

AMAG PHARMACEUTICALS INC.

Form 10-Q

November 04, 2016

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark

One)

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

For the quarterly period ended September 30, 2016

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

(I.R.S. Employer

Incorporation or Organization)

Identification No.)

1100 Winter Street

02451

Waltham, Massachusetts

(Address of Principal Executive Offices) (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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "accelerated filer," "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Non-accelerated filer

Large accelerated filer Accelerated filer (Do not check if a

Smaller Reporting Company

smaller reporting company)

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 31, 2016, there were 34,209,743 shares of the registrant's Common Stock, par value \$0.01 per share, outstanding.

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AMAG PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2016

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

AMAG PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

(Unaudited)

	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$305,279	\$228,705
Investments	308,792	237,626
Accounts receivable, net	70,079	85,678
Inventories	38,157	40,645
Receivable from collaboration	—	428
Prepaid and other current assets	14,474	13,592
Total current assets	736,781	606,674
Property, plant and equipment, net	25,255	28,725
Goodwill	639,484	639,188
Intangible assets, net	1,122,535	1,196,771
Restricted cash	2,593	2,593
Other long-term assets	1,005	2,259
Total assets	\$2,527,653	\$2,476,210
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$4,742	\$4,906
Accrued expenses	126,363	106,363
Current portion of long-term debt	62,791	17,500
Current portion of acquisition-related contingent consideration	100,359	96,967
Deferred revenues	34,653	20,185
Total current liabilities	328,908	245,921
Long-term liabilities:		
Long-term debt, net	747,869	803,669
Convertible 2.5% notes, net	177,146	170,749
Acquisition-related contingent consideration	127,094	125,592
Deferred tax liabilities	192,608	189,145
Deferred revenues	12,513	5,093
Other long-term liabilities	3,562	3,777
Total liabilities	1,589,700	1,543,946
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; 34,209,212 and 34,733,117 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	342	347
Additional paid-in capital	1,230,595	1,233,786
Accumulated other comprehensive loss	(3,394)	(4,205)
Accumulated deficit	(289,590)	(297,664)
Total stockholders' equity	937,953	932,264

Total liabilities and stockholders' equity	\$2,527,653	\$2,476,210
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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,	
	2016	2015	2016	2015
Revenues:				
U.S. product sales, net	\$115,777	\$88,917	\$308,324	\$250,984
Service revenues, net	27,965	7,177	71,863	7,177
License fee, collaboration and other revenues	40	58	313	51,380
Total revenues	143,782	96,152	380,500	309,541
Costs and expenses:				
Cost of product sales	25,706	19,088	65,942	59,793
Cost of services	4,984	3,261	15,705	3,261
Research and development expenses	17,116	19,809	45,579	34,981
Selling, general and administrative expenses	57,216	46,141	172,314	110,054
Impairment charges of intangible assets	—	—	15,963	—
Acquisition-related costs	—	8,500	—	11,153
Restructuring expenses	—	738	712	1,752
Total costs and expenses	105,022	97,537	316,215	220,994
Operating income (loss)	38,760	(1,385)	64,285	88,547
Other income (expense):				
Interest expense	(18,309)	(14,222)	(55,002)	(34,794)
Loss on debt extinguishment	—	(10,449)	—	(10,449)
Interest and dividend income	838	524	2,319	967
Other income (expense)	(24)	(9,182)	197	(9,180)
Total other income (expense)	(17,495)	(33,329)	(52,486)	(53,456)
Income (loss) before income taxes	21,265	(34,714)	11,799	35,091
Income tax expense (benefit)	5,069	(14,130)	3,725	9,513
Net income (loss)	\$16,196	\$(20,584)	\$8,074	\$25,578
Net income (loss) per share:				
Basic	\$0.47	\$(0.62)	\$0.23	\$0.84
Diluted	\$0.43	\$(0.62)	\$0.23	\$0.73
Weighted average shares outstanding used to compute net income (loss)				
per share:				
Basic	34,171	33,223	34,377	30,379
Diluted	42,111	33,223	34,764	34,962

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		Nine Months	
	Ended September		Ended September	
	30,		30,	
	2016	2015	2016	2015
Net income (loss)	\$16,196	\$(20,584)	\$8,074	\$25,578
Other comprehensive income (loss):				
Unrealized gains (losses) on securities:				
Holding gains (losses) arising during period, net of tax	(336) 228	811	(107)
Reclassification adjustment for gains (losses) included in net income (loss)	—	—	—	4
Net unrealized gains (losses) on securities	(336) 228	811	(103)
Total comprehensive income (loss)	\$15,860	\$(20,356)	\$8,885	\$25,475

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,	
	2016	2015
Cash flows from operating activities:		
Net income	\$8,074	\$25,578
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	68,960	51,346
Impairment of intangible assets	15,963	—
Amortization of premium/discount on purchased securities	518	1,505
Write-down of inventory to net realizable value	—	869
Non-cash equity-based compensation expense	16,809	11,572
Non-cash loss on debt extinguishment	—	6,426
Amortization of debt discount and debt issuance costs	9,015	8,463
Gains on investments, net	24	—
Change in fair value of contingent consideration	5,106	4,525
Deferred income taxes	2,573	17,557
Changes in operating assets and liabilities:		
Accounts receivable, net	15,599	(24,075)
Inventories	(1,369)	(1,013)
Receivable from collaboration	428	4,518
Prepaid and other current assets	(1,293)	(89)
Accounts payable and accrued expenses	19,940	(4,013)
Deferred revenues	21,888	(35,575)
Repayment of term loan attributable to original issue discount	—	(12,491)
Other assets and liabilities	1,467	2,981
Net cash provided by operating activities	183,702	58,084
Cash flows from investing activities:		
Acquisition of Lumara Health, net of acquired cash	—	562
Acquisition of CBR, net	—	(682,163)
Proceeds from sales or maturities of investments	71,733	74,021
Purchase of investments	(142,175)	(326,080)
Change in restricted cash	—	(3)
Capital expenditures	(3,360)	(440)
Net cash used in investing activities	(73,802)	(934,103)
Cash flows from financing activities:		
Proceeds from the issuance of common stock, net of underwriting discount and other expenses	—	407,477
Long-term debt principal payments	(13,127)	(327,509)
Proceeds from long-term debt	—	839,125
Payment of debt issuance costs	—	(10,000)
Payment of contingent consideration	(212)	(322)
Payments for repurchases of common stock	(20,000)	—
Proceeds from the exercise of stock options	1,424	15,482
Proceeds from the issuance of common stock under ESPP	760	—
Payments of employee tax withholding related to equity-based compensation	(2,171)	—
Net cash (used in) provided by financing activities	(33,326)	924,253

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Net increase in cash and cash equivalents	76,574	48,234
Cash and cash equivalents at beginning of the period	228,705	119,296
Cash and cash equivalents at end of the period	\$305,279	\$167,530

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 biopharmaceutical company focused on developing and delivering important therapeutics, conducting clinical research in areas of unmet need and creating education and support programs for the patients and families we serve. Our products support the health of patients in the areas of maternal health, anemia management and cancer supportive care, including Makena[®] (hydroxyprogesterone caproate injection), Feraheme[®] (ferumoxytol) for intravenous (“IV”) use and MuGard[®] Mucoadhesive Oral Wound Rinse. Through services related to the preservation of umbilical cord blood stem cell and cord tissue units (the “CBR Services”) operated through Cord Blood Registry (“CBR”), we also help families to preserve newborn stem cells, which are used today in transplant medicine for certain cancers and blood, immune and metabolic disorders, and have the potential to play a valuable role in the ongoing development of regenerative medicine. 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 Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2015 (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.

Principles of Consolidation

The accompanying condensed consolidated financial statements include our accounts and the accounts of our wholly-owned subsidiaries. Our results of operations for the three and nine months ended September 30, 2016, include the results of CBR, which we acquired in August 2015. 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 and services revenue; product sales allowances and accruals; allowance for doubtful accounts; investments; 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 and restructuring liabilities; income taxes and equity-based compensation expense. Actual results could differ materially from those estimates.

Concentrations and Significant Customer Information

Financial instruments which potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents, investments, 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, certificates of deposit and municipal securities. As of September 30, 2016, we did not have a material concentration in

any single investment.

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Our operations are located entirely within the U.S. We focus primarily on developing, manufacturing, and commercializing Makena and Feraheme and marketing and selling the CBR Services. We perform ongoing credit evaluations of our product sales 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, 2016 and 2015:

	Three Months Ended September 30, 2016		Nine Months Ended September 30, 2015	
AmerisourceBergen Drug Corporation	20 %	28 %	22 %	25 %
Caremark LLC (Specialty Pharmacy)	10 %	<10 %	10 %	— %
McKesson Corporation	<10 %	13 %	<10 %	11 %

In addition, approximately 17% of our total revenues for the nine months ended September 30, 2015 were principally related to deferred Feraheme revenue recognized in connection with the termination of our license, development and commercialization agreement (the “Takeda Agreement”) with Takeda Pharmaceutical Company Limited (“Takeda”), which is headquartered in Japan, and which revenues were thus generated from outside the U.S. Substantially all of the revenues generated during the nine months ended September 30, 2016 were generated within the U.S.

Our net accounts receivable primarily represented amounts due for products sold directly to wholesalers, distributors, and specialty pharmacies and amounts due for CBR Services sold directly to consumers. Accounts receivable for our products and services are recorded net of reserves for estimated chargeback obligations, prompt payment discounts and any allowance for doubtful accounts.

Customers which represented greater than 10% of our accounts receivable balance as of September 30, 2016 and December 31, 2015 were as follows:

	September 30, 2016		December 31, 2015	
AmerisourceBergen Drug Corporation	12 %	43 %		
Caremark LLC (Specialty Pharmacy)	10 %	<10 %		

We are currently dependent on a single supplier for Feraheme drug substance (produced in two separate facilities) and finished drug product. In addition, we rely on single sources for certain materials required to support the CBR Services. We would be exposed to a significant loss of revenue from the sale of our products and services if our suppliers and/or manufacturers could not fulfill demand for any reason.

Revenue Recognition

Our primary sources of revenue during the reporting periods were: (a) product revenues from Makena and Feraheme; (b) service revenues associated with the CBR Services; and (c) license fees, collaboration and other revenues, which primarily included milestone payments received from our collaboration agreements, royalties received from our license agreements, and international product revenues of Feraheme derived from our former collaboration agreement with Takeda. Revenue is recognized when the following criteria are met:

• Persuasive evidence of an arrangement exists;

• Delivery of product has occurred or services have been rendered;

• The sales price charged is fixed or determinable; and

Collection is reasonably assured.

Product Revenue

Our U.S. product sales, which primarily represented revenues from Makena and Feraheme for the three and nine months ended September 30, 2016 and 2015, were offset by provisions for allowances and accruals as follows (in thousands):

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Gross U.S. product sales	\$201,303	\$145,131	\$530,076	\$407,238
Provision for U.S. product sales allowances and accruals:				
Contractual adjustments	61,504	41,851	161,023	116,236
Governmental rebates	24,022	14,363	60,729	40,018
Total provision for U.S. product sales allowances and accruals	85,526	56,214	221,752	156,254
U.S. product sales, net	\$115,777	\$88,917	\$308,324	\$250,984

We recognize U.S. product sales net of certain allowances and accruals in our condensed consolidated statement of operations at the time of sale. 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. Governmental rebates relate to our reimbursement arrangements with state Medicaid programs.

We did not materially adjust our product sales allowances and accruals during the three and nine months ended September 30, 2016. During the nine months ended September 30, 2015, we reduced our Makena related Medicaid and chargeback reserves, which were initially recorded at the time we consummated our acquisition of Lumara Health Inc. ("Lumara Health"), which acquisition was completed on November 12, 2014 (the "Lumara Health Acquisition Date"), by \$5.3 million and \$1.9 million, respectively. These adjustments were recorded to goodwill during the quarter ended September 30, 2015, as it was within one year of the Lumara Health Acquisition Date. 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.

Multiple Element Arrangements

For multiple element arrangements, we allocate revenue to all deliverables based on their relative selling prices. We determine the selling price to be used for allocating revenue to deliverables as follows: (a) vendor specific objective evidence; (b) third-party evidence of selling price and (c) the best estimate of the selling price. Vendor specific objective evidence generally exists only when we sell the deliverable separately and it is the price actually charged by us for that deliverable. Any discounts given to the customer are allocated by applying the relative selling price method.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in our condensed consolidated balance sheets. Deferred revenue associated with our service revenues includes (a) amounts collected in advance of unit processing and (b) amounts associated with unearned storage fees collected at the beginning of the storage contract term, net of allocated discounts. Amounts not expected to be recognized within the next year are classified as long-term deferred revenues.

Service Revenue

Our service revenues for the CBR Services include the following two deliverables: (a) enrollment, including the provision of a collection kit and cord blood and cord tissue unit processing, which are delivered at the beginning of the relationship (the "processing services"), with revenue for this deliverable recognized after the collection and successful processing of the cord blood and cord tissue; and (b) the storage of newborn cord blood and cord tissue units (the "storage services"), for either an annual fee or a prepayment of 18 years or the lifetime of the newborn donor (the "lifetime option"), with revenue for this deliverable recognized ratably over the applicable storage period. For the lifetime option, storage fees are not charged during the lifetime of the newborn donor. However, if the newborn donor dies and his/her legal guardian chooses to continue to store the newborn stem cells and/or cord tissue, the number of remaining years of storage covered by the lifetime option without additional charge is calculated by taking the average of male and female life expectancies based on lifetime actuarial tables published by the Social Security Administration in effect at the time of the newborn's birth and subtracting the age at death. As there are other vendors

who provide processing services and storage services at separately stated list prices, the processing services and storage services, including the first year storage, each have standalone value to the customer, and therefore represent separate deliverables. The selling price for the processing services is estimated based on the best estimate of selling price because we do not have vendor specific objective evidence or third-party evidence of selling price for these elements. The selling price for the storage services is determined based on vendor specific objective evidence as we have standalone renewals to support the selling price.

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Reclassifications

Certain amounts in the prior period have been reclassified in order to conform to the current period presentation. In accordance with Accounting Standards Update (“ASU”) No. 2015-3, Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs, which we adopted in the first quarter of 2016, we reclassified total debt issuance costs related to our outstanding debt obligations from other long-term assets to the carrying amount of our debt, as a direct deduction, in our condensed consolidated balance sheets as of December 31, 2015. See Note S, “Recently Issued and Proposed Accounting Pronouncements” for additional information.

