30, 2018 and 2017:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| AmerisourceBergen Drug Corporation | 24% | 28% | 26% | 26% |
| McKesson Corporation | 25% | 26% | 26% | 23% |

Our net accounts receivable primarily represent amounts due for products sold directly to wholesalers, distributors, specialty pharmacies, and our authorized generic partner. Accounts receivable for our products are recorded net of reserves for estimated chargeback obligations, prompt payment discounts and any allowance for doubtful accounts. At September 30, 2018 and December 31, 2017, four and two customers accounted for 10% or more of our accounts receivable balance, respectively, representing approximately 74% and 57% in the aggregate of our total accounts receivable, respectively.

We are currently dependent on a single supplier for Feraheme drug substance (produced in two separate facilities) as well as for drug substance and final packaging services for Intrarosa. In addition, we currently have a single supplier for Makena drug substance, which is used for each of our intramuscular and auto-injector products, and primarily use one of two suppliers of finished drug product for our Makena vial product and a single supplier for our auto-injector product. We have been and may continue to be exposed to a significant loss of revenue from the sale of our products in the event that our suppliers and/or manufacturers are not able to fulfill demand for any reason.

Revenue Recognition

Effective January 1, 2018, we adopted Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers ("ASC 606"), using the modified retrospective transition method. We recognized the cumulative effect of applying the new revenue standard to all contracts with customers that were not completed as of January 1, 2018 as an adjustment to the opening balance of stockholders' equity at the beginning of 2018. The adjustment recorded was for incremental contract acquisition costs related to the CBR business. The comparative information has not been restated and continues to be reported under the accounting standards in effect for the periods presented. This standard

applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. ASC 606 also impacts certain other areas, such as the accounting for costs to obtain or fulfill a contract. The standard also requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The adoption of ASC 606 did not have an impact on the amount of reported revenues with respect to our product revenue.

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Reclassifications

Certain amounts in prior periods have been reclassified to reflect the impact of the held for sale and discontinued operations treatment of the CBR business in order to conform to the current period presentation.

C. DISCONTINUED OPERATIONS AND HELD FOR SALE

On August 6, 2018, we completed the sale of our CBR business to GI Partners pursuant to the CBR Purchase Agreement. We received $519.3 million in cash at closing and recognized a gain of $89.6 million on the sale during the three and nine months ended September 30, 2018. Although we are providing limited transitional services related to GI for certain agreed-upon sales and marketing, technology, human resources and finance functions for several months post-closing, we do not expect to have any (and have not had any) significant involvement in the operations of the CBR business following the close of the sale.

We determined that the sale of CBR represented a strategic shift that would have a major effect on our business and therefore met the criteria for classification as discontinued operations at June 30, 2018. All historical operating results for CBR were reflected within discontinued operations in the condensed consolidated statements of operations for all periods presented. Further, all assets and liabilities associated with CBR were classified as assets and liabilities held for sale in our condensed consolidated balance sheets for the historical period presented.

Assets and liabilities held for sale were reflected separately in our condensed consolidated balance sheets and were comprised of the following as of September 30, 2018 and December 31, 2017 (in thousands):

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash | $ — | $ 29,259 |
| Accounts receivable, net | — | 12,042 |
| Inventories (raw materials) | — | 2,913 |
| Prepaid and other current assets | — | 1,294 |
| Total current assets held for sale | $ — | $ 45,508 |
| | | |
| Property, plant and equipment, net | $ — | $ 18,092 |
| Intangible assets, net | — | 328,991 |
| Goodwill | — | 216,971 |
| Other long-term assets | — | 496 |
| Restricted cash | — | 161 |
| Total long-term assets held for sale | $ — | $ 564,711 |
| | | |
| Liabilities | | |
| Current liabilities: | | |
| Accounts payable | $ — | $ 2,618 |
| Accrued expenses | — | 8,758 |
| Deferred revenues, short term | — | 42,494 |
| Total current liabilities held for sale | $ — | $ 53,870 |
| | | |
| Deferred revenues, long-term | — | 24,387 |
| Deferred tax liabilities | — | 71,046 |
| Other long-term liabilities | — | 388 |
| Total long-term liabilities held for sale | $ — | $ 95,821 |

The results of operations of the CBR business were classified as discontinued operations for all periods presented in our condensed consolidated financial statements. The following is a summary of net income from discontinued operations for the

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three and nine months ended September 30, 2018 and 2017:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Service revenues, net | $12,163 | $29,410 | $71,217 | $84,365 |
| Costs and expenses: | | | | |
| Cost of services | 1,576 | 5,559 | 12,559 | 16,130 |
| Selling, general and administrative expenses | 4,749 | 19,345 | 39,899 | 63,237 |
| Total costs and expenses | 6,325 | 24,904 | 52,458 | 79,367 |
| Operating income | 5,838 | 4,506 | 18,759 | 4,998 |
| Other income | — | — | 114 | — |
| Income from discontinued operations | 5,838 | 4,506 | 18,873 | 4,998 |
| Gain on sale of CBR business | 89,581 | — | 89,581 | — |
| Income tax (benefit) expense | (98) | 854 | 3,346 | 1,796 |
| Net income from discontinued operations | $95,517 | $3,652 | $105,108 | $3,202 |

The cash flows related to discontinued operations have not been segregated and are included in the Consolidated Statements of Cash Flows. For the nine months ended September 30, 2018 and 2017, capital expenditures related to the CBR business were $1.6 million and $3.0 million, respectively. Depreciation and amortization expense related to the CBR business for the same periods was $8.4 million and $17.1 million, respectively. Excluding the gain of $89.6 million recognized on the sale of the CBR business and the related transaction expenses of $14.1 million presented in the Consolidated Statements of Cash Flows for the nine months ended September 30, 2018, there were no other significant operating or investing non-cash items related to the CBR business for either period presented.

D. REVENUE RECOGNITION

On January 1, 2018, we adopted ASC 606 applying the modified retrospective transition method to all contracts that were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for prior periods. There was no impact to revenue for the three and nine months ended September 30, 2018 as a result of adoption.

Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps:

a.Identify the contract(s) with a customer;
b.Identify the performance obligations in the contract;
c.Determine the transaction price;
d.Allocate the transaction price to the performance obligations in the contract; and
e.Recognize revenue when (or as) the performance obligations are satisfied.

We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, if the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract, determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Our major sources of revenue during the reporting periods were product revenues from Makena (including both our branded and unbranded products), Feraheme and Intrarosa. The adoption of ASC 606 did not have an impact on our product revenue.



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Revenue and Allowances

The following table provides information about disaggregated revenue by products for the three and nine months ended September 30, 2018 and 2017 (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Product sales, net | | | | |
| Makena | $80,221 | $97,635 | $275,377 | $286,771 |
| Feraheme | 36,963 | 26,095 | 99,796 | 79,492 |
| Intrarosa | 4,925 | 360 | 10,331 | 360 |
| MuGard | 129 | 241 | 302 | 567 |
| Total | $122,238 | $124,331 | $385,806 | $367,190 |

Total gross product sales were offset by product sales allowances and accruals for the three and nine months ended September 30, 2018 and 2017 as follows (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Gross product sales | $238,856 | $235,299 | $776,458 | $676,377 |
| Provision for product sales allowances and accruals: | | | | |
| Contractual adjustments | 93,213 | 80,110 | 290,896 | 225,622 |
| Governmental rebates | 23,405 | 30,858 | 99,756 | 83,565 |
| Total | 116,618 | 110,968 | 390,652 | 309,187 |
| Product sales, net | $122,238 | $124,331 | $385,806 | $367,190 |

The following table summarizes the product revenue allowance and accrual activity for the three and nine months ended September 30, 2018 (in thousands):

| | Contractual Adjustments | Governmental Rebates | Total |
|---|---|---|---|
| Balance at December 31, 2017 | $ 62,164 | $ 50,598 | $112,762 |
| Provisions related to current period sales | 199,716 | 71,514 | 271,230 |
| Adjustments related to prior period sales | (2,034) | 4,837 | 2,803 |
| Payments/returns relating to current period sales | (132,618) | (2,453) | (135,071) |
| Payments/returns relating to prior period sales | (55,973) | (51,142) | (107,115) |
| Balance at June 30, 2018 | 71,255 | 73,354 | 144,609 |
| Provisions related to current period sales | 93,824 | 20,719 | 114,543 |
| Adjustments related to prior period sales | (614) | 2,710 | 2,096 |
| Payments/returns relating to current period sales | (102,627) | (52,040) | (154,667) |
| Payments/returns relating to prior period sales | (2,207) | (7,002) | (9,209) |
| Balance at September 30, 2018 | $ 59,631 | $ 37,741 | $97,372 |

We receive payments from customers based upon contractual billing schedules; accounts receivable are recorded when the right to consideration becomes unconditional.

Performance Obligations and Product Revenue

At contract inception, we assess the goods promised in our contracts with customers and identify a performance obligation for each promise to transfer to the customer a good (or bundle of goods) that is distinct. To identify the performance obligations, we consider all of the goods promised in the contract regardless of whether they are explicitly stated or are implied by customary business practices. We determined that the following distinct goods represent separate performance obligations:

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•Supply of Makena (branded and unbranded) product
•Supply of Feraheme product
•Supply of Intrarosa product

We principally sell our products to wholesalers, specialty distributors, specialty pharmacies and other customers, including our authorized generic partner (collectively, "Customers"), who purchase products directly from us. Our Customers subsequently resell the products to healthcare providers and patients. In addition to distribution agreements with Customers, we enter into arrangements with healthcare providers and payers that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of our products.

For the majority of our Customers, we transfer control at the point in time when the goods are delivered. In instances when we perform shipping and handling activities, these are considered fulfillment activities, and accordingly, the costs are accrued when the related revenue is recognized. Taxes collected from Customers and remitted to governmental authorities are excluded from revenues.

Variable Consideration
Under ASC 606, we are required to make estimates of the net sales price, including estimates of variable consideration (such as rebates, chargebacks, discounts, co-pay assistance and other deductions), and recognize the estimated amount as revenue, when we transfer control of the product to our customers. In addition, we estimate variable consideration related to our share of net distributable profits from our authorized generic partner. Variable consideration must be determined using either an "expected value" or a "most likely amount" method.

We record product revenues net of certain allowances and accruals in our condensed consolidated statements of operations. Product sales allowances and accruals are primarily comprised of both direct and indirect fees, discounts and rebates and provisions for estimated product returns. Direct fees, discounts and rebates are contractual fees and price adjustments payable to Customers that purchase products directly from us. Indirect fees, discounts and rebates are contractual price adjustments payable to healthcare providers and organizations, such as certain physicians, clinics, hospitals, group purchasing organizations ("GPOs"), and dialysis organizations that typically do not purchase products directly from us but rather from wholesalers and specialty distributors. Consideration payable to a Customer, or other parties that purchase goods from a Customer, are considered to be a reduction of the transaction price, and therefore, of revenue.

Product sales allowances and accruals are based on definitive contractual agreements or legal requirements (such as Medicaid laws and regulations) related to the purchase and/or utilization of the product by these entities and are recorded in the same period that the related revenue is recognized. We use the expected value method for estimating variable consideration. We estimate product sales allowances and accruals using either historical, actual and/or other data, including estimated patient usage, applicable contractual rebate rates, contract performance by the benefit providers, other current contractual and statutory requirements, historical market data based upon experience of our products and other products similar to them, specific known market events and trends such as competitive pricing and new product introductions, current and forecasted Customer buying patterns and inventory levels, and the shelf life of our products. As part of this evaluation, we also review changes to federal and other legislation, changes to rebate contracts, changes in the level of discounts, and changes in product sales trends. Although allowances and accruals are recorded at the time of product sale, rebates are typically paid out in arrears, one to three months after the sale.

The estimate of variable consideration, which is included in the transaction price, may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved in a future period. Estimating variable consideration and the related constraint requires the use of significant

management judgment and actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known. No amounts were constrained as of September 30, 2018.

Discounts

We typically offer a 2% prompt payment discount to certain customers as an incentive to remit payment in accordance with the stated terms of the invoice, generally 30 days. Because we anticipate that those customers who are offered this discount will take advantage of the discount, 100% of the prompt payment discount at the time of sale is accrued, based on the gross amount of each invoice. We adjust the accrual quarterly to reflect actual experience.

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Chargebacks

Chargeback reserves represent the estimated obligations resulting from the difference between the prices at which we sell our products to wholesalers and the sales price ultimately paid to wholesalers under fixed price contracts by third-party payers, including governmental agencies. The chargeback estimates are determined based on actual product sales data and forecasted customer buying patterns. Actual chargeback amounts are determined at the time of resale to the qualified healthcare provider, and we generally issue credits for such amounts within several weeks of receiving notification from the wholesaler. Estimated chargeback amounts are recorded at the time of sale and adjusted quarterly to reflect actual experience.

Distributor/Wholesaler and Group Purchasing Organization Fees

Fees under arrangements with distributors and wholesalers are usually based upon units of product purchased during the prior month or quarter and are usually paid by us within several weeks of the receipt of an invoice from the wholesaler or distributor, as the case may be. Fees under the arrangements with GPOs are usually based upon member purchases during the prior quarter and are generally billed by the GPO within 30 days after period end. In accordance with ASC 606, since the consideration given to the Customer is not for a distinct good or service, the consideration is a reduction of the transaction price of the vendor’s products or services. We have included these fees in contractual adjustments in the table above. We generally pay such amounts within several weeks of the receipt of an invoice from the distributor, wholesaler or GPO. Accordingly, we accrue the estimated fee due at the time of sale, based on the contracted price invoiced to the Customer. We adjust the accrual quarterly to reflect actual experience.

Product Returns

Consistent with industry practice, we generally offer wholesalers, specialty distributors and other customers a limited right to return our products based on the product’s expiration date. Currently the expiration periods for our products have a range of three to five years. Product returns are estimated based on the historical return patterns and known or expected changes in the marketplace. We track actual returns by individual production lots. Returns on lots eligible for credits under our returned goods policy are monitored and compared with historical return trends and rates. We expect that wholesalers and healthcare providers will not stock significant inventory due to the cost of the product, the expense to store our products, and/or that our products are readily available for distribution. We record an estimate of returns at the time of sale. If necessary, our estimated rate of returns may be adjusted for actual return experience as it becomes available and for known or expected changes in the marketplace. We did not significantly adjust our reserve for product returns during the three and nine months ended September 30, 2018. To date, our product returns have been relatively limited; however, returns experience may change over time. We may be required to make future adjustments to our product returns estimate, which would result in a corresponding change to our net product sales in the period of adjustment and could be significant.

Sales Rebates

We contract with various private payer organizations, primarily pharmacy benefit managers, for the payment of rebates with respect to utilization of our products. We determine our estimates for rebates, if applicable, based on actual product sales data and our historical product claims experience. Rebate amounts generally are invoiced quarterly and are paid in arrears, and we expect to pay such amounts within several weeks of notification by the provider. We regularly assess our reserve balance and the rate at which we accrue for claims against product sales. If we determine in future periods that our actual rebate experience is not indicative of expected claims, if actual claims experience changes, or if other factors affect estimated claims rates, we may be required to adjust our current accumulated reserve estimate, which would affect net product sales in the period of the adjustment and could be significant.

Governmental Rebates

Governmental rebate reserves relate to our reimbursement arrangements with state Medicaid programs. We determine our estimates for Medicaid rebates, if applicable, based on actual product sales data and our historical product claims experience. In estimating these reserves, we provide for a Medicaid rebate associated with both those expected instances where Medicaid will act as the primary insurer as well as in those instances where we expect Medicaid will act as the secondary insurer. Rebate amounts generally are invoiced quarterly and are paid in arrears, and we expect to pay such amounts within several weeks of notification by the Medicaid or provider entity. We regularly assess our Medicaid reserve balance and the rate at which we accrue for claims against product sales. If we determine in future periods that our actual rebate experience is not indicative of expected claims, if actual claims experience changes, or if other factors affect estimated claims rates, we may be required to adjust our current Medicaid accumulated reserve estimate, which would affect net product sales in the period of the adjustment and could be significant.

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Other Discounts

Other discounts which we offer include voluntary patient assistance programs, such as co-pay assistance programs, which are intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payers. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue.

E. MARKETABLE SECURITIES

As of September 30, 2018 and December 31, 2017, our marketable securities were classified as available-for-sale in accordance with accounting standards which provide guidance related to accounting and classification of certain investments in marketable securities. Available-for-sale marketable securities are those securities which we view as available for use in current operations, if needed. We generally classify our available-for-sale marketable securities as short-term investments on our condensed consolidated balance sheets even though the stated maturity date may be one year or more beyond the current balance sheet date.

The following is a summary of our marketable securities as of September 30, 2018 and December 31, 2017 (in thousands):

| | September 30, 2018 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
| Short-term marketable securities:* | | | | |
| Corporate debt securities | $53,862 | $ 1 | $ (174) | $53,689 |
| Certificates of deposit | 13,000 | — | — | 13,000 |
| U.S. treasury and government agency securities | 6,149 | — | (29) | 6,120 |
| Commercial paper | 5,462 | — | — | 5,462 |
| Total short-term marketable securities | $78,473 | $ 1 | $ (203) | $78,271 |
| Long-term marketable securities:** | | | | |
| Corporate debt securities | $55,017 | $ 2 | $ (580) | $54,439 |
| U.S. treasury and government agency securities | 6,236 | — | (78) | 6,158 |
| Certificates of deposit | 1,500 | — | — | 1,500 |
| Total long-term marketable securities | 62,753 | 2 | (658) | 62,097 |
| Total marketable securities | $141,226 | $ 3 | $ (861) | $140,368 |

* Represents marketable securities with a remaining maturity of less than one year.
** Represents marketable securities with a remaining maturity of one to three years.

