AMAG PHARMACEUTICALS INC.
Form 10-Q
November 06, 2015
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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, 2015

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 (State or Other Jurisdiction of Incorporation or Organization)	04-2742593 (I.R.S. Employer Identification No.)
1100 Winter Street Waltham, Massachusetts (Address of Principal Executive Offices)	02451 (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):

Large accelerated filer	Accelerated filer
Non-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 November 2, 2015, there were 34,703,924 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, 2015

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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, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 167,530	$ 119,296
Investments	275,343	24,890
Accounts receivable, net	73,689	38,172
Inventories	37,217	40,610
Receivable from collaboration	—	4,518
Deferred tax assets	53,164	32,094
Prepaid and other current assets	17,725	14,456
Restricted cash	30,755	—
Total current assets	655,423	274,036
Property, plant and equipment, net	30,357	1,519
Goodwill	637,400	205,824
Intangible assets, net	1,211,547	887,908
Restricted cash	2,397	2,397
Other long-term assets	17,289	17,249
Total assets	$ 2,554,413	$ 1,388,933
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,661	$ 7,301
Accrued expenses	102,656	80,093
Payable to former CBR shareholders	36,259	—
Current portion of long-term debt	17,500	34,000
Current portion of acquisition-related contingent consideration	96,756	718
Deferred revenues	10,012	44,376
Total current liabilities	266,844	166,488
Long-term liabilities:		
Long-term debt, net	815,067	293,905
Convertible 2.5% notes, net	172,594	167,441
Acquisition-related contingent consideration	126,189	217,984
Deferred tax liabilities	247,615	77,619
Deferred revenues	1,889	—
Other long-term liabilities	4,254	5,543

Total liabilities	1,634,452	928,980
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 at September 30, 2015 and 58,750,000 authorized at December 31, 2014; 34,703,770 and 25,599,550 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	347	256
Additional paid-in capital	1,228,199	793,757
Accumulated other comprehensive loss	(3,720)	(3,617)
Accumulated deficit	(304,865)	(330,443)
Total stockholders' equity	919,961	459,953
Total liabilities and stockholders' equity	$ 2,554,413	$ 1,388,933

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,	
	2015	2014	2015	2014
Revenues:				
U.S. product sales, net	$ 88,917	$ 23,009	$ 250,984	$ 63,017
Service revenues, net	7,177	—	7,177	—
License fee and other collaboration revenues	58	2,485	51,380	8,114
Total revenues	96,152	25,494	309,541	71,131
Costs and expenses:				
Cost of product sales	19,088	2,968	59,793	8,548
Cost of services	3,261	—	3,261	—
Research and development expenses	19,809	5,358	34,981	16,396
Selling, general and administrative expenses	46,141	10,958	110,054	44,733
Acquisition-related costs	8,500	1,917	11,153	1,917
Restructuring expenses	738	—	1,752	—
Total costs and expenses	97,537	21,201	220,994	71,594
Operating income (loss)	(1,385)	4,293	88,547	(463)
Other income (expense):				
Interest expense	(14,222)	(3,129)	(34,794)	(7,656)
Loss on debt extinguishment	(10,449)	—	(10,449)	—
Interest and dividend income, net	524	291	967	809
Other income (expense)	(9,182)	3	(9,180)	119
Total other income (expense)	(33,329)	(2,835)	(53,456)	(6,728)
Net income (loss) before income taxes	(34,714)	1,458	35,091	(7,191)
Income tax benefit (expense)	14,130	—	(9,513)	—
Net income (loss) before income taxes	$ (20,584)	$ 1,458	$ 25,578	$ (7,191)
Net income (loss) per share:				
Basic	$ (0.62)	$ 0.07	$ 0.84	$ (0.33)
Diluted	$ (0.62)	$ 0.06	$ 0.73	$ (0.33)
Weighted average shares outstanding used to compute net income (loss) per share:				
Basic	33,223	21,984	30,379	21,912
Diluted	33,223	23,467	34,962	21,912

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

(IN THOUSANDS)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net income (loss)	$ (20,584)	$ 1,458	$ 25,578	$ (7,191)
Other comprehensive income (loss):				
Unrealized (losses) gains on securities:				
Holding (losses) gains arising during period, net of tax	(228)	(305)	107	(76)
Reclassification adjustment for (losses) gains included in net income (loss)	—	9	(4)	12
Net unrealized (losses) gains on securities	(228)	(296)	103	(64)
Total comprehensive income (loss)	$ (20,812)	$ 1,162	$ 25,681	$ (7,255)

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,	
	2015	2014
Cash flows from operating activities:		
Net income (loss)	$ 25,578	$ (7,191)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	51,346	655
Amortization of premium/discount on purchased securities	1,505	1,823
Write-down of inventory to net realizable value	869	1,119
Gain (loss) on disposal of property and equipment	—	(102)
Non-cash equity-based compensation expense	11,572	6,153
Non-cash loss on debt extinguishment	6,426	—
Amortization of debt discount and debt issuance costs	8,463	4,531
Gains on investments, net	(2)	(17)
Change in fair value of contingent consideration	4,525	(2,535)
Deferred income taxes	17,557	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(24,075)	(4,031)
Inventories	(1,013)	(2,496)
Receivable from collaboration	4,518	(654)
Prepaid and other current assets	(89)	(2,211)
Other long-term assets	5,959	1,001
Accounts payable and accrued expenses	(4,013)	87
Other short-term liabilities	(1,688)	—
Deferred revenues	(35,575)	(6,659)
Other long-term liabilities	(1,288)	137
Repayment of term loan attributable to original issue discount	(12,491)	—
Net cash provided by (used in) operating activities	58,084	(10,390)
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	74,021	58,592
Purchase of investments	(326,080)	(63,747)
Change in restricted cash	(3)	2,883
Capital expenditures, net of proceeds from sale of assets	(440)	(42)
Net cash (used in) investing activities	(934,103)	(2,314)
Cash flows from financing activities:		
	407,477	—

Proceeds from the issuance of common stock, net of underwriting discount and other expenses		
Long-term debt principal payments	(327,509)	—
Proceeds from issuance of convertible 2.5% notes	—	200,000
Proceeds from long-term debt	839,125	—
Payment of debt issuance costs	(10,000)	(6,711)
Proceeds from issuance of warrants	—	25,620
Purchase of convertible bond hedges	—	(39,760)
Payment of contingent consideration	(322)	(186)
Proceeds from the exercise of stock options	15,482	2,909
Net cash provided by financing activities	924,253	181,872
Net increase in cash and cash equivalents	48,234	169,168
Cash and cash equivalents at beginning of the period	119,296	26,986
Cash and cash equivalents at end of the period	$ 167,530	$ 196,154
Supplemental data of cash flow information:		
Cash paid for taxes	$ 1,794	$ —
Cash paid for interest	$ 23,766	$ 2,514

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 use our business and clinical expertise to bring medical therapies and other innovations to market that provide clear benefits and improve people's lives. We have a diverse portfolio of products and services with a focus on maternal health, anemia management and cancer supportive care, including Makena® (hydroxyprogesterone caproate injection), services related to the preservation of umbilical cord blood stem cell and cord tissue units operated through Cord Blood Registry® ("CBR"), Feraheme® (ferumoxytol) Injection for Intravenous ("IV") use and MuGard® Mucoadhesive Oral Wound Rinse. 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."

On August 17, 2015, we acquired CBR Acquisition Holdings Corp. ("CBR Holdings"), at which time CBR Holdings became a wholly-owned subsidiary of AMAG. CBR Holdings, through its wholly-owned subsidiary, Cbr Systems, Inc., operated CBR, which we purchased for $700.0 million in cash consideration, subject to estimated working capital, indebtedness and other adjustments. CBR is a private umbilical cord blood stem cell and cord tissue bank which offers pregnant women and their families the ability to collect, process and cryogenically preserve newborn umbilical cord blood stem cells and cord tissue units (the "CBR Services"). We market and sell CBR Services directly to consumers. Additional details regarding the CBR acquisition can be found in Note C, "Business Combinations."