C. BUSINESS COMBINATIONS

As part of our strategy to expand our product and service portfolio, in August 2015, we acquired CBR and the CBR Services and in November 2014, we acquired Lumara Health and its product Makena. In addition, in June 2013, we entered into a license agreement (the “MuGard License Agreement”) with Abeona Therapeutics, Inc. (“Abeona”) pursuant to which we acquired the U.S. commercial rights to MuGard for the management of oral mucositis and stomatitis (the “MuGard Rights”).

CBR Acquisition

On August 17, 2015 (the “CBR Acquisition Date”), we acquired CBR for \$700.0 million in cash consideration, subject to estimated working capital, indebtedness and other adjustments. We believe CBR is a strong strategic fit for our growing business and offers a unique opportunity to reach a broader population of expectant mothers who may benefit from our product offerings in the maternal health space, including Makena.

We accounted for the acquisition of CBR as a business combination using the acquisition method of accounting.

Under the acquisition method of accounting, the total purchase price of an acquisition is allocated to the net tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values as of the date of acquisition. We have allocated the purchase price to the net tangible and intangible assets acquired and liabilities assumed, based on available information and various assumptions we believed were reasonable, with the remaining purchase price recorded as goodwill.

The following table summarizes the components of the total purchase price paid for CBR, as adjusted for the final net working capital, indebtedness and other adjustments (in thousands):

	Total Acquisition Date Fair Value
Cash consideration	\$ 700,000
Estimated working capital, indebtedness and other adjustments	(17,837)
Purchase price paid at closing	682,163
Cash paid on finalization of the net working capital, indebtedness and other adjustments	193
Total purchase price	\$ 682,356

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The following table summarizes the fair values assigned to the CBR assets acquired and liabilities assumed by us along with the resulting goodwill at the CBR Acquisition Date, as adjusted for certain measurement period adjustments for CBR recorded since the CBR Acquisition Date (in thousands):

	Total Acquisition Date Fair Value
Accounts receivable	\$ 8,660
Inventories	3,825
Prepaid and other current assets	8,480
Restricted cash - short-term	30,752
Property, plant and equipment	29,401
Customer relationships	297,000
Trade name and trademarks	65,000
Favorable lease asset	358
Deferred income tax assets	5,062
Other long-term assets	496
Accounts payable	(2,853)
Accrued expenses	(13,770)
Deferred revenues - short-term	(3,100)
Payable to former CBR shareholders	(37,947)
Deferred income tax liabilities	(149,873)
Other long-term liabilities	(506)
Total estimated identifiable net assets	\$ 240,985
Goodwill	441,371
Total	\$ 682,356

During 2016, we recorded measurement period adjustments related to the filing of pre-acquisition federal and state income tax returns and the finalization of other tax-related matters. These measurement period adjustments resulted in a net increase to goodwill of \$0.3 million and were reflected as current period adjustments during the second quarter of 2016 in accordance with the guidance in ASU 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments (“ASU 2015-16”).

The gross contractual amount of accounts receivable at the CBR Acquisition Date of \$11.7 million was adjusted to its fair value of \$8.7 million. The fair value amounts for CBR’s customer relationships, trade names and trademarks were determined based on assumptions that market participants would use in pricing an asset, based on the most advantageous market for the assets (i.e., its highest and best use). We determined the fair value of the customer relationships, using an income approach, which is a valuation technique that provides an estimate of the fair value of an asset based on market participant expectations of the cash flows an asset would generate over its remaining life. Some of the more significant assumptions used in the income approach from the perspective of a market participant include the estimated net cash flows for each year for the identifiable intangible asset, the discount rate that measures the risk inherent in each cash flow stream, as well as other factors. The fair value of the trade names and trademarks was determined using the relief from royalty method, which is also an income approach. We believe the fair values assigned to the CBR customer relationships, and the trade names and trademarks are based upon reasonable estimates and assumptions given available facts and circumstances as of the CBR Acquisition Date. If these assets are not successful, sales and profitability may be adversely affected in future periods, and as a result, the value of the assets may become impaired.

The customer relationships will be amortized to selling, general and administrative expenses based on an economic consumption model over an expected useful life of approximately 20 years. The trade names and trademark intangible asset is deemed to be an indefinite-lived asset, which is not amortized but will be subject to periodic assessments of

impairment.

Based on the fair value adjustments primarily related to deferred revenue and identifiable intangible assets acquired, we recorded a net deferred tax liability of \$144.8 million in acquisition accounting using a combined federal and state statutory income tax rate of 37.0%. The net deferred tax liability represents the \$149.9 million of deferred tax liabilities recorded in acquisition accounting, primarily related to the fair value adjustments to CBR's deferred revenue and identifiable intangible assets, partially offset by \$5.1 million of deferred tax assets acquired from CBR.

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During the third quarter of 2016, we finalized the fair values assigned to the assets acquired and liabilities assumed by us at the CBR Acquisition Date.

Lumara Health Acquisition

On November 12, 2014, the Lumara Health Acquisition Date, we acquired Lumara Health at which time Lumara Health became our wholly-owned subsidiary. By virtue of the acquisition, we acquired Lumara Health's existing commercial product, Makena. Under the terms of the acquisition agreement, we acquired 100% of the equity ownership of Lumara Health, excluding the assets and liabilities of the Women's Health Division and certain other assets and liabilities, which were divested by Lumara Health prior to closing, for \$600.0 million in cash, subject to certain net working capital and other adjustments, and issued approximately 3.2 million shares of our common stock, having a value of approximately \$112.0 million at the time of closing, to the holders of common stock of Lumara Health. The acquisition of Lumara Health provided a strategic commercial entry into the maternal health business. The addition of Makena, the only FDA-approved therapy to reduce the risk of preterm birth in certain at-risk women, added a complementary commercial platform to our portfolio and transformed us into a multi-product specialty pharmaceutical company.

We agreed to pay additional merger consideration, up to a maximum of \$350.0 million, based upon the achievement of certain net sales milestones of Makena for the period from December 1, 2014 through December 31, 2019. This contingent consideration is recorded as a liability and measured at fair value based upon significant unobservable inputs. During the three months ended September 30, 2016, based on our achievement of the \$300.0 million annual net Makena sales milestone, the first \$100.0 million milestone to the former Lumara Health security holders was triggered, which we expect to pay in the fourth quarter of 2016. See Note E, "Fair Value Measurements," to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q and Note C, "Business Combinations," to the Financial Statements in our Annual Report for additional information.

The following table summarizes the components of the total purchase price paid for Lumara Health, as adjusted for the final net working capital and other adjustments (in thousands):

	Total Acquisition Date Fair Value
Cash consideration	\$ 600,000
Fair value of AMAG common stock issued	111,964
Fair value of contingent milestone payments	205,000
Estimated working capital and other adjustments	821
Purchase price paid at closing	917,785
Less:	
Cash received on finalization of the net working capital and other adjustments	(562)
Cash acquired from Lumara Health	(5,219)
Total purchase price	\$ 912,004

At the closing, \$35.0 million of the cash consideration was contributed to a separate escrow fund to secure the former Lumara Health security holders' obligations to indemnify us for certain matters, including breaches of representations and warranties, covenants included in the Lumara Health acquisition agreement, payments made by us to dissenting stockholders, specified tax claims, excess parachute claims, and certain claims related to the Women's Health Division of Lumara Health, which was divested by Lumara Health prior to the closing. As of September 30, 2016, the funds held in escrow have been fully distributed to the former Lumara Health security holders.

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The following table summarizes the fair values assigned to assets acquired and liabilities assumed by us along with the resulting goodwill at the Lumara Health Acquisition Date, as adjusted for certain measurement period adjustments for Lumara Health recorded during 2015 (in thousands):

	Total Acquisition Date Fair Value
Accounts receivable	\$ 36,852
Inventories	30,300
Prepaid and other current assets	3,322
Deferred income tax assets	102,355
Property and equipment	60
Makena base technology	797,100
IPR&D	79,100
Restricted cash - long term	1,997
Other long-term assets	3,412
Accounts payable	(3,807)
Accrued expenses	(36,561)
Deferred income tax liabilities	(295,676)
Other long-term liabilities	(4,563)
Total estimated identifiable net assets	\$ 713,891
Goodwill	198,113
Total	\$ 912,004

During 2015, we finalized the fair values assigned to the assets acquired and liabilities assumed by us at the Lumara Health Acquisition Date. See Note C, "Business Combinations," to the Financial Statements in our Annual Report for additional information.

Unaudited Pro Forma Supplemental Information

The following supplemental unaudited pro forma information presents our revenues and net income (loss) on a pro forma basis, assuming that the CBR acquisition occurred on January 1, 2014. For purposes of preparing the following pro forma information, certain items recorded during the three and nine months ended September 30, 2015, such as \$8.5 million and \$11.2 million of acquisition-related costs, respectively, \$10.4 million loss on debt extinguishment and \$9.2 million of other one-time fees and expenses incurred in connection with the CBR acquisition financing, are reflected in 2014 and 2015 as if the CBR acquisition occurred on January 1, 2014. The pro forma amounts do not include any expected cost savings or restructuring actions which may be achievable or which have occurred subsequent to the acquisition of CBR or the impact of any non-recurring activity. The following table presents unaudited pro forma results (in thousands, except per share data):

	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2015
Pro forma revenues	\$ 110,244	\$ 381,650
Pro forma net income (loss)	\$(5,116)	\$ 24,220
Pro forma net income (loss) per diluted share	\$(0.15)	\$ 0.69

The pro forma adjustments reflected in the pro forma net income (loss) in the above table primarily represent adjustments to historical amortization of intangible assets, adjustments to historical depreciation of property, plant and equipment and reductions to historical CBR revenues due to fair value adjustments in purchase accounting to

intangible assets, property, plant and equipment and deferred revenue, respectively. In addition, the pro forma combined net income (loss) includes increased interest expense due to the increase in total term loan borrowings and the issuance of the 2023 Senior Notes (as defined below) in connection with the CBR acquisition. Income taxes for all periods were adjusted accordingly. This pro forma financial information is not necessarily indicative of our consolidated operating results that would have been reported had the transactions been completed as described herein, nor is such information necessarily indicative of our consolidated results for any future period.

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Goodwill

In connection with the CBR acquisition, we recognized \$441.4 million of goodwill, primarily due to the synergies expected from combining our operations with CBR and to deferred tax liabilities related to fair value adjustments of intangible assets and deferred revenue. In connection with the Lumara Health acquisition, we recognized \$198.1 million of goodwill, primarily due to the net deferred tax liabilities recorded on the fair value adjustments to Lumara Health's inventories and identifiable intangible asset. The \$639.5 million of goodwill resulting from the CBR and Lumara Health acquisitions is not deductible for income tax purposes.

D. INVESTMENTS

As of September 30, 2016 and December 31, 2015, our investments equaled \$308.8 million and \$237.6 million, respectively, and consisted of securities classified as available-for-sale in accordance with accounting standards which provide guidance related to accounting and classification of certain investments in debt and equity securities.

The following is a summary of our investments as of September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	\$116,674	\$ 7	\$ (84)	\$116,597
Due in one to three years	135,719	398	(20)	136,097
U.S. treasury and government agency securities				
Due in one year or less	1,032	1	—	1,033
Due in one to three years	8,891	25	(2)	8,914
Commercial paper				
Due in one year or less	31,852	—	—	31,852
Certificates of deposit				
Due in one year or less	11,800	—	—	11,800
Municipal securities				
Due in one year or less	2,500	—	(1)	2,499
Total investments	\$308,468	\$ 431	\$ (107)	\$308,792

	December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	\$27,964	\$ —	\$ (38)	\$27,926
Due in one to three years	173,652	3	(904)	172,751
Commercial paper				
Due in one year or less	34,452	2	(5)	34,449
Municipal securities				
Due in one year or less	2,500	—	—	2,500
Total investments	\$238,568	\$ 5	\$ (947)	\$237,626

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Impairments and Unrealized Gains and Losses on Investments

We did not recognize any other-than-temporary impairment losses in our condensed consolidated statements of operations related to our securities during the three or nine months ended September 30, 2016 and 2015. 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, 2016, none of our investments has been 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 investments could have a material adverse effect on our earnings in future periods.

E. FAIR VALUE MEASUREMENTS

The following tables represent the fair value hierarchy as of September 30, 2016 and December 31, 2015, for those assets and liabilities that we measure at fair value on a recurring basis (in thousands):

Fair Value Measurements at September 30, 2016 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	\$5,689	\$ 5,689	\$ —	\$ —
Corporate debt securities	252,694	—	252,694	—
U.S. treasury and government agency securities	9,947	—	9,947	—
Commercial paper	31,852	—	31,852	—
Certificates of deposit	11,800	—	11,800	—
Municipal securities	2,499	—	2,499	—
Total Assets	\$314,481	\$ 5,689	\$ 308,792	\$ —
Liabilities:				
Contingent consideration - Lumara Health	\$225,137	\$ —	\$ —	\$ 225,137
Contingent consideration - MuGard	2,316	—	—	2,316
Total Liabilities	\$227,453	\$ —	\$ —	\$ 227,453

Fair Value Measurements at December 31, 2015 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	\$73,676	\$ 73,676	\$ —	\$ —
Corporate debt securities	200,677	—	200,677	—
Commercial paper	34,449	—	34,449	—
Municipal securities	2,500	—	2,500	—
Total Assets	\$311,302	\$ 73,676	\$ 237,626	\$ —
Liabilities:				
Contingent consideration - Lumara Health	\$214,895	\$ —	\$ —	\$ 214,895
Contingent consideration - MuGard	7,664	—	—	7,664
Total Liabilities	\$222,559	\$ —	\$ —	\$ 222,559

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Investments

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 investments are classified as Level 2 assets under the fair value hierarchy as these assets were 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 analyses of prices received from third parties to determine whether prices are reasonable estimates of fair value. After completing our analyses, we did not adjust or override any fair value measurements provided by our pricing services as of September 30, 2016. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during the nine months ended September 30, 2016.

Contingent consideration

There were no contingent consideration obligations related to the CBR acquisition. 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, 2015	\$ 222,559
Payments made	(212)
Adjustments to fair value of contingent consideration	5,106
Balance as of September 30, 2016	\$ 227,453

The \$5.1 million of adjustments to the fair value of the contingent consideration liability during the nine months ended September 30, 2016 were due to a \$10.2 million increase to the Makena contingent consideration and a \$5.1 million decrease to the MuGard contingent consideration. During the second quarter of 2016, we revised our forecast of total projected net sales for MuGard and reassessed the fair value of the contingent consideration liability related to the MuGard Rights. As a result, we reduced our MuGard-related contingent consideration liability by \$5.6 million. These adjustments were included in selling, general and administrative expenses in our condensed consolidated statements of operations. We have classified \$100.0 million of the Makena contingent consideration and \$0.4 million of the MuGard contingent consideration as short-term liabilities in our condensed consolidated balance sheet as of September 30, 2016. The \$100.0 million Makena contingent consideration reflects a \$100.0 million milestone payment to be paid in the fourth quarter of 2016 to the former Lumara Health security holders based on the achievement of a net sales milestone of Makena in the third quarter of 2016.