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| | December 31, 2017 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
| Short-term marketable securities:* | | | | |
| Corporate debt securities | $57,257 | $ — | $ (68) | $57,189 |
| Certificates of deposit | 9,151 | — | — | 9,151 |
| U.S. treasury and government agency securities | 1,999 | — | (13) | 1,986 |
| Commercial paper | 1,999 | — | — | 1,999 |
| Total short-term marketable securities | $70,406 | $ — | $ (81) | $70,325 |
| Long-term marketable securities:** | | | | |
| Corporate debt securities | $59,282 | $ 1 | $ (320) | $58,963 |
| U.S. treasury and government agency securities | 7,381 | — | (76) | 7,305 |
| Total long-term marketable securities | 66,663 | 1 | (396) | 66,268 |
| Total marketable securities | $137,069 | $ 1 | $ (477) | $136,593 |

* Represents marketable securities with a remaining maturity of less than one year.
** Represents marketable securities with a remaining maturity of one to three years.

Impairments and Unrealized Gains and Losses on Marketable Securities
We did not recognize any other-than-temporary impairment losses in our condensed consolidated statements of operations related to our marketable securities during the three and nine months ended September 30, 2018 and 2017. We considered various factors, including the length of time that each security was in an unrealized loss position and our ability and intent to hold these securities until the recovery of their amortized cost basis occurs. As of September 30, 2018, we had no material losses in an unrealized loss position for more than one year. Future events may occur, or additional information may become available, which may cause us to identify credit losses where we do not expect to receive cash flows sufficient to recover the entire amortized cost basis of a security and may necessitate the recording of future realized losses on securities in our portfolio. Significant losses in the estimated fair values of our marketable securities could have a material adverse effect on our earnings in future periods.

F. FAIR VALUE MEASUREMENTS
The following tables represent the fair value hierarchy as of September 30, 2018 and December 31, 2017, for those assets and liabilities that we measure at fair value on a recurring basis (in thousands):

| | Fair Value Measurements at September 30, 2018 Using: | | | |
|---|---|---|---|---|
| | Total | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Assets: | | | | |
| Cash equivalents | $120,778 | $ 120,778 | $ — | $ — |
| Corporate debt securities | 108,128 | — | 108,128 | — |
| U.S. treasury and government agency securities | 12,278 | — | 12,278 | — |
| Certificates of deposit | 14,500 | — | 14,500 | — |
| Commercial paper | 5,462 | — | 5,462 | — |
| Total assets | $261,146 | $ 120,778 | $ 140,368 | $ — |
| Liabilities: | | | | |
| Contingent consideration - MuGard | $823 | $ — | $ — | $ 823 |
| Total liabilities | $823 | $ — | $ — | $ 823 |

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| | Fair Value Measurements at December 31, 2017 Using: | | | |
|---|---|---|---|---|
| | Total | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Assets: | | | | |
| Cash equivalents | $4,591 | $ 4,591 | $ — | $ — |
| Corporate debt securities | 116,152 | — | 116,152 | — |
| U.S. treasury and government agency securities | 9,291 | — | 9,291 | — |
| Certificates of deposit | 9,151 | — | 9,151 | — |
| Commercial paper | 1,999 | — | 1,999 | — |
| Total assets | $141,184 | $ 4,591 | $ 136,593 | $ — |
| Liabilities: | | | | |
| Contingent consideration - Lumara Health | $49,187 | $ — | $ — | $ 49,187 |
| Contingent consideration - MuGard | 898 | — | — | 898 |
| Total liabilities | $50,085 | $ — | $ — | $ 50,085 |

Marketable Securities

Our cash equivalents, are classified as Level 1 assets under the fair value hierarchy as these assets have been valued using quoted market prices in active markets and do not have any restrictions on redemption. Our marketable securities are classified as Level 2 assets under the fair value hierarchy as these assets are primarily determined from independent pricing services, which normally derive security prices from recently reported trades for identical or similar securities, making adjustments based upon other significant observable market transactions. At the end of each reporting period, we perform quantitative and qualitative analysis of prices received from third parties to determine whether prices are reasonable estimates of fair value. After completing our analysis, we did not adjust or override any fair value measurements provided by our pricing services as of September 30, 2018. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during the nine months ended September 30, 2018.

Contingent Consideration

We recorded contingent consideration related to the November 2014 acquisition of Lumara Health, Inc. (“Lumara Health”) for our Makena product and related to our June 2013 license agreement for MuGard (the “MuGard License Agreement”) with Abeona Therapeutics, Inc. (“Abeona”), under which we acquired the U.S. commercial rights for the management of oral mucositis and stomatitis (the “MuGard Rights”).

The fair value measurements of contingent consideration obligations and the related intangible assets arising from business combinations are classified as Level 3 assets under the fair value hierarchy as these assets have been valued using unobservable inputs. These inputs include: (a) the estimated amount and timing of projected cash flows; (b) the probability of the achievement of the factors on which the contingency is based; and (c) the risk-adjusted discount rate used to present value the probability-weighted cash flows. Significant increases or decreases in any of those inputs in isolation could result in a significantly lower or higher fair value measurement.

The following table presents a reconciliation of contingent consideration obligations related to the acquisition of Lumara Health and the MuGard Rights (in thousands):

| | |
|---|---|
| Balance as of December 31, 2017 | $50,085 |
| Payments made | (87) |
| Adjustments to fair value of contingent consideration | (49,175) |
| Balance as of September 30, 2018 | $823 |

During the nine months ended September 30, 2018, we reduced the fair value of our contingent consideration liability by approximately $49.2 million based primarily on actual Makena net sales to date and our expectations for future

performance, which indicated that achievement of future milestones is not probable. This adjustment was based on our estimates, which are reliant on a number of external factors as well as the exercise of judgment.

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The fair value of the contingent milestone payments payable by us to the former stockholders of Lumara Health has been determined based on our probability-adjusted discounted cash flows estimated to be realized from the net sales of Makena from December 1, 2014 through December 31, 2019.

The fair value of the contingent royalty payments payable by us to Abeona under the MuGard License Agreement was determined based on various market factors, including an analysis of estimated sales using a discount rate of approximately 13%. As of September 30, 2018, we estimated that the undiscounted royalty amounts we could pay under the MuGard License Agreement, based on current projections, may range from approximately $2.0 million to $6.0 million over the remainder of the ten year period, which commenced on June 6, 2013, the acquisition date, which is our best estimate of the period over which we expect the majority of the asset's cash flows to be derived.

We believe the estimated fair values of Lumara Health and the MuGard Rights are based on reasonable assumptions; however; our actual results may vary significantly from the estimated results.

Debt

We estimate the fair value of our debt obligations by using quoted market prices obtained from third-party pricing services, which is classified as a Level 2 input. As of September 30, 2018, the estimated fair value of our 2022 Convertible Notes and 2019 Convertible Notes (each as defined below) was $335.2 million and $21.4 million, respectively, which differed from their carrying values. See Note R, "Debt" for additional information on our debt obligations.

G. INVENTORIES

Our major classes of inventories were as follows as of September 30, 2018 and December 31, 2017 (in thousands):

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Raw materials | $ 11,318 | $ 9,505 |
| Work in process | 1,866 | 4,146 |
| Finished goods | 14,769 | 20,792 |
| Total inventories | $ 27,953 | $ 34,443 |

H. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following as of September 30, 2018 and December 31, 2017 (in thousands):

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Computer equipment and software | $ 1,438 | $ 1,401 |
| Furniture and fixtures | 1,442 | 1,442 |
| Leasehold improvements | 2,938 | 2,938 |
| Laboratory and production equipment | 6,000 | 654 |
| Construction in progress | 59 | 5,068 |
| | 11,877 | 11,503 |
| Less: accumulated depreciation | (4,830) | (3,599) |
| Property and equipment, net | $ 7,047 | $ 7,904 |

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I. GOODWILL AND INTANGIBLE ASSETS, NET

Goodwill

Our $422.5 million goodwill balance represents goodwill of the continuing business following the goodwill allocation required by the CBR transaction discussed in Note C “Discontinued Operations and Held for Sale.” We determined that CBR met the definition of a business and as a result, in accordance with ASC 350 - Intangibles - Goodwill and Other, allocated goodwill on a relative fair value basis between CBR and the continuing business for the purposes of determining the carrying value of CBR. Further, we performed a qualitative goodwill impairment test for our continuing business at June 30, 2018 to assess whether there were indicators that its fair value was less than its carrying value. As a result of this evaluation, we determined that there was no impairment of the goodwill of our continuing business at June 30, 2018.

We test goodwill at the reporting unit level for impairment on an annual basis and between annual tests if events and circumstances indicate it is more likely than not that the fair value of a reporting unit is less than its carrying value. Events that could indicate impairment and trigger an interim impairment assessment include, but are not limited to, an adverse change in current economic and market conditions, including a significant prolonged decline in market capitalization, a significant adverse change in legal factors, unexpected adverse business conditions, and an adverse action or assessment by a regulator. Our annual impairment test date is October 31. We have determined that we operate in a single operating segment and have a single reporting unit.

Intangible Assets

As of September 30, 2018 and December 31, 2017, our identifiable intangible assets consisted of the following (in thousands):

| | September 30, 2018 | | | | December 31, 2017 | | | |
|---|---|---|---|---|---|---|---|---|
| | Cost | Accumulated Amortization | Cumulative Impairments | Net | Cost | Accumulated Amortization | Cumulative Impairments | Net |
| Finite-lived intangible assets: | | | | | | | | |
| Makena base technology | $797,100 | $ 390,724 | $ 319,246 | $87,130 | $797,100 | $ 255,754 | $ 319,246 | $222,100 |
| Makena auto-injector developed technology | 79,100 | 4,697 | — | 74,403 | — | — | — | — |
| Intrarosa developed technology | 77,655 | 8,441 | — | 69,214 | 77,655 | 3,376 | — | 74,279 |
| | 953,855 | 403,862 | 319,246 | 230,747 | 874,755 | 259,130 | 319,246 | 296,379 |
| Indefinite-lived intangible assets: | | | | | | | | |
| Makena IPR&D | — | — | — | — | 79,100 | — | — | 79,100 |
| Total intangible assets | $953,855 | $ 403,862 | $ 319,246 | $230,747 | $953,855 | $ 259,130 | $ 319,246 | $375,479 |

During the first quarter of 2018, following the U.S. Food and Drug Administration (the “FDA”) approval of Makena for administration via a pre-filled subcutaneous auto-injector (the “Makena auto-injector”), we reclassified the Makena IPR&D as the Makena auto-injector developed technology and placed it into service. Amortization of the Makena auto-injector developed technology is being recognized on a straight-line basis over 8.8 years.

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As of September 30, 2018, the weighted average remaining amortization period for our finite-lived intangible assets was approximately 7.7 years. Total amortization expense for the nine months ended September 30, 2018 and 2017 was $144.7 million and $69.6 million, respectively. Amortization expense is recorded in cost of product sales in our condensed consolidated statements of operations. We expect amortization expense related to our finite-lived intangible assets to be as follows (in thousands):

| Period | Estimated Amortization Expense |
|---|---|
| Remainder of Year Ending December 31, 2018 | $ 28,860 |
| Year Ending December 31, 2019 | 35,010 |
| Year Ending December 31, 2020 | 26,636 |
| Year Ending December 31, 2021 | 26,488 |
| Year Ending December 31, 2022 | 26,469 |
| Thereafter | 87,284 |
| Total | $ 230,747 |

J. CURRENT AND LONG-TERM LIABILITIES

Accrued expenses consisted of the following as of September 30, 2018 and December 31, 2017 (in thousands):

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Commercial rebates, fees and returns | $89,157 | $101,852 |
| Professional, license, and other fees and expenses | 21,442 | 23,657 |
| Salaries, bonuses, and other compensation | 23,623 | 15,882 |
| Interest expense | 3,533 | 13,525 |
| Intrarosa-related license fees | — | 10,000 |
| Research and development expense | 3,998 | 1,816 |
| Total accrued expenses | $141,753 | $166,732 |

K. INCOME TAXES

The following table summarizes our effective tax rate and income tax (benefit) expense from continuing operations for the three and nine months ended September 30, 2018 and 2017 (in thousands except for percentages):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Effective tax rate | 4 % | 43 % | (40 )% | 41 % |
| Income tax (benefit) expense | $(2,352) | $(115,197) | $42,204 | $(145,317) |

For the three and nine months ended September 30, 2018, we recognized an income tax benefit of $2.4 million and income tax expense of $42.2 million, respectively, representing an effective tax rate of 4% and (40)%, respectively. The difference between the 2018 statutory federal tax rate of 21% and the effective tax rates for the three and nine months ended September 30, 2018, was primarily attributable to the establishment of a valuation allowance on net deferred tax assets other than refundable alternative minimum tax (“AMT”) credits, the impact of non-deductible stock compensation and other non-deductible expenses, partially offset by a benefit from contingent consideration, state income taxes and orphan drug credits. We have established a valuation allowance on our deferred tax assets other than refundable credits to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets. Our valuation allowance on our deferred tax assets, other than refundable AMT credits, increased during the three and nine months ended September 30, 2018 primarily because the deferred tax liabilities associated with the CBR business, which was reclassified to discontinued operations for the three and nine months ended September 30, 2018, are no longer available as a source of income to realize the benefits of the net deferred tax assets.

In December 2017, the Tax Cuts and Jobs Act (the "2017 Tax Act") was enacted. The 2017 Tax Act included significant changes to the U.S. corporate income tax system, including a reduction of the federal corporate income tax rate from 35% to 21%, effective January 1, 2018. Deferred tax assets and liabilities are measured using enacted rates in effect for

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the year in which those temporary differences are expected to be recovered or settled. As a result of the reduction in the federal tax rate from 35% to 21%, we revalued our ending net deferred tax liabilities at December 31, 2017 and recognized a provisional $17.6 million tax benefit. We are still assessing the implications of the 2017 Tax Act on both a federal and state level. Any additional impacts will be recorded as they are identified during the measurement period as provided for in accordance with Staff Accounting Bulletin No. 118, which addresses the application of GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the 2017 Tax Act.

For the three and nine months ended September 30, 2017, we recognized an income tax benefit of $115.2 million and $145.3 million, respectively, representing an effective tax rate of 43% and 41%, respectively. The difference between the expected 2017 statutory federal tax rate of 35% and the effective tax rates for the three and nine months ended September 30, 2017 was primarily attributable to the impact of state income taxes and the federal research and development tax credit, partially offset by non-deductible stock compensation.

The primary drivers of the increase in tax expense for the three and nine months ended September 30, 2018 as compared to the three and nine months ended September 30, 2017 is primarily attributable to an increase in valuation allowance on net deferred tax assets other than refundable AMT credits and a decrease in the federal tax benefit attributable to the decrease in the statutory federal rate from 35% to 21%, as well as an increase in nondeductible expenses, partially offset by contingent consideration.

L. ACCUMULATED OTHER COMPREHENSIVE LOSS

The following table summarizes the changes in the accumulated balances of other comprehensive loss during the three and nine months ended September 30, 2018 and 2017 (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Beginning balance | $(4,295) | $(3,633) | $(3,908) | $(3,838) |
| Holding gains (losses) arising during period, net of tax | 134 | (4) | (253) | 201 |
| Ending balance | $(4,161) | $(3,637) | $(4,161) | $(3,637) |

M. BASIC AND DILUTED NET INCOME (LOSS) PER SHARE

We compute basic net income (loss) per share by dividing net income (loss) by the weighted average number of common shares outstanding during the relevant period. Diluted net income (loss) per common share has been computed by dividing net income (loss) by the diluted number of common shares outstanding during the period. Except where the result would be antidilutive to net income, diluted net income per common share is computed assuming the impact of the conversion of the 2.5% convertible senior notes due 2019 (the “2019 Convertible Notes”) and the 3.25% convertible senior notes due 2022 (the “2022 Convertible Notes”), the exercise of outstanding stock options, the vesting of restricted stock units (“RSUs”), and the exercise of warrants.

We have a choice to settle the conversion obligation of our 2022 Convertible Notes and the 2019 Convertible Notes (together, the “Convertible Notes”) in cash, shares, or any combination of the two. Our current policy is to settle the principal balance of the Convertible Notes in cash. As such, we apply the treasury stock method to these securities and the dilution related to the conversion premium, if any, of the Convertible Notes is included in the calculation of diluted weighted-average shares outstanding to the extent each issuance is dilutive based on the average stock price during each reporting period being greater than the conversion price of the respective Convertible Notes. The dilutive effect of the warrants, stock options and RSUs has been calculated using the treasury stock method.