Also, on August 17, 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 ("Jefferies"), 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"). We borrowed the full $350.0 million available under the 2015 Term Loan Facility on August 17, 2015. We used the net proceeds from the August 2015 Offering, discussed below, the offering of the 2023 Senior Notes and borrowings under the 2015 Term Loan Facility along with existing cash to fund the acquisition of CBR, to repay the remaining $323.0 million outstanding principal amount under our then existing five-year term loan facility (the "2014 Term Loan Facility"), and to pay prepayment premiums, fees and expenses in connection with the foregoing. See Note Q, "Debt," for more information.

On August 5, 2015, we sold approximately 3.6 million shares of our common stock at a public offering price of $63.75 per share (the "August 2015 Offering"), resulting in net proceeds to us of approximately $218.6 million.

On July 22, 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 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 global rights to the DIF program (the "DIF Rights"), which was recorded in research and development expenses in our condensed consolidated statements of operations. We have concluded that Velo is a variable interest entity ("VIE"), in which we are not the primary beneficiary. We do not have power, through our variable interest, to direct the activities that most significantly impact the economic performance of Velo. Specifically, we do not have any voting rights or final decision-making authority over Velo's operational or financial activities. Accordingly, we did not consolidate Velo as of September 30, 2015. The $10.0 million payment represents the maximum exposure to any potential losses associated with this VIE. DIF has been granted both orphan drug and fast-track review designations by the U.S. Food and Drug Administration ("FDA") for the use in treating severe preeclampsia. Under the option agreement, Velo will complete a dose ranging study and a Phase 2b/3a clinical study. 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

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in sales milestone payments based on the achievement of annual sales milestones at targets ranging from $100.0 million to $900.0 million. We anticipate that results from the pivotal Phase 2b/3a study could be available as early as 2018.

In November 2014, we acquired Lumara Health Inc. (“Lumara Health”), a privately held pharmaceutical company specializing in women’s health. In connection with the acquisition of Lumara Health, we acquired Makena, a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy 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 to specialty pharmacies, specialty distributors, home infusion companies and former compounding pharmacies, which, in turn, sell Makena to healthcare providers, hospitals, government agencies and integrated delivery systems. Additional details regarding the acquisition of Lumara Health can be found in Note C, “Business Combinations.”

We also market and sell Feraheme, which 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. We began selling Feraheme in the U.S. 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 June 2013, we entered into a license agreement with Abeona Therapeutics, Inc. (“Abeona”) (formerly known as PlasmaTech Biopharmaceuticals, Inc. and Access Pharmaceuticals, Inc.) (the “MuGard License Agreement”), under which we acquired the U.S. commercial rights to MuGard for the management of oral mucositis (the “MuGard Rights”).

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, 2014. 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 on Form 10-K for the year ended December 31, 2014.

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 nine months ended September 30, 2015, include the results of Lumara Health, which we acquired on November 12, 2014 (the "Lumara Acquisition Date") and CBR Holdings, since August 17, 2015 (the "CBR Acquisition Date").

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 and services sales and collaboration agreements; product sales allowances and accruals; potential other than temporary impairment of investments; 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

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consideration; debt obligations; accrued expenses; income taxes and equity based compensation expense. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist principally of cash held in commercial bank accounts, money market funds and U.S. Treasury securities having an original maturity of less than three months. We consider all highly liquid investments with a maturity of three months or less as of the acquisition date to be cash equivalents. At September 30, 2015 and December 31, 2014, substantially all of our cash and cash equivalents were held in either commercial bank accounts or money market funds.

Restricted Cash

As of September 30, 2015, we classified $30.8 million as short-term restricted cash for certain payments owed to former CBR shareholders in connection with a sale transaction involving CBR, which was completed in September 2012 and which payment obligations were assumed by us in our August 2015 acquisition of CBR. The related liability was recorded in “Payable to former CBR shareholders” on our condensed consolidated balance sheet at September 30, 2015 and was paid in full in October 2015. As of September 30, 2015 and December 31, 2014, we classified $2.4 million as long-term restricted cash, which included $2.0 million held in a restricted fund previously established by Lumara Health in connection with its Chapter 11 plan of reorganization to pay potential claims against its former directors and officers and a $0.4 million security deposit delivered to the landlord of our Waltham, Massachusetts headquarters in the form of a revocable letter of credit.

Concentrations and Significant Customer Information

Financial instruments which potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents, investments, and accounts receivable. As of September 30, 2015, our cash, cash equivalents and investments amounted to approximately $442.9 million. We currently invest our excess cash primarily in corporate debt securities, commercial paper, certificates of deposit and municipal securities. As of September 30, 2015, approximately $35.3 million of our total $167.5 million cash and cash equivalents balance was invested in institutional money market funds, of which $34.3 million was invested in a single fund.

Our operations are located primarily within the U.S. We focus on developing, manufacturing, and commercializing Makena and Feraheme and commercializing MuGard. In addition, we are focused on marketing and selling the CBR Services. We perform ongoing credit evaluations of our customers and generally do not require collateral. The

following table sets forth customers or partners who represented 10% or more of our total revenues for the three and nine months ended September 30, 2015 and 2014:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2015		2014		2015		2014	
AmerisourceBergen Drug Corporation	28	%	40	%	25	%	39	%
McKesson Corporation	13	%	24	%	11	%	24	%
Cardinal Health, Inc.	7	%	18	%	5	%	18	%
Takeda Pharmaceuticals Company Limited	—	%	10	%	17	%	10	%

In addition, approximately 25% and 27% of our Feraheme end-user demand during the nine months ended September 30, 2015 and 2014, respectively, was generated by members of a single group purchasing organization with which we have contracted. Revenues from outside of the U.S. amounted to approximately 17% and 11% of our total revenues for the nine months ended September 30, 2015 and 2014, respectively, and were principally related to deferred Feraheme revenue recognized in connection with the termination of our license, development and commercialization agreement with Takeda Pharmaceutical Company Limited (“Takeda”), which is headquartered in Japan.

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 are recorded net of reserves for estimated chargeback obligations, prompt payment discounts

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and any allowance for doubtful accounts. Customers which represented greater than 10% of our accounts receivable balances as of September 30, 2015 and December 31, 2014 were as follows:

	September 30, 2015	December 31, 2014
AmerisourceBergen Drug Corporation	41 %	45 %
McKesson Corporation	8 %	12 %

We are currently solely dependent on a single supplier for Feraheme drug substance (produced in two separate facilities) and finished drug product and a single supply chain for Makena finished drug product. In addition, we rely on single sources for certain materials required to provide 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 cannot fulfill demand for any reason.

Revenue Recognition

We recognize revenue from the sale of our products and services as well as license fee, collaboration and other revenues, including milestone payments, other product revenues, and royalties we receive from our licensees. 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 Sales Revenue

Our U.S. product sales, which primarily represented revenues from both Makena and Feraheme in the first nine months of 2015 and Feraheme in the first nine months of 2014, were offset by provisions for allowances and accruals as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Gross U.S. product sales	$ 145,131	$ 41,396	$ 407,238	$ 113,550
Provision for U.S. product sales allowances and accruals:				
Contractual adjustments	41,851	18,179	116,236	49,953
Governmental rebates	14,363	208	40,018	580
Total provision for U.S. product sales allowances and accruals	56,214	18,387	156,254	50,533

U.S. product sales, net	$ 88,917	$ 23,009	$ 250,984	$ 63,017

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, 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 primarily reflect the addition of Makena to our product portfolio in connection with the November 2014 acquisition of Lumara Health. During the nine months ended September 30, 2015, we reduced our Makena related Medicaid and other reserves by $5.3 million and we reduced our chargeback reserves by $1.9 million, all of which were initially recorded at the time of the Lumara acquisition. These adjustments were recorded to goodwill during the nine months ended September 30, 2015, as they occurred within the acquisition measurement period. We did not materially adjust our product sales allowances and accruals during the three or nine months ended September 30, 2014. 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.

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Service Revenue

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 (i) vendor specific objective evidence; (ii) third-party evidence of selling price and (iii) 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.