The fair value of the contingent milestone payments payable by us to the former stockholders of Lumara Health was 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 cash flows were discounted at a rate of 5.0%, which we believe is reasonable given the estimated likelihood of the pay-out. As of September 30, 2016, the total undiscounted milestone payment amounts we could pay in connection with the Lumara Health acquisition was \$350.0 million through December 31, 2019, including the \$100.0 million milestone payment to be paid in the fourth quarter of 2016.

The fair value of the contingent royalty payments payable by us to Abeona was determined based on various market factors, including an analysis of estimated sales using a discount rate of approximately 9%. As of September 30, 2016, we estimated that the undiscounted royalty amounts we could pay under the MuGard License Agreement, based on current projections, may range from \$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.

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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, 2016, the estimated fair value of our 2023 Senior Notes, Convertible Notes and 2015 Term Loan Facility (each as defined below) was \$473.0 million, \$223.0 million and \$336.9 million, respectively, which differed from their carrying values. See Note Q, "Debt" for additional information on our debt obligations.

F. INVENTORIES

Our major classes of inventories were as follows as of September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016	December 31, 2015
Raw materials	\$ 14,825	\$ 19,673
Work in process	3,185	1,985
Finished goods	20,147	18,987
Total inventories	\$ 38,157	\$ 40,645

G. PROPERTY, PLANT AND EQUIPMENT, NET

Property, plant and equipment, net consisted of the following as of September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016	December 31, 2015
Land	\$ 700	\$ 700
Land improvements	300	300
Building and improvements	9,500	9,500
Computer equipment and software	13,866	13,193
Furniture and fixtures	2,299	1,725
Leasehold improvements	3,683	1,717
Laboratory and production equipment	5,938	5,683
Construction in progress	678	786
	36,964	33,604
Less: accumulated depreciation	(11,709)	(4,879)
Property, plant and equipment, net	\$ 25,255	\$ 28,725

H. GOODWILL AND INTANGIBLE ASSETS, NET

Goodwill

Our \$639.5 million goodwill balance consisted of \$198.1 million of goodwill acquired through the November 2014 Lumara Health acquisition and \$441.4 million acquired through the August 2015 CBR acquisition. During the nine months ended September 30, 2016, the CBR goodwill increased by \$0.3 million related to measurement period net tax adjustments. These measurement period adjustments have been reflected as current period adjustments in accordance with ASU 2015-16, discussed below in Note S, "Recently Issued and Proposed Accounting Pronouncements." As of September 30, 2016, we had no accumulated impairment losses related to goodwill.

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Intangible Assets

As of September 30, 2016 and December 31, 2015, our identifiable intangible assets consisted of the following (in thousands):

	September 30, 2016				December 31, 2015		
	Cost	Accumulated Amortization	Impairments	Net	Cost	Accumulated Amortization	Net
Amortizable intangible assets:							
Makena base technology	\$797,100	\$ 105,207	\$ —	\$691,893	\$797,100	\$ 56,540	\$740,560
CBR customer relationships	297,000	10,458	—	286,542	297,000	1,061	295,939
CBR Favorable lease	358	119	239	—	358	63	295
MuGard Rights	16,893	1,169	15,724	—	16,893	1,016	15,877
	1,111,351	116,953	15,963	978,435	1,111,351	58,680	1,052,671
Indefinite-lived intangible assets:							
Makena IPR&D	79,100	—	—	79,100	79,100	—	79,100
CBR trade names and trademarks	65,000	—	—	65,000	65,000	—	65,000
Total intangible assets	\$1,255,451	\$ 116,953	\$ 15,963	\$1,122,535	\$1,255,451	\$ 58,680	\$1,196,771

As of September 30, 2016, the weighted average remaining amortization period for our finite-lived intangible assets was approximately nine years.

The Makena base technology and IPR&D intangible assets were acquired in November 2014 in connection with our acquisition of Lumara Health. Amortization of the Makena base technology asset is being recognized using an economic consumption model over 20 years, which we believe is an appropriate amortization period due to the estimated economic lives of the product rights and related intangibles.

The CBR intangible assets (the CBR customer relationships, favorable lease and trade names and trademarks) were acquired in August 2015 in connection with our acquisition of CBR. Amortization of the CBR customer relationships is being recognized using an estimated useful life of 20 years, which we believe is an appropriate amortization period due to the estimated economic lives of the CBR intangible assets. The favorable lease was being amortized on a straight-line basis over the remaining term of the lease. On May 4, 2016, we entered into a sublease arrangement for a portion of our CBR office space in San Bruno, California with a sublessee at a rate lower than the market rate used to determine the favorable lease intangible asset. We reevaluated the favorable lease asset based on the negotiated sublease rate, resulting in an impairment charge for the full \$0.2 million net intangible asset in the second quarter of 2016.

The MuGard Rights were acquired from Abeona in June 2013. Amortization of the MuGard Rights was being recognized using an economic consumption model over ten years, which represented our best estimate of the period over which we expected the majority of the asset's cash flows to be derived. Based on events in the second quarter of 2016, we determined that broader reimbursement coverage for MuGard by government payors was unlikely based on recent interactions with those agencies and assessed the MuGard Rights for potential impairment. From this assessment, we concluded that based on the lack of broad reimbursement and insurance coverage for MuGard and the resulting decrease in expected revenues and cash flows, the projected undiscounted cash flows were less than the book value, indicating impairment of this intangible asset. As a result of an analysis of the fair value of the net MuGard Rights intangible asset as compared to its recorded book value, we recognized an impairment charge for the full \$15.7 million net intangible asset in the second quarter of 2016.

See Note C, "Business Combinations," for additional information on our intangible assets.

Total amortization expense for the nine months ended September 30, 2016 and 2015, was \$58.3 million and \$13.9 million, respectively. Amortization expense for Makena base technology and the MuGard Rights is recorded in cost of

product sales in our condensed consolidated statements of operations. Amortization expense for the CBR related intangibles is recorded in selling, general and administrative expenses in our condensed consolidated statements of operations. We expect amortization expense related to our finite-lived intangible assets to be as follows (in thousands):

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Period	Estimated Amortization Expense
Remainder of Year Ending December 31, 2016	\$ 21,121
Year Ending December 31, 2017	90,826
Year Ending December 31, 2018	97,992
Year Ending December 31, 2019	68,993
Year Ending December 31, 2020	46,271
Thereafter	653,232
Total	\$ 978,435

I. CURRENT AND LONG-TERM LIABILITIES

Accrued Expenses

Accrued expenses consisted of the following as of September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016	December 31, 2015
Commercial rebates, fees and returns	\$ 78,371	\$ 45,161
Professional, license, and other fees and expenses	28,376	27,070
Interest expense	5,761	18,411
Salaries, bonuses, and other compensation	13,328	12,838
Restructuring expense	527	2,883
Total accrued expenses	\$ 126,363	\$ 106,363

Deferred Revenues

Our deferred revenue balances as of September 30, 2016 and December 31, 2015 were primarily related to our CBR Services revenues and includes: (a) amounts collected in advance of unit processing and (b) amounts associated with unearned storage fees collected at the beginning of the storage contract term, net of allocated discounts.

J. INCOME TAXES

The following table summarizes our effective tax rate and income tax expense (benefit) for the three and nine months ended September 30, 2016 and 2015 (in thousands except for percentages):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Effective tax rate	24 %	41 %	32 %	27 %
Income tax expense (benefit)	\$5,069	\$(14,130)	\$3,725	\$9,513

For the three and nine months ended September 30, 2016, we recognized an income tax expense of \$5.1 million and \$3.7 million, respectively, representing an effective tax rate of 24% and 32%, respectively. The difference between the expected statutory federal tax rate of 35% and the effective tax rates for the three and nine months ended September 30, 2016, was primarily attributable to contingent consideration associated with Lumara Health, including the tax deductible portion of the anticipated payout, and federal research and development and orphan drug tax credits, partially offset by the impact of state income taxes, non-deductible stock compensation, and other non-deductible expenses. The effective tax rate for the nine months ended September 30, 2016, was also impacted by the impairment of the net intangible asset for the MuGard Rights and related contingent consideration fair value adjustment. We recorded a net tax benefit in the second quarter of 2016 for these discrete events at a combined federal and state statutory income tax rate of 39%.

For the three and nine months ended September 30, 2015, we recognized income tax benefit and expense of \$14.1 million and \$9.5 million, respectively, representing an effective tax rate of 41% and 27%, respectively. The difference between the expected statutory federal tax rate of 35% and the 41% effective tax rate for the three months ended September 30, 2015, was

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attributable to the impact of a valuation allowance release related to certain deferred tax assets and the impact of state income taxes, partially offset by non-deductible transaction costs associated with the acquisition of CBR and non-deductible contingent consideration expense associated with Lumara Health. The difference between the expected statutory federal tax rate of 35% and the 27% effective tax rate for the nine months ended September 30, 2015, was attributable to the impact of a valuation allowance release related to certain deferred tax assets, partially offset by the impact of state income taxes, non-deductible transaction costs associated with the acquisition of CBR, and non-deductible contingent consideration expense associated with Lumara Health.

K. ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

The table below presents information about the effects of net income (loss) of significant amounts reclassified out of accumulated other comprehensive income (loss), net of tax, associated with unrealized gains (losses) on securities during the three and nine months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Beginning balance	\$(3,058)	\$(3,948)	\$(4,205)	\$(3,617)
Other comprehensive income (loss) before reclassifications	(336)	228	811	(107)
Reclassification adjustment for (losses) gains included in net income (loss)	—	—	—	4
Ending balance	\$(3,394)	\$(3,720)	\$(3,394)	\$(3,720)

L. 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 (loss), diluted net income (loss) per common share would be computed assuming the impact of the conversion of the \$200.0 million of 2.5% convertible senior notes due February 15, 2019 (the “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 under the Convertible Notes in cash, shares or any combination of the two. Pursuant to certain covenants in our six-year \$350.0 million term loan facility (the “2015 Term Loan Facility”), which we entered into in 2015 to partially fund the acquisition of CBR, we may be restricted from settling the conversion obligation in whole or in part with cash unless certain conditions in the 2015 Term Loan Facility are satisfied. We utilize the if-converted method to reflect the impact of the conversion of the Convertible Notes. This method assumes the conversion of the Convertible Notes into shares of our common stock and reflects the elimination of \$1.9 million of interest expense related to the Convertible Notes during the three months ended September 30, 2016.

The dilutive effect of the warrants, stock options and RSUs has been calculated using the treasury stock method. The components of basic and diluted net income (loss) per share for the three and nine months ended September 30, 2016 and 2015, were as follows (in thousands, except per share data):

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net income (loss)	\$16,196	\$(20,584)	\$8,074	\$25,578
Weighted average common shares outstanding	34,171	33,223	34,377	30,379
Effect of dilutive securities:				
Stock options and RSUs	558	—	387	1,568
Warrants	—	—	—	3,015
Convertible 2.5% notes	7,382	—	—	—
Shares used in calculating dilutive net income (loss) per share	42,111	33,223	34,764	34,962
Net income (loss) per share:				
Basic	\$0.47	\$(0.62)	\$0.23	\$0.84
Diluted	\$0.43	\$(0.62)	\$0.23	\$0.73

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 income (loss) per share because their inclusion would have been anti-dilutive (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Options to purchase shares of common stock	2,218	2,989	2,778	791
Shares of common stock issuable upon the vesting of RSUs	249	712	654	157
Warrants	7,382	7,382	7,382	—
Convertible 2.5% notes	—	7,382	7,382	7,382
Total	9,849	18,465	18,196	8,330

In connection with the issuance of the 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 Convertible Notes.

M. EQUITY BASED COMPENSATION

We currently maintain four equity compensation plans, namely our Third Amended and Restated 2007 Equity Incentive Plan, as amended (the “2007 Plan”), our Amended and Restated 2000 Stock Plan (the “2000 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”). All outstanding stock options granted under each of our equity compensation plans other than our 2015 ESPP (discussed below) have an exercise price equal to the closing price of a share of our common stock on the grant date.

Our 2007 Plan was originally approved by our stockholders in November 2007, and succeeded our 2000 Plan, under which no further grants may be made. Any shares that remained available for issuance under the 2000 Plan as of the date of adoption of the 2007 Plan are included in the number of shares that may be issued under the 2007 Plan. Any shares subject to outstanding awards granted under the 2000 Plan that expire or terminate for any reason prior to exercise will be added to the total number of shares of our stock available for issuance under the 2007 Plan. The total

number of shares issuable pursuant to awards under the 2007 Plan is 6,995,325. As of September 30, 2016, there were 1,722,478 shares remaining available for issuance under the 2007 Plan, which excludes shares subject to outstanding awards under the 2000 Plan. All outstanding options under the 2007 Plan have either a seven or ten-year term and all outstanding options under the 2000 Plan have a ten-year term.

In November 2014, we assumed the Lumara Health 2013 Plan in connection with the acquisition of Lumara Health. The total number of shares issuable pursuant to awards under this plan as of the effective date of the acquisition and after taking into account any adjustments as a result of the acquisition, is 200,000 shares. As of September 30, 2016, there were 40,356 shares remaining available for issuance under the Lumara Health 2013 Plan, which are available for grants to certain employees,

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officers, directors, consultants, and advisors of AMAG and our subsidiaries who are newly-hired or who previously performed services for Lumara Health. All outstanding options under the Lumara Health 2013 Plan have a ten-year term.

In May 2015, our stockholders approved our 2015 ESPP, which authorizes the issuance of up to 200,000 shares of our common stock to eligible employees. The terms of the 2015 ESPP permit eligible employees to purchase shares (subject to certain plan and tax limitations) in semi-annual offerings through payroll deductions of up to an annual maximum of 10% of the employee's "compensation" as defined in the 2015 ESPP. Shares are purchased at a price equal to 85% of the fair market value of our common stock on either the first or last business day of the offering period, whichever is lower. Plan periods consist of six-month periods typically commencing June 1 and ending November 30 and commencing December 1 and ending May 31. As of September 30, 2016, 41,679 shares have been issued under our 2015 ESPP.