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The components of basic and diluted net income (loss) per share for the three and nine months ended September 30, 2018 and 2017 were as follows (in thousands, except per share data):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Net loss from continuing operations | $(64,678) | $(155,713) | $(148,592) | $(205,890) |
| Net income from discontinued operations | 95,517 | 3,652 | 105,108 | 3,202 |
| Net income (loss) | $30,839 | $(152,061) | $(43,484) | $(202,688) |
| | | | | |
| Weighted average common shares outstanding | 34,492 | 35,311 | 34,339 | 34,948 |
| | | | | |
| Basic and diluted net income (loss) per share: | | | | |
| Loss from continuing operations | $(1.88) | $(4.41) | $(4.33) | $(5.89) |
| Income from discontinued operations | 2.77 | 0.10 | 3.06 | 0.09 |
| Basic and diluted net income (loss) per share: | $0.89 | $(4.31) | $(1.27) | $(5.80) |

The following table sets forth the potential common shares issuable upon the exercise of outstanding options, the vesting of RSUs, the exercise of warrants (prior to consideration of the treasury stock method), and the conversion of the Convertible Notes, which were excluded from our computation of diluted net (loss) income per share because their inclusion would have been anti-dilutive (in thousands):

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2018 | 2017 |
| Options to purchase shares of common stock | 3,700 | 3,389 |
| Shares of common stock issuable upon the vesting of RSUs | 1,135 | 1,140 |
| Warrants | 1,008 | 1,008 |
| 2022 Convertible Notes | 11,695 | 11,695 |
| 2019 Convertible Notes | 790 | 790 |
| Total | 18,328 | 18,022 |

In connection with the issuance of the 2019 Convertible Notes, in February 2014, we entered into convertible bond hedges. The convertible bond hedges are not included for purposes of calculating the number of diluted shares outstanding, as their effect would be anti-dilutive. The convertible bond hedges are generally expected, but not guaranteed, to reduce the potential dilution and/or offset the cash payments we are required to make upon conversion of the remaining 2019 Convertible Notes. During the three and nine months ended September 30, 2018 and 2017, our average common stock price was below the exercise price of the warrants.

N. EQUITY BASED COMPENSATION

We currently maintain three equity compensation plans; our Fourth Amended and Restated 2007 Equity Incentive Plan, as amended (the “2007 Plan”), the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan (the “Lumara Health 2013 Plan”) and our 2015 Employee Stock Purchase Plan (“2015 ESPP”). In June 2018 at our annual meeting of stockholders, our stockholders approved (a) an amendment to our 2007 Plan to, among other things, increase the number of shares of our common stock available for issuance thereunder by 1,043,000 shares and (b) an amendment to our 2015 ESPP to increase the maximum number of shares of our common stock that will be made available for sale thereunder by 500,000 shares. All outstanding stock options granted under each of our equity compensation plans other than our 2015 ESPP have an exercise price equal to the closing price of a share of our common stock on the grant date.

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Stock Options

The following table summarizes stock option activity for the nine months ended September 30, 2018:

| | 2007 Equity Plan | 2013 Lumara Equity Plan | Inducement Grants | Total |
|---|---|---|---|---|
| Outstanding at December 31, 2017 | 2,590,373 | 125,536 | 815,450 | 3,531,359 |
| Granted | 836,846 | 35,400 | 102,393 | 974,639 |
| Exercised | (133,547) | (2,812) | — | (136,359) |
| Expired or terminated | (549,156) | (30,675) | (90,000) | (669,831) |
| Outstanding at September 30, 2018 | 2,744,516 | 127,449 | 827,843 | 3,699,808 |

Restricted Stock Units

The following table summarizes RSU activity for the nine months ended September 30, 2018:

| | 2007 Equity Plan | 2013 Lumara Equity Plan | Inducement Grants | Total |
|---|---|---|---|---|
| Outstanding at December 31, 2017 | 966,623 | 11,611 | 91,541 | 1,069,775 |
| Granted | 752,797 | 1,600 | 48,418 | 802,815 |
| Vested | (370,388) | (10,650) | (47,764) | (428,802) |
| Expired or terminated | (306,234) | (460) | (2,502) | (309,196) |
| Outstanding at September 30, 2018 | 1,042,798 | 2,101 | 89,693 | 1,134,592 |

In March 2018, we granted RSUs under our 2007 Plan to certain members of our senior management covering a maximum of 206,250 shares of common stock. These performance-based RSUs will vest, if at all, on March 1, 2021, based on our total shareholder return performance measured against the median total shareholder return of a defined group of companies over a three-year period. As of September 30, 2018, the maximum shares of common stock that may be issued under these awards is 188,250. The maximum aggregate total fair value of these RSUs is $3.5 million, which is being recognized as expense over a period of three years from the date of grant, net of any actual forfeitures.

Equity-Based Compensation Expense

Equity-based compensation expense for the three and nine months ended September 30, 2018 and 2017 consisted of the following (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Cost of product sales | $281 | $432 | $588 | $690 |
| Research and development | 568 | 799 | 1,896 | 2,651 |
| Selling, general and administrative | 4,202 | 4,410 | 12,149 | 12,037 |
| Total equity-based compensation expense | 5,051 | 5,641 | 14,633 | 15,378 |
| Income tax effect | — | (1,674) | — | (4,569) |
| After-tax effect of equity-based compensation expense | $5,051 | $3,967 | $14,633 | $10,809 |

We reduce the compensation expense being recognized to account for estimated forfeitures, which we estimate based primarily on historical experience, adjusted for unusual events such as corporate restructurings, which may result in higher than expected turnover and forfeitures. Under current accounting guidance, forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We adopted ASU No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting during the first quarter of 2017. We will continue to use the current method of estimated forfeitures each period rather than accounting for forfeitures as they occur.

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## O. STOCKHOLDERS' EQUITY

### Change in Stockholders' Equity

Total stockholders' equity decreased by $28.0 million during the nine months ended September 30, 2018. This decrease was primarily driven by the following:

- $43.5 million due to our net loss for the nine months ended September 30, 2018;
- $14.6 million increase related to equity-based compensation expense;
- $1.1 million increase related to the cumulative effect adjustment to our accumulated deficit from the adoption of ASC 606, net of tax;
- $2.6 million decrease due to the payment of employee tax withholdings related to equity-based compensation; and
- $2.6 million increase from net shares issued related to the exercise of stock options.

### Share Repurchase Program

In January 2016, we announced that our Board authorized a program to repurchase up to $60.0 million in shares of our common stock. The repurchase program does not have an expiration date and may be suspended for periods or discontinued at any time. Under the program, we may purchase our stock from time to time at the discretion of management in the open market or in privately negotiated transactions. The number of shares repurchased and the timing of the purchases will depend on a number of factors, including share price, trading volume and general market conditions, along with working capital requirements, general business conditions and other factors. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate purchases of our shares under this program. As of September 30, 2018, we repurchased and retired a cumulative total of 2,198,010 shares of common stock under this repurchase program for $39.5 million at an average purchase price of $17.97 per share. As of September 30, 2018, $20.5 million remains available for the repurchase of shares under the program. We did not repurchase any of our common stock during the first nine months of 2018.

## P. COMMITMENTS AND CONTINGENCIES

### Commitments

Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. These include commitments related to our facility leases, purchases of inventory, debt obligations, and other purchase obligations.

### Purchase Obligations

Purchase obligations primarily represent minimum purchase commitments for inventory. As of September 30, 2018, our minimum purchase commitments totaled $66.4 million.

### Contingent Consideration Related to Business Combinations

In connection with our acquisition of Lumara Health in November 2014, we agreed to pay up to $350.0 million based on the achievement of certain sales milestones, of which $150.0 million has been paid. During the nine months ended September 30, 2018, we reversed the accrual for a $50.0 million milestone payment based on actual Makena net sales to date and our expectations for future performance, which indicated that achievement of the future milestone was not probable. As we update our analysis in future periods, actual results may vary significantly from the estimated results, which are reliant on a number of external factors as well as the exercise of judgment.

### Contingent Regulatory and Commercial Milestone Payments

In September 2018, we exercised our option to acquire the global rights to AMAG-423 pursuant to an option agreement entered into in July 2015 with Velo Bio, LLC, a privately-held life-sciences company ("Velo"), the terms of which were amended at the time of exercise. AMAG-423 is a polyclonal antibody currently in clinical development for the treatment of severe preeclampsia in pregnant women and has been granted both orphan drug and fast-track review designations by the FDA. In connection with the exercise of the option and consummation of the acquisition, we have assumed responsibility to complete

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the Phase 2b/3a clinical study that Velo initiated in the second quarter of 2017 and will incur the necessary clinical, regulatory and other costs required to pursue FDA approval. As part of the acquisition, in September 2018 we paid Velo an upfront option exercise fee of $12.5 million, which was recorded as IPR&D expense as the product candidate is in development and has no alternative future use. We will also be obligated to pay Velo a $30.0 million milestone payment upon FDA approval of the product. In addition, if we are successful with the commercial launch of the product, we will be obligated to pay sales milestone payments to Velo of up to $240.0 million in the aggregate, triggered at various annual net sales thresholds between $300.0 million and $900.0 million and low-single digit royalties based on net sales. Further, we have assumed additional obligations under a previous agreement entered into by Velo with a third-party, including a $5.0 million milestone payment upon regulatory approval and $10.0 million upon first commercial sale, payable in quarterly installments as a percentage of quarterly gross sales. We will also be obligated to pay the third-party low-single digit royalties based on net sales.

In connection with a license agreement we entered into with Endoceutics, Inc. (“Endoceutics”) in February 2017 (the “Endoceutics License Agreement”), we are required to pay Endoceutics certain sales milestone payments, including a first sales milestone payment of $15.0 million, which would be triggered when Intrarosa annual net U.S. sales exceed $150.0 million, and a second milestone payment of $30.0 million, which would be triggered when annual net U.S. sales of Intrarosa exceed $300.0 million. If annual net U.S. sales of Intrarosa exceed $500.0 million, there are additional sales milestone payments totaling up to $850.0 million, which would be triggered at various sales thresholds. We are also obligated to pay tiered royalties to Endoceutics equal to a percentage of net sales of Intrarosa in the U.S. ranging from mid-teens for calendar year net sales up to $150.0 million to mid twenty percent for any calendar year net sales that exceed $1.0 billion for the commercial life of Intrarosa, with deductions (a) after the later of (i) the expiration date of the last to expire of a licensed patent containing a valid patent claim or (ii) ten years after the first commercial sale of Intrarosa for the treatment of vulvar and vaginal atrophy (“VVA”) or female sexual dysfunction (“FSD”) in the U.S. (as applicable), (b) for generic competition and (c) for third party payments, subject to an aggregate cap on such deductions of royalties otherwise payable to Endoceutics.

In connection with a license agreement we entered into with Palatin Technologies, Inc. (“Palatin”) in January 2017 (the “Palatin License Agreement”), we are required to pay Palatin up to $380.0 million in regulatory and commercial milestone payments, of which $20.0 million was paid in the second quarter of 2018 following the acceptance by the FDA of our New Drug Application (“NDA”) for Vyleesi. As of September 30, 2018, the remaining potential milestone payments include $60.0 million upon FDA approval of Vyleesi and up to $300.0 million of aggregate sales milestone payments upon the achievement of certain annual net sales milestones over the course of the license. We are also obligated to pay Palatin tiered royalties on annual net sales of Vyleesi and any other products containing Vyleesi (collectively, the “Vyleesi Products”), on a product-by-product basis, in the Palatin Territory ranging from the high-single digits to the low double-digits.

In connection with a development and license agreement (the “Antares License Agreement”) with Antares Pharma, Inc. (“Antares”), we are required to pay royalties to Antares on net sales of the Makena auto-injector commencing on the launch of the Makena auto-injector in a particular country until the Makena auto-injector is no longer sold or offered for sale in such country or the Antares License Agreement is terminated (the “Antares Royalty Term”). The royalty rates range from high single digit to low double digits and are tiered based on levels of net sales of the Makena auto-injector and decrease after the expiration of licensed patents or where there are generic equivalents to the Makena auto-injector being sold in a particular country. Antares is also entitled to sales-based milestone payments upon the achievement of certain annual net sales.

Contingencies

Legal Proceedings

We accrue a liability for legal contingencies when we believe that it is both probable that a liability has been incurred and that we can reasonably estimate the amount of the loss. We review these accruals and adjust them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new information is obtained and our views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in our accrued liabilities would be recorded in the period in which such determination is made. For certain matters referenced below, the liability is not probable or the amount cannot be reasonably estimated

and, therefore, accruals have not been made. In addition, in accordance with the relevant authoritative guidance, for any matters in which the likelihood of material loss is at least reasonably possible, we will provide disclosure of the possible loss or range of loss. If a reasonable estimate cannot be made, however, we will provide disclosure to that effect. We expense legal costs as they are incurred.

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Sandoz Patent Infringement Lawsuit

In March 2016, we initiated a patent infringement suit regarding an Abbreviated New Drug Application submitted to the FDA by Sandoz Inc. ("Sandoz") requesting approval to engage in commercial manufacture, use and sale of a generic version of ferumoxytol. On March 23, 2018, we and Sandoz entered a stipulation of dismissal in the United States District Court for the District of New Jersey pursuant to a settlement agreement that dismissed and resolved this action. According to the terms of the settlement, if Sandoz receives FDA approval by a certain date, Sandoz may launch its generic version of Feraheme on July 15, 2021, or earlier under certain circumstances customary for settlement agreements of this nature. Sandoz will pay a royalty on the sales of its generic version of Feraheme to us until the expiration of the last Feraheme patent listed in the Orange Book. If Sandoz is unable to secure approval by such date, Sandoz will launch an authorized generic version of Feraheme on July 15, 2022 for up to twelve months. Sandoz's right to distribute, and our obligation to supply, the authorized generic product shall be in accordance with standard commercial terms and profit splits.

Other

On July 20, 2015, the Federal Trade Commission (the "FTC") notified us that it was conducting an investigation into whether Lumara Health or its predecessor engaged in unfair methods of competition with respect to Makena or any hydroxyprogesterone caproate product. The FTC noted in its letter that the existence of the investigation does not indicate that the FTC has concluded that Lumara Health or its predecessor has violated the law and we believe that our contracts and practices comply with relevant law and policy, including the federal Drug Quality and Security Act (the "DQSA"), which was enacted in November 2013, and public statements from and enforcement actions by the FDA regarding its implementation of the DQSA. We have provided the FTC with a response providing a brief overview of the DQSA for context, which we believe was helpful, including: (a) how the statute outlined that large-scale compounding of products that are copies or near-copies of FDA-approved drugs (like Makena) is not in the interests of public safety; (b) our belief that the DQSA has had a significant impact on the compounding of hydroxyprogesterone caproate; and (c) how our contracts with former compounders allow those compounders to continue to serve physicians and patients with respect to supplying medically necessary alternative/altered forms of hydroxyprogesterone caproate. We believe we have fully cooperated with the FTC and we have had no further interactions with the FTC on this matter since we provided our response to the FTC in August 2015.

On or about April 6, 2016, we received Notice of a Lawsuit and Request to Waive Service of a Summons in a case entitled Plumbers' Local Union No. 690 Health Plan v. Actavis Group et. al. ("Plumbers' Union"), which was filed in the Court of Common Pleas of Philadelphia County, First Judicial District of Pennsylvania and, after removal to federal court, is now pending in the United States District Court for the Eastern District of Pennsylvania (Civ. Action No. 16-65-AB). Thereafter, we were also made aware of a related complaint entitled Delaware Valley Health Care Coalition v. Actavis Group et. al. ("Delaware Valley"), which was filed with the Court of Common Pleas of Philadelphia County, First Judicial District of Pennsylvania District Court of Pennsylvania (Case ID: 160200806). The complaints name K-V Pharmaceutical Company ("KV") (Lumara Health's predecessor company), certain of its successor entities, subsidiaries and affiliate entities (the "Subsidiaries"), along with a number of other pharmaceutical companies. We acquired Lumara Health in November 2014, a year after KV emerged from bankruptcy protection, at which time it, along with its then existing subsidiaries, became our wholly-owned subsidiary. We have not been served with process or waived service of summons in either case. The actions are being brought alleging unfair and deceptive trade practices with regard to certain pricing practices that allegedly resulted in certain payers overpaying for certain of KV's generic products. On July 21, 2016, the Plaintiff in the Plumbers' Union case dismissed KV with prejudice to refiling and on October 6, 2016, all claims against the Subsidiaries were dismissed without prejudice. We are in discussions with Plaintiff's counsel to similarly dismiss all claims in the Delaware Valley case. Because the Delaware Valley case is in the earliest stages and we have not been served with process in this case, we are currently unable to predict the outcome or reasonably estimate the range of potential loss associated with this matter, if any.

We may periodically become subject to other legal proceedings and claims arising in connection with ongoing business activities, including claims or disputes related to patents that have been issued or that are pending in the field of research on which we are focused. Other than the above actions, we are not aware of any material claims against us as of September 30, 2018.

Q. COLLABORATION, LICENSE AND OTHER STRATEGIC AGREEMENTS

Our commercial strategy includes expanding our portfolio through the in-license or acquisition of additional pharmaceutical products or companies, including revenue-generating commercial products and late-state development assets as well as forming alliances with other companies to facilitate the sale and distribution of our products. As of September 30, 2018, we were a party to the following collaborations and license agreements:

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Velo

As described above in Note P, “Commitments and Contingencies,” in September 2018, we exercised our option to acquire the global rights to the AMAG-423 program, which we account for as an asset acquisition under ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business (“ASU 2017-01”).