We have identified two deliverables contained in the revenue arrangements for the CBR Services, which involve the storage of umbilical cord blood and/or cord tissue products, namely: (i) enrollment, including the provision of a collection kit and unit processing, with revenue for this deliverable recognized after the collection and successful processing of a cord blood/cord tissue unit; and (ii) the storage of a specimen for either an annual fee or a prepayment of 18 years or the lifetime of the newborn donor ("lifetime option"). 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 and in effect at the time of the newborn's birth and subtracting the age at death. We have allocated revenue between these two deliverables using the relative selling price method. The selling price for the enrollment, collection kit and processing deliverable and the lifetime option are estimated based on the published selling prices because we do not have vendor specific objective evidence or third-party evidence of selling price for these elements. The selling price for the annual storage option is determined based on vendor specific objective evidence as we have standalone renewals to support the selling price.

Deferred revenue includes (i) amounts collected in advance of unit processing and (ii) 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.

IPR&D

IPR&D acquired in a business combination is capitalized on our condensed consolidated balance sheet at the acquisition date fair value, net of any accumulated impairment losses. IPR&D is tested for impairment on an annual basis or more frequently if indicators of impairment are present, until completion or abandonment of the projects. If we determine that IPR&D becomes impaired or is abandoned, the carrying value of the IPR&D is written down to its fair value with the related impairment charge recognized in our condensed consolidated statement of operations in the period in which the impairment occurs. Upon successful completion of each project and launch of the product, we will make a separate determination of the estimated useful life of the IPR&D intangible asset and the related amortization will be recorded as an expense prospectively over its estimated useful life.

C.BUSINESS COMBINATIONS

CBR Acquisition

On August 17, 2015, we acquired CBR Holdings, at which time CBR Holdings became a wholly-owned subsidiary of AMAG. CBR Holdings, through its wholly-owned subsidiary, Cbr Systems, Inc., operated CBR, a privately held umbilical cord blood stem cell and cord tissue collection, processing and storage company, which we purchased 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.

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The following table summarizes the components of the estimated total purchase price for CBR, subject to finalization of the net working capital, indebtedness and other adjustments as of the CBR Acquisition Date (in thousands):

Cash consideration	$ 700,000
Estimated working capital, indebtedness and other adjustments	(17,837)
Purchase price paid at closing	682,163
Plus: Estimated purchase price payable to sellers	188
Total purchase price	$ 682,351

The net working capital and other adjustments were estimated to be $17.8 million at closing, which included $7.2 million for the excess of the payable to former CBR shareholders over the restricted cash balance at closing. Subsequent to the closing, we estimated that the net working capital and other adjustments will be approximately $17.6 million, resulting in an increase to the cash consideration paid for CBR of approximately $0.2 million. Accordingly, we recorded a $0.2 million reduction to other amounts due from the sellers recorded in prepaid expenses and other current assets in the condensed consolidated balance sheet at September 30, 2015.

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 made a preliminary allocation of the purchase price to the net tangible and intangible assets acquired and liabilities assumed, based on available information and various assumptions we believe are reasonable, with the remaining purchase price recorded as goodwill. Due to the close proximity of the acquisition date to the quarter ended September 30, 2015, we were unable to complete our analysis of fair value.

The following table summarizes the preliminary fair values assigned to the CBR assets acquired and the liabilities assumed by us along with the resulting goodwill at the CBR Acquisition Date (in thousands):

Accounts receivable	$ 9,509
Inventories	4,443
Prepaid and other current assets	8,487
Restricted cash - short-term	30,752
Property, plant and equipment	29,669
Customer relationships	297,000
Trade name and trademarks	65,000
Favorable lease	423
Deferred income tax assets	4,555
Other long-term assets	198
Accounts payable	(2,853)
Accrued expenses	(13,575)
Deferred revenues	(3,100)
Payable to former CBR shareholders	(37,947)
Deferred income tax liabilities	(149,497)
Total estimated identifiable net assets	$ 243,064

Goodwill	439,287
Total	$ 682,351

The values assigned to the assets and liabilities presented in the table above are preliminary and subject to change as additional information becomes available concerning the acquisition date fair value and tax basis of the assets acquired and liabilities assumed in the transaction. Any adjustments to the preliminary fair value of these acquired assets and liabilities assumed will be made as soon as practicable but not later than one year from the CBR Acquisition Date.

The gross contractual amount of accounts receivable at the CBR Acquisition Date was $11.6 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

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and best use). The final fair value determination for the identifiable intangible assets may differ from the preliminary estimates, and such differences could be material. 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 (including service revenues, cost of services, research and development costs, selling general and administrative costs and working capital/contributory asset charges), 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 an income approach. No assurances can be given that the underlying assumptions used to determine the fair value of the customer relationships, trade names and trademarks will not change. For this and other reasons, actual results may vary significantly from the estimated results. 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 CBR 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 preliminary fair value adjustments primarily related to deferred revenue and identifiable intangible assets acquired, we recorded a net deferred tax liability of $144.9 million in our condensed consolidated balance sheet as of September 30, 2015 using a combined federal and state statutory income tax rate of 37%. The net deferred tax liability represents the $149.5 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) offset by $4.6 million of deferred tax assets acquired from CBR.

These tax estimates are preliminary and subject to change based on, among other things, management’s final determination of the fair values of the tangible and identifiable intangible assets acquired and liabilities assumed by jurisdiction, the deductibility of acquisition-related costs and other costs deducted by CBR prior to the acquisition, and management’s assessment of the combined company’s ability to utilize the future benefits from acquired and legacy deferred tax assets.

Acquisition-related costs are not included as a component of consideration transferred and are expensed as incurred. We incurred approximately $8.5 million and $11.2 million of acquisition-related costs in the three and nine months ended September 30, 2015, respectively, related to the CBR acquisition. These costs primarily represented financial advisory fees, legal fees, due diligence and other costs and expenses.

During the post-closing period in the three months ended September 30, 2015, CBR generated approximately $7.2 million of revenue. We determined that separate disclosure of CBR's earnings for the post acquisition period in the three and nine months ended September 30, 2015 is not practicable due to the integration of CBR's operations into our business upon acquisition.

Lumara Health Acquisition

On November 12, 2014, 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, net debt and transaction expense adjustments, and issued approximately 3.2 million shares of our common stock, par value $0.01 per share, having a value of approximately $112.0 million at the time of closing, to the holders of common stock of Lumara Health.

We have 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,

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2019. This contingent consideration is recorded as a liability and measured at fair value based upon significant unobservable inputs. 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 on Form 10-K for the year ended December 31, 2014 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):

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

In June 2015, we received $0.6 million from the former stockholders of Lumara Health in connection with the final settlement of the net working capital, net debt and transaction expenses as of the Lumara Acquisition Date. In addition, during the nine months ended September 30, 2015, we adjusted the preliminary fair values assigned to the assets acquired and the liabilities assumed by us at the Lumara Acquisition Date, as discussed in Note H, “Goodwill, IPR&D and Other Intangible Assets, Net.” These measurement period adjustments have been reflected as a current period adjustment to these balances during the nine months ended September 30, 2015 in accordance with the guidance in Accounting Standards Update (“ASU”) 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments (“ASU 2015-16”), which we adopted early.

The following table summarizes the fair values assigned to assets acquired and the 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 the nine months ended September 30, 2015 (in thousands):

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 marketed product	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

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Unaudited Pro Forma Supplemental Information

The following supplemental unaudited pro forma information presents our revenue and net income (loss) on a pro forma combined basis, including Lumara Health and CBR, and assuming that the CBR acquisition occurred on January 1, 2014 and that the Lumara Health acquisition occurred on January 1, 2013. For purposes of preparing the following pro forma information, certain items recorded during the three and nine months ended September 30, 2015, such as the $8.5 million and $11.2 million of acquisition-related costs, the $10.4 million loss on debt extinguishment, $9.2 million of other one-time fees and expenses incurred in connection with the CBR acquisition financing are reflected in 2014 as if the CBR acquisition occurred on January 1, 2014. Certain items recorded in 2014, such as the $1.9 million of acquisition-related costs incurred in connection with the acquisition of Lumara Health have been excluded from 2014 as the pro forma results assume the Lumara Health acquisition occurred on January 1, 2013. The pro forma amounts do not include any expected cost savings or restructuring actions which may be achievable or which may occur subsequent to the acquisition of Lumara Health or CBR or the impact of any non-recurring activity. The following table presents unaudited pro forma consolidated results (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Pro forma combined revenues	$ 110,244	$ 100,091	$ 381,650	$ 257,536
Pro forma combined net income (loss)	$ (5,116)	$ (983)	$ 24,220	$ (52,043)
Pro forma net income (loss) per diluted share	$ (0.15)	$ (0.04)	$ 0.69	$ (2.07)

The pro forma adjustments reflected in the pro forma combined 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 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.