During the nine months ended September 30, 2016, we also granted equity through inducement grants outside of these plans to certain employees to induce them to accept employment with us (collectively, "Inducement Grants"). The options were granted at an exercise price equal to the fair market value of a share of our common stock on the respective grant dates and will be exercisable in four equal annual installments beginning on the first anniversary of the respective grant dates. The RSU grants will vest in three equal annual installments beginning on the first anniversary of the respective grant dates. The foregoing grants were made pursuant to inducement grants outside of our stockholder approved equity plans as permitted under the NASDAQ Stock Market listing rules. We assessed the terms of these awards and determined there was no possibility that we would have to settle these awards in cash and therefore, equity accounting was applied.

Stock Options

The following table summarizes stock option activity for the nine months ended September 30, 2016:

	2007 Equity Plan	2000 Equity Plan	2013 Lumara Equity Plan	Inducement Grants	Total
Outstanding at December 31, 2015	1,963,162	14,040	96,000	830,975	2,904,177
Granted	532,659	—	56,150	110,000	698,809
Exercised	(86,584)	—	—	—	(86,584)
Expired or terminated	(191,938)	—	(47,532)	(86,250)	(325,720)
Outstanding at September 30, 2016	2,217,299	14,040	104,618	854,725	3,190,682

Restricted Stock Units

The following table summarizes RSU activity for the nine months ended September 30, 2016:

	2007 Equity Plan	2000 Equity Plan	2013 Lumara Equity Plan	Inducement Grants	Total
Outstanding at December 31, 2015	446,330	—	52,350	155,675	654,355
Granted	652,226	—	—	64,500	716,726
Vested	(194,970)	—	(16,749)	(58,569)	(270,288)
Expired or terminated	(88,424)	—	(8,990)	(5,500)	(102,914)
Outstanding at September 30, 2016	815,162	—	26,611	156,106	997,879

Equity-based compensation expense

Equity-based compensation expense for the three and nine months ended September 30, 2016 and 2015 consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Cost of product sales	\$118	\$159	\$395	\$254
Research and development	858	1,028	2,583	2,071

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Selling, general and administrative	4,492	3,701	13,831	9,247
Total equity-based compensation expense	\$5,468	\$4,888	\$16,809	\$11,572
Income tax effect	(1,568)	(871)	(4,637)	(3,464)
After-tax effect of equity-based compensation expense	\$3,900	\$4,017	\$12,172	\$8,108

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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 have not recognized any excess tax benefits from equity-based compensation in additional paid-in capital because the excess tax benefits have not yet reduced cash taxes paid. Accordingly, there was no impact recorded in cash flows from financing activities or cash flows from operating activities as reported in the accompanying condensed consolidated statements of cash flows.

N. STOCKHOLDERS' EQUITY

Share Repurchase Program

In January 2016, we announced that our board of directors 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. During the nine months ended September 30, 2016, we repurchased and retired 831,744 shares of common stock under this repurchase program for \$20.0 million at an average purchase price of \$24.05 per share. We did not repurchase any of our common stock during the third quarter of 2016.

Change in Stockholders' Equity

Total stockholders' equity increased by \$5.7 million during the nine months ended September 30, 2016. This increase was primarily driven by \$8.1 million from our net income, \$16.8 million related to equity-based compensation expense, partially offset by \$20.0 million related to the repurchase of our securities under our stock repurchase program.

O. 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 and other purchases related to our products, debt obligations, and other purchase obligations.

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.

Sandoz Patent Infringement Lawsuit

On February 5, 2016, we received a Paragraph IV certification notice letter 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. A generic version of Feraheme can be marketed only with the approval of the FDA of the respective application for such generic version. The Drug Price Competition and Patent Term Restoration Act of 1984, as amended, requires an applicant whose subject drug is a drug listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations,” also known as the “Orange Book,” to notify the patent holder of their application

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and potential infringement of their patent rights. The Paragraph IV certification notice is required to contain a detailed factual and legal statement explaining the basis for the applicant's opinion that the proposed product does not infringe the subject patents, that such patents are invalid, or both. Receipt of the certification notice triggers a 45 day window during which a patent infringement suit may be filed in federal district court against the applicant seeking approval of a product. In its notice letter, Sandoz claims that our ferumoxytol patents are invalid, unenforceable and/or not infringed by Sandoz's manufacture, use, sale or offer for sale of the generic version. In March 2016, we initiated a patent infringement suit alleging that Sandoz' ANDA filing itself constituted an act of infringement and that if it is approved, the manufacture, use, offer for sale, sale or importation of Sandoz' ferumoxytol products would infringe our patents. By the filing of this complaint, the FDA is generally prohibited from granting approval of Sandoz' application until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in the generic's favor, or expiration of the patent(s) (though such stay may be shortened or lengthened if either party fails to cooperate in the litigation). If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30 months stay period, the stay is lifted and the FDA may thereafter approve the application based on the applicable standards for approval. On May 2, 2016, Sandoz filed a response to our patent infringement suit. Any future unfavorable outcome in this matter could negatively affect the magnitude and timing of future Feraheme revenues. We intend to vigorously enforce our intellectual property rights relating to ferumoxytol.

European Patent Organization Appeal

In July 2010, Sandoz filed with the European Patent Office (the "EPO") an opposition to a previously issued patent which covers ferumoxytol in EU jurisdictions. In October 2012, at an oral hearing, the Opposition Division of the EPO revoked this patent. We recorded a notice of appeal at the EPO in December 2012, which suspended the revocation of our patent. The oral proceedings for the appeal occurred in June 2015, where the decision revoking the patent was set aside and remitted back to the Opposition Division for further consideration. In June 2016, we elected not to continue to challenge the opposition at the EPO, which will result in the loss of our European patent rights for ferumoxytol. This decision was based on a number of factors, including the fact that we withdrew ferumoxytol from the EU market in 2015 and our strategic focus of resources on U.S.-based commercial efforts. The decision not to challenge the opposition will not affect the fact that in the event that we seek to obtain a new marketing authorization for ferumoxytol in the future, under EU regulations ferumoxytol may still be entitled to the remaining part of the eight years of data protection and ten years of market exclusivity granted at the date of its original approval, which we believe could create barriers to entry for any generic version of ferumoxytol into the EU market until sometime between 2020 and 2022.

Other

On July 20, 2015, the Federal Trade Commission (the "FTC") notified us that it is 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. We have fully cooperated with the FTC and provided a thorough response to the FTC in August 2015 and are awaiting their review of our response. 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 that provides a brief overview of the DQSA for context, which we believe will be 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.

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

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dismissed KV with prejudice to refile 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 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, 2016.

P. 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-stage development assets. As of September 30, 2016, we were a party to the following collaborations:

Velo

In July 2015, we entered into an option agreement with Velo Bio, LLC ("Velo"), a privately held life-sciences company that granted us an option to acquire the rights (the "DIF Rights") to an orphan drug candidate, digoxin immune fab ("DIF"), a polyclonal antibody in clinical development for the treatment of severe preeclampsia in pregnant women. We made an upfront payment of \$10.0 million in the third quarter of 2015 for the option to acquire the DIF Rights. DIF has been granted both orphan drug and fast-track review designations by the FDA for use in treating severe preeclampsia. Under the option agreement, Velo will complete a Phase 2b/3a clinical study, which we expect to begin in the first half of 2017. Following the conclusion of the DIF Phase 2b/3a study, we may terminate, or, for additional consideration, exercise or extend, our option to acquire the DIF Rights. If we exercise the option to acquire the DIF Rights, we would be responsible for additional costs in pursuing FDA approval, and would be obligated to pay certain milestone payments and single-digit royalties based on regulatory approval and commercial performance of the product to Velo. If we exercise the option, we will be responsible for payments totaling up to \$65.0 million (including the payment of the option exercise price and the regulatory milestone payments) and up to an additional \$250.0 million in sales milestone payments based on the achievement of annual sales milestones at targets ranging from \$100.0 million to \$900.0 million.

We have determined that Velo is a variable interest entity ("VIE") as it does not have enough equity to finance its activities without additional financial support. As we do not have the power to direct the activities of the VIE that most significantly affect its economic performance, which we have determined to be the Phase 2b/3a clinical study, we are not the primary beneficiary of and do not consolidate the VIE.

Antares

In September 2014, Lumara Health entered into a development and license agreement (the "Antares Agreement") with Antares Pharma, Inc. ("Antares"), which in connection with our acquisition of Lumara Health in November of 2014, 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 an Antares' auto-injection system for use with hydroxyprogesterone caproate (the "auto-injector"). In consideration for the license, to support joint meetings and a development strategy with the FDA, and for initial tooling and process validation, Lumara Health paid Antares an up-front payment in October 2014. Under the Antares 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 auto-injector, including the U.S. We are required to pay royalties to Antares on net sales of the auto-injector commencing on the launch of the auto-injector in a particular country until the auto-injector is no longer developed, marketed, sold or offered for sale in such country ("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 auto-injector and decrease after the expiration of licensed patents or where there are generic equivalents to the auto-injector being sold in a particular country. Antares is the exclusive supplier of the device components of our auto-injector system and Antares remains responsible for the manufacture and supply of the device components and

assembly of the auto-injector. We are responsible for the supply of the drug to be used in the assembly of the finished auto-injector. The development and license agreement terminates at the end of the Antares Royalty Term, but is subject to early termination by us for convenience, by Antares if we do not submit regulatory filings in the U.S. by a certain date and by either party upon an uncured breach by or bankruptcy of the other party.

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Abeona

Please refer to Note C, “Business Combinations,” to the Financial Statements in our Annual Report for a detailed description of the MuGard License Agreement.

Q. DEBT

Our outstanding debt obligations as of September 30, 2016 and December 31, 2015 consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
2023 Senior Notes	\$489,320	\$488,481
2015 Term Loan Facility	321,340	332,688
Convertible Notes	177,146	170,749
Total long-term debt	987,806	991,918
Less: current maturities	62,791	17,500
Long-term debt, net of current maturities	\$925,015	\$974,418

2023 Senior Notes

On August 17, 2015, in connection with the CBR acquisition, we completed a private placement of \$500 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. The Indenture contains certain customary negative covenants, which are subject to a number of limitations and exceptions. Certain of the covenants will be suspended during any period in which the 2023 Senior Notes receive investment grade ratings.

The 2023 Senior Notes, which are senior unsecured obligations of the Company, will mature on September 1, 2023 and bear interest at a rate of 7.875% per year, with interest payable semi-annually on September 1 and March 1 of each year, beginning on March 1, 2016. We may redeem some or all of the 2023 Senior Notes at any time, or from time to time, on or after September 1, 2018 at the redemption prices listed in the Indenture, plus accrued and unpaid interest to, but not including, the date of redemption. In addition, prior to September 1, 2018, we may redeem up to 35% of the aggregate principal amount of the 2023 Senior Notes utilizing the net cash proceeds from certain equity offerings, at a redemption price of 107.875% of the principal amount thereof, plus accrued and unpaid interest to, but not including, the date of redemption; provided that at least 65% of the aggregate amount of the 2023 Senior Notes originally issued under the Indenture remain outstanding after such redemption. We may also redeem all or some of the 2023 Senior Notes at any time, or from time to time, prior to September 1, 2018, at a price equal to 100% of the principal amount of the 2023 Senior Notes to be redeemed, plus a “make-whole” premium plus accrued and unpaid interest, if any, to the date of redemption. Upon the occurrence of a “change of control,” as defined in the Indenture, we are required to offer to repurchase the 2023 Senior Notes at 101% of the aggregate principal amount thereof, plus any accrued and unpaid interest to, but not including, the repurchase date. The Indenture contains customary events of default, which allow either the trustee or the holders of not less than 25% in aggregate principal amount of the then-outstanding 2023 Senior Notes to accelerate, or in certain cases, which automatically cause the acceleration of, the amounts due under the 2023 Senior Notes.

At September 30, 2016, the principal amount of the outstanding borrowings was \$500 million and the carrying value of the outstanding borrowings, net of issuance costs and other lender fees and expenses, was \$489.3 million.

2015 Term Loan Facility

On August 17, 2015, to fund a portion of the purchase price of CBR, we entered into a credit agreement with a group of lenders, including Jefferies Finance LLC as administrative and collateral agent, that provided us with, among other things, a six-year \$350.0 million term loan facility. We borrowed the full \$350.0 million available under the 2015 Term Loan Facility on August 17, 2015. The credit agreement also allows for the incurrence of incremental loans in

an amount up to \$225.0 million. At September 30, 2016, the principal amount of the outstanding borrowings was \$332.5 million and the carrying value of the outstanding borrowings, net of issuance costs and other lender fees and expenses, was \$321.3 million. The unamortized original issue costs and other lender fees and expenses, including a prepayment penalty, included \$6.8 million of the unamortized original issue costs and other lender fees and expenses from our then existing five-year term loan facility as a result of accounting guidance for the modification of debt arrangements.

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The 2015 Term Loan Facility bears interest, at our option, at the London Interbank Offered Rate (“LIBOR”) plus a margin of 3.75% or the prime rate plus a margin of 2.75%. The LIBOR is subject to a 1.00% floor and the prime rate is subject to a 2.00% floor. As of September 30, 2016, the stated interest rate, based on the LIBOR, was 4.75%, and the effective interest rate was 5.65%.

We must repay the 2015 Term Loan Facility in installments of \$4.4 million per quarter due on the last day of each quarter beginning with the quarter ended December 31, 2015. The 2015 Term Loan Facility matures on August 17, 2021.

The 2015 Term Loan Facility includes an annual mandatory prepayment of the debt in an amount equal to 50% of our excess cash flow (as defined in the 2015 Term Loan Facility) as measured on an annual basis, beginning with the year ending December 31, 2016. As a result, as of September 30, 2016, \$45.3 million was estimated and reclassified from long-term debt to current portion of long-term debt in our condensed consolidated balance sheet as the first excess payment is expected to be made in April 2017. On or after December 31, 2016, the applicable excess cash flow percentage shall be reduced based on the total net leverage ratio as of the last day of the period. Excess cash flow is generally defined as our adjusted Earnings Before Interest, Taxes, Depreciation and Amortization (“EBITDA”) less debt service costs, unfinanced capital expenditures, unfinanced acquisition expenditures, contingent consideration paid, and current income taxes as well as other adjustments specified in the credit agreement.