Prasco

In anticipation of the entry of generic competition to our branded Makena intramuscular product following the February 2018 expiration of Makena’s orphan drug exclusivity, we entered into a Distribution and Supply Agreement (the “Prasco Agreement”) with Prasco, LLC (“Prasco”). The Prasco Agreement grants Prasco an exclusive, non-sublicensable, nontranferable license to purchase, distribute and sell a generic version of Makena in the U.S. In July 2018, following the approval by the FDA of a generic version of the Makena single-dose intramuscular injection in late June 2018, in order to participate in the generic market, we authorized Prasco to launch the authorized generic of both the single-dose and multi-dose intramuscular injection of Makena. Under the Prasco Agreement, we are responsible for the manufacture and supply of the generic Makena product to be sold to Prasco at a predetermined supply price and Prasco is also required to pay us a certain percentage of the net distributable profits from the sale of the generic Makena product. We account for revenue recognized under the Prasco Agreement in accordance with ASC 606. Pursuant to the terms of the Prasco Agreement, in certain circumstances we may be required to pay penalties if we fail to supply a certain percentage of product ordered by Prasco. The Prasco Agreement will continue for a set period of time, including mutually agreed to additional renewals, but is subject to early termination by us for convenience after a certain period of time or if Prasco is subject to a change of control or by either party for, among other things, uncured breach by or bankruptcy of the other party or for lack of commercial viability, FDA notice, or by mutual agreement.

Antares

Through our acquisition of Lumara Health, we are party to the Antares License Agreement, which grants us an exclusive, worldwide, royalty-bearing license, with the right to sublicense, to certain intellectual property rights, including know-how, patents and trademarks, to develop, use, sell, offer for sale and import and export the Makena auto-injector. Under the Antares License Agreement, we are responsible for the clinical development and preparation, submission and maintenance of all regulatory applications in each country where we desire to market and sell the Makena auto-injector, including the U.S. We are required to pay royalties to Antares on net sales of the Makena auto-injector for the Antares Royalty Term. The royalty rates range from high single digit to low double digits and are tiered based on levels of net sales of the Makena auto-injector and decrease after the expiration of licensed patents or where there are generic equivalents to the Makena auto-injector being sold in a particular country. In addition, we are required to pay Antares sales milestone payments upon the achievement of certain annual net sales. The Antares License Agreement terminates at the end of the Antares Royalty Term, but is subject to early termination by us for convenience and by either party upon an uncured breach by or bankruptcy of the other party. In March 2018, the Antares License Agreement was amended to, among other things, transfer the agreement to AMAG from our subsidiary, amend certain confidentiality provisions, and to provide for co-termination with the Antares Manufacturing Agreement (described below).

We are also party to a Manufacturing Agreement with Antares (the “Antares Manufacturing Agreement”) that sets forth the terms and conditions pursuant to which Antares agreed to sell to us on an exclusive basis, and we agreed to purchase, the fully packaged Makena auto-injector for commercial distribution. Antares remains responsible for the manufacture and supply of the device components and assembly of the Makena auto-injector. We are responsible for the supply of the drug to be used in the assembly of the finished auto-injector product. The Antares Manufacturing Agreement terminates at the expiration or earlier termination of the Antares License Agreement, but is subject to early termination by us for certain supply failure situations, and by either party upon an uncured breach by or bankruptcy of the other party or our permanent cessation of commercialization of the Makena auto-injector for efficacy or safety reasons.

Endoceutics

In February 2017, we entered into the Endoceutics License Agreement with Endoceutics. Pursuant to the Endoceutics License Agreement, Endoceutics granted us the right to develop and commercialize pharmaceutical products containing dehydroepiandrosterone ("DHEA"), including Intrarosa, at dosage strengths of 13 mg or less per dose and formulated for intravaginal delivery, excluding any combinations with other active pharmaceutical ingredients, in the U.S. for the treatment of VVA and FSD. The transactions contemplated by the Endoceutics License Agreement closed on April 3, 2017. We accounted for the Endoceutics License Agreement as an asset acquisition under ASU 2017-01. Upon the closing of the Endoceutics License Agreement, we made an upfront payment of $50.0 million and issued 600,000 shares of unregistered common stock to Endoceutics, which had a value of $13.5 million, as measured on April 3, 2017, the

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date of closing. In addition, we paid Endoceutics $10.0 million in the third quarter of 2017 upon the delivery by Endoceutics of Intrarosa launch quantities and $10.0 million in the second quarter of 2018 following the first anniversary of the closing. In the second quarter of 2017, we recorded a total of $83.5 million of consideration, of which $77.7 million was allocated to the Intrarosa developed technology intangible asset and $5.8 million was recorded as IPR&D expense based on their relative fair values.

In addition, we also pay tiered royalties to Endoceutics equal to a percentage of net sales of Intrarosa in the U.S. ranging from mid-teens for calendar year net sales up to $150.0 million to mid twenty percent for any calendar year net sales that exceed $1.0 billion for the commercial life of Intrarosa, with deductions (a) after the later of (i) the expiration date of the last to expire of a licensed patent containing a valid patent claim or (ii) ten years after the first commercial sale of Intrarosa for the treatment of VVA or FSD in the U.S. (as applicable), (b) for generic competition and (c) for third party payments, subject to an aggregate cap on such deductions of royalties otherwise payable to Endoceutics. Endoceutics is also eligible to receive certain sales milestone payments, including a first sales milestone payment of $15.0 million, which would be triggered when Intrarosa annual net U.S. sales exceed $150.0 million, and a second milestone payment of $30.0 million, which would be triggered when annual net U.S. sales of Intrarosa exceed $300.0 million. If annual net U.S. sales of Intrarosa exceed $500.0 million, there are additional sales milestone payments totaling up to $850.0 million, which would be triggered at various sales thresholds.

In the third quarter of 2017, Endoceutics initiated a clinical study to support an application for U.S. regulatory approval for Intrarosa for the treatment of HSDD in post-menopausal women. We and Endoceutics have agreed to share the direct costs related to such studies based upon a negotiated allocation with us funding up to $20.0 million. We may, with Endoceutics' consent (not to be unreasonably withheld, conditioned or delayed), conduct any other studies of Intrarosa for the treatment of VVA and FSD anywhere in the world for the purpose of obtaining or maintaining regulatory approval of or commercializing Intrarosa for the treatment of VVA or FSD in the U.S. All data generated in connection with the above described studies would be owned by Endoceutics and licensed to us pursuant to the Endoceutics License Agreement.

We have the exclusive right to commercialize Intrarosa for the treatment of VVA and FSD in the U.S., subject to the terms of the Endoceutics License Agreement, including having final decision making authority with respect to commercial strategy, pricing and reimbursement and other commercialization matters. We have agreed to use commercially reasonable efforts to market, promote and otherwise commercialize Intrarosa for the treatment of VVA and, if approved, FSD in the U.S. Endoceutics has the right to directly conduct additional commercialization activities for Intrarosa for the treatment of VVA and FSD in the U.S. and has the right to conduct activities related generally to the field of intracrinology, in each case, subject to our review and approval and our right to withhold approval in certain instances. Each party's commercialization activities and budget are described in a commercialization plan, which is updated annually.

In April 2017, we entered into an exclusive commercial supply agreement with Endoceutics pursuant to which Endoceutics, itself or through affiliates or contract manufacturers, agreed to manufacture and supply Intrarosa to us (the "Endoceutics Supply Agreement") and will be our exclusive supplier of Intrarosa in the U.S., subject to certain rights for us to manufacture and supply Intrarosa in the event of a cessation notice or supply failure (as such terms are defined in the Endoceutics Supply Agreement). Under the Endoceutics Supply Agreement, Endoceutics has agreed to maintain at all times a second source supplier for the manufacture of DHEA and the drug product and to identify, validate and transfer manufacturing intellectual property to the second source supplier by April 2019. The Endoceutics Supply Agreement will remain in effect until the termination of the Endoceutics License Agreement, unless terminated earlier by either party for an uncured material breach or insolvency of the other party, or by us if we exercise our rights to manufacture and supply Intrarosa following a cessation notice or supply failure.

The Endoceutics License Agreement expires on the date of expiration of all royalty obligations due thereunder unless earlier terminated in accordance with the Endoceutics License Agreement.

Palatin

In January 2017, we entered into the Palatin License Agreement with Palatin under which we acquired (a) an exclusive license in all countries of North America (the "Palatin Territory"), with the right to grant sub-licenses, to research, develop and commercialize the Vyleesi Products, an investigational product designed to be a treatment for

HSDD in pre-menopausal women, (b) a worldwide non-exclusive license, with the right to grant sub-licenses, to manufacture the Vyleesi Products, and (c) a non-exclusive license in all countries outside the Palatin Territory, with the right to grant sub-licenses, to research and develop (but not commercialize) the Vyleesi Products. The transaction closed in February 2017 and was accounted for as an asset acquisition under ASU 2017-01.

Under the terms of the Palatin License Agreement, in February 2017 we paid Palatin $60.0 million as a one-time upfront payment and subject to agreed-upon deductions reimbursed Palatin approximately $25.0 million for reasonable, documented, out-of-pocket expenses incurred by Palatin in connection with the development and regulatory activities necessary to submit an

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NDA in the U.S. for Vyleesi for the treatment of HSDD in pre-menopausal women. During 2017, we fulfilled these payment obligations to Palatin. The $60.0 million upfront payment made in February 2017 to Palatin was recorded as IPR&D expense as the product candidate had not received regulatory approval. In June 2018, our NDA submission to the FDA for Vyleesi was accepted, which triggered the payment of a $20.0 million milestone obligation, which we paid in the second quarter of 2018 and recorded as an IPR&D expense in the first quarter of 2018 when acceptance was deemed probable.

In addition, the Palatin License Agreement requires us to make contingent payments of (a) $60.0 million upon FDA approval of Vyleesi, and (b) up to $300.0 million of aggregate sales milestone payments upon the achievement of certain annual net sales milestones over the course of the license. The first sales milestone payment of $25.0 million will be triggered when Vyleesi annual net sales exceed $250.0 million. We are also obligated to pay Palatin tiered royalties on annual net sales in North America of the Vyleesi Products, on a product-by-product basis, in the Palatin Territory ranging from the high-single digits to the low double-digits. The royalties will expire on a product-by-product and country-by-country basis upon the latest to occur of (a) the earliest date on which there are no valid claims of Palatin patent rights covering such Vyleesi Product in such country, (b) the expiration of the regulatory exclusivity period for such Vyleesi Product in such country and (c) 10 years following the first commercial sale of such Vyleesi Product in such country. These royalties are subject to reduction in the event that: (a) we must license additional third-party intellectual property in order to develop, manufacture or commercialize a Vyleesi Product or (b) generic competition occurs with respect to a Vyleesi Product in a given country, subject to an aggregate cap on such deductions of royalties otherwise payable to Palatin. After the expiration of the applicable royalties for any Vyleesi Product in a given country, the license for such Vyleesi Product in such country would become a fully paid-up, royalty-free, perpetual and irrevocable license. The Palatin License Agreement expires on the date of expiration of all royalty obligations due thereunder, unless earlier terminated in accordance with the Palatin License Agreement.

R. DEBT

Our outstanding debt obligations as of September 30, 2018 and December 31, 2017 consisted of the following (in thousands):

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| 2023 Senior Notes | $— | $466,291 |
| 2022 Convertible Notes | 258,376 | 248,194 |
| 2019 Convertible Notes | 20,999 | 20,198 |
| Total long-term debt | 279,375 | 734,683 |
| Less: current maturities | (20,999) | — |
| Long-term debt, net of current maturities | $258,376 | $734,683 |

2023 Senior Notes

In August 2015, in connection with the CBR acquisition, we completed a private placement of $500.0 million aggregate principal amount of 7.875% Senior Notes due 2023 (the “2023 Senior Notes”). The 2023 Senior Notes were issued pursuant to an Indenture, dated as of August 17, 2015 (the “Indenture”), by and among us, certain of our subsidiaries acting as guarantors of the 2023 Senior Notes and Wilmington Trust, National Association, as trustee. In October 2017, we repurchased $25.0 million of the 2023 Senior Notes in a privately negotiated transaction, resulting in a loss on extinguishment of debt of $1.1 million. In September 2018, we repurchased the remaining $475.0 million of the 2023 Senior Notes at a premium of $28.1 million using the proceeds from the CBR sale, which resulted in a loss on extinguishment of debt of $35.9 million, inclusive of the premium paid.

Convertible Notes

The outstanding balances of our Convertible Notes as of September 30, 2018 consisted of the following (in thousands):

| | 2022 Convertible Notes | 2019 Convertible Notes | Total |
|---|---|---|---|
| Liability component: | | | |
| Principal | $ 320,000 | $ 21,417 | $341,417 |
| Less: debt discount and issuance costs, net | 61,624 | 418 | 62,042 |
| Net carrying amount | $ 258,376 | $ 20,999 | $279,375 |
| Equity Component | $ 72,576 | $ 9,905 | $82,481 |

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In accordance with accounting guidance for debt with conversion and other options, we separately account for the liability and equity components of our Convertible Notes by allocating the proceeds between the liability component and the embedded conversion option (the "Equity Component") due to our ability to settle the Convertible Notes in cash, common stock or a combination of cash and common stock, at our option. The carrying amount of the liability components was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected our non-convertible debt borrowing rate for similar debt. The Equity Component of the Convertible Notes was recognized as a debt discount and represents the difference between the proceeds from the issuance of the Convertible Notes and the fair value of the liability of the Convertible Notes on their respective dates of issuance. The excess of the principal amount of the liability component over its carrying amount is amortized to interest expense using the effective interest method over five years. The Equity Component is not remeasured as long as it continues to meet the conditions for equity classification.

2022 Convertible Notes

In the second quarter of 2017, we issued $320.0 million aggregate principal amount of convertible senior notes due in 2022 (the "2022 Convertible Notes") and received net proceeds of $310.4 million from the sale of the 2022 Convertible Notes, after deducting fees and expenses of $9.6 million. The approximate $9.6 million of debt issuance costs primarily consisted of underwriting, legal and other professional fees, and we allocated these costs to the liability and equity components based on the allocation of the proceeds. Of the total $9.6 million of debt issuance costs, $2.2 million was allocated to the Equity Component and recorded as a reduction to additional paid-in capital and $7.4 million was allocated to the liability component and is now recorded as a reduction of the 2022 Convertible Notes in our condensed consolidated balance sheets. The portion allocated to the liability component is amortized to interest expense using the effective interest method over five years.

The 2022 Convertible Notes are governed by the terms of an indenture between us, as issuer, and Wilmington Trust, National Association, as the trustee. The 2022 Convertible Notes are senior unsecured obligations and bear interest at a rate of 3.25% per year, payable semi-annually in arrears on June 1 and December 1 of each year, beginning on December 1, 2017. The 2022 Convertible Notes will mature on June 1, 2022, unless earlier repurchased or converted. Upon conversion of the 2022 Convertible Notes, such 2022 Convertible Notes will be convertible into, at our election, cash, shares of our common stock, or a combination thereof, at a conversion rate of 36.5464 shares of common stock per $1,000 principal amount of the 2022 Convertible Notes, which corresponds to an initial conversion price of approximately $27.36 per share of our common stock.

The conversion rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the issuance of stock dividends and payment of cash dividends. At any time prior to the close of business on the business day immediately preceding March 1, 2022, holders may convert their 2022 Convertible Notes at their option only under the following circumstances:

1) during any calendar quarter (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;

2) during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price per $1,000 principal amount of the 2022 Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; or

3) upon the occurrence of specified corporate events.

On or after March 1, 2022, until the close of business on the business day immediately preceding the maturity date, holders may convert all or any portion of their 2022 Convertible Notes, in multiples of $1,000 principal amount, at the option of the holder regardless of the foregoing circumstances. The 2022 Convertible Notes were not convertible as of September 30, 2018.

We determined the expected life of the debt was equal to the five-year term on the 2022 Convertible Notes. The effective interest rate on the liability component was 9.49% for the period from the date of issuance through September 30, 2018. As of September 30, 2018, the "if-converted value" did not exceed the remaining principal amount

of the 2022 Convertible Notes.

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2019 Convertible Notes

In February 2014, we issued $200.0 million aggregate principal amount of the 2019 Convertible Notes. We received net proceeds of $193.3 million from the sale of the 2019 Convertible Notes, after deducting fees and expenses of $6.7 million. We used $14.1 million of the net proceeds from the sale of the 2019 Convertible Notes to pay the cost of the convertible bond hedges, as described below (after such cost was partially offset by the proceeds to us from the sale of warrants in the warrant transactions described below). In May 2017 and September 2017, we entered into privately negotiated transactions with certain investors to repurchase approximately $158.9 million and $19.6 million, respectively, aggregate principal amount of the 2019 Convertible Notes for an aggregate repurchase price of approximately $171.3 million and $21.4 million, respectively, including accrued interest. Pursuant to ASC Topic 470, Debt, the accounting for the May 2017 repurchase of the 2019 Convertible Notes was evaluated on a creditor-by-creditor basis with regard to the 2022 Convertible Notes to determine modification versus extinguishment accounting. We concluded that the May 2017 repurchase of the 2019 Convertible Notes should be accounted for as an extinguishment and we recorded a debt extinguishment gain of $0.2 million related to the difference between the consideration paid, the fair value of the liability component and carrying values at the repurchase date. As a result of the September 2017 repurchase of the 2019 Convertible Notes, we recorded a debt extinguishment loss of $0.3 million related to the difference between the consideration paid, the fair value of the liability component and carrying value at the repurchase date.

The 2019 Convertible Notes are governed by the terms of an indenture between us, as issuer, and Wilmington Trust, National Association, as the trustee. The 2019 Convertible Notes are senior unsecured obligations and bear interest at a rate of 2.5% per year, payable semi-annually in arrears on February 15 and August 15 of each year. The 2019 Convertible Notes will mature on February 15, 2019 unless earlier repurchased or converted. Upon conversion of the remaining 2019 Convertible Notes, such 2019 Convertible Notes will be convertible into, at our election, cash, shares of our common stock, or a combination thereof, at a conversion rate of 36.9079 shares of common stock per $1,000 principal amount of the 2019 Convertible Notes, which corresponds to an initial conversion price of approximately $27.09 per share of our common stock.