Goodwill

Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the fair values of the net assets acquired and liabilities assumed. In connection with our August 2015 acquisition of CBR, we recognized $439.3 million of goodwill as of September 30, 2015, primarily due to deferred tax liabilities recorded

on the fair value adjustments, primarily those adjustments relating to intangible assets and deferred revenue, and to the synergies expected from combining our operations with CBR. In connection with our November 2014 acquisition of Lumara Health, we recognized $198.1 million of goodwill as of September 30, 2015, primarily due to the net deferred tax liabilities recorded on the fair value adjustments to Lumara Health's inventories and identifiable intangible asset. The $637.4 million of goodwill resulting from the CBR and Lumara Health acquisitions is not deductible for income tax purposes.

D.INVESTMENTS

As of September 30, 2015 and December 31, 2014, our investments equaled $275.3 million and $24.9 million, respectively, and consisted of securities classified as available-for-sale.

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The following is a summary of our investments as of September 30, 2015 and December 31, 2014 (in thousands):

	September 30, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	$ 26,244	$ 8	$ (10)	$ 26,242
Due in one to three years	147,615	25	(276)	147,364
Commercial paper				
Due in one year or less	7,488	2	—	7,490
Certificates of deposit				
Due in one year or less	10,000	1	—	10,001
Municipal securities				
Due in one year or less	13,874	11	—	13,885
Due in one to three years	70,249	117	(5)	70,361
Total investments	$ 275,470	$ 164	$ (291)	$ 275,343

	December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	$ 11,656	$ 3	$ (4)	$ 11,655
Due in one to three years	13,258	10	(33)	13,235
Total investments	$ 24,914	$ 13	$ (37)	$ 24,890

The $250.5 million increase in our total investments was primarily due to the $188.8 million of net proceeds from our March 2015 public equity offering, as discussed in Note N, “Stockholders’ Equity.”

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 any of the three or nine month periods ended September 30, 2015 and 2014. 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. 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 which 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.

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E.FAIR VALUE MEASUREMENTS

The following tables represent the fair value hierarchy as of September 30, 2015 and December 31, 2014 for those assets and liabilities that we measure at fair value on a recurring basis (in thousands):

	Fair Value Measurements at September 30, 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:				
Money market funds	$ 35,325	$ 35,325	$ —	$ —
Corporate debt securities	173,606	—	173,606	—
Commercial paper	7,490	—	7,490	—
Certificates of deposit	10,001	—	10,001	—
Municipal securities	84,246	—	84,246	—
Total Assets	$ 310,668	$ 35,325	$ 275,343	$ —
Liabilities:				
Contingent consideration-Lumara Health	$ 214,285	$ —	$ —	$ 214,285
Contingent consideration-MuGard	8,660	—	—	8,660
Total Liabilities	$ 222,945	$ —	$ —	$ 222,945

	Fair Value Measurements at December 31, 2014 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$ 77,254	$ 77,254	$ —	$ —
Corporate debt securities	24,890	—	24,890	—
Total Assets	$ 102,144	$ 77,254	$ 24,890	$ —
Liabilities:				
Contingent consideration - Lumara Health	$ 206,600	$ —	$ —	$ 206,600
Contingent consideration - MuGard	12,102	—	—	12,102
Total Liabilities	$ 218,702	$ —	$ —	$ 218,702

Investments

Our money market funds are classified as Level 1 assets under the fair value hierarchy as these assets have been valued using quoted market prices in active markets without any valuation adjustment. 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, 2015. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during the nine months ended September 30, 2015.

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Contingent consideration

We accounted for the acquisitions of Lumara Health, CBR and the MuGard Rights as business combinations under the acquisition method of accounting. Additional details regarding the Lumara Health acquisition can be found in Note C, "Business Combinations." 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 determined using unobservable inputs ("Level 3"). 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 acquisitions of Lumara Health and the MuGard Rights measured on a recurring basis using Level 3 inputs as of September 30, 2015 (in thousands):

Balance as of December 31, 2014	$ 218,702
Payments made	(322)
Adjustments to fair value of contingent consideration	4,525
Other adjustments	40
Balance as of September 30, 2015	$ 222,945

The $4.5 million of adjustments to the fair value of the contingent consideration liability were due primarily to a $7.7 million increase to the Makena contingent consideration related to the time value of money, partially offset by a $3.2 million reduction to the MuGard contingent consideration due to changes in estimated amounts and timing of cash flows related to the royalties we expect to pay to Abeona under the MuGard License Agreement. These adjustments are included in selling, general and administrative expenses in our condensed consolidated statements of operations. We have classified $96.1 million of the Makena contingent consideration and $0.7 million of the MuGard contingent consideration as short-term liabilities in our condensed consolidated balance sheet as of September 30, 2015.

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%, which we believe is reasonable given the estimated likelihood of the pay-out.

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 12%. As of September 30,

2015, we estimate that the undiscounted royalty amounts we could pay under the MuGard License Agreement, based on current projections, may range from $10.0 million to $18.0 million over a ten year period beginning 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, we cannot provide assurance that the underlying assumptions used to forecast the cash flows will materialize as we estimated and thus, our actual results may vary significantly from the estimated results.

Debt

We estimate the fair value of our debt obligations by using quoted market prices obtained from third-party pricing services, which is classified as a Level 2 input. As of September 30, 2015, the estimated fair value of our 2023 Senior Notes and 2.5% Convertible Notes were approximately $477.5 million and $322.1 million, respectively, and the estimated fair value of our term loan facilities were approximately equal to their respective book values. See Note Q, "Debt" for additional information on our debt obligations.

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F.Inventories

Our major classes of inventories were as follows as of September 30, 2015 and December 31, 2014 (in thousands):

	September 30, 2015	December 31, 2014
Raw materials	$ 18,556	$ 14,188
Work in process	1,506	5,965
Finished goods	17,155	20,457
Inventories included in current assets	37,217	40,610
Included in other long-term assets:		
Raw materials	2,654	7,798
Total inventories	$ 39,871	$ 48,408

The decrease in inventories as of September 30, 2015 as compared to December 31, 2014, was primarily due to inventory sold to customers, partially offset by the inclusion of CBR inventory acquired in connection with the August 2015 acquisition of CBR, which consists of cord blood and cord tissue collection kits and processing bags.

In the fourth quarter of 2014, we recorded the acquired Makena inventory at a fair value of $30.3 million, which required a $26.1 million step-up adjustment to recognize the inventory at its expected net realizable value. We are amortizing and recognizing the step-up adjustment primarily as cost of product sales in our condensed consolidated statements of operations as the related inventories are sold. During the three and nine months ended September 30, 2015, we recognized $1.6 million and $7.5 million of the fair value adjustment as cost of product sales, respectively. In connection with the fair value step-up adjustment of the Makena inventory, we have recorded a portion of the associated raw material inventory and associated step-up adjustment in other long-term assets as we believe that the amount of inventory purchased in the acquisition exceeds our normal inventory cycle.

During the nine months ended September 30, 2015, we expensed $3.6 million of Makena inventory and $0.6 million of Feraheme inventory, which may not be saleable, and was recorded in cost of product sales in our condensed consolidated statements of operations. This amount included a fair value adjustment of $3.3 million.

G.PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following as of September 30, 2015 and December 31, 2014 (in thousands):

	September 30, 2015	December 31, 2014
Land	$ 700	$ —
Land improvements	300	
Building and improvements	9,500	—
Computer equipment and software	12,625	—
Furniture and fixtures	1,785	1,574
Leasehold improvements	1,710	430
Laboratory and production equipment	5,165	493
Construction in progress	1,278	—
	33,063	2,497
Less: accumulated depreciation	(2,706)	(978)
Property, plant and equipment, net	$ 30,357	$ 1,519

We acquired land and a building in Tucson, Arizona as well as other fixed assets in connection with the CBR acquisition.