The 2015 Term Loan Facility has a lien on substantially all of our assets, including a pledge of 100% of the equity interests in our domestic subsidiaries and a pledge of 65% of the voting equity interests and 100% of the non-voting equity interests in our direct foreign subsidiaries. The 2015 Term Loan Facility contains customary events of default and affirmative and negative covenants for transactions of this type. All obligations under the 2015 Term Loan Facility are unconditionally guaranteed by substantially all of our direct and indirect domestic subsidiaries, with certain exceptions. These guarantees are secured by substantially all of the present and future property and assets of such subsidiaries, with certain exclusions.

2.5% Convertible Notes

On February 14, 2014, we issued \$200.0 million aggregate principal amount of the Convertible Notes. We received net proceeds of \$193.3 million from the sale of the 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 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).

The Convertible Notes are governed by the terms of an indenture between us, as issuer, and Wilmington Trust, National Association, as the trustee. The 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 Convertible Notes will mature on February 15, 2019, unless earlier repurchased or converted. Upon conversion of the Convertible Notes, at a holder’s election, such Convertible Notes will be convertible into cash, shares of our common stock, or a combination thereof, at our election (subject to certain limitations in the 2015 Term Loan Facility), at a conversion rate of approximately 36.9079 shares of common stock per \$1,000 principal amount of the 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. At any time prior to the close of business on the business day immediately preceding May 15, 2018, holders may convert their 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 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 event.

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 Convertible Notes, in multiples of \$1,000 principal amount, at the

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option of the holder regardless of the foregoing circumstances. Based on the last reported sale price of our common stock during the last 30 trading days of the second quarter of 2016, the Convertible Notes were not convertible as of September 30, 2016.

In accordance with accounting guidance for debt with conversion and other options, we separately account for the liability and equity components of the Convertible Notes by allocating the proceeds between the liability component and the embedded conversion option (“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 (subject to certain limitations in the 2015 Term Loan Facility). The carrying amount of the liability component 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 (“debt discount”) 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.

Our outstanding Convertible Note balances as of September 30, 2016 consisted of the following (in thousands):

	September 30, 2016
Liability component:	
Principal	\$ 199,998
Less: debt discount and issuance costs, net	(22,852)
Net carrying amount	\$ 177,146
Equity component	\$38,188

In connection with the issuance of the Convertible Notes, we incurred approximately \$6.7 million of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, and allocated these costs to the liability and equity components based on the allocation of the proceeds. Of the total \$6.7 million of debt issuance costs, \$1.3 million was allocated to the equity component and recorded as a reduction to additional paid-in capital and \$5.4 million was allocated to the liability component and is now recorded as a reduction of the 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.

We determined the expected life of the debt was equal to the five-year term on the Convertible Notes. As of September 30, 2016, the principal amount of the Convertible Notes was \$200.0 million and the carrying value of the Convertible Notes was \$177.1 million. The effective interest rate on the liability component was 7.23% for the period from the date of issuance through September 30, 2016. As of September 30, 2016, the “if-converted value” did not exceed the remaining principal amount of the Convertible Notes.

The following table sets forth total interest expense recognized related to the Convertible Notes during the three and nine months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended September 30, 2016		Nine Months Ended September 30, 2015	
Contractual interest expense	\$ 1,250	\$ 1,250	\$ 3,750	\$ 3,750
Amortization of debt issuance costs	273	253	797	733
Amortization of debt discount	1,920	1,777	5,602	5,153
Total interest expense	\$3,443	\$3,280	\$10,149	\$9,636

Convertible Bond Hedge and Warrant Transactions

In connection with the pricing of the Convertible Notes and in order to reduce the potential dilution to our common stock and/or offset cash payments due upon conversion of the Convertible Notes, in February 2014 we entered into convertible bond hedge transactions covering approximately 7.4 million shares of our common stock underlying the \$200.0 million aggregate principal amount of the Convertible Notes with the call spread counterparties. The convertible bond hedges have an exercise price of approximately \$27.09 per share, subject to adjustment upon certain events, and are exercisable when and if the Convertible Notes are converted. If upon conversion of the 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

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cash with an aggregate value approximately equal to the 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 related to the convertible bond hedges being exercised. The convertible bond hedges are separate transactions entered into by us and are not part of the terms of the Convertible Notes or the warrants, discussed below. Holders of the Convertible Notes will not have any rights with respect to the convertible bond hedges. We paid \$39.8 million for these convertible bond hedges and recorded this amount as a reduction to additional paid-in capital, net of tax, in 2014.

In February 2014, we also entered into separate warrant transactions with each of the call spread counterparties relating to, in the aggregate, approximately 7.4 million shares of our common stock underlying the \$200.0 million aggregate principal amount of the Convertible Notes. The initial exercise price of the warrants is \$34.12 per share, subject to adjustment upon certain events, which is 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. We received \$25.7 million for these warrants and recorded this amount to additional paid-in capital in 2014.

Aside from the initial payment of \$39.8 million to the call spread counterparties for the convertible bond hedges, which was partially offset by the receipt of \$25.7 million for the warrants, we are not required to make any cash payments to the call spread counterparties under the convertible bond hedges and will not receive any proceeds if the warrants are exercised.

R. RESTRUCTURING

In connection with the CBR and Lumara Health acquisitions, we initiated restructuring programs in the third quarter of 2015 and the fourth quarter of 2014, respectively, which included severance benefit expenses primarily related to certain former CBR and Lumara Health employees. As a result of these restructurings, we recorded no charges and approximately \$0.7 million in the three and nine months ended September 30, 2016, respectively, as compared to \$0.7 million and \$1.8 million in the same periods in 2015. We expect to pay substantially all of these restructuring costs by the end of 2016.

The following table outlines the components of our restructuring expenses which were included in current liabilities for the three and nine months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended September 30, 2016		Nine Months Ended September 30, 2015	
Accrued restructuring, beginning of period	\$1,107	\$1,253	\$2,883	\$1,953
Employee severance, benefits and related costs	—	635	898	1,490
Payments	(580)	(736)	(3,254)	(2,291)
Accrued restructuring, end of period	\$527	\$1,152	\$527	\$1,152

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 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"). The new standard clarifies existing guidance related to accounting for cash receipts and cash payments and classification on the statement of cash flows. ASU 2016-15 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, and early adoption is permitted. We are currently evaluating the impact of ASU 2016-15 on our 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”). The new 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 in our condensed consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (“ASU 2016-09”). The new standard involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or

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liabilities and classification on the statement of cash flows. ASU 2016-09 will be effective for us on January 1, 2017. We are currently evaluating the potential impact that this standard may have on our financial position, results of operations and statement of cash flows.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (“ASU 2016-02”). This statement 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. We are currently evaluating the impact of ASU 2016-02 in our condensed consolidated financial statements and we currently expect that most of our operating lease commitments will be subject to the new standard and recognized as operating lease liabilities and right-of-use assets upon our adoption of ASU 2016-02.

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”), which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. ASU 2016-01 is effective for us on January 1, 2018. We are currently evaluating the impact of our pending adoption of ASU 2016-01 in our condensed consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory (“ASU 2015-11”). The new standard applies only to inventory for which cost is determined by methods other than last-in, first-out and the retail inventory method, which includes inventory that is measured using first-in, first-out or average cost. Inventory within the scope of ASU 2015-11 is required to be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. ASU 2015-11 will be effective for us on January 1, 2017. The adoption of ASU 2015-11 is not expected to have a material impact on our results of operations, cash flows or financial position.

In April 2015, the FASB issued ASU No. 2015-03, Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs (“ASU 2015-03”). The amendments in ASU 2015-03 require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. In August 2015, the FASB issued ASU No. 2015-15, Interest – Imputation of Interest (Subtopic 835-30): Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements (“ASU 2015-15”), which allows presentation of debt issuance costs related to line-of-credit arrangements as either in accordance with the amendments in ASU 2015-03, or as an asset with subsequent amortization of the debt issuance costs ratably over the term of the arrangement. We adopted ASU 2015-03 retrospectively in the first quarter of 2016. As a result, we presented unamortized debt issuance costs as direct deductions from the carrying amounts of the related debt liabilities. We previously included the \$11.2 million of unamortized debt issuance costs in “other long-term assets” in our condensed consolidated balance sheet as of December 31, 2015.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements - Going Concern: Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (“ASU 2014-15”). ASU 2014-15 is intended to define management’s responsibility to evaluate whether there is substantial doubt about an organization’s ability to continue as a going concern and to provide related footnote disclosures, if required. ASU 2014-15 will be effective for annual reporting periods ending after December 15, 2016, which will be our fiscal year ending December 31, 2016, and to annual and interim periods thereafter. We are in the process of evaluating the impact of adoption of ASU 2014-15 in our condensed consolidated financial statements and related disclosures and do not expect it to have a material impact on our results of operations, cash flows or financial position.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, as a new Topic, Accounting Standards Codification Topic 606 (“ASU 2014-09”). The new revenue recognition standard provides a five-step analysis of transactions to determine when and how revenue is recognized. The core principle is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In March

2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customer Topic 606s, Principal versus Agent Considerations, which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU 2016-10, Revenue from Contracts with Customers Topic 606, Identifying Performance Obligations and Licensing, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU 2016-12, Revenue from Contracts with Customers Topic 606, Narrow-Scope Improvements and Practical Expedients, related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectibility, non-cash consideration and the presentation of sales and other similar taxes collected from customers. We are currently evaluating the method of adoption and the potential impact that Topic 606 may have on our financial position and results of operations. These ASUs are effective for entities for interim and annual reporting periods beginning after December 15, 2017, including interim periods within that year,

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which for us is the period beginning January 1, 2018. Early adoption is permitted any time after the original effective date, which for us is January 1, 2017. Entities have the choice to apply these ASUs either retrospectively to each reporting period presented or by recognizing the cumulative effect of applying these standards at the date of initial application and not adjusting comparative information. We have not yet selected a transition method and are currently evaluating the impact of this standard in our condensed consolidated financial statements.

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

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, 2015 (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 other 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 develop and deliver important therapeutics, conduct research and create education and support programs; beliefs that newborn stem cells have the potential to play a valuable role in the development of regenerative medicine; plans to continue to expand the impact of our portfolio by delivering on our growth strategy; expectations that Velo will begin a Phase 2b/3a study in the first half of 2017; expectations for our next-generation development programs for Makena, including the definitive PK study designed to demonstrate comparable bioavailability, including bioequivalence for area under the curve, the anticipated timing to file the sNDA, the timing of an anticipated approval for the subcutaneous auto-injector, including the expected FDA review period, and our ability to obtain orphan drug exclusivity for the auto-injector; expectations and plans as to regulatory developments and activities, including requirements and initiatives for clinical trials and studies and post-approval commitments for our products; expectations for our Phase 3 clinical trial for the broader indication for Feraheme, including the expected timing of an sNDA submission; expectations as to the impacts of recent regulatory developments on our business and competition; expectations regarding our intellectual property, including patent protection and related litigation, and the impact generic and other competition could have on our business; the market opportunities for each of our products and services; plans regarding our sales and marketing initiatives, including our contracting and discounting strategy and efforts to increase patient compliance and continue educational programs for patients and physicians; our expectations concerning increased sales of Makena as a result of gains in market share and our recent partnership with a leading provider of home nursing services; 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 or services 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; the strategic fit of the CBR Services into our maternal health portfolio; 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; expected increases in research and development expenses and the timing of our planned research and development projects; expectations regarding our financial results, including revenues, cost of product sales and services, selling, general and administrative expenses, restructuring costs, amortization and other income (expense); our investing activities; estimates and beliefs related to our debt, including our 2023 Senior Notes, Convertible Notes and the 2015 Term Loan Facility; the impact of volume-based and other rebates and incentives; 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 Convertible Notes; and our expectations for our cash, revenue, cash equivalents, investments 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

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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 biopharmaceutical company focused on developing and delivering important therapeutics, conducting clinical research in areas of unmet need and creating education and support programs for the patients and families we serve. Our products support the health of patients in the areas of maternal health, anemia management and cancer supportive care, including Makena® (hydroxyprogesterone caproate injection), Feraheme® (ferumoxytol) for Intravenous (“IV”) use and MuGard® Mucoadhesive Oral Wound Rinse. Through services related to the preservation of umbilical cord blood stem cell and cord tissue units (the “CBR Services”) operated through Cord Blood Registry (“CBR”), we also help families to preserve newborn stem cells, which are used today in transplant medicine for certain cancers and blood, immune and metabolic disorders, and have the potential to play a valuable role in the ongoing development of regenerative medicine.

We intend to expand the impact of these and future products and services for patients by delivering on our growth strategy, which includes organic growth, as well as the pursuit of products and companies that align with our existing therapeutic areas or those that could benefit from our proven core competencies. Currently, our primary sources of revenue are from product sales of Makena and Feraheme and service revenue from the CBR Services.

AMAG’s Portfolio of Products and Services

In November 2014, we acquired Lumara Health Inc. (“Lumara Health”) and its product Makena, a progestin indicated to reduce the risk of preterm birth in women pregnant with a single baby who have a history of singleton spontaneous preterm birth. Makena was approved by the FDA in February 2011 and was granted orphan drug exclusivity through February 3, 2018. We sell Makena primarily to specialty pharmacies and specialty distributors, who, in turn, sell Makena to healthcare providers, hospitals, government agencies and integrated delivery systems. Additional details regarding the Lumara Health acquisition can be found in Note C, “Business Combinations,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10 Q.

In August 2015, we acquired CBR. CBR is the largest private newborn stem cell bank in the world that offers pregnant women and their families the ability to preserve their newborns’ umbilical cord blood and cord tissue for potential future use, which we market and sell directly to consumers. Additional details regarding the acquisition of CBR can be found in Note C, “Business Combinations,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10 Q.

Feraheme was approved for marketing in the U.S. in June 2009 by the FDA for use as an IV iron replacement therapy for the treatment of iron deficiency anemia (“IDA”) in adult patients with chronic kidney disease (“CKD”). We began selling Feraheme in July 2009 through our commercial organization, including a specialty sales force. We sell Feraheme to authorized wholesalers and specialty distributors, who, in turn, sell Feraheme to healthcare providers who administer Feraheme primarily within hospitals, hematology and oncology centers, and nephrology clinics.

In July 2015, we entered into an option agreement with Velo Bio, LLC (“Velo”), a privately held life-sciences company that granted us an option to acquire the rights (the “DIF Rights”) to an orphan drug candidate, digoxin immune fab (“DIF”), a polyclonal antibody in clinical development for the treatment of severe preeclampsia in pregnant women. Under the option agreement, Velo will complete a Phase 2b/3a clinical study, which we expect to begin in the first half of 2017. Following the conclusion of the DIF Phase 2b/3a study, we may terminate, or, for additional consideration, exercise or extend, our option to acquire the DIF Rights. Additional details regarding the Velo agreement can be found in Note P, “Collaboration, License and Other Strategic Agreements,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10 Q.