The conversion rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the issuance of stock dividends and payment of cash dividends. Beginning on or after May 15, 2018 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert all or any portion of their 2019 Convertible Notes, in multiples of $1,000 principal amount, at the option of the holder. The 2019 Convertible Notes were convertible as of September 30, 2018.

We determined the expected life of the debt was equal to the five-year term of the 2019 Convertible Notes. The effective interest rate on the liability component was 7.79% for the period from the date of issuance through September 30, 2018. As of September 30, 2018, the “if-converted value” did not exceed the remaining principal amount of the 2019 Convertible Notes.

Convertible Notes Interest Expense

The following table sets forth total interest expense recognized related to the Convertible Notes during the three and nine months ended September 30, 2018 and 2017 (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Contractual interest expense | $2,734 | $2,840 | $8,202 | $6,033 |
| Amortization of debt issuance costs | 355 | 348 | 1,040 | 944 |
| Amortization of debt discount | 3,391 | 3,264 | 9,942 | 7,909 |
| Total interest expense | $6,480 | $6,452 | $19,184 | $14,886 |

Convertible Bond Hedge and Warrant Transactions

In connection with the pricing of the 2019 Convertible Notes and in order to reduce the potential dilution to our common stock and/or offset cash payments due upon conversion of the 2019 Convertible Notes, in February 2014, we entered into convertible bond hedge transactions and separate warrant transactions of our common stock underlying

the aggregate principal amount of the 2019 Convertible Notes with the call spread counterparties. In connection with the May 2017 and September 2017 repurchases of the 2019 Convertible Notes, as discussed above, we entered into agreements with the call spread counterparties to terminate a portion of the then existing convertible bond hedge transactions in an amount corresponding to the amount of such 2019 Convertible Notes repurchased and to terminate a portion of the then-existing warrant transactions.

As of September 30, 2018, the remaining bond hedge transactions covered approximately 0.8 million shares of our common stock underlying the remaining $21.4 million principal amount of the 2019 Convertible Notes. The convertible bond

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hedges have an exercise price of approximately $27.09 per share, subject to adjustment upon certain events, and are exercisable when and if the 2019 Convertible Notes are converted. If upon conversion of the 2019 Convertible Notes, the price of our common stock is above the exercise price of the convertible bond hedges, the call spread counterparties will deliver shares of our common stock and/or cash with an aggregate value equal to the approximate difference between the price of our common stock at the conversion date and the exercise price, multiplied by the number of shares of our common stock underlying the convertible bond hedges being exercised. The convertible bond hedges were separate transactions entered into by us and were not part of the terms of the 2019 Convertible Notes or the warrants, discussed below. Holders of the 2019 Convertible Notes will not have any rights with respect to the convertible bond hedges.

As of September 30, 2018, the remaining warrant transactions covered approximately 1.0 million shares of our common stock underlying the remaining $21.4 million principal amount of the 2019 Convertible Notes. The initial exercise price of the warrants is $34.12 per share, subject to adjustment upon certain events, which was 70% above the last reported sale price of our common stock of $20.07 on February 11, 2014. The warrants would separately have a dilutive effect to the extent that the market value per share of our common stock, as measured under the terms of the warrants, exceeds the applicable exercise price of the warrants. The warrants were issued to the call spread counterparties pursuant to the exemption from registration set forth in Section 4(a)(2) of the Securities Act of 1933, as amended.

Future Payments

Future annual principal payments on our long-term debt as of September 30, 2018 were as follows (in thousands):

| Period | Future Annual Principal Payments |
|---|---|
| Remainder of Year Ending December 31, 2018 | $— |
| Year Ending December 31, 2019 | 21,417 |
| Year Ending December 31, 2020 | — |
| Year Ending December 31, 2021 | — |
| Year Ending December 31, 2022 | 320,000 |
| Thereafter | — |
| Total | $341,417 |

S. RECENTLY ISSUED AND PROPOSED ACCOUNTING PRONOUNCEMENTS

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”) or other standard setting bodies that are adopted by us as of the specified effective date.

In August 2018, the FASB issued ASU No. 2018-13, Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement (“ASU 2018-13”). This standard eliminates, adds and modifies certain disclosure requirements for fair value measurements as part of its disclosure framework project. ASU 2018-13 is effective for annual reporting periods beginning after December 15, 2019 and interim periods within those annual periods and early adoption is permitted. We are currently evaluating the impact of our adoption of ASU 2018-13 on our condensed consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”). This standard requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. ASU 2016-13 will be effective for us for fiscal years beginning on or after January 1, 2020, including interim periods within those annual reporting periods and early adoption is permitted. We are currently evaluating the impact of our adoption of ASU 2016-13 on our condensed consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (“ASU 2016-02”). This standard requires entities to recognize on its balance sheet assets and liabilities associated with the rights and obligations created by leases with terms greater than twelve months. This statement is effective for annual reporting periods beginning after December 15, 2018 and interim periods within those annual periods and early adoption is permitted. As of September

30, 2018 we have completed our identification of the population of leases. Our next phase of implementation will include calculation of the financial statement impact of adoption. We currently expect to recognize material operating lease liabilities and right-of-use assets related to our current operating lease commitments upon our adoption of ASU 2016-02 on January 1, 2019. In addition, we are evaluating our internal control framework and required disclosures to identify any changes that may need to be made in response to the new guidance.

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T. RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash ("ASU 2016-18"), which requires amounts generally described as restricted cash and restricted cash equivalents to be included with cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. We adopted the standard on January 1, 2018 using the retrospective approach and modified the presentation of our condensed consolidated statements of cash flows in accordance with the standard. The adoption of ASU 2016-18 did not have a material impact on our condensed consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments ("ASU 2016-15"). This standard clarifies certain aspects of the statement of cash flows, including the classification of debt prepayment or debt extinguishment costs or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate owned life insurance policies, distributions received from equity method investees and beneficial interests in securitization transactions. This new standard also clarifies that an entity should determine each separately identifiable source or use within the cash receipts and payments on the basis of the nature of the underlying cash flows. In situations in which cash receipts and payments have aspects of more than one class of cash flows and cannot be separated by source or use, the appropriate classification should depend on the activity that is likely to be the predominant source or use of cash flows for the item. We adopted the standard on January 1, 2018 using the retrospective approach. ASU 2016-15 did not have a material impact on our condensed consolidated financial statements upon adoption.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-01"). This new standard amends certain aspects of accounting and disclosure requirements of financial instruments, including the requirement that equity investments with readily determinable fair values be measured at fair value with changes in fair value recognized in our results of operations. This new standard does not apply to investments accounted for under the equity method of accounting or those that result in consolidation of the investee. Equity investments that do not have readily determinable fair values may be measured at fair value or at cost minus impairment adjusted for changes in observable prices. A financial liability that is measured at fair value in accordance with the fair value option is required to be presented separately in other comprehensive income for the portion of the total change in the fair value resulting from change in the instrument-specific credit risk. In addition, a valuation allowance should be evaluated on deferred tax assets related to available-for-sale debt securities in combination with other deferred tax assets. We adopted the standard on January 1, 2018 using the modified retrospective approach. The adoption of ASU 2016-01 did not have a material impact on our condensed consolidated financial statements.

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

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2017 (our "Annual Report").

Except for the historical information contained herein, the matters discussed in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In this Quarterly Report on Form 10-Q terminology such as "may," "will," "could," "should," "would," "expect," "anticipate," "continue," "believe," "plan," "estimate," "intend" or other similar words and expressions (as well as ot words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Examples of forward-looking statements contained in this report include, without limitation, statements regarding the following: plans to continue to expand the impact of our current and future products for patients by delivering on our

growth strategy; plans for our product candidates, including timing for data release and regulatory submissions; the timing of additional generic competition to the Makena intramuscular ("IM") product and the impact of generic competition on sales and rebates; expectations related to our filing of a supplemental New Drug Application ("NDA") for the treatment of HSDD in post-menopausal women with Intrarosa; anticipated clinical, developmental, regulatory and other undertakings and cooperation efforts by our licensing parties; the impact and benefits of the CBR disposition and transitional services; expectations regarding our intellectual property, including patent protection and related litigation, and the impact and timing that generic and other competition could have on our business; beliefs regarding the intellectual property of our licensing and collaboration partners, and our rights to such property; the market opportunities for each of our products; plans regarding our sales and marketing initiatives; expectations regarding our future sales of Feraheme, Intrarosa and Makena; the impact of our

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license and collaboration agreements on our results of operations; our expectation of costs to be incurred in connection with, and revenue sources to fund, our future operations; our expectations regarding the contribution of revenues from our products to the funding of our ongoing operations; expectations regarding the manufacture of all drug substance, drug products and key materials at our third-party manufacturers or suppliers; our expectations regarding customer returns and other revenue-related reserves and accruals; estimates regarding our effective tax rate and our ability to realize our net operating loss carryforwards and other tax attributes; the impact of accounting pronouncements; expectations regarding our financial results, including revenues, product sales allowances and accruals, cost of product sales, research and development expenses, selling, general and administrative expenses, amortization and other income (expense); our investing activities and the impact of our operations on our cash, cash equivalents and marketable securities balances; our belief that our cash, cash equivalents and marketable securities as of September 30, 2018, and the cash we currently expect to receive, will be sufficient to satisfy our cash flow needs for the foreseeable future (including the remainder of 2018); our expectation that our anticipated spending as we enter 2019 may exceed our expected revenues; expectations related to the timing and amounts of milestone payments to former Lumara Health security holders, Palatin, Endoceutics and Velo; estimates and beliefs related to our debt; the valuation of certain intangible assets, goodwill, contingent consideration, debt and other assets and liabilities, including our methodology and assumptions regarding fair value measurements; the manner in which we intend or are required to settle the conversion of our 2022 Convertible Notes and 2019 Convertible Notes; the timing and amounts (if any) of share repurchases; and our expectations for our cash, revenue, cash equivalents, marketable securities balances, capital needs and information with respect to any other plans and strategies for our business. Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements.

Any forward-looking statement should be considered in light of the factors discussed in Part II, Item 1A below under “Risk Factors” in this Quarterly Report on Form 10-Q and in Part I, Item 1A in our Annual Report. We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the U.S. Securities and Exchange Commission, to publicly update or revise any such statements to reflect any change in company expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a pharmaceutical company focused on bringing innovative products to patients with unmet medical needs. We do this by leveraging our development and commercial expertise to invest in and grow our pharmaceutical products across a range of therapeutic areas, including women’s health. Our currently marketed products support the health of patients in the areas of maternal and women’s health, anemia management and cancer supportive care, including Makena® (hydroxyprogesterone caproate injection), Intrarosa® (prasterone) vaginal inserts, Feraheme® (ferumoxytol injection) for intravenous (“IV”) use, and MuGard® Mucoadhesive Oral Wound Rinse. In addition to our marketed products, our portfolio includes two product candidates, Vyleesi™ (bremelanotide), which is being developed for the treatment of hypoactive sexual desire disorder (“HSDD”) in pre-menopausal women and digoxin immune Fab (ovine) (now referred to as AMAG-423), which is being studied for the treatment of severe preeclampsia.

Since August 2015, we had provided services related to the preservation of umbilical cord blood stem cell and cord tissue units operated through Cord Blood Registry® (“CBR”). On August 6, 2018, we completed the sale of our wholly-owned subsidiary, CBR Acquisition Holdings Corp, and the CBR business to GI Chill Acquisition LLC, an affiliate of GI Partners, a private equity investment firm (together “GI”) pursuant to the June 14, 2018 Stock Purchase Agreement between us and GI. We received $519.3 million in cash at closing and recognized a gain of $89.6 million on the sale during the three and nine months ended September 30, 2018. For additional information, see Note C “Discontinued Operations and Held for Sale” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

We intend to expand the impact of our current and future products for patients by delivering on our growth strategy, which includes collaborating on and acquiring promising therapies at various stages of development, and advancing them through the clinical and regulatory process to deliver new treatment options to patients. Our primary sources of revenue are from product sales of Makena, Feraheme and Intrarosa. Except as otherwise stated below, the following discussions of our results of operations reflect the results of our continuing operations, excluding the results related to the CBR business. The CBR business has been separated from continuing operations and reflected as a discontinued operation. See Note C, “Discontinued Operations and Held for Sale” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

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AMAG's Portfolio of Products and Product Candidates

AMAG-423

In September 2018, we exercised our option to acquire the global rights to AMAG-423 pursuant to an option agreement entered into in July 2015 with Velo Bio, LLC, a privately-held life sciences company ("Velo"), the terms of which were amended at the time of exercise. AMAG-423 is a polyclonal antibody currently in clinical development for the treatment of severe preeclampsia in pregnant women and has been granted both orphan drug and fast-track review designations by the U.S. Food and Drug Administration (the "FDA"). In connection with the exercise of the option and the consummation of the acquisition, we paid Velo an upfront option exercise fee of $12.5 million in September 2018, which was recorded in acquired in-process research and development ("IPR&D") expense. See Note P, "Commitments and Contingencies," to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for more information on the AMAG-423 acquisition.

Preeclampsia is a multi-system disorder that occurs only during pregnancy and the postpartum period and affects both the mother and baby. Preeclampsia is the leading cause of maternal morbidity and mortality and typically develops in women after 20 weeks of pregnancy and is characterized by elevated blood pressure, as well as vascular abnormalities, that can lead to end organ damage, intrauterine growth restriction and premature delivery. Premature delivery can lead to a number of serious health consequences for the infant, including intraventricular hemorrhage (bleeding in the brain) or necrotizing enterocolitis (severe inflammation of the infant bowels). Approximately 140,000 pregnant women in the U.S. are affected by preeclampsia, with approximately 50,000 impacted by severe preeclampsia, a more serious form of the condition that can be life threatening to both the mother and the baby. There are currently no effective treatments that address the underlying condition, rather treatments include medications to address the symptoms, such as antihypertensives and early delivery of the baby.

We have assumed responsibility to complete the Phase 2b/3a clinical study that Velo initiated in the second quarter of 2017 and will incur the necessary clinical, regulatory and other costs required to pursue FDA approval. Approximately 200 antepartum women with severe preeclampsia between 23 and 32 weeks gestation will be enrolled in the multi-center, randomized, double-blind, placebo-controlled, parallel-group Phase 2b/3a study, including the 26 patients who were enrolled prior to the transfer of the study to us. No additional patients will be enrolled during the study transition, and we expect to re-initiate new patient enrollment in early 2019. Participants in the study will receive AMAG-423 or placebo intravenously four times a day over four days. The study's primary endpoint is to demonstrate a reduction in the percentage of babies who develop severe intraventricular hemorrhage, necrotizing enterocolitis or death by 36 weeks corrected gestational age between the AMAG-423 and placebo arms. Secondary endpoints include the maternal incidence of pulmonary edema during treatment and the period of time between treatment and delivery.

Vyleesi

In January 2017, we entered into a license agreement with Palatin Technologies, Inc. ("Palatin") pursuant to which Palatin granted us the North American rights to research, develop and commercialize Vyleesi (previously referred to as bremelanotide), which is being developed for the treatment of HSDD in pre-menopausal women. Vyleesi is designed to be an on demand therapy used in anticipation of sexual activity and self-administered by the patient in the thigh or abdomen via a single-use subcutaneous auto-injector. Two Phase 3 studies conducted by Palatin for the treatment of HSDD in pre-menopausal women met the pre-specified co-primary efficacy endpoints of improvement in desire and decrease in distress associated with low sexual desire as measured using validated patient-reported outcome instruments. Each trial consisted of over 600 patients randomized in a 1:1 ratio to either the treatment arm or placebo arm, each with a 24 week evaluation period. The most frequent adverse events were nausea, flushing and headache, which were generally mild-to-moderate in severity and were transient. Approximately 17% of patients discontinued participation in the Vyleesi arm due to adverse events in both studies versus 2% in placebo. Women in the trials had the option, after completion of the randomized trial, to continue in an ongoing open-label safety extension study for an additional 52 weeks, which gathered additional data on the safety of long-term and repeated use of Vyleesi. Nearly 80% of patients who completed the randomized portion of the study elected to remain in the open-label portion of the study. All of the patients in the extension study, which was completed in 2017, received Vyleesi.

In June 2018, the FDA accepted the New Drug Application ("NDA") for Vyleesi for the treatment of HSDD in pre-menopausal women. The Prescription Drug User Fee Act ("PDUFA") date for completion of FDA review of the Vyleesi NDA is March 23, 2019 and we expect an Advisory Committee meeting for Vyleesi to be held in January 2019. Additional details regarding the license with Palatin (the "Palatin License Agreement") can be found in Note Q, "Collaboration, License and Other Strategic Agreements," to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

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Makena

Makena is indicated to reduce the risk of preterm birth in women pregnant with a single baby who have a history of singleton spontaneous preterm birth. We acquired the rights to Makena in connection with our acquisition of Lumara Health Inc. in November 2014. Makena was approved by the FDA in February 2011 as an intramuscular ("IM") injection (the "Makena IM product") packaged in a multi-dose vial and in February 2016 as a single-dose preservative-free vial. The orphan drug exclusivity period that was granted to the Makena IM product in 2011 expired in February 2018. In July 2018, we launched our own authorized generic of both the single- and multi-dose vials through our generic partner, Prasco, LLC. As a result of this partnership, we are able to provide patients and healthcare providers with access to therapeutically equivalent versions of the branded Makena IM injection.