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H.GOODWILL, IPR&D AND OTHER INTANGIBLE ASSETS, NET

Goodwill

In connection with our August 2015 acquisition of CBR, we recognized $439.3 million of goodwill as of September 30, 2015. In connection with our November 2014 acquisition of Lumara Health, we recognized $205.8 million of goodwill as of December 31, 2014. During the nine months ended September 30, 2015, the Lumara Health goodwill balance decreased by $7.7 million, which was comprised primarily of a $7.2 million reduction associated with adjustments to our Makena revenue reserves and a $5.0 million reduction related to net deferred tax liabilities, partially offset by a $4.5 million increase associated with the final settlement of net working capital with the former stockholders of Lumara Health. These measurement period adjustments have been reflected as a current period adjustment to these balances during the nine months ended September 30, 2015 in accordance with the guidance in ASU 2015-16, which we adopted early. As of September 30, 2015, we had no accumulated impairment losses related to goodwill. See Note C, “Business Combinations.”

IPR&D and Other Intangible Assets, Net

As of September 30, 2015 and December 31, 2014, our identifiable intangible assets consisted of the following (in thousands):

	September 30, 2015			December 31, 2014		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Amortizable intangible assets:						
Makena base technology	$ 797,100	$ 42,825	$ 754,275	$ 797,100	$ 4,834	$ 792,266
CBR customer relationships	297,000	357	296,643	—	—	—
Favorable lease	423	25	398	—	—	—
MuGard Rights	16,893	762	16,131	16,893	351	16,542
	1,111,416	43,969	1,067,447	813,993	5,185	808,808
Indefinite-lived intangible assets:						
Makena IPR&D	79,100	—	79,100	79,100	—	79,100
CBR trade names and trademarks	65,000	—	65,000	—	—	—
Total intangible assets	$ 1,255,516	$ 43,969	$ 1,211,547	$ 893,093	$ 5,185	$ 887,908

As of September 30, 2015, the weighted average remaining amortization periods for our definite-lived intangible assets were as follows:

	Weighted Average Remaining Amortization Periods (in Years)
Makena base technology	8.6
CBR customer relationships	10.4
Favorable lease	1.5
MuGard Rights	5.9

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

The MuGard Rights were acquired from Abeona in June 2013. Amortization of the MuGard Rights is being recognized using an economic consumption model over ten years, which represents our best estimate of the period over which we expect the majority of the asset's cash flows to be derived. We believe this is the best approximation of the period over which we will derive the majority of value of the MuGard Rights.

The CBR intangible assets (the CBR customer relationships and the favorable lease) 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 twenty years, which we believe is an appropriate amortization period due to the estimated

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economic lives of the CBR intangible assets. The favorable lease is being amortized on a straight-line basis over the remaining term of the lease.

Total amortization expense for the three months ended September 30, 2015 and 2014 was $13.9 million and $0.1 million, respectively, and for the nine months ended September 30, 2015 and 2014 was $38.8 million and $0.2 million, respectively. The increase in amortization expense is due to the amortization of the Makena and CBR related intangible assets. Amortization expense for Makena and MuGard is recorded in cost of product sales in our condensed consolidated statements of operations. Amortization expense for 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):

Period	Estimated Amortization Expense
Remainder of 2015	$ 14,295
2016	77,324
2017	92,191
2018	99,532
2019	70,750
Thereafter	713,355
Total	$ 1,067,447

I.ACCRUED EXPENSES

As of September 30, 2015 and December 31, 2014, our accrued expenses consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
Commercial rebates, fees and returns	$ 53,288	$ 44,807
Professional, license, and other fees and expenses	37,016	23,157
Salaries, bonuses, and other compensation	11,200	10,176
Restructuring expense	1,152	1,953
Total accrued expenses	$ 102,656	$ 80,093

J.Income Taxes

The following table summarizes our effective tax rate and income tax expense for the three and nine months ended September 30, 2015 and 2014 (in thousands except for percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2015		2014		2015		2014	
Effective tax rate	41	%	—	%	27	%	—	%
Income tax benefit (expense)	$ 14,130		$ —		$ (9,513)		$ —	

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.

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 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

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associated with the acquisition of CBR, and non-deductible contingent consideration expense associated with Lumara Health.

We did not recognize any income tax benefit or expense for the three or nine months ended September 30, 2014 as we were subject to a full valuation allowance due to our net operating loss position at those times.

During the three months ended September 30, 2015, we reduced our net deferred tax liabilities initially recorded at the time of the Lumara acquisition by $5.4 million. These adjustments were recorded to goodwill during the three months ended September 30, 2015, as they occurred within the acquisition measurement period. The decrease in net deferred tax liabilities was primarily attributable to an increase in net operating loss carryforwards expected to be utilized in future periods, which was partially offset by the tax impact of the Makena revenue reserve measurement period adjustments recorded during the nine months ended September 30, 2015.

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 loss, net of tax, associated with unrealized gains (losses) on securities during the three and nine months ended September 30, 2015 and 2014 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Beginning Balance	$ (3,948)	$ (3,259)	$ (3,617)	$ (3,491)
Other comprehensive income (loss) before reclassifications	228	(305)	(107)	(76)
Gain (loss) reclassified from other accumulated comprehensive loss	—	9	4	12
Ending Balance	$ (3,720)	$ (3,555)	$ (3,720)	$ (3,555)

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 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 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 2015 Term Loan Facility, which we entered into 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, including a total leverage ratio. During the three and nine months ended September 30, 2015, we utilized 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 the interest expense related to the Convertible Notes. Prior to the acquisition of Lumara Health in November 2014, we intended to settle the principal value of the Convertible Notes in cash and the excess conversion premium in shares. The dilutive effect of the conversion premium is reflected in the calculation of diluted earnings per share for the three months ended September 30, 2014, as if it were a freestanding written call option on our shares. The impact of the conversion premium has been considered in the calculation of diluted net income per share for the three months ended September 30, 2014 by applying the closing price of our common stock on September 30, 2014 to calculate the number of shares issuable under the conversion premium. 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. See Note Q, "Debt," for additional information.

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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, 2015 and 2014 were as follows (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net income (loss)	$ (20,584)	$ 1,458	$ 25,578	$ (7,191)
Weighted average common shares outstanding	33,223	21,984	30,379	21,912
Effect of dilutive securities:				
Warrants	—	—	3,015	—
Stock options and RSUs	—	369	1,568	—
Convertible 2.5% notes	—	1,114	—	—
Shares used in calculating dilutive net income (loss) per share	33,223	23,467	34,962	21,912
Net income (loss) per share:				
Basic	$ (0.62)	$ 0.07	$ 0.84	$ (0.33)
Diluted	$ (0.62)	$ 0.06	$ 0.73	$ (0.33)

The following table sets forth the potential common shares issuable upon the exercise of outstanding options, the vesting of RSUs and the exercise of warrants (prior to consideration of the treasury stock method), and the conversion of the 2.5% 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,	
	2015	2014	2015	2014
Options to purchase shares of common stock	2,989	2,013	791	3,081
Shares of common stock issuable upon the vesting of RSUs	712	289	157	760
Warrants	7,382	7,382	—	7,382
Convertible 2.5% notes	7,382	6,268	7,382	7,382
Total	18,465	15,952	8,330	18,605

During the three and nine months ended September 30, 2014, the average common stock price was below the exercise price of the warrants.

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") (under which we no longer grant awards), 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.

In November 2007, the 2000 Plan was succeeded by our 2007 Plan and, accordingly, no further grants may be made under the 2000 Plan. 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 available for issuance under the 2007 Plan. As of September 30, 2015, there were 2,221,192 shares remaining available for issuance under the 2007 Plan, including 1,700,000 shares which were added to the 2007 Plan upon approval by our stockholders of an amendment to our 2007 Plan at our Meeting of Stockholders held on May 21, 2015 (the "Annual Meeting"). Such 2,221,192 amount does not include shares subject to outstanding awards under

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the 2000 Plan. Further, 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, was 200,000 shares. As of September 30, 2015, there were 2,650 shares remaining available for issuance under the Lumara Health 2013 Plan, which are available for grants to certain employees, 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.