In June 2013, we entered into a license agreement with Abeona Therapeutics, Inc., under which we acquired the U.S. commercial rights to MuGard for the management of oral mucositis and stomatitis (the “MuGard Rights”). Additional details regarding the acquisition of the MuGard Rights can be found in Note C, “Business Combinations,” in our Annual Report.

Makena Developments

In February 2016, the FDA approved our prior approval supplement to the original Makena New Drug Application (“NDA”) filed with the FDA in July 2015 seeking approval of a single-dose preservative-free formulation of Makena to be manufactured by Hospira, Inc. (now owned by The Pfizer CentreOne group of Pfizer, Inc.), which also manufactures our

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multidose vial of Makena. We began promoting the single-dose preservative-free formulation of Makena to physicians in the second quarter of 2016. In July 2016, we received approval of our October 2014 prior approval supplement for Piramal Pharma Solutions (formerly Coldstream Laboratories, Inc.) to also manufacture the single-dose preservative-free formulation of Makena. In addition, during 2016, we entered into an agreement with a leading provider of home nursing services (which had previously utilized compounded hydroxyprogesterone caproate) pursuant to which the provider performs at-home administration of Makena and, in connection with a recent amendment, will also co-promote Makena to certain healthcare providers.

We continue to advance our next-generation development program for Makena, seeking to enhance the product profile for patients and their healthcare providers. We are developing an auto-injector device for subcutaneous administration of Makena (the “auto-injector”), including chemistry, manufacturing and controls (“CMC”) development with Antares Pharma, Inc. We recently met with the FDA to discuss our proposed development and regulatory strategy, focusing on our plans to conduct a definitive pharmacokinetic (“PK”) study, which is designed to demonstrate comparable bioavailability, including demonstrating bioequivalence for area under the curve, which we believe is the most relevant PK parameter for Makena. Further, in order to submit the results of a comparative pain study with the supplemental new drug application (“sNDA”) filing, we are conducting a comparative pain study intended to capture certain measures to support clinical superiority of the subcutaneous auto-injector over the existing intramuscular injection. This decision was based on our dialogue with the FDA that orphan drug exclusivity may be granted if the FDA determines that the auto-injector is clinically superior to the existing intramuscular injection as demonstrated by a significant reduction in pain in a substantial portion of the target population. In October 2016, we initiated both the PK study and the pain study, both of which are randomized, open label parallel studies with a 1:1 randomization. Based on our current timelines and assumptions, we anticipate filing an sNDA for approval of the auto-injector in the second quarter of 2017 and, as a result of our decision to contemporaneously submit the results of our comparative pain study, the review period is expected to be ten months.

Makena was approved under the provisions of the FDA’s “Subpart H” Accelerated Approval regulations. As a condition of approval under Subpart H, the FDA required that Makena’s sponsor perform certain adequate and well-controlled post-approval clinical studies to verify and describe the clinical benefit of Makena as well as fulfill certain other post-approval commitments. We have completed a PK trial of women taking Makena and are currently conducting two other studies to fulfill these obligations, one of which is due to the FDA by December 2018 and the other by October 2020.

Feraheme Developments

In pursuit of a broader indication for Feraheme to include the treatment of IDA in adult patients who had failed or could not tolerate oral iron or in whom oral iron was contraindicated, we are conducting a new head-to-head Phase 3 clinical trial evaluating Feraheme in adults with IDA, excluding patients on hemodialysis. This new trial is a randomized, double-blind multicenter non-inferiority trial that will evaluate the incidence of moderate to severe hypersensitivity reactions (including anaphylaxis) and moderate to severe hypotension with Feraheme compared to ferric carboxymaltose infusion. Two thousand patients will be randomized in a 1:1 ratio into one of two treatment groups, those receiving 1.02 grams of Feraheme IV infusion or those receiving 1.5 grams of ferric carboxymaltose IV infusion. We initiated this trial in the first quarter of 2016 and expect to file an sNDA in mid-2017.

MuGard Developments

Based on events in the second quarter of 2016, we determined that broader reimbursement coverage for MuGard by government payors was unlikely based on recent interactions with those agencies and assessed the MuGard Rights for potential impairment. From this assessment, we concluded that based on the lack of broad reimbursement and insurance coverage for MuGard and the resulting decrease in expected revenues and cash flows, the projected

undiscounted cash flows were less than the book value, indicating impairment of this intangible asset. As a result of an analysis of the fair value of the net MuGard Rights intangible asset as compared to its recorded book value, we recognized an impairment charge for the full \$15.7 million net intangible asset in the second quarter of 2016.

Results of Operations - Three Months Ended September 30, 2016 and 2015

Revenues

Total revenues for the three months ended September 30, 2016 and 2015 consisted of the following (in thousands except for percentages):

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	Three Months Ended September 30,				2016 to 2015	
	2016	2015	\$ Change		% Change	
U.S. product sales, net						
Makena	\$93,387	\$65,155	\$28,232	43	%	
Feraheme	22,256	23,227	(971)	(4)	%	
MuGard	134	535	(401)	(75)	%	
Total	115,777	88,917	26,860	30	%	
Service revenues, net	27,965	7,177	20,788	>100	%	
License fee, collaboration and other revenues	40	58	(18)	(31)	%	
Total Revenues	\$143,782	\$96,152	\$47,630	50	%	

Our total revenues for the three months ended September 30, 2016 increased by \$47.6 million as compared to the same period in 2015, primarily as the result of a \$28.2 million increase in our net Makena sales and a \$20.8 million increase of CBR Services revenue due to the full period recognition of CBR Services revenue in 2016 compared to a partial period in 2015 following our August 2015 acquisition of CBR.

Product Sales

Total gross U.S. product sales were offset by product sales allowances and accruals for the three months ended September 30, 2016 and 2015 as follows (in thousands except for percentages):

	Three Months Ended September 30,				2016 to 2015	
	2016	Percent of gross U.S. product sales	2015	Percent of gross U.S. product sales	\$ Change	% Change
Gross U.S. product sales	\$201,303		\$145,131		\$56,172	39 %
Provision for U.S. product sales allowances and accruals:						
Contractual adjustments	61,504	31 %	41,851	29 %		
Governmental rebates	24,022	12 %	14,363	10 %		
Total	85,526	42 %	56,214	39 %		
U.S. product sales, net	\$115,777		\$88,917		\$26,860	30 %

We expect gross product sales to increase for the remainder of 2016 primarily based on increased units sold of our products.

Net U.S. product sales increased by \$26.9 million, or approximately 30%, during the three months ended September 30, 2016 as compared to the same period in 2015 primarily due a \$28.2 million increase in net Makena sales, partially offset by a \$1.0 million decrease in net Feraheme sales. We anticipate that sales of Makena will continue to increase for the remainder of 2016 as compared to the third quarter of 2016 as we continue to gain market share from compounded product due to the availability of the single-dose, preservative-free formulation of Makena, which was approved in February 2016. We anticipate that we will also continue to gain market share through broader reimbursement of Makena, improved patient compliance and continued educational programs for patients and physicians regarding treatment with Makena. We anticipate that sales of Feraheme will increase for the fourth quarter of 2016 as compared to the third quarter of 2016.

We recognize U.S. product sales net of certain allowances and accruals in our condensed consolidated statement of operations at the time of sale. 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. Governmental rebates relate to our reimbursement arrangements with state Medicaid

programs. The increases in contractual adjustments and governmental rebates as a percentage of gross U.S. product sales primarily relate to the growth in sales to state Medicaid agencies.

We did not materially adjust our product sales allowances and accruals during the three months ended September 30, 2016. During the three months ended September 30, 2015, we reduced our Makena related Medicaid and chargeback reserves, which were initially recorded at the time of the Lumara Health acquisition, by \$4.0 million and \$1.9 million, respectively. These

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adjustments were recorded to goodwill during the quarter ended September 30, 2015. We may revise our estimated revenue reserves related to Makena as we continue to obtain additional experience or as our customer mix changes. 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.

Service Revenues

The \$20.8 million increase in service revenues recorded in the three months ended September 30, 2016 as compared to the same period in 2015 was due to the full period recognition of CBR Services revenue in 2016 compared to a partial period in 2015 following our August 2015 acquisition of CBR. We expect service revenues to increase for the remainder of 2016 due to continued efforts to increase new enrollments of cord blood and cord tissue units in our storage facility and recurring revenue from our growing base of stored units.

Costs and Expenses

Cost of Product Sales

Cost of product sales for the three months ended September 30, 2016 and 2015 were as follows (in thousands except for percentages):

	Three Months Ended September 30,		2016 to 2015	
	2016	2015	\$ Change	% Change
Cost of product sales	\$25,706	\$19,088	\$6,618	35 %
Percentage of net product sales	22 %	21 %		

Our cost of product sales are primarily comprised of manufacturing costs, costs of managing our contract manufacturers, and costs for quality assurance and quality control associated with our U.S. product sales, the amortization of product-related intangible assets and the inventory step-up in connection with the November 2014 acquisition of Lumara Health. Cost of product sales excludes the impairment of intangible assets described separately below under "Impairments of Intangible Assets." The \$6.6 million increase in our cost of product sales for the three months ended September 30, 2016 as compared to the same period in 2015 was primarily attributable to a \$5.8 million increase in amortization of the Makena product intangible asset and a \$1.3 million increase in production costs and overhead, partially offset by \$0.5 million decrease of inventory reserves.

We expect our cost of product sales as a percentage of net product sales excluding any impact from the amortization of the Makena intangible asset and the amortization of inventory step-up of Makena inventory to continue to increase slightly for the remainder of 2016 as compared to the first three quarters of 2016 primarily due to increased sales of the single-dose preservative-free formulation of Makena, which we began promoting to physicians in the second quarter of 2016, compared to sales of the multidose vial of Makena.

Cost of Services

Cost of services for the three months ended September 30, 2016 and 2015 were as follows (in thousands except for percentages):

	Three Months Ended September 30,		2016 to 2015	
	2016	2015	\$ Change	% Change
Cost of services	\$4,984	\$3,261	\$1,723	53 %
Percentage of service revenues	18 %	45 %		

Cost of services includes the transportation of the umbilical cord blood stem cells and cord tissue from the hospital and direct material plus labor costs for processing, cryogenic storage and collection kit materials. The \$1.7 million increase in cost of services recorded in the three months ended September 30, 2016 as compared to the same period in 2015 was due to the full period recognition of CBR Services revenue in 2016 compared to a partial period in 2015 following our August 2015 acquisition of CBR. The decrease in the cost of services as a percentage of service revenues reflects a higher purchase accounting adjustment to the CBR deferred revenue balance in 2015 as compared to 2016.

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We expect our cost of services as a percentage of service revenues to remain relatively constant in future periods as the deferred revenues adjustment associated with the CBR Services revenues becomes more consistent on an annual basis going forward.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2016 and 2015 consisted of the following (in thousands except for percentages):

	Three Months Ended September 30, 2016 2015 \$ Change % Change				
External research and development expenses					
Feraheme-related costs	\$7,159	\$1,878	\$5,281	>100	%
Makena-related costs	5,464	3,396	2,068	61	%
Velo option	—	10,000	(10,000)	(100)	%
Other external costs	602	742	(140)	(19)	%
Total	13,225	16,016	(2,791)	(17)	%
Internal research and development expenses	3,891	3,793	98	3	%
Total research and development expenses	\$17,116	\$19,809	\$(2,693)	(14)	%

Total research and development expenses incurred in the three months ended September 30, 2016 decreased by \$2.7 million, or 14%, as compared to the same period in 2015. The decrease was primarily due to the \$10.0 million upfront payment related to the Velo option in the third quarter of 2015 partially offset by \$5.3 million in new costs related to our Phase 3 clinical trial evaluating Feraheme in adults with IDA, which was initiated in the first quarter of 2016, and approximately \$2.1 million in increased costs primarily related to our Makena next-generation development program. We expect our research and development expenses to continue to increase during the remainder of 2016 as compared to the first nine months of 2016 due to increased costs associated with accelerated enrollment in the Phase 3 clinical trial evaluating Feraheme in adults with IDA and due to the Makena subcutaneous auto-injector development program.

Research and Development Activities

We track our external costs on a major project basis, in most cases through the later of the completion of the last trial in the project or the last submission of a regulatory filing to the FDA. We do not track our internal costs by project since our research and development personnel work on a number of projects concurrently and much of these costs benefit multiple projects or our operations in general. The following major research and development projects were ongoing as of September 30, 2016:

Makena: This project currently includes studies conducted as part of the post-approval commitments under the provisions of the FDA's "Subpart H" Accelerated Approval regulations including: (a) an ongoing efficacy and safety clinical study of Makena; (b) an ongoing follow-up study of the children born to mothers from the efficacy and safety clinical study; and (c) a completed PK trial of women taking Makena. In addition, this project includes studies conducted as part of our Makena auto-injector development program, including an ongoing definitive PK study and comparative pain study;

Feraheme to treat IDA in CKD patients: This project currently includes the following: (a) a completed clinical study evaluating Feraheme treatment as compared to treatment to another IV iron; (b) a completed global multi-center randomized clinical trial to determine the safety and efficacy of repeat doses of Feraheme as compared to iron sucrose for the treatment of IDA in patients with hemodialysis dependent CKD ("FACT"), which we recently completed and are in the process of analyzing the data. This project also includes a pediatric program as part of our post-approval Pediatric Research Equity Act requirement to support pediatric CKD labeling of Feraheme, which we have elected to

suspend due to difficulty in enrollment, and plan to work with the FDA to discuss the path forward regarding this post-approval commitment for Feraheme; and

Feraheme to treat IDA regardless of the underlying cause: This project currently includes a randomized, double-blind multicenter non-inferiority trial that will evaluate the incidence of moderate to severe hypersensitivity reactions (including anaphylaxis) and moderate to severe hypotension with Feraheme compared to ferric carboxymaltose infusion in adults with IDA, which was initiated in the first quarter of 2016.

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From November 12, 2014 (the date of the Lumara Health acquisition) through September 30, 2016, we have incurred aggregate external research and development expenses of approximately \$20.7 million related to our current program for Makena, described above. We currently estimate that the total remaining external costs associated with this development project will be in the range of approximately \$16.2 million to \$20.7 million over the next several years.

Through September 30, 2016, we have incurred aggregate external research and development expenses of approximately \$41.8 million related to our current program for the development of Feraheme to treat IDA in CKD patients, described above. We do not anticipate additional external costs associated with this project.