In February 2018, Makena was approved by the FDA for administration via a pre-filled subcutaneous auto-injector (the "Makena auto-injector"), a drug-device combination product. The Makena auto-injector offers an alternative administration option for patients and providers and was designed with features, such as a shorter, thinner, non-visible needle compared to the Makena IM product, to help address some of the known barriers to treatment of recurrent preterm birth, including the lack of patient acceptance and adherence. Our commercial strategy for Makena currently focuses on driving awareness of the availability and benefits of the Makena auto-injector and converting current IM prescribers to the Makena auto-injector.

Feraheme

Feraheme was approved for marketing by the FDA in June 2009 for the treatment of iron deficiency anemia ("IDA") in adult patients with chronic kidney disease ("CKD") only and was launched commercially shortly thereafter. In February 2018, we received FDA approval to expand the Feraheme label to treat all eligible adult IDA patients who have intolerance to oral iron or have had unsatisfactory response to oral iron in addition to patients who have CKD. IDA is widely prevalent in many different patient populations, such as patients with gastrointestinal disease, cancer and chemotherapy-induced anemia or abnormal uterine bleeding. For many of these patients, treatment with oral iron is unsatisfactory or is not tolerated. It is estimated that more than 4.5 million people in the U.S. have IDA (CKD and non-CKD) and we estimate that a small fraction of the patients who are diagnosed with IDA regardless of the underlying cause are currently being treated with IV iron.

The recently expanded Feraheme label is supported by two positive pivotal Phase 3 trials which evaluated Feraheme versus iron sucrose or placebo in a broad population of patients with IDA. It was also supported by positive results from a third Phase 3 randomized, double-blind non-inferiority trial that evaluated the incidence of moderate-to-severe hypersensitivity reactions (including anaphylaxis) and moderate-to-severe hypotension with Feraheme compared to Injectafer® (ferric carboxymaltose injection) (the "Feraheme comparator trial"). This Feraheme comparator trial demonstrated non-inferiority to Injectafer® based on the primary endpoint of the incidence of moderate-to-severe hypersensitivity reactions (including anaphylaxis) and moderate-to-severe hypotension (Feraheme incidence 0.6%; Injectafer® incidence 0.7%). Adverse event rates were similar across both treatment groups; however, the incidence of severe hypophosphatemia (defined by blood phosphorous of <0.6 mmol/L at week 2) was less in the patients receiving Feraheme (0.4% of patients) compared to those receiving Injectafer® (38.7% of patients).

Intrarosa

In February 2017, we entered into a license agreement (the "Endoceutics License Agreement") with Endoceutics, Inc. ("Endoceutics") pursuant to which Endoceutics granted us rights to Intrarosa, an FDA-approved product for the treatment of moderate to severe dyspareunia (pain during sexual intercourse), a symptom of vulvar and vaginal atrophy ("VVA"), due to menopause.

Intrarosa was approved by the FDA in November 2016 and was launched commercially in July 2017. Intrarosa is the only FDA-approved, vaginally administered, daily steroid, which is prescribed for the treatment of moderate to severe dyspareunia, a symptom of VVA, due to menopause. The effectiveness of Intrarosa on moderate to severe dyspareunia in post-menopausal women was examined in two primary 12-week placebo-controlled efficacy trials. All women in both studies were assessed for improvement from baseline to week 12 for four co-primary efficacy endpoints: (a) most bothersome symptom (moderate to severe dyspareunia), (b) the percentage of vaginal superficial cells, (c) the

percentage of parabasal cells, and (d) vaginal pH. All primary endpoints were statistically significant. Women taking Intrarosa experienced a significant reduction in moderate to severe dyspareunia, as well as statistically significant improvements in the percentage of vaginal superficial cells, parabasal cells and vaginal pH.

Endoceutics initiated a clinical study in the third quarter of 2017 to support an application for U.S. regulatory approval of Intrarosa for the treatment of hypoactive sexual desire disorder (“HSDD”) in post-menopausal women. We and Endoceutics have agreed to share the direct costs related to two Phase 3 clinical studies based upon a negotiated allocation with us funding up to $20.0 million, including the HSDD trial. If the studies are successful, we will file a supplemental New Drug Application

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with the FDA for the treatment of HSDD in post-menopausal women. Furthermore, each party's commercialization activities and budget are described in a commercialization plan, which is updated annually. Additional details regarding the Endoceutics License Agreement can be found in Note Q, "Collaboration, License and Other Strategic Agreements," to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Critical Accounting Policies

Except as described in Note B, "Basis of Presentation and Summary of Significant Accounting Policies," and Note D, "Revenue Recognition," to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, with respect to changes in our revenue recognition policy related to our adoption of the requirements of Accounting Standards Codification Topic 606, Revenue from Contracts with Customers, there have been no significant changes to our critical accounting policies and estimates during the nine months ended September 30, 2018, compared to the critical accounting policies and estimates disclosed in Part II, Item 7, of our Annual Report.

Results of Operations - Three Months Ended September 30, 2018 and 2017

Revenues

Total revenues for the three months ended September 30, 2018 and 2017 consisted of the following (in thousands except for percentages):

| | Three Months Ended September 30, | | 2018 to 2017 | |
|---|---|---|---|---|
| | 2018 | 2017 | $ Change | % Change |
| Product sales, net | | | | |
| Makena | $80,221 | $97,635 | $(17,414) | (18)% |
| Feraheme | 36,963 | 26,095 | 10,868 | 42 % |
| Intrarosa | 4,925 | 360 | 4,565 | >100 % |
| MuGard | 129 | 241 | (112) | (46)% |
| Total revenues | $122,238 | $124,331 | $(2,093) | (2)% |

Net product sales decreased by $2.1 million, or approximately 2%, during the three months ended September 30, 2018 as compared to the same period in 2017. The $17.4 million decrease in Makena net sales was primarily impacted by a supply disruption of our IM products, as discussed further below, and the entry of generic competition. The decrease of total revenues was partially offset by a $10.9 million increase in Feraheme net sales following the approval of its expanded label in February 2018 and a $4.6 million increase in Intrarosa net sales, which was launched commercially in July 2017.

Product Sales

Total gross product sales were offset by product sales allowances and accruals for the three months ended September 30, 2018 and 2017 as follows (in thousands, except for percentages):

| | Three Months Ended September 30, | | | | | | 2018 to 2017 | | |
|---|---|---|---|---|---|---|---|---|---|
| | 2018 | Percent of gross product sales | | 2017 | Percent of gross product sales | | $ Change | % Change | |
| Gross product sales | $238,856 | | | $235,299 | | | $3,557 | 2 | % |
| Provision for product sales allowances and accruals: | | | | | | | | | |
| Contractual adjustments | 93,213 | 39 | % | 80,110 | 34 | % | 13,103 | 16 | % |
| Governmental rebates | 23,405 | 10 | % | 30,858 | 13 | % | (7,453) | (24)% | |
| Total | 116,618 | 49 | % | 110,968 | 47 | % | 5,650 | 5 | % |

| | | | | |
|---|---|---|---|---|
| Product sales, net | $122,238 | $124,331 | $(2,093) | (2)% |

We expect that sales of Feraheme, Intrarosa and the Makena auto-injector will increase for the remainder of 2018 and throughout 2019. In addition, we expect overall Makena net sales to continue to decline due to (i) volume and pricing pressure as a result of current generic competition to Makena, (ii) the expectation of additional generic competitors in the market and (iii) continued manufacturing-related issues. As previously disclosed, we continue to experience delays at our third-party manufacturer, which has resulted in our single-dose vial being out of stock and we expect will result in an out of stock situation

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for our multi-dose vial in the near future. We are attempting to mitigate this supply issue by manufacturing at our secondary supplier; however, we anticipate that revenues for the IM products will continue to decrease. We expect that such decline will be partially offset by Makena auto-injector sales. The continued impact of generic competition to our Makena sales is dependent on the timing, number and behavior of current and future generic competitors.

Product Sales Allowances and Accruals

We record product revenue net of certain allowances and accruals in our condensed consolidated statements of operations. Our contractual adjustments include provisions for returns, pricing and prompt payment discounts, as well as wholesaler distribution fees, rebates to hospitals that qualify for 340B pricing, and volume-based and other commercial rebates and other discounts. Governmental rebates relate to our reimbursement arrangements with state Medicaid programs. The increases in contractual adjustments as a percentage of gross product sales for the three months ended September 30, 2018 as compared to the same period in 2017 primarily related to a higher mix of business through commercial reimbursement channels and additional discounts offered to commercial entities. The decreases in governmental rebates as a percentage of gross product sales for the three months ended September 30, 2018 as compared to the same period in 2017 are primarily related to a shift in the mix of business.

We did not materially adjust our product sales allowances and accruals during the three months ended September 30, 2018 or 2017. If we determine in future periods that our actual experience is not indicative of our expectations, if our actual experience changes, or if other factors affect our estimates, we may be required to adjust our allowances and accruals estimates, which would affect our net product sales in the period of the adjustment and could be significant.

Costs and Expenses

Cost of Product Sales

Cost of product sales for the three months ended September 30, 2018 and 2017 were as follows (in thousands except for percentages):

| | Three Months Ended September 30, | | 2018 to 2017 | |
|---|---|---|---|---|
| | 2018 | 2017 | $ Change | % Change |
| Cost of product sales | $46,489 | $31,085 | $15,404 | 50 % |
| Percentage of net product sales | 38 % | 25 % | | |

Amortization of intangible assets related to Makena and Intrarosa comprised $30.9 million and $23.7 million, respectively of the $46.5 million and $31.1 million cost of product sales for the three months ended September 30, 2018 and 2017, respectively. The non-amortization related increase in cost of product sales of $8.2 million was due to a larger portion of product sales from higher cost products as well as royalty obligations related to the Makena auto-injector and Intrarosa products.

We expect our cost of product sales, excluding amortization expense, to increase as a percentage of net product sales for the remainder of 2018 and throughout 2019, due to a shift in our product mix toward products with higher royalty obligations, such as the Makena auto-injector and Intrarosa.

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Research and Development Expenses

Research and development expenses for the three months ended September 30, 2018 and 2017 consisted of the following (in thousands except for percentages):

| | Three Months Ended September 30, | | 2018 to 2017 | |
|---|---|---|---|---|
| | 2018 | 2017 | $ Change | % Change |
| External research and development expenses | | | | |
| Feraheme-related costs | $1,611 | $(370) | $1,981 | <(100 %) |
| Makena-related costs | 721 | 3,616 | (2,895) | (80)% |
| Vyleesi-related costs | 1,582 | 6,516 | (4,934) | (76)% |
| Intrarosa-related costs | 1,623 | 336 | 1,287 | >100 % |
| Other external costs | 101 | 824 | (723) | (88)% |
| Total | 5,638 | 10,922 | (5,284) | (48)% |
| Internal research and development expenses | 4,495 | 5,352 | (857) | (16)% |
| Total research and development expenses | $10,133 | $16,274 | $(6,141) | (38)% |

Total research and development expenses incurred in the three months ended September 30, 2018 decreased by $6.1 million as compared to the same period in 2017. The $4.9 million decrease of Vyleesi-related costs reflects the completion of certain agreed-upon Palatin reimbursement costs incurred in 2017 in preparation for the March 2018 NDA submission, partially offset by increased costs associated with manufacturing process development and the manufacture of drug product for Vyleesi in preparation for potential approval in 2019. Makena-related costs reflect a $2.9 million decline due to the completion of the Makena auto-injector development program in 2017 partially offset by costs incurred in the Makena sub-part H trials. The decreased spend for Vyleesi and Makena was partially offset by a $2.0 million increase in Feraheme-related costs related to an ongoing pediatric study and a $1.3 million increase of costs for the Intrarosa HSDD study in post-menopausal women.

We expect our research and development expenses to increase during the remainder of 2018 and throughout 2019, as we increase our investment to accelerate enrollment in the AMAG-423 clinical trial. We also expect to incur additional costs as we prepare for the Advisory Committee meeting for Vyleesi and continue to invest in Intrarosa development, including the HSDD study. We cannot determine with certainty the duration and completion costs of our current or future clinical trials of our products or product candidates as the duration, costs and timing of clinical trials depends on a variety of factors including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rates and significant and changing government regulation.

Acquired In-Process Research and Development

During the three months ended September 30, 2018, we recorded $12.5 million for acquired IPR&D related to the upfront option exercise fee paid to Velo in September 2018 in connection with our acquisition of AMAG-423.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended September 30, 2018 and 2017 consisted of the following (in thousands except for percentages):

| | Three Months Ended September 30, | | 2018 to 2017 | |
|---|---|---|---|---|
| | 2018 | 2017 | $ Change | % Change |
| Compensation, payroll taxes and benefits | $34,538 | $28,177 | $6,361 | 23 % |
| Professional, consulting and other outside services | 33,702 | 29,304 | 4,398 | 15 % |
| Fair value of contingent consideration liability | 9 | (49,929) | 49,938 | >(100%) |
| Equity-based compensation expense | 4,202 | 4,410 | (208) | (5)% |
| Total selling, general and administrative expenses | $72,451 | $11,962 | $60,489 | >100 % |

Total selling, general and administrative expenses, excluding the $49.9 million contingent consideration liability expense reversal in the third quarter of 2017, increased by $10.6 million, or approximately 17%, in the three months ended September 30, 2018 as compared to the same period in 2017. This increase included a $6.4 million increase in compensation, payroll taxes and benefits primarily driven by the establishment of our women's health sales force in mid-2017 and related organizational growth, as well as a significant increase in external costs related to the commercialization of Intrarosa.

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We expect that total selling, general and administrative expenses will increase for the remainder of 2018 and throughout 2019 as we prepare for the potential launch of Vyleesi, assuming FDA approval in March 2019, and as we continue to invest in Intrarosa.

Impairment of Intangible Assets

There were no impairments of intangible assets for the three months ended September 30, 2018. During the three months ended September 30, 2017, we determined that a revised long-term forecast, resulting from certain information we received in the third quarter of 2017, constituted a triggering event with respect to our Makena base technology intangible asset, which relates solely to the Makena IM product. We determined that as of September 30, 2017, the fair value of the Makena base technology intangible asset was less than the carrying value and accordingly, we recorded an impairment charge of $319.2 million in the third quarter of 2017.

Other Expense, Net

Other expense, net for the three months ended September 30, 2018 increased by $31.0 million compared to the same period in 2017, primarily due to a $35.9 million loss on extinguishment of debt (including a $28.1 million redemption premium) incurred as a result of the early redemption of the 7.875% Senior Notes due 2023 (the "2023 Senior Notes"). The $31.0 million increase was partially offset by a $3.5 million reduction in interest expense in the three months ended September 30, 2018 due primarily to this redemption.

Income Tax Benefit

The following table summarizes our effective tax rate and income tax benefit for the three months ended September 30, 2018 and 2017 (in thousands except for percentages):

| | Three Months Ended September 30, | |
|---|---|---|
| | 2018 | 2017 |
| Effective tax rate | 4 % | 43 % |
| Income tax benefit | $(2,352) | $(115,197) |

For the three months ended September 30, 2018, we recognized an income tax benefit of $2.4 million, representing an effective tax rate of 4%. The difference between the 2018 statutory federal tax rate of 21% and the 4% effective tax rate for the three months ended September 30, 2018 was primarily attributable to the valuation allowance established against our current period losses generated, the impact of non-deductible stock compensation and other non-deductible expenses, partially offset by a benefit from contingent consideration, state income taxes and orphan drug credits. We established a valuation allowance on our deferred tax assets other than refundable credits to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets. The deferred tax liabilities associated with the CBR business, which was sold during the three months ended September 30, 2018, are no longer expected to be available as a source of income to realize the benefits of our net deferred tax assets.

For the three months ended September 30, 2017, we recognized an income tax benefit of $115.2 million, representing an effective tax rate of 43%. The difference between the expected 2017 statutory federal tax rate of 35% and the 43% effective tax rate for the three months ended September 30, 2017 was primarily attributable to the impact of state income taxes, federal research and development and orphan drug tax credits, and contingent consideration associated with Lumara Health, partially offset by the establishment of a valuation allowance related to certain deferred tax assets. During the three months ended September 30, 2017, we entered into a three-year cumulative loss position and established a valuation allowance on certain deferred tax assets to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets.

The primary drivers of the increase in tax expense for the three months ended September 30, 2018 as compared to the three months ended September 30, 2017 is primarily attributable to an increase in valuation allowance on our current period losses generated and a decrease in the federal tax benefit attributable to the decrease in the statutory federal rate from 35% to 21%, as well as an increase in non-deductible expenses, partially offset by contingent consideration.