At our Annual Meeting, 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. As of September 30, 2015, no shares have been issued under our 2015 ESPP.

During the nine months ended September 30, 2015, we also granted equity through inducement grants outside of the equity plans, as discussed below, to certain newly hired executive officers and employees.

Stock Options

The following table summarizes stock option activity in our equity plans for the nine months ended September 30, 2015:

	2007 Equity Plan	2000 Equity Plan	2013 Lumara Equity Plan	Total
Outstanding at December 31, 2014	2,051,017	35,266	44,000	2,130,283
Granted	840,475	—	76,000	916,475
Exercised	(652,181)	(21,226)	—	(673,407)
Expired or terminated	(257,146)	—	—	(257,146)
Outstanding at September 30, 2015	1,982,165	14,040	120,000	2,116,205

Restricted Stock Units

The following table summarizes RSU activity in our equity plans for the nine months ended September 30, 2015:

	2007 Equity Plan	2000 Equity Plan	2013 Lumara Equity Plan	Total
Outstanding at December 31, 2014	360,826	—	20,000	380,826
Granted	253,954	—	60,225	314,179
Vested	(72,832)	—	—	(72,832)
Expired or terminated	(95,243)	—	(2,875)	(98,118)
Outstanding at September 30, 2015	446,705	—	77,350	524,055

Other Equity Compensation Grants

During the nine months ended September 30, 2015, our Board or Compensation Committee granted options to purchase 220,000 shares of our common stock and 82,250 RSUs to certain new-hire employees to induce them to accept employment with us (collectively, “Inducement Awards”). 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

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to settle these awards in cash and therefore, equity accounting was applied. As of September 30, 2015, there were 873,100 options and 187,575 RSUs outstanding under Inducement Awards.

Equity-based compensation expense

Equity-based compensation expense for the three and nine months ended September 30, 2015 and 2014 consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Cost of product sales	$ 159	$ 32	$ 254	$ 89
Research and development	1,028	466	2,071	1,274
Selling, general and administrative	3,701	1,448	9,247	4,790
Total equity-based compensation expense	$ 4,888	$ 1,946	$ 11,572	$ 6,153
Income tax effect	(871)	—	(3,464)	—
After-tax effect of equity-based compensation expense	$ 4,017	$ 1,946	$ 8,108	$ 6,153

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.

As a result of our historical net losses, we did not provide an income tax effect incurred during the three and nine months ended September 30, 2014.

N.STOCKHOLDERS’ EQUITY

August 2015 Public Offering of Common Stock

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.

March 2015 Public Offering of Common Stock

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.

2015 Annual Meeting

At our Annual Meeting, our stockholders approved proposals to (i) amend our Certificate of Incorporation, as amended and restated and then currently in effect, to increase the number of authorized shares of our common stock from 58,750,000 shares to 117,500,000 shares (which amendment was subsequently filed with the Secretary of State of the State of Delaware) and (ii) amend our 2007 Plan to, among other things, increase the number of shares of our common stock available for issuance thereunder by 1,700,000 shares.

Change in Stockholders' Equity

Total stockholders' equity increased by $460.0 million during the nine months ended September 30, 2015. This increase was primarily driven by $188.8 million and $218.6 million in net proceeds related to the March 2015 and August 2015 public offerings of common stock, respectively, as discussed above, $25.6 million from our net income, $15.5 million from the exercise of stock options and $11.6 million related to equity-based compensation expense.

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O.COMMITMENTS AND 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.

Makena Securities Litigation

During October and November 2011, three complaints were filed in the United States District Court for the Eastern District of Missouri (the “Court”) against K-V Pharmaceutical Company (“KV”) (since renamed as Lumara Health) and certain individual defendants, alleging violations of the anti-fraud provisions of the federal securities laws on behalf of all purchasers of the publicly traded securities of KV between February 14, 2011 and April 4, 2011: Julianello v. K-V Pharmaceutical Co., et al. (filed October 19, 2011); Mukku v. K-V Pharmaceutical Co., et al. (filed October 31, 2011), and Cheong v. K-V Pharmaceutical Co., et al. (filed November 2, 2011). On March 8, 2012, the three cases were consolidated and the consolidated action is now referred to as In Re K-V Pharmaceutical Company Securities Litigation, Case No. 4:11-CV-1816-AGF. On May 4, 2012, the Court appointed Lori Anderson as the Lead Plaintiff in the matter, and an amended complaint was filed on July 24, 2012. The amended complaint alleged class members were damaged by purchasing KV stock at artificially inflated prices due to defendants’ purportedly misleading statements regarding KV’s exclusivity over Makena. On April 22, 2013, the individual defendants moved to dismiss the complaint and oral argument was held before the Court on November 26, 2013. KV joined in the motion to dismiss on February 10, 2014. On March 27, 2014, the Court entered an order granting defendants’ motion to dismiss the class action complaint without prejudice to the plaintiff’s ability to file a second amended complaint with respect to a limited issue of whether defendants’ statements about Lumara Health’s financial assistance program for Makena were materially false or misleading. On April 16, 2014, plaintiff filed a motion to reconsider asking the Court to reconsider its order restricting the scope of plaintiff’s ability to amend its complaint. The Court denied plaintiff’s motion to reconsider and entered a judgment granting defendants’ motion to dismiss on June 6, 2014. On July 1, 2014, plaintiff filed a Notice of Appeal with the United States Court of Appeals for the Eighth Circuit (the “Court of Appeals”). The Court of Appeals heard oral argument on March 12, 2015 and on July 2, 2015, affirmed the Court’s decision to dismiss the case. The time periods for the plaintiffs to appeal this decision have lapsed. Therefore, we consider this matter closed.

European Patent Organization Appeal

In July 2010, Sandoz GmbH ("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 on June 16, 2015, where the decision revoking the patent was set aside and remitted back to the Opposition Division for further consideration. In the event that we do not experience a successful outcome at the Opposition Division, under EU regulations ferumoxytol would still be entitled to eight years of data protection and ten years of market exclusivity from the date of approval, which we believe would create barriers to entry for any generic version of ferumoxytol into the EU market until sometime between 2020 and 2022. This decision had no impact on our revenues for the nine months ended September 30, 2015. However, any future unfavorable outcome in this matter could negatively affect the magnitude and timing of future revenues, if we were to resume commercialization efforts in the EU. We do not expect to incur any related liability regardless of the outcome of the appeal and therefore did not record any liability as of September 30, 2015. We continue to believe the patent is valid and intend to vigorously prosecute the patent before the Opposition Division.

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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 has engaged in unfair methods of competition with respect to Makena or any hydroxyprogesterone caproate product. We are fully cooperating with the FTC and have provided a thorough response to the FTC 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 (i) 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, (ii) our belief that the DQSA has had a significant impact on the compounding of hydroxyprogesterone caproate, and (iii) how our contracts with former compounders do allow those compounders to continue to serve physicians and patients with respect to supplying medically necessary alternative/altered forms of hydroxyprogesterone caproate. Given the early stages of this inquiry, we cannot at this time assess potential outcome of this investigation.

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 at September 30, 2015. We expense legal costs as they are incurred.

Purchase Commitments

In connection with our acquisition of CBR, we have certain minimum purchase commitments associated with an agreement entered into by CBR prior to our acquisition. This agreement expires in December 2018, with the remaining amount of minimum purchase commitments totaling $7.9 million.

P.COLLABORATIVE AGREEMENTS

Our commercial strategy includes the formation of collaborations with other pharmaceutical companies to expand our portfolio through the in-license or acquisition of additional pharmaceutical products, services or companies, including revenue-generating commercial products, services and late-stage development assets.

In December 2014, we entered into an agreement (the "Takeda Termination Agreement"), which terminated our License, Development and Commercialization Agreement with Takeda (as amended, the "Takeda Agreement"). Under the terms of the Takeda Agreement, Takeda had exclusive rights to develop and commercialize Feraheme as a therapeutic agent in certain agreed-upon territories outside of the U.S. Pursuant to the Takeda Termination Agreement, the termination of the Takeda Agreement was effective on a rolling basis, whereby the termination was effective for a particular geographic territory (i.e., countries under the regulatory jurisdictions of Health Canada, the European Medicines Agency and SwissMedic) upon the earlier of effectiveness of the transfer to us or a withdrawal of the marketing authorization for such territory, with the final effective termination date to be on the third such effective date. On April 13, 2015, the marketing authorization for ferumoxytol was withdrawn in the EU and Switzerland. On June 25, 2015, the transfer from Takeda to us of the Feraheme marketing authorization in Canada became effective and marked the final termination date of the Takeda Agreement.