We incurred approximately \$57.8 million of aggregate external research and development expenses related to our program for the development of Feraheme to treat IDA regardless of the underlying cause up to the submission of our sNDA in 2013. In January 2014, after we received a complete response letter from the FDA for the sNDA informing us that our sNDA could not be approved in its present form and stating that we had not provided sufficient information to permit labeling of Feraheme for safe and effective use for the proposed broader indication. In the third quarter of 2015, we commenced start up activities related to this program, including the head-to-head Phase 3 clinical trial, described above. We began enrolling patients in the head-to-head trial in the first quarter of 2016 and have spent approximately \$18.2 million since the first quarter of 2016. We currently estimate that the total remaining external costs associated with this development project will be in the range of approximately \$11.8 million to \$16.8 million through the first half of 2017.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended September 30, 2016 and 2015 consisted of the following (in thousands except for percentages):

	Three Months Ended September 30,				
	2016	2015	\$ Change	% Change	
Compensation, payroll taxes and benefits	\$19,940	\$16,273	\$3,667	23	%
Professional, consulting and other outside services	25,944	22,924	3,020	13	%
Fair value of contingent consideration liability	3,708	2,886	822	28	%
Amortization expense related to customer relationship intangible	3,132	357	2,775	>100	%
Equity-based compensation expense	4,492	3,701	791	21	%
Total selling, general and administrative expenses	\$57,216	\$46,141	\$11,075	24	%

Total selling, general and administrative expenses incurred in the three months ended September 30, 2016 increased by \$11.1 million, or approximately 24%, as compared to the same period in 2015 for the following reasons:

\$3.7 million increase in compensation, payroll taxes and benefits primarily due to increased headcount resulting from the August 2015 CBR acquisition;

\$1.9 million increase in sales and marketing, consulting, professional fees, and other expenses due to costs related to CBR marketing activities and revenue driven spend related to Makena;

\$1.1 million increase in general and administrative, consulting, professional fees and other expenses primarily due to increased costs associated with the CBR acquisition;

\$0.8 million increase to the contingent consideration liability due to a \$1.0 million increase in the Makena-related contingent consideration, partially offset by a \$0.2 million reduction of the MuGard-related contingent consideration primarily resulting from a revision of our total projected MuGard sales in the third quarter of 2016;

\$2.8 million increase in amortization expense related to the CBR customer relationship intangible; and

\$0.8 million increase in equity-based compensation expense due primarily to an increase in the number of equity awards to new and existing employees, including additional employees from the CBR acquisition.

We expect that total selling, general and administrative expenses will remain relatively consistent for the remainder of 2016 as compared to the third quarter of 2016.

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Acquisition-related Costs

There were no acquisition-related costs recorded in the three months ended September 30, 2016. Acquisition-related costs of \$8.5 million incurred in the three months ended September 30, 2015 included costs for financial advising, legal fees, due diligence, and other costs and expenses related to our August 2015 acquisition of CBR.

Restructuring Expenses

In connection with the August 2015 CBR acquisition and the November 2014 Lumara Health acquisition, we initiated restructuring programs, which included severance benefits related to former CBR and Lumara Health employees. We did not record any charges in the three months ended September 30, 2016 and recorded charges of approximately \$0.7 million in the three months ended September 30, 2015. We expect to pay substantially all of these restructuring costs by the end of 2016.

Other Income (Expense)

Other expense for the three months ended September 30, 2016 decreased by \$15.8 million as compared to the same period in 2015 primarily as the result of the following:

- \$10.4 million loss on debt extinguishment in 2015 as the result of the early repayment of the remaining \$323.0 million outstanding principal amount of our then existing five-year term loan facility (the “2014 Term Loan Facility”);
- \$9.2 million of other expense representing fees paid in 2015, including a \$6.8 million bridge loan commitment fee and \$2.4 million in fees and expenses paid in 2015 as part of the early repayment of the 2014 Term Loan Facility; and
- These decreases described above were partially offset by an additional \$4.1 million in interest expense in the third quarter of 2016, which was primarily comprised of the amortization of debt discount, contractual interest expense and amortization of debt issuance costs due to the full period recognition in 2016 of the debt obligations incurred in the third quarter of 2015, compared to a partial period in 2015.

We expect our net other income (expense) to remain relatively constant for the remainder of 2016 as compared to the third quarter of 2016.

Income Tax Expense (Benefit)

The following table summarizes our effective tax rate and income tax expense for the three months ended September 30, 2016 and 2015 (in thousands except for percentages):

	Three Months Ended			
	September 30,			
	2016		2015	
Effective tax rate	24	%	41	%
Income tax expense (benefit)	\$5,069		\$(14,130)	

For the three months ended September 30, 2016, we recognized income tax expense of \$5.1 million, representing an effective tax rate of 24%. The difference between the expected statutory federal tax rate of 35% and the 24% effective tax rate for the three months ended September 30, 2016 was primarily attributable to contingent consideration associated with Lumara Health, including the tax deductible portion of the anticipated payout, and federal research and development and orphan drug tax credits, partially offset by the impact of state income taxes, non-deductible stock compensation, and other non-deductible expenses. For the three months ended September 30, 2015, we recognized an income tax benefit of \$14.1 million, representing an effective tax rate of 41%. The difference between the expected statutory federal tax rate of 35% and the 41% effective tax rate for the three months ended September 30, 2015 was attributable to the impact of a valuation allowance release related to certain deferred tax assets and the impact of state income taxes, partially offset by non-deductible transaction costs associated with the acquisition of CBR and non-deductible contingent consideration expense associated with Lumara Health.

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Results of Operations – Nine Months Ended September 30, 2016 and 2015

Revenues

Total revenues for the nine months ended September 30, 2016 and 2015 consisted of the following (in thousands except for percentages):

	Nine Months Ended September 30,		2016 to 2015		
	2016	2015	\$ Change	% Change	
U.S. product sales, net					
Makena	\$236,824	\$184,258	\$52,566	29	%
Feraheme	70,774	65,235	5,539	8	%
MuGard	726	1,491	(765)	(51)	%
Total	308,324	250,984	57,340	23	%
Service revenues, net	71,863	7,177	64,686	>100	%
License fee, collaboration and other revenues	313	51,380	(51,067)	(99)	%
Total Revenues	\$380,500	\$309,541	\$70,959	23	%

Our total revenues for the nine months ended September 30, 2016 increased by \$71.0 million as compared to the same period in 2015, primarily as the result of an increase of \$64.7 million of CBR Services revenue in the nine months ended September 30, 2016 and a \$52.6 million increase in our net Makena sales. This increase in revenues was partially offset by a \$51.1 million decrease in license fee, collaboration and other revenues during the nine months ended September 30, 2016 as compared to the same period in 2015. Under the terms of the 2014 termination of a license, development and commercialization agreement (as amended, the “Takeda Agreement”) with Takeda Pharmaceutical Company Limited (“Takeda”), in 2015 we recognized revenues of \$5.2 million for payments made by Takeda as well as \$44.4 million of previously deferred revenues associated with the amortization of the then-remaining deferred revenue balance.

Product Sales

Total gross U.S. product sales were offset by product sales allowances and accruals for the nine months ended September 30, 2016 and 2015 as follows (in thousands except for percentages):

	Nine Months Ended September 30, 2016			2016 to 2015		
	2016	Percent of gross U.S. product sales	2015	Percent of gross U.S. product sales	\$ Change	% Change
Gross U.S. product sales	\$530,076		\$407,238		\$122,838	30 %
Provision for U.S. product sales allowances and accruals:						
Contractual adjustments	161,023	30 %	116,236	29 %		
Governmental rebates	60,729	11 %	40,018	10 %		
Total	221,752	42 %	156,254	38 %		
U.S. product sales, net	\$308,324		\$250,984		\$57,340	23 %

Total net product sales increased by \$57.3 million, or approximately 23%, during the nine months ended September 30, 2016 as compared to the same period in 2015 primarily due a \$52.6 million increase in net Makena sales and a \$5.5 million increase in net Feraheme sales.

We did not materially adjust our product sales allowances and accruals during the nine months ended September 30, 2016. During the nine months ended September 30, 2015, we reduced our Makena related Medicaid and chargeback

reserves, which were initially recorded at the time of the Lumara Health acquisition, by \$4.0 million and \$1.9 million, respectively. These adjustments were recorded to goodwill during the nine months ended September 30, 2015.

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Service Revenues

The \$64.7 million increase in service revenues in the nine months ended September 30, 2016 as compared to the same period in 2015 was due to the full period recognition of CBR Services revenue in 2016 compared to a partial period in 2015 following our August 2015 acquisition of CBR.

License Fee, Collaboration and Other Revenues

Our license fee, collaboration and other revenues for the nine months ended September 30, 2016 decreased by \$51.1 million as compared to the same period in 2015 primarily as a result of the termination of the Takeda Agreement. We expect that our license fee, collaboration and other revenues, if any, will be immaterial for the remainder of 2016.

Costs and Expenses

Cost of Product Sales

Cost of product sales for the nine months ended September 30, 2016 and 2015 were as follows (in thousands except for percentages):

	Nine Months Ended September 30,		2016 to 2015	
	2016	2015	\$ Change	% Change
Cost of product sales	\$65,942	\$59,793	\$6,149	10 %
Percentage of net product sales	21 %	24 %		

The \$6.1 million increase in our cost of product sales for the nine months ended September 30, 2016 as compared to the same period in 2015 was primarily attributable to a \$10.7 million increase in amortization of the Makena product intangible asset and a \$2.9 million increase in production costs and overhead, partially offset by a \$3.7 million decrease in amortization of the Makena inventory step-up and a \$3.8 million decrease related to inventory reserves. Cost of product sales excludes the impairment of intangible assets described separately below under "Impairments of Intangible Assets."

Cost of Services

Cost of services for the nine months ended September 30, 2016 and 2015 were as follows (in thousands except for percentages):

	Nine Months Ended September 30,		2016 to 2015	
	2016	2015	\$ Change	% Change
Cost of services	\$15,705	\$3,261	\$12,444	>100 %
Percentage of service revenues	22 %	45 %		

The \$12.4 million increase in cost of services in the nine months ended September 30, 2016 as compared to the same period in 2015 was due to the full period recognition of CBR Services revenue in 2016 compared to a partial period in 2015 following our August 2015 acquisition of CBR.

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2016 and 2015 consisted of the following (in thousands except for percentages):

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	Nine Months Ended September 30, 2016 to 2015				
	2016	2015	\$ Change	% Change	
External research and development expenses					
Feraheme-related costs	\$18,661	\$5,534	\$13,127	>100	%
Makena-related costs	13,364	8,158	5,206	64	%
Velo option	—	10,000	(10,000)	(100)	%
Other external costs	1,943	1,250	693	55	%
Total	33,968	24,942	9,026	36	%
Internal research and development expenses	11,611	10,039	1,572	16	%
Total research and development expenses	\$45,579	\$34,981	\$10,598	30	%

Total research and development expenses incurred in the nine months ended September 30, 2016 increased by \$10.6 million, or 30%, as compared to the same period in 2015. The increase was primarily due to approximately \$18.3 million in new costs related to our Phase 3 clinical trial evaluating Feraheme in adults with IDA, which was initiated in the first quarter of 2016, and approximately \$4.3 million in costs related to our Makena next-generation development program, partially offset by a \$10.0 million upfront payment made to Velo in 2015 and a \$3.4 million reduction due to the completion of our FACT study in 2016.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the nine months ended September 30, 2016 and 2015 consisted of the following (in thousands except for percentages):

	Nine Months Ended September 30, 2016 to 2015				
	2016	2015	\$ Change	% Change	
Compensation, payroll taxes and benefits	\$59,615	\$43,192	\$16,423	38	%
Professional, consulting and other outside services	84,365	52,733	31,632	60	%
Fair value of contingent consideration liability	5,106	4,525	581	13	%
Amortization expense related to customer relationship intangible	9,397	357	9,040	>100	%
Equity-based compensation expense	13,831	9,247	4,584	50	%
Total selling, general and administrative expenses	\$172,314	\$110,054	\$62,260	57	%

Total selling, general and administrative expenses incurred in the nine months ended September 30, 2016 increased by \$62.3 million, or approximately 57%, as compared to the same period in 2015 for the following reasons:

\$16.4 million increase in compensation, payroll taxes and benefits primarily due to increased headcount associated with the August 2015 CBR acquisition;

\$22.7 million increase in sales and marketing, consulting, professional fees, and other expenses primarily due to costs related to CBR marketing activities and pre-approval and launch activities of the single-dose formulation of Makena;

\$8.9 million increase in general and administrative, consulting, professional fees and other expenses primarily due to increased costs associated with CBR acquisition;

\$0.6 million increase to the contingent consideration liability due to a \$2.6 million increase to the Makena-related contingent consideration, partially offset by a \$2.0 million reduction of the MuGard-related contingent consideration resulting from a revision of our total projected MuGard sales in the first nine months of 2016;

\$9.0 million increase in amortization expense related to the CBR customer relationship intangible; and

\$4.6 million increase in equity-based compensation expense due primarily to an increase in the number of equity awards to new and existing employees, including additional employees from the CBR acquisition.

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Impairment of Intangible Assets

Impairments of finite-lived intangible assets was \$16.0 million for the nine months ended September 30, 2016, due to an impairment charge of \$15.7 million in the second quarter of 2016 related to the impairment of the remaining net intangible asset for the MuGard Rights based on the lack of broad reimbursement and insurance coverage for MuGard and the impairment of the remaining \$0.2 million, net, CBR-favorable lease intangible asset due the subleasing of a portion of our CBR office space in San Bruno, California at a rate below the market rate used to determine the favorable lease intangible asset. As part of our ongoing assessment of potential impairment indicators related to our finite-lived and indefinite-lived intangible assets, we will closely monitor the performance of our product portfolio and our intangible assets. If our ongoing assessments reveal indications of impairment, we may determine that an impairment charge is necessary and such charge could be material.

Acquisition-related Costs

There were no acquisition-related costs recorded in the nine months ended September 30, 2016. Acquisition-related costs of \$11.2 million incurred in the nine months ended September 30, 2015 included costs for financial advising, legal fees, due diligence, and other costs and expenses related to our August 2015 acquisition of CBR.

Restructuring Expenses

In connection with the August 2015 CBR acquisition and the November 2014 Lumara Health acquisition, we initiated restructuring programs, which included severance benefits related to former CBR and Lumara Health employees. As a result of these restructurings, we recorded charges of approximately \$0.7 million and \$1.8 million in the nine months ended September 30, 2016 and 2015, respectively.