Net Income from Discontinued Operations

Net income from discontinued operations was $95.5 million during the third quarter of 2018 as compared to $3.7 million in the same period in 2017. Of the $95.5 million net income from discontinued operations, $89.6 million represented a gain on the sale of the CBR business, which closed on August 6, 2018. For additional information, see Note C, “Discontinued

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Operations and Held for Sale" to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Results of Operations - Nine Months Ended September 30, 2018 and 2017

Revenues

Total revenues for the nine months ended September 30, 2018 and 2017 consisted of the following (in thousands except for percentages):

| | Nine Months Ended September 30, | | 2018 to 2017 | |
|---|---|---|---|---|
| | 2018 | 2017 | $ Change | % Change |
| Product sales, net | | | | |
| Makena | $275,377 | $286,771 | $(11,394) | (4)% |
| Feraheme | 99,796 | 79,492 | 20,304 | 26 % |
| Intrarosa | 10,331 | 360 | 9,971 | >100 % |
| MuGard | 302 | 567 | (265) | (47)% |
| Total | 385,806 | 367,190 | 18,616 | 5 % |
| Other revenues | 75 | 53 | 22 | 42 % |
| Total revenues | $385,881 | $367,243 | $18,638 | 5 % |

Net product sales increased by $18.6 million, or approximately 5%, during the nine months ended September 30, 2018 as compared to the same period in 2017, primarily due to a $20.3 million increase in Feraheme net sales following the approval of its expanded label in February 2018 and $10.0 million in Intrarosa net sales, which was launched commercially in July 2017. The increase of total revenues was partially offset by a $11.4 million decrease in Makena net sales, which were impacted by a supply disruption of our IM products and the entry of generic competition.

Product Sales

Total gross product sales were offset by product sales allowances and accruals for the nine months ended September 30, 2018 and 2017 as follows (in thousands, except for percentages):

| | Nine Months Ended September 30, | | | | 2018 to 2017 | |
|---|---|---|---|---|---|---|
| | 2018 | Percent of gross product sales | 2017 | Percent of gross product sales | $ Change | % Change |
| Gross product sales | $776,458 | | $676,377 | | $100,081 | 15 % |
| Provision for product sales allowances and accruals: | | | | | | |
| Contractual adjustments | 290,896 | 37 % | 225,622 | 33 % | 65,274 | 29 % |
| Governmental rebates | 99,756 | 13 % | 83,565 | 12 % | 16,191 | 19 % |
| Total | 390,652 | 50 % | 309,187 | 45 % | 81,465 | 26 % |
| Product sales, net | $385,806 | | $367,190 | | $18,616 | 5 % |

We did not materially adjust our product sales allowances and accruals during the nine months ended September 30, 2018 or 2017.

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Costs and Expenses

Cost of Product Sales

Cost of product sales for the nine months ended September 30, 2018 and 2017 were as follows (in thousands except for percentages):

| | Nine Months Ended September 30, | | 2018 to 2017 | |
|---|---|---|---|---|
| | 2018 | 2017 | $ Change | % Change |
| Cost of product sales | $187,176 | $90,761 | $96,415 | >100 % |
| Percentage of net product sales | 49 % | 25 % | | |

Amortization of intangible assets related to Makena and Intrarosa comprised $144.7 million and $69.6 million, respectively, of the $187.2 million and $90.8 million cost of product sales for the nine months ended September 30, 2018 and 2017, respectively. The non-amortization related increase of $21.3 million in cost of product sales was due to a larger portion of product sales from higher cost products and royalty obligations related to the Makena auto-injector and Intrarosa products.

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2018 and 2017 consisted of the following (in thousands except for percentages):

| | Nine Months Ended September 30, | | 2018 to 2017 | |
|---|---|---|---|---|
| | 2018 | 2017 | $ Change | % Change |
| External research and development expenses | | | | |
| Feraheme-related costs | $3,033 | $7,046 | $(4,013) | (57)% |
| Makena-related costs | 4,118 | 10,736 | (6,618) | (62)% |
| Vyleesi-related costs | 7,716 | 26,521 | (18,805) | (71)% |
| Intrarosa-related costs | 4,885 | 498 | 4,387 | >100 % |
| Other external costs | 286 | 3,516 | (3,230) | (92)% |
| Total | 20,038 | 48,317 | (28,279) | (59)% |
| Internal research and development expenses | 12,597 | 14,704 | (2,107) | (14)% |
| Total research and development expenses | $32,635 | $63,021 | $(30,386) | (48)% |

Total research and development expenses incurred in the nine months ended September 30, 2018 decreased by $30.4 million, as compared to the same period in 2017. The $18.8 million decrease in Vyleesi-related costs reflects the completion of certain agreed-upon Palatin reimbursement costs incurred in 2017 in preparation for the March 2018 NDA submission, partially offset by increased costs associated with manufacturing process development and the manufacture of drug product for Vyleesi in preparation for potential approval in 2019. Makena-related costs reflect a $6.6 million decline due to the completion of the Makena auto-injector development program in 2017, partially offset by costs incurred in the Makena sub-part H trials. Feraheme-related costs decreased by $4.0 million due to the completion of the IDA study in 2017, partially offset by costs related to an ongoing pediatric study. The decreased spend for Feraheme, Makena, and Vyleesi was partially offset by an increase of $4.4 million for the Intrarosa HSDD study in post-menopausal women.

Acquired In-Process Research and Development

During the nine months ended September 30, 2018, we recorded $32.5 million for acquired IPR&D related to AMAG-423 and Vyleesi as the respective product candidates had not received regulatory approval. Of the $32.5 million, $12.5 million was paid to Velo in September 2018 as an upfront option exercise fee in connection with our acquisition of AMAG-423 and $20.0 million was paid to Palatin in the second quarter of 2018 related to the milestone obligation associated with the FDA acceptance of the Vyleesi NDA.

During the nine months ended September 30, 2017, we recorded IPR&D expense of $65.8 million primarily related to (a) a $60.0 million one-time upfront payment under the terms of the Palatin License Agreement, which we entered into in February 2017, and which we characterized as acquired IPR&D as the product candidate had not received regulatory approval and (b) $5.8 million, which represented a portion of the $83.5 million of consideration recorded to date under the terms of the Endoceutics License Agreement, based on our determination that the this portion of the total consideration did not have an alternative future use.

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Selling, General and Administrative Expenses

Selling, general and administrative expenses for the nine months ended September 30, 2018 and 2017 consisted of the following (in thousands except for percentages):

| | Nine Months Ended September 30, | | 2018 to 2017 | |
|---|---|---|---|---|
| | 2018 | 2017 | $ Change | % Change |
| Compensation, payroll taxes and benefits | $98,213 | $72,852 | $25,361 | 35 % |
| Professional, consulting and other outside services | 100,593 | 81,736 | 18,857 | 23 % |
| Fair value of contingent consideration liability | (49,175) | (47,143) | (2,032) | 4 % |
| Equity-based compensation expense | 12,149 | 12,037 | 112 | 1 % |
| Total selling, general and administrative expenses | $161,780 | $119,482 | $42,298 | 35 % |

Total selling, general and administrative expenses increased $42.3 million, or approximately 35%, in the nine months ended September 30, 2018 as compared to the same period in 2017 as a result of:

- $25.4 million increase in compensation, payroll taxes and benefits primarily driven by the establishment of our women's health sales force in mid-2017 and related organizational growth; and
- $18.9 million increase in external spending related to Intrarosa and Vyleesi marketing activities and the launches of the expanded Feraheme label and the Makena auto-injector.

In addition, total selling, general and administrative expenses for each of the nine months ended September 30, 2018 and 2017 included a $49.2 million and $47.1 million reversal, respectively, to the fair value of contingent consideration liability primarily due to changes in our estimated Makena revenues and associated milestone payments.

Impairment of Intangible Assets

There were no impairments of intangible assets for the nine months ended September 30, 2018. During the nine months ended September 30, 2017, we determined that a revised long-term forecast, resulting from certain information we received in the third quarter of 2017, constituted a triggering event with respect to our Makena base technology intangible asset, which relates solely to the Makena IM product. We determined that as of September 30, 2017, the fair value of the Makena base technology intangible asset was less than the carrying value and, accordingly, we recorded an impairment charge of $319.2 million in the third quarter of 2017.

Other Expense, Net

Other expense, net for the nine months ended September 30, 2018 increased by $18.1 million compared to the same period in 2017. This increase was primarily driven by a $35.9 million loss on extinguishment of debt (including a $28.1 million redemption premium), incurred during the nine months ended September 30, 2018 as a result of the early redemption of the 2023 Senior Notes, partially offset by a $9.8 million loss on extinguishment of debt in 2017 and a $7.0 million reduction in interest expense in the nine months ended September 30, 2018 due primarily to these redemptions.

Income Tax Expense (Benefit)

The following table summarizes our effective tax rate and income tax expense (benefit) for the nine months ended September 30, 2018 and 2017 (in thousands except for percentages):

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2018 | 2017 |
| Effective tax rate | (40)% | 41 % |
| Income tax expense (benefit) | $42,204 | $(145,317) |

For the nine months ended September 30, 2018, we recognized an income tax expense of $42.2 million, representing an effective tax rate of (40)%. The difference between the expected 2018 statutory federal tax rate of 21% and the (40)% effective tax rate for the nine months ended September 30, 2018 was primarily attributable to the establishment of a valuation allowance on net deferred tax assets other than refundable AMT credits, the impact of non-deductible stock compensation and other non-deductible expenses, partially offset by a benefit from contingent consideration,

state income taxes and orphan drug credits. We have established a valuation allowance on our deferred tax assets other than refundable credits to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets.

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Our valuation allowance on our deferred tax assets, other than refundable AMT credits, increased during the nine months ended September 30, 2018 primarily because the deferred tax liabilities associated with the CBR business, which was reclassified to discontinued operations for the nine months ended September 30, 2018, are no longer available as a source of income to realize the benefits of the net deferred tax assets.

For the nine months ended September 30, 2017 we recognized an income tax expense of $145.3 million, representing an effective tax rate of 41%. The difference between the expected 2017 statutory federal tax rate of 35% and the 41% effective tax rate for the nine months ended September 30, 2017 was primarily attributable to the impact of state income taxes, federal research and development and orphan drug tax credits, and contingent consideration associated with Lumara Health, partially offset by the establishment of a valuation allowance related to certain deferred tax assets. During the nine months ended September 30, 2017, we entered into a three-year cumulative loss position and established a valuation allowance on certain deferred tax assets to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets.

The primary drivers of the increase in tax expense for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017 is primarily attributable to an increase in valuation allowance on net deferred tax assets other than refundable AMT credits and a decrease in the federal tax benefit attributable to the decrease in the statutory federal rate from 35% to 21%, as well as an increase in nondeductible expenses, partially offset by contingent consideration.

Net Income from Discontinued Operations

Net income from discontinued operations was $105.1 million for the nine months ended September 30, 2018 as compared to $3.2 million in the same period in 2017. Of the $105.1 million net income from discontinued operations, $89.6 million represented a gain on the sale of the CBR business, which closed on August 6, 2018. For additional information, see Note C, “Discontinued Operations and Held for Sale” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Liquidity and Capital Resources

General

We currently finance our operations primarily from cash generated from our operating activities, including sales of our products. Cash, cash equivalents, marketable securities and certain financial obligations as of September 30, 2018 and December 31, 2017 consisted of the following (in thousands except for percentages):

| | September 30, 2018 | December 31, 2017 | $ Change | % Change |
|---|---|---|---|---|
| Cash and cash equivalents | $ 287,166 | $ 162,855 | $124,311 | 76 % |
| Marketable securities | 140,368 | 136,593 | 3,775 | 3 % |
| Total | $ 427,534 | $ 299,448 | $128,086 | 43 % |
| | | | | |
| Outstanding principal on 2023 Senior Notes | $ — | $ 475,000 | $(475,000) | (100 )% |
| Outstanding principal on 2022 Convertible Notes | 320,000 | 320,000 | — | — % |
| Outstanding principal on 2019 Convertible Notes | 21,417 | 21,417 | — | — % |
| Total | $ 341,417 | $ 816,417 | $(475,000) | (58 )% |

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Cash Flows

The following table presents a summary of our primary sources and uses of cash for the nine months ended September 30, 2018 and 2017 (in thousands):

| | September 30, 2018 | September 30, 2017 | $ Change |
|---|---|---|---|
| Net cash provided by operating activities | $ 84,893 | $ 86,648 | $(1,755) |
| Net cash provided by investing activities | 513,136 | 106,259 | 406,877 |
| Net cash used in financing activities | (503,138) | (209,238) | (293,900) |
| Net increase (decrease) in cash, cash equivalents, and restricted cash | $ 94,891 | $ (16,331) | $111,222 |

Operating Activities

Cash flows from operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. We have historically financed our operating and capital expenditures primarily through cash flows earned through our operations. We expect cash provided by operating activities in addition to our cash, cash equivalents and marketable securities will continue to be a primary source of funds to finance operating needs and capital expenditures.

Operating cash flow is derived by adjusting our net income (loss) for:

- Non-cash operating items, such as depreciation and amortization and equity-based compensation;
- Changes in operating assets and liabilities, which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in results of operations;
- Changes in deferred incomes taxes; and
- Changes associated with the fair value of contingent payments associated with our acquisitions of businesses.

For the period ending September 30, 2018 compared to September 30, 2017, net cash flows provided by operating activities decreased by $1.8 million, driven primarily by an increase in net income as adjusted for non-cash charges of $13.9 million and an $15.7 million decrease due to changes in operating assets and liabilities. The aforementioned cash flows from operating activities include cash flows from the operating activities of the CBR business, which is included in discontinued operations. Subsequent to the closing of the CBR transaction on August 6, 2018, we no longer generated cash flows from that business. See Note C, “Discontinued Operations and Held for Sale,” of the notes to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for further detail regarding our discontinued operations.

Investing Activities

Cash flows used in investing activities was $513.1 million for the nine months ended September 30, 2018 due to $519.3 million in proceeds from the sale of CBR offset by net purchases of marketable securities of $4.3 million and capital expenditures of $1.9 million. Cash provided by investing activities for the nine months ended September 30, 2017 was $106.3 million due to net proceeds from the sale of marketable securities of $168.6 million, offset by $55.8 million of cash used to purchase the Intrarosa asset and fund capital expenditures of $6.6 million.

Financing Activities

Cash used in financing activities was $503.1 million for the nine months ended September 30, 2018 due to the repayment of the $475.0 million balance of our 2023 Senior Notes and a related redemption premium of $28.1 million. Cash used in financing activities for the nine months ended September 30, 2017 was $209.2 million driven by $328.1 million of principal payments made during 2017 and the full repayment of the remaining balance of our 2015 Term Loan Facility and $191.5 million used for the repurchase of a portion of our 2019 Convertible Notes, partially offset by $310.4 million net proceeds related to the issuance of our 2022 Convertible Notes.

Future Liquidity Considerations

We believe that our cash, cash equivalents and marketable securities as of September 30, 2018, and the cash we expect to receive from sales of our products and earnings on our investments, will be sufficient to satisfy our cash flow needs for the foreseeable future. As we enter 2019 and look to our significant portfolio investment opportunities, we intend to spend more than our expected revenues and will therefore utilize a portion of our $427.5 million of cash and investments. This period of

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cash outflow is consistent with our evolving business plan to develop and launch innovative products that address unmet medical needs and can deliver long-term, durable revenue growth. Our expected utilization of cash includes, but is not limited to, the following:

- Costs associated with manufacturing process development and the manufacture of drug product for Vyleesi to support its mid-2019 commercialization, if approved;
- Launch-related commercialization costs for Vyleesi we expect to incur in preparation for the launch and thereafter, if approved;
- A $60.0 million milestone obligation to Palatin conditioned and payable upon FDA approval of Vyleesi;
- Clinical trial costs for AMAG-423;
- Repayment of the $21.4 million outstanding principal balance on our 2019 Convertible Notes in cash in February 2019; and
- Potential business development opportunities.

For a detailed discussion regarding the risks and uncertainties related to our liquidity and capital resources, please refer to our Risk Factors in Part I, Item 1A of our Annual Report and in Part II, Item IA of this Quarterly Report on Form 10-Q.

Borrowings and Other Liabilities

In August 2015, in connection with the CBR acquisition, we completed a private placement of $500.0 million aggregate principal amount of 7.875% Senior Notes due 2023 (the “2023 Senior Notes”). In October 2017, we repurchased $25.0 million principal of the 2023 Senior Notes in a privately negotiated transaction with cash on hand. In September 2018, we repurchased the remaining $475.0 million of the 2023 Senior Notes using the proceeds from the CBR sale. For additional information, see Note R, “Debt,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

In the second quarter of 2017, we issued $320.0 million aggregate principal amount of convertible senior notes due 2022 (the “2022 Convertible Notes”), as discussed in more detail in Note Q, “Debt,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. We received net proceeds of $310.4 million from the sale of the 2022 Convertible Notes, after deducting fees and expenses of $9.6 million. The 2022 Convertible Notes are senior unsecured obligations and bear interest at a rate of 3.25% per year, payable semi-annually in arrears on June 1 and December 1 of each year, beginning on December 1, 2017. The 2022 Convertible Notes will mature on June 1, 2022, unless earlier repurchased or converted. Upon conversion of the 2022 Convertible Notes, such 2022 Convertible Notes will be convertible into, at our election, cash, shares of our common stock, or a combination thereof, at a conversion rate of 36.5464 shares of common stock per $1,000 principal amount of the 2022 Convertible Notes, which corresponds to an initial conversion price of approximately $27.36 per share of our common stock. The conversion rate is subject to adjustment from time to time. The 2022 Convertible Notes were not convertible as of September 30, 2018.