In connection with the final termination of the Takeda Agreement, we recognized into revenues the remaining balances of deferred revenue related to the upfront and milestone payments we received from Takeda during the life of the agreement as well as amounts associated with the terms of the Takeda Termination Agreement. During the nine months ended September 30, 2015, we recognized $44.4 million in revenues associated with the amortization of the remaining deferred revenue balance and have recorded it in license fee, collaboration and other revenues in our condensed consolidated statement of operations. In addition, we recognized $5.2 million of additional revenues in the nine months ended September 30, 2015 related to payments made by Takeda upon the final termination date as required under the terms of the Takeda Termination Agreement.

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Q.Debt

Our outstanding debt obligations as of September 30, 2015 and December 31, 2014 consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
2023 Senior Notes	$ 490,108	$ —
2015 Term Loan Facility	342,459	—
2.5% Convertible Notes	172,594	167,441
2014 Term Loan Facility	-	327,905
Total long-term debt	1,005,161	495,346
Less: current maturities	17,500	34,000
Long-term debt, net of current maturities	$ 987,661	$ 461,346

2023 Senior Notes

On August 17, 2015, in connection with the CBR acquisition, we completed a private placement of $500.0 million aggregate principal amount of 2023 Senior Notes. The 2023 Senior Notes were issued pursuant to an Indenture, dated as of August 17, 2015 (the “Indenture”), by and among the Company, certain subsidiaries of the Company 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 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 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 25% in aggregate principal amount of the then-outstanding 2023 Senior Notes to accelerate, or in certain cases, will automatically cause the acceleration of, the amounts due under the 2023 Senior Notes.

At September 30, 2015, the carrying value of the outstanding borrowings, net of unamortized original issue costs and other lender fees and expenses, was $490.1 million. In connection with the CBR acquisition, we incurred a $6.8 million bridge loan commitment fee, which was included in other income (expense) in our condensed consolidated statement of operations and paid in the third quarter of 2015.

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 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, 2015, the carrying value of the outstanding borrowings, net of unamortized original

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issue costs and other lender fees and expenses, was $342.5 million. The unamortized original issue costs and other lender fees and expenses, including a prepayment penalty, included $7.3 million of the unamortized original issue costs and other lender fees and expenses from the 2014 Term Loan Facility as a result of accounting guidance for the modification of debt arrangements. We also recorded $2.4 million of fees and expenses from the 2014 Term Loan Facility in other income (expense) in our condensed consolidated statement of operations.

We must repay the 2015 Term Loan Facility in installments of (a) $4.4 million per quarter due on the last day of each quarter beginning with the quarter ending 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. 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 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 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;

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(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 events.

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 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 calendar quarter ended September 30, 2015, the Convertible Notes are convertible for the calendar quarter ended September 30, 2015 pursuant to clause (1) above.

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 September 30, 2015 consisted of the following (in thousands):

	September 30, 2015
Liability component:	
Principal	$ 200,000
Less: debt discount, net	(27,406)
Net carrying amount	$ 172,594
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 were allocated to the equity component and recorded as a reduction to additional paid-in capital

and $5.4 million were allocated to the liability component and recorded as assets on the balance sheet. 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, 2015, the carrying value of the Convertible Notes was $172.6 million and the fair value of the Convertible Notes was $322.1 million. The effective interest rate on the liability component was 7.23% for the period from the date of issuance through September 30, 2015. As of September 30, 2015, the “if-converted value” exceeded the remaining principal amount of the Convertible Notes by $93.3 million.

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The following table sets forth total interest expense recognized related to the Convertible Notes during the three and nine months ended September 30, 2015 and 2014 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Contractual interest expense	$ 1,250	$ 1,250	$ 3,750	$ 3,125
Amortization of debt issuance costs	253	234	733	564
Amortization of debt discount	1,777	1,645	5,153	3,967
Total interest expense	$ 3,280	$ 3,129	$ 9,636	$ 7,656

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, on February 11, 2014 and February 13, 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 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 the first quarter of 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 the first quarter of 2014.

Aside from the initial payment of $39.8 million to the call spread counterparties for the convertible bond hedges, which is 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.

2014 Term Loan Facility

On November 12, 2014, we borrowed $340.0 million under the 2014 Term Loan Facility to fund a portion of the purchase price of Lumara Health. On August 17, 2015, we repaid the remaining $323.0 million outstanding principal amount and recognized a $10.4 million loss on debt extinguishment as a result of the early repayment, which we have recorded in other income (expense) in our condensed consolidated statement of operations.

R.RESTRUCTURING

In connection with the August 2015 CBR acquisition and the November 2014 Lumara Health acquisition, we initiated a restructuring program in the third quarter of 2015 and the fourth quarter of 2014, which included severance benefits primarily related to certain former CBR and Lumara Health employees, respectively. As a result of these restructurings, we recorded charges of approximately $0.7 million and $1.8 million in the three and nine months ended

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September 30, 2015, respectively. In addition, we currently expect to record $2.1 million of additional restructuring charges. 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, 2015 and 2014 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Accrued restructuring, beginning of period	$ 1,253	$ —	$ 1,953	$ —
Employee severance, benefits and related costs	635	—	1,490	—
Payments	(736)	—	(2,291)	—
Accrued restructuring, end of period	$ 1,152	$ —	$ 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 September 2015, the FASB issued Accounting Standards Update (“ASU”) 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments. This statement eliminates the requirement for an acquirer to retrospectively adjust provisional amounts recorded in a business combination to reflect new information about the facts and circumstances that existed as of the acquisition date and that, if known, would have affected measurement or recognition of amounts initially recognized. As an alternative, the amendment requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The amendments require that the acquirer record, in the financial statements of the period in which adjustments to provisional amounts are determined, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. The new standard is effective prospectively for fiscal years beginning after December 15, 2015, including interim periods within those fiscal years, with early adoption permitted. The guidance is to be applied prospectively to adjustments to provisional amounts that occur after the effective date of the guidance, with earlier application permitted for financial statements that have not been issued. Our early adoption of ASU 2015-16 in the third quarter of 2015 did not have a material impact on our financial position or results of operations.

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. 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 this standard 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. The new standard will be effective for us on January 1, 2017. The adoption of this standard is not expected to have an impact on our results of operations, cash flows or financial position.

In May 2015, the FASB issued ASU 2015-07, Fair Value Measurement (Topic 820): Disclosures for Investments in Certain Entities That Calculate Net Asset Value per Share (or Its Equivalent) (“ASU 2015-07”). Under this standard, investments measured at net asset value, as a practical expedient for fair value, will be excluded from the fair value hierarchy. The only criterion for categorizing investments in the fair value hierarchy will be the observability of the inputs. The standard is effective for us for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted, including for financial statement periods that have not yet been issued. We do not expect the adoption of ASU 2015-07 to have a material impact on our disclosures.

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. ASU 2015-03 is effective for annual and interim periods beginning on or after December 15, 2015. As of September 30, 2015 we have $11.8 million in debt issuance costs

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associated with our current debt obligations that would be reclassified from a long-term asset to a reduction in the carrying amount of our debt.

In February 2015, the FASB issued ASU No. 2015-02, “Consolidation (Topic 810) - Amendments to the Consolidation Analysis.” This statement eliminates the deferral of the requirements of ASU No. 2009-17, “Consolidations (Topic 810) - Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities” for certain interests in investment funds and provides a scope exception from Topic 810 for certain investments in money market funds. The ASU also makes several modifications to the consolidation guidance for VIEs and general partners’ investments in limited partnerships, as well as modifications to the evaluation of whether limited partnerships are VIEs or voting interest entities. The guidance is effective for interim and annual reporting periods beginning after December 15, 2015, and early adoption is permitted. The adoption of this standard is not expected to have an impact on our results of operations, cash flows or financial position.

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 on our condensed consolidated financial statements and related disclosures and do not expect it to have a material impact our results of operations, cash flows or financial position.

In May 2014, the FASB issued ASU 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 August 2015, the FASB finalized a one year delay in the effective date of this standard, which will now be effective for us on January 1, 2018, however early adoption is permitted any time after the original effective date, which for us is January 1, 2017. We have not yet selected a transition method and are currently evaluating the impact of ASU 2014-09 on our condensed consolidated financial statements.

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

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2014 (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, words such as "may" "will," "expect," "intend," and similar 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: our plans to continue to expand the impact of our product portfolio by delivering on our growth strategy; plans to bring to market therapies that provide clear benefits and improve patients' lives; plans to diversify and grow our product portfolio, including our intent to continue to expand and diversify our portfolio through the in license or purchase of additional pharmaceutical products, services or companies; expectations that results from the Velo pivotal Phase 2b/3a study could be available as early as 2018; expectations and plans as to regulatory and commercial developments and activities, including the pursuit of a broader indication for Feraheme, requirements and initiatives for clinical trials and studies, post-approval commitments for our products and the next generation development programs for Makena; expectations regarding our response to the FDA on the complete response letter for approval of the single-dose preservative-free vial of Makena and our expectations of the timing of the related commercial launch; expectations regarding the regulatory timelines for the Makena auto-injector, including expectations of the related approval and launch; the growth of our maternal health business; expectations as to what impact recent regulatory developments will have on our business and competition, including recent changes to the Feraheme product information and label; our expectations on the timing of initiation for our new Feraheme trial for adults patients with IDA; the market opportunities for each of our products; plans regarding our sales and marketing initiatives, including our contracting and discounting strategy and efforts to increase patient compliance and access; 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 on-going operations; the potential significance of costs in integrating CBR into our current business; expectations regarding the manufacture of all drug substance, drug products and key materials for our CBR Services at our third-party manufacturers or suppliers; the strategic fit of the CBR Services into our maternal health business; 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; the effect of product price increases; expected increases in research and development expenses; 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; expectations regarding our cash, cash equivalents and investments balances and capital needs; 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; our expectations regarding

competitive pressures and the impact on growth on our product sales; our plans regarding manufacturing; the timing of our planned research and development projects; 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 and investments balances and information with respect to any other plans and strategies for our business. Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements. Any forward-looking statement should be considered in light of the factors discussed in Part II, Item 1A below under “Risk Factors” in this Quarterly Report on Form 10-Q and in Part I, Item 1A in our Annual Report. We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the U.S. Securities and Exchange Commission to publicly update or revise any such statements to reflect any change in company expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

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Overview

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We use our business and clinical expertise to bring medical therapies and other innovations to market that provide clear benefits and improve people's lives. We have a diverse portfolio of products and services with a focus on maternal health, anemia management and cancer supportive care, including Makena® (hydroxyprogesterone caproate injection), services related to the preservation of umbilical cord blood stem cell and cord tissue units operated through Cord Blood Registry® ("CBR"), Feraheme® (ferumoxytol) Injection for Intravenous ("IV") use and MuGard® Mucoadhesive Oral Wound Rinse. We intend to continue 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 sales of Makena, CBR Services and Feraheme.

AMAG's Portfolio of Products and Services

On August 17, 2015, we acquired CBR Acquisition Holdings Corp. ("CBR Holdings"), at which time CBR Holdings became a wholly-owned subsidiary of AMAG. CBR Holdings, through its wholly-owned subsidiary, Cbr Systems, Inc., operated CBR, which we purchased for $700.0 million in cash consideration, subject to estimated working capital, indebtedness and other adjustments. CBR is a private umbilical cord blood stem cell and cord tissue bank which offers pregnant women and their families the ability to collect, process and cryogenically preserve newborn umbilical cord blood stem cells and cord tissue units (the "CBR Services"). As of September 30, 2015, CBR stores more than 600,000 preserved umbilical cord blood stem cell and cord tissue units. We market and sell CBR Services directly to consumers. Additional details regarding the acquisition of CBR Holdings can be found in Note C, "Business Combinations," to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

On July 22, 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 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 global rights to the DIF program (the "DIF Rights"), which was recorded in research and development expenses in our condensed consolidated statements of operations. DIF has been granted both orphan drug and fast-track review designations by the U.S. Food and Drug Administration ("FDA") for the use in treating severe preeclampsia. Under the option agreement, Velo will complete a dose ranging study and a Phase 2b/3a clinical study. 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 anticipate that results from the pivotal

Phase 2b/3a study could be available as early as 2018.

In November 2014, we acquired Lumara Health Inc. (“Lumara Health”) at which time Lumara Health became our wholly-owned subsidiary. Under the terms of the acquisition agreement (the “Lumara Agreement”), we purchased 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 consideration, subject to net working capital, net debt and transaction expenses, and issued approximately 3.2 million shares of our common stock, par value $0.01 per share, having a value of approximately $112.0 million at the time of closing, to the holders of common stock of Lumara Health. The Lumara Agreement provides for future contingent payments of up to $350.0 million in cash (or upon mutual agreement between us and the former Lumara Health security holders, future contingent payments may also be made in common stock or some combination thereof) payable by us to the former Lumara Health security holders based upon the achievement of certain sales milestones through calendar year 2019. By virtue of the acquisition of Lumara Health, we acquired Makena, a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy 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 to specialty pharmacies, specialty distributors, home infusion companies and former compounding pharmacies

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which, in turn, sell Makena to healthcare providers, hospitals, government agencies and integrated delivery systems. Additional details regarding the Lumara Agreement 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 the U.S. 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 June 2013, we entered into a license agreement with Abeona Therapeutics, Inc. (“Abeona”) (formerly known as PlasmaTech Biopharmaceuticals, Inc. and Access Pharmaceuticals, Inc.), under which we acquired the U.S. commercial rights to MuGard for the management of oral mucositis (the “MuGard Rights”).

Makena Regulatory Developments

In October 2014, we filed a prior approval supplement to the original Makena New Drug Application (“NDA”) with the FDA, seeking approval of a single-dose (1 mL) preservative-free vial of Makena. In May 2015, we received a complete response letter from the FDA for the prior approval supplement requesting additional information related to manufacturing procedures for the single-dose vial at our third-party manufacturer, Coldstream Laboratories, Inc. (“Coldstream”). We are currently working with Coldstream to develop the required information requested by the FDA in the complete response letter. We remain committed to commercializing a single-dose vial of Makena and plan to provide a response to the FDA’s complete response letter. In addition, in July 2015, we filed a prior approval supplement to the original Makena NDA with the FDA, seeking approval of Hospira, Inc., our current manufacturer of the multi-dose vial of Makena, to manufacture the single-dose (1 mL) preservative-free vial of Makena. We are expecting a decision from the FDA in the fourth quarter of 2015 and, if approved, are planning for a commercial launch of the single-dose vial of Makena in the first quarter of 2016.

We have continued to advance our multi-pronged next generation development programs for Makena (which we previously referred to as our lifecycle management program) seeking to enhance the product profile for patients and their healthcare providers. We are working to develop an auto-injector device for subcutaneous administration of Makena, including chemistry, manufacturing and controls (“CMC”) development with an experienced device partner and pilot clinical studies to establish the appropriate subcutaneous dose. We are planning for a single dose pharmacokinetics (“PK”) bioequivalence study to capture certain clinical measures to support clinical superiority over the existing intramuscular injection. We are also in the early stages of developing a longer-acting formulation of Makena, including conducting formulation work and pre-clinical studies to optimize the drug release profile.

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 marketing clinical studies to verify and describe the clinical benefit of Makena as well as fulfill certain other post approval commitments. We are currently conducting these studies to fulfill these obligations. In October 2015, in response to our request, we were notified by the FDA that the previously agreed-upon completion dates for two of these studies have been extended by two years to December 2018 and October 2020.

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 has engaged in unfair methods of competition with respect to Makena or any hydroxyprogesterone caproate product. We are fully cooperating with the FTC and have provided a thorough response to the FTC and are awaiting their review of our response. The FTC noted in its initial 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 (i) 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, (ii) our belief that the DQSA has had a significant impact on the compounding of