Other Income (Expense)

Other expense for the nine months ended September 30, 2016 increased by \$1.0 million as compared to the same period in 2015 primarily as the result of the following:

An additional \$20.2 million in interest expense for the nine months ended September 30, 2016 as compared to the same period in 2015, which was primarily comprised of the amortization of debt discount, contractual interest expense and amortization of debt issuance costs due to the full period recognition in 2016 of the debt obligations incurred in the third quarter of 2015, compared to a partial period in 2015;

The additional interest expense was partially offset by a non-recurring \$10.4 million loss on debt extinguishment in 2015 as the result of the early repayment of the remaining \$323.0 million outstanding principal amount of our 2014 Term Loan Facility; and

An offset of \$9.2 million of non-recurring other expense representing fees paid in 2015 as part of the financing for the CBR acquisition, including a \$6.8 million bridge loan commitment fee and \$2.4 million in fees and expenses paid in 2015 as part of the early repayment of the 2014 Term Loan Facility.

Income Tax Expense

The following table summarizes our effective tax rate and income tax expense for the nine months ended September 30, 2016 and 2015 (in thousands except for percentages):

	Nine Months	
	Ended September	
	30,	
	2016	2015
Effective tax rate	32 %	27 %
Income tax expense	\$3,725	\$9,513

For the nine months ended September 30, 2016, we recognized income tax expense of \$3.7 million, representing an effective tax rate of 32%. The difference between the expected statutory federal tax rate of 35% and the 32% effective tax rate for the nine months ended September 30, 2016, was primarily attributable to contingent consideration associated with Lumara Health, including the tax deductible portion of the anticipated payout, and federal research and development and orphan drug tax credits, partially offset by the impact of state income taxes, non-deductible

stock compensation, and other non-deductible expenses. The effective tax rate for the nine months ended September 30, 2016 was also impacted by the impairment of the net

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intangible asset for the MuGard Rights and related contingent consideration fair value adjustment. We recorded a net tax benefit in the nine months ended September 30, 2016 for these discrete events at a combined federal and state statutory income tax rate of 39%. For the nine months ended September 30, 2015, we recognized income tax expense of \$9.5 million, representing an effective tax rate of 27%. The difference between the expected statutory federal tax rate of 35% and the 27% effective tax rate was attributable to the impact of a valuation allowance release related to certain deferred tax assets, partially offset by the impact of state income taxes, non-deductible transaction costs associated with the acquisition of CBR, and non-deductible contingent consideration expense associate with Lumara Health.

Liquidity and Capital Resources

General

We currently finance our operations primarily from the sale of our products and services and cash generated from our investing and financing activities. We expect to continue to incur significant expenses as we continue to market, sell and contract for the manufacture of Makena and Feraheme, market and sell the CBR Services, pursue the next-generation development program for Makena, and further develop and seek U.S. regulatory approval for Feraheme for the treatment of IDA in a broad range of patients. 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 1A of this Quarterly Report on Form 10-Q.

Cash, cash equivalents, investments and certain financial obligations as of September 30, 2016 and December 31, 2015 consisted of the following (in thousands except for percentages):

	September 30, 2016	December 31, 2015	\$ Change	% Change	
Cash and cash equivalents	\$ 305,279	\$ 228,705	\$76,574	33	%
Investments	308,792	237,626	71,166	30	%
Total	\$ 614,071	\$ 466,331	\$ 147,740	32	%
Outstanding principal on 2023 Senior Notes	\$ 500,000	\$ 500,000	\$—	—	%
Outstanding principal on Convertible Notes	199,998	200,000	(2)	—	%
Outstanding principal on 2015 Term Loan Facility	332,500	345,625	(13,125)	(4)	%
Total	\$ 1,032,498	\$ 1,045,625	\$ (13,127)	(1)	%

The \$147.7 million increase in cash, cash equivalents and investments as of September 30, 2016, as compared to December 31, 2015, was primarily due to cash flow from product and service sales, partially offset by expenditures to fund our operations, service our debt, and \$20.0 million of cash used to repurchase our common stock during the first nine months of 2016.

In March 2015, we sold approximately 4.6 million shares of our common stock at a public offering price of \$44.00 per share, resulting in net proceeds to us of approximately \$188.8 million. In addition, in August 2015, we sold approximately 3.6 million shares of our common stock at a public offering price of \$63.75 per share, resulting in net proceeds to us of approximately \$218.6 million.

We expect that our cash, cash equivalents and investments balances will be positively impacted by increasing operating profits in the fourth quarter of 2016; however we anticipate that the cash, cash equivalents and investments balances will decrease in the aggregate due to a \$100.0 million milestone to be paid in the fourth quarter of 2016 to the former Lumara Health security holders based on our achievement of a \$300.0 million annual net Makena sales milestone. Our expectation assumes our continued investment in the development and commercialization of our

products. We believe that our cash, cash equivalents and investments as of September 30, 2016, and the cash we currently expect to receive from sales of our products and services, and earnings on our investments, will be sufficient to satisfy our cash flow needs for the foreseeable future.

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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”) and entered into a credit agreement with a group of lenders, including Jefferies Finance LLC, who acted as administrative and collateral agent, that provided us with, among other things, a six-year \$350.0 million term loan facility (the “2015 Term Loan Facility”). The 2023 Senior Notes, which are senior unsecured obligations, will mature on September 1, 2023 and will bear interest at a rate of 7.875% per year, with interest payable semi-annually on September 1 and March 1 of each year, beginning on March 1, 2016. We borrowed the full \$350.0 million available under the 2015 Term Loan Facility in August 2015. In addition, the 2015 Term Loan Facility includes an annual mandatory prepayment of the debt in an amount equal to 50% of our excess cash flow (as defined in the 2015 Term Loan Facility) as measured on an annual basis, beginning with the fiscal year ending December 31, 2016. As a result, as of September 30, 2016, \$45.3 million was estimated and reclassified from long-term debt to current portion of long-term debt in our condensed consolidated balance sheet as the first excess payment is expected to be made in April 2017. On or after December 31, 2016, the applicable excess cash flow percentage shall be reduced based on the total net leverage ratio as of the last day of the period. For additional information, see Note Q, “Debt,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10 Q.

In February 2014, we issued \$200.0 million aggregate principal amount of 2.5% convertible senior notes due February 15, 2019 (the “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. The 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 Convertible Notes will mature on February 15, 2019, unless repurchased or converted earlier. The Convertible Notes will be convertible into cash, shares of our common stock, or a combination thereof, at our election (subject to certain limitations in the 2015 Term Loan Facility), at a conversion rate of approximately 36.9079 shares of common stock per \$1,000 principal amount of the 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. Based on the last reported sale price of our common stock during the last 30 trading days of the second quarter of 2016, the Convertible Notes were not convertible as of September 30, 2016.

Share Repurchase Program

In January 2016, we announced that our board of directors had 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. During the nine months ended September 30, 2016, we repurchased and retired 831,744 shares of common stock, respectively, under this repurchase program for \$20.0 million at an average purchase price of \$24.05 per share.

Cash flows from operating activities

Net cash provided by operating activities for the nine months ended September 30, 2016 was \$183.7 million as compared to \$58.1 million for the same period in 2015. The increase in net cash provided by operating activities was primarily due to a change in accounts receivable of \$39.7 million and the net increase in CBR deferred revenues of \$57.5 million, partially offset by a decrease in net income of approximately \$17.5 million. We expect to generate cash from operations as we continue to grow our business, partially offset by increased expenditures to support our

growth.

Cash flows from investing activities

Net cash used in investing activities in the nine months ended September 30, 2016 was \$73.8 million as compared to \$934.1 million for the same period in 2015. Cash used in investing activities decreased during the nine months ended September 30, 2016 primarily due to \$682.2 million of net cash used to fund the 2015 acquisition of CBR and a \$183.9 million decrease in cash used to purchase investments. The cash flows from investing activities during the nine months ended September 30, 2015 reflect the investment of a portion of the \$188.8 million we received following the sale of 4.6 million shares of our common stock in an underwritten public offering in the first quarter of 2015.

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Cash flows from financing activities

Net cash used in financing activities in the nine months ended September 30, 2016 was \$33.3 million as compared to net cash provided by financing activities of \$924.3 million for the same period in 2015. Cash flows from financing activities decreased during the nine months ended September 30, 2016 as compared to the same period in 2015 primarily due to the \$407.5 million in net proceeds from the aggregate issuance of common stock from our March 2015 and August 2015 public offerings, \$839.1 million received from the proceeds of new debt offerings in 2015, partially offset by the repayment of the 2014 Term Loan in 2015. In addition, during 2016, we used \$20.0 million of cash to repurchase shares of our common stock under our share repurchase program.

Off-Balance Sheet Arrangements

As of September 30, 2016, 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,” 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, 2016 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 O, “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 factor below, there have been no material changes from the Risk Factors disclosed in Part I, Item 1A, of our Annual Report.

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We may not be successful in developing, gaining regulatory approval for and commercializing any products from Makena's next-generation development programs, which could have a negative impact on our business.

We are seeking to expand Makena's drug delivery technologies and formulations as part of our multi-pronged next-generation development programs to deliver new and improved versions of Makena. The next-generation development programs for Makena are an important strategy for our business, especially in light of the expiration of Makena's orphan drug exclusivity in February 2018, and the possibility that generic versions of Makena could enter the market following such loss of exclusivity.

For example, we are developing an auto-injector device for subcutaneous administration of Makena (the "auto-injector"), which could possibly provide Makena with additional exclusivity through the combination of potential additional orphan drug exclusivity and patent protection on the new dosing, route of administration, and auto-injector. We have recently met with the FDA to discuss our proposed development and regulatory strategy focusing on establishing bioequivalence of the subcutaneous auto-injector compared to the intramuscular administration of Makena. We intend to seek regulatory approval by submitting pharmacokinetic ("PK") data from a bioequivalence study we plan to conduct, which is designed to demonstrate comparable bioavailability. In accordance with FDA guidance, we utilize the term 'bioequivalence' in the context of a supplemental new drug application ("sNDA") to mean "relative bioavailability," and not the strict bioequivalence that is typically required for generic ANDA filings. We can make no assurances that the study will demonstrate adequate comparability on any or all PK parameters to permit approval without clinical data. If any such parameters differ from the intramuscular injection of Makena, we can make no assurances that the FDA will accept our rationale that these potential differences have no clinical impact on safety or efficacy, and the FDA may request that we conduct one or more clinical studies in order to gain approval.

Further, we plan to conduct a comparative pain study intended to capture certain measures to support clinical superiority of the subcutaneous auto-injector over the existing intramuscular injection to support our submission for new orphan drug exclusivity. These plans are based on our dialogue with the FDA that improvement in pain may be considered a clinically superior adverse event profile of the subcutaneous auto-injector. The FDA has substantial discretion in the determination of clinical superiority of the auto-injector and, therefore, we can make no assurances that comparative pain study data or other information that we generate or submit, even if statistically successful, will be adequate for the FDA to grant new orphan drug exclusivity for the auto-injector. Based on our current timelines and assumptions, we anticipate filing an sNDA for approval of the auto-injector in the second quarter of 2017 and, as a result of our decision to contemporaneously submit the results of our comparative pain study, the review period is expected to be ten months. This timing may impact our ability to receive approval for the auto-injector before the expiration of Makena's orphan drug exclusivity period in February 2018, which could permit generics to enter the market prior to commercialization of the auto-injector and could have an adverse impact on our Makena sales.

Further, the degree of protection afforded by any intellectual property that we may in-license or develop may not enable us to protect or commercially exploit the auto-injector technology, providing us with little or no competitive advantage. There is also a risk that others may circumvent any patents licensed or issued to us relating to the auto-injector, including any intellectual property covering the injector device, or that another company may develop a product that circumvents any new orphan drug exclusivity. We are relying on third-party manufacturers to aid in the design of the injector device as part of the auto-injector, and we may encounter difficulties finalizing a safe and effective subcutaneous delivery system design. Further, we are currently in discussions with third-party manufacturers to secure commercial supply of certain components and for assembly of the auto-injector. We may not be able to reach agreement on acceptable terms or encounter difficulties including problems involving scale-up, yields, quality control and assurance, product reliability, and manufacturing costs, any of which could result in significant delays in production.

Even if we succeed in gaining FDA approval for an auto-injector for Makena, we will likely be competing against generics of the current formulation of Makena after February 2018. These generics could be less expensive than our potential new and improved version of Makena. As a result of the lower cost for the generics or a lack of perceived benefit of the subcutaneous auto-injector for Makena, physicians may choose to prescribe the generic, which could cause sales of Makena to decline. In addition, insurance companies and government payors, such as state Medicaid agencies, who currently provide coverage for Makena may make it more difficult for physicians to prescribe our new version of Makena by charging higher copays, implementing prior authorizations, or not reimbursing for our new version at all. Furthermore, other companies are or may be working on developing additional formulations or routes of administration for products that reduce or prevent preterm birth. For example, an oral hydroxyprogesterone caproate product is currently in development and its developer has stated that it intends to discuss a Phase 3 development plan with the FDA. If such products are approved, they could be, or be perceived to be, more efficacious, safer, less expensive, easier to administer, available for a broader patient population, or provide more

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favorable insurance coverage or reimbursement, and could reduce our revenues and the value of our product development efforts.

We have limited experience in the development of an auto-injector for Makena and in developing and implementing next-generation development programs. If we are not successful in implementing Makena's next-generation development programs, if the subcutaneous auto-injector is not approved before the expiration of Makena's orphan drug exclusivity in February 2018 or at all, or if the subcutaneous auto-injector does not receive orphan drug exclusivity, our business may suffer.

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, 2016.

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, 2016 through July 31, 2016	—	\$ —	—	1,507,727
August 1, 2016 through August 31, 2016	6,066	23.99	—	1,678,557
September 1, 2016 through September 30, 2016	433	24.90	—	1,631,987
Total	6,499	\$ 24.05	—	

(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 2016. We have repurchased and retired \$20.0 million of our common stock under the share repurchase program to date. These shares were purchased pursuant to a repurchase program authorized by our board of directors that was announced in January 2016 to repurchase up to \$60.0 million of our common stock, of which \$40.0 million remains outstanding as of September 30, 2016. 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
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
William K.
Heiden
Chief
Executive
Officer
(Principal
Executive
Officer)

Date: November
3, 2016

AMAG
PHARMACEUTICALS, INC.

By: /s/ Edward
Myles
Edward
Myles
Senior Vice
President of
Finance,
Chief
Financial
Officer and
Treasurer (Principal
Financial
and
Accounting
Officer)

Date: November
3, 2016

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