In February 2014, we issued $200.0 million aggregate principal amount of 2.5% convertible senior notes due February 15, 2019 (the “2019 Convertible Notes”). In May 2017 and September 2017, we entered into privately negotiated transactions with certain investors to repurchase approximately $158.9 million and $19.6 million, respectively, aggregate principal amount of the 2019 Convertible Notes for an aggregate repurchase price of approximately $171.3 million and $21.4 million, respectively, including accrued interest, as discussed in more detail in Note R, “Debt,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. The remaining 2019 Convertible Notes are senior unsecured obligations and bear interest at a rate of 2.5% per year, payable semi-annually

in arrears on February 15 and August 15 of each year. The 2019 Convertible Notes will mature on February 15, 2019, unless repurchased or converted earlier. The 2019 Convertible Notes will be convertible into cash, shares of our common stock, or a combination thereof, at our election, at a conversion rate of 36.9079 shares of common stock per $1,000 principal amount of the 2019 Convertible Notes, which corresponds to a conversion price of approximately $27.09 per share of our common stock. The conversion rate is subject to adjustment from time to time. The 2019 Convertible Notes were convertible as of September 30, 2018.

Share Repurchase Program

In January 2016, we announced that our Board authorized a program to repurchase up to $60.0 million in shares of our common stock. The repurchase program does not have an expiration date and may be suspended for periods or discontinued at any time. Under the program, we may purchase our stock from time to time at the discretion of management in the open market

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or in privately negotiated transactions. The number of shares repurchased and the timing of the purchases will depend on a number of factors, including share price, trading volume and general market conditions, along with working capital requirements, general business conditions and other factors. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate purchases of our shares under this program. As of September 30, 2018, we repurchased and retired a cumulative total of 2,198,010 shares of common stock under this repurchase program for $39.5 million at an average purchase price of $17.97 per share. As of September 30, 2018, $20.5 million remains available for the repurchase of shares under the program. We did not repurchase any of our common stock during the first three quarters of 2018.

Off-Balance Sheet Arrangements

As of September 30, 2018, we did not have any off-balance sheet arrangements as defined in Regulation S-K, Item 303(a)(4)(ii).

Impact of Recently Issued and Proposed Accounting Pronouncements

See Note S, “Recently Issued and Proposed Accounting Pronouncements,” and Note T, “Recently Adopted Accounting Pronouncements,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for information regarding new accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk:

There have been no material changes with respect to the information appearing in Part II, Item 7A, “Quantitative and Qualitative Disclosures About Market Risk,” in our Annual Report.

Item 4. Controls and Procedures:

Managements’ Evaluation of our Disclosure Controls and Procedures

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our “disclosure controls and procedures” (as defined in the Exchange Act Rule 13a-15(e), or Rule 15d-15(e)), with the participation of our management, have each concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective and were designed to ensure that information we are required to disclose in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure, and is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms. It should be noted that any system of controls is designed to provide reasonable, but not absolute, assurances that the system will achieve its stated goals under all reasonably foreseeable circumstances. Our principal executive officer and principal financial officer have each concluded that our disclosure controls and procedures as of the end of the period covered by this report are effective at a level that provides such reasonable assurances.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) that occurred during the three months ended September 30, 2018 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings:

See Note P, “Commitments and Contingencies,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for information regarding our legal proceedings, including how we accrue liabilities for legal contingencies.

Item 1A. Risk Factors:

With the exception of the risk factors below, there have been no material changes from the Risk Factors disclosed in Part I, Item 1A, of our Annual Report.

Our revenues for the Makena franchise may continue to be negatively impacted by recent and future generic entries into the market and a supply disruption of certain of our Makena products.

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Our ability to continue to successfully commercialize Makena is dependent upon a number of factors, including our ability to differentiate Makena from other treatment options, especially now that a generic competitor has entered the market. Although we recently launched our own authorized generic presentation of Makena to mitigate the anticipated decrease in Makena revenue as generic entrants gain market share, our Makena products will continue to experience pricing and supply chain pressure and as a result, our Makena revenues may fall below expectations which could cause our financial condition and results of operations to be adversely impacted.

The long-term success of the Makena franchise is highly dependent on our ability to successfully commercialize the Makena auto-injector, which was approved for commercialization in February 2018, and which is intended to provide us with an alternative treatment method to the Makena IM product. Although there is no direct competition with the Makena auto-injector, the auto-injector competes for the same patients as generic versions of the Makena IM product, including our own authorized generic of the Makena IM product. We may not be able to convince patients or healthcare providers to use or to switch from using the IM method of administration to the auto-injector, including if patients or healthcare providers are hesitant or apprehensive to use an auto-injector product due to perceptions regarding lack of improvement in safety, efficacy or pain associated with the Makena auto-injector or if the auto-injector is not priced competitively or is not provided comparable insurance coverage. If we do not convert a sufficient number of patients to the auto-injector product, we could lose a significant amount of our Makena revenue and market share to generic competitors.

In addition, we have lost and could lose additional market share if we are unable to deliver sufficient quantities of Makena inventory to meet demand. Due to continued manufacturing issues at our primary third-party manufacturer, we are currently experiencing a supply disruption of our Makena IM products, which has resulted in our single-dose vial being out of stock and we expect will result in an out of stock situation for our multi-dose vial in the near future. Although we are attempting to mitigate this supply issue by manufacturing at our secondary supplier, we can make no guarantees that additional supply will be available in a timely manner and we anticipate that our revenues for the IM products could continue to be adversely impacted. We are currently working with healthcare providers, distribution partners and our manufacturers to minimize the impact of the current supply disruption of the IM products by encouraging new patient starts on the auto-injector. However, due to increased demand of the auto-injector product we could face supply issues for that product as well. Further, although we recently secured approval for a supplier for Makena API, we continue to work to secure a secondary source API supplier, which has experienced and may continue to experience approval delays. These supply issues have caused and will continue to cause a disruption in our ability to meet commercial demand of Makena more generally, which has and could continue to negatively impact revenues.

Further, we rely on Prasco, LLC (“Prasco”) for our successful commercialization of our own generic formulation. We have limited experience working with a generic vendor and Prasco may not be able to continue to enter into contracts with retail and specialty pharmacies or distributors on favorable terms, or at all. In addition, we are responsible for supplying product to Prasco, and if we continue to experience problems with our supply chain, revenues with respect to our authorized generic formulation of Makena IM product could be adversely affected and we could be subject to certain penalties, which could be substantial.

If we and Prasco are not able to capture sufficient market share, if generics are sold at a significant discount to Makena’s price, if we continue to experience supply disruptions related to our Makena IM products or if we become unable to meet commercial demand for our Makena auto-injector or authorized generic, our Makena revenues could be materially and adversely affected and, ultimately, could negatively impact our stock price and results of operations.

We have limited experience with development stage products and cannot ensure that we will be successful in gaining approval of our product candidates, including Vyleesi and AMAG-423, on a timely basis, or at all, or that such approvals, if obtained, will not contain restrictions that the FDA may impose on the use or distribution of such product candidates or that we will be successful in commercializing our product candidates.

Our long-term success and revenue growth depends upon our ability to continue to successfully develop new products. Drug development is inherently risky and the U.S. Food and Drug Administration (the “FDA”) imposes substantial requirements on the development of such candidates to become eligible for marketing approval. The FDA has

substantial discretion in the approval process and may decide that our data is insufficient for approval. Clinical data is often susceptible to varying interpretations, and many companies in the pharmaceutical and biotechnology industries that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products. The FDA could also determine that our manufacturing processes are not properly designed, are not conducted in accordance with federal laws or otherwise not properly managed. If we do not obtain FDA approval for our product candidates, including Vyleesi or AMAG-423, as discussed below, or if we experience significant delays or setbacks in obtaining approval, our ability to grow our business and leverage our product portfolio and the future prospects of our business could be materially adversely affected.

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In January 2017, we acquired an exclusive license from Palatin to research, develop and commercialize Vyleesi in North America. During 2016, Palatin completed two Phase 3 clinical trials to treat HSDD in pre-menopausal women. The trials consisted of double-blind placebo-controlled, randomized parallel group studies comparing a subcutaneous dose of 1.75 mg Vyleesi versus placebo, in each case, delivered via an auto-injector. In both clinical trials, Vyleesi met the pre-specified co-primary efficacy endpoints of median improvement in desire and decrease in distress associated with low sexual desire as measured using validated patient-reported outcome instruments; however, the change in the number of satisfying sexual events, the key secondary endpoint, was not significantly different from placebo in either clinical trial. The most frequent adverse events were nausea, flushing and headache, which were generally mild-to-moderate in severity. Approximately 18% of patients discontinued participation in the Vyleesi arm due to adverse events in both studies. In June 2018, the FDA accepted our NDA for Vyleesi, which has a PDUFA date of March 23, 2019 and we expect an Advisory Committee meeting for Vyleesi to be held in January 2019. Advisory Committee decisions are not binding, but an adverse decision at the advisory committee may have a negative impact on the outcome of the regulatory review of Vyleesi. In addition, if the Advisory Committee reports a negative recommendation in its briefing package to the FDA, which is publicly available, our stock could be adversely impacted.

Despite the successful completion of the Phase 3 clinical trials, the approval of Vyleesi for commercial sale in the U.S. could be delayed or denied or we may be required to conduct additional studies for a number of reasons, including:

- The FDA may determine that Vyleesi does not demonstrate safety and efficacy in accordance with regulatory agency standards based on the results of the Phase 3 trials, including the co-primary and secondary endpoints and safety results;
- The FDA may determine that the magnitude of efficacy demonstrated in the Vyleesi studies does not amount to a clinically meaningful benefit to pre-menopausal women with HSDD and thus that the product cannot be approved despite statistically significant efficacy results;
- The FDA could analyze and/or interpret data from preclinical testing and clinical trials in different ways than we or Palatin interpret them;
- The auto-injector device that we plan to use to administer Vyleesi may not be adequate or may not be considered adequate by the FDA;
- We may be unable to establish, and obtain FDA approval for, a commercially viable manufacturing process for Vyleesi in a timely manner, or at all;
- Adverse medical events reported during the trials, including increases in blood pressure noted in prior clinical trials and a serious adverse event of hepatitis of unknown etiology;
- The failure of clinical investigational sites and the records kept at such sites, including the clinical trial data, to be in compliance with the FDA's current good clinical practices regulations ("cGCP"), including the failure to pass FDA inspections of clinical trial sites; and
- The FDA may change their approval policies or adopt new regulations.

Additionally, in September 2018, we exercised our option to acquire the global rights to develop and market digoxin immune Fab (ovine), a polyclonal antibody in development for the treatment of severe preeclampsia in pregnant women, pursuant to an option agreement entered into in July 2015 agreement with Velo Bio, LLC, a privately-held

life sciences company ("Velo"), the terms of which were amended at the time of exercise. In connection with the acquisition, we have taken over a 200 patient multi-center, randomized, double-blind, placebo-controlled, parallel-group Phase 2b/3a trial, which was initiated by Velo in July 2017. The approval of AMAG-423 for commercial sale in the U.S. could be delayed, limited or denied or we may be required to conduct additional studies for a number of reasons, including:

- The Phase 2b/3a trial may produce negative or inconclusive results or may not demonstrate to the FDA's satisfaction that AMAG-423 is safe and effective, particularly in light of the limited amount of data to date demonstrating that AMAG-423 effectively treats severe preeclampsia in this patient population;

- Slower than expected rate of patient enrollment, particularly since only 26 patients have been enrolled to date, which could continue as a result of any number of factors, including failure of our third-party vendors, including our CROs, to effectively perform their obligations to us in a timely manner, a lack of patients who meet the enrollment

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criteria, our inability to establish sufficient trial sites, including outside of the U.S., in a timely manner, or our inability to secure sufficient supply of drug product to meet the accelerated clinical timeline;

- There is no FDA approved treatment for severe preeclampsia and there is not an established regulatory pathway, which may increase the uncertainty and risk of approval;

- The size of the patient population required to establish efficacy to the satisfaction of the FDA may be larger than we anticipated;

- Adverse medical events reported during the trials;

- The supply or quality of AMAG-423 for our clinical trial needs may be insufficient, inadequate or delayed; and

- FDA may not deem our third party manufacturers' processes or facilities adequate for approval.

Furthermore, the degree of protection afforded by any intellectual property related to AMAG-423 may not enable us to protect or commercially exploit AMAG-423, providing us with little or no competitive advantage. For example, digoxin immune FAB (ovine) has been approved and marketed in the U.S. for many years and accordingly, no longer has composition of matter patent protection. We do have four issued U.S. patents covering methods of using AMAG-423 to treat women exhibiting symptoms of preeclampsia or eclampsia, each of which expires in November 2022. If possible, we plan to seek additional patent protection for AMAG-423 through additional patent applications; however, we may not be able to obtain additional patent protection that would provide us with a competitive advantage.

Further, AMAG-423 has received Orphan Drug designation from the FDA. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, defined, in part, as a patient population of fewer than 200,000. The company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. We cannot guarantee that our clinical data or other information that we generate or submit will be adequate for AMAG-423 to receive new orphan drug exclusivity. Even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, orphan drug exclusivity marketing rights may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. If we do not receive Orphan Drug designation, or if the FDA approves another drug for the same indication, we may have limited market exclusivity.

Any failure or delay in obtaining regulatory approval for Vyleesi or AMAG-423 could adversely affect our ability to successfully commercialize such products. In addition, share prices have declined significantly in certain instances where companies have failed to obtain FDA approval of a product or where the timing of FDA approval is delayed. If we are required to conduct additional studies, our share price could decline significantly. Further, the market for products that address unmet medical needs is highly speculative and if we have over-estimated the market opportunity for any of our products or product candidates, or if we are unsuccessful in gaining market share, then our business and results of operations could be materially and adversely affected.

Even if regulatory approval to market Vyleesi or AMAG-423 is granted by the FDA, the approvals may impose limitations on the indicated use for which the drug product may be marketed and additional post-approval requirements with which we and, in the case of Vyleesi, Palatin would need to comply in order to maintain approval of Vyleesi or AMAG-423. Our business could be seriously harmed if we and/or Palatin do not complete any

post-approval requirements and the FDA, as a result, requires us to change sections of the labeling.

The manufacture of AMAG-423 involves a complicated and time-consuming process with limited manufacturers.

AMAG-423 is a polyclonal antibody that is produced through a time intensive, complex process in which immunogens consisting of an analog of digoxin medication are produced in a laboratory and used to immunize sheep, which then produce certain antibodies. These antibodies are collected, separated, purified, and formulated into digoxin immune Fab (ovine). There is currently only one third-party that can manufacture AMAG-423, which utilizes its own flock of sheep located solely in Australia for the production of the antibodies used to produce AMAG-423. We currently do not have commercial supply agreements to manufacture AMAG-423 and may not be able to enter into such agreements on acceptable terms, if at all. In addition, even if we enter into such agreements, since there would only be one source of supply, if there are any disruptions to

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any part of the supply chain process, including the ability to obtain certain raw materials or any issues with the sheep used to produce the antibodies, such as diseases or natural disasters, our ability to complete the Phase 2b/3a trial or commercialize AMAG-423, if approved, would be adversely affected.

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

The following table provides certain information with respect to our purchases of shares of our stock during the three months ended September 30, 2018.

| Period | Total Number of Shares Purchased [1] | Average Price Paid Per Share | Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs [2] | Maximum Number of Shares (or approximate dollar value) That May Yet Be Purchased Under the Plans or Programs [2] |
|---|---|---|---|---|
| July 1, 2018 through July 31, 2018 | 6,791 | $ 19.93 | — | 929,998 |
| August 1, 2018 through August 31, 2018 | 2,742 | 24.72 | — | 840,428 |
| September 1, 2018 through September 30, 2018 | 2,951 | 22.33 | — | 1,025,322 |
| Total | 12,484 | $ 21.55 | — | |

(1) Represents the surrender of shares of our common stock withheld by us to satisfy the minimum tax withholding obligations in connection with the vesting of restricted stock units held by our employees.

(2) We did not repurchase any of our common stock during the third quarter of 2018. We have repurchased and retired $39.5 million of our common stock under our share repurchase program through September 30, 2018. These shares were purchased pursuant to a repurchase program authorized by our Board that was announced in January 2016 to repurchase up to $60.0 million of our common stock, of which $20.5 million remains authorized for repurchase as of September 30, 2018. The repurchase program does not have an expiration date and may be suspended for periods or discontinued at any time.

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Item 6. Exhibits:

| Exhibit Number | Description |
|---|---|
| 10.1+ | Contract Manufacturing Agreement, dated September 1, 2018, by and between AMAG Pharmaceuticals, Inc. and Fresenius Kabi Austria GmbH (Certain confidential information contained in this exhibit was omitted by means of redacting a portion of the text and replacing it with [***]. This exhibit has been filed separately with the SEC without any redactions pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended) |
| 31.1+ | Certification Pursuant to Rule 13a_14(a)/15d_14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2+ | Certification Pursuant to Rule 13a_14(a)/15d_14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32.1++ | Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 32.2++ | Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 101.INS+ | XBRL Instance Document |
| 101.SCH+ | XBRL Taxonomy Extension Schema Document |
| 101.CAL+ | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF+ | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB+ | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE+ | XBRL Taxonomy Extension Presentation Linkbase Document |

+ Exhibits marked with a plus sign (“+”) are filed herewith.
++ Exhibits marked with a double plus sign (“++”) are furnished herewith.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AMAG PHARMACEUTICALS, INC.

| | |
|---|---|
| By: | /s/ William K. Heiden<br>William K. Heiden<br>President and Chief Executive Officer (Principal Executive Officer) |
| Date: | November 2, 2018 |

AMAG PHARMACEUTICALS, INC.

| | |
|---|---|
| By: | /s/ Edward Myles<br>Edward Myles<br>Executive Vice President of Finance, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer) |
| Date: | November 2, 2018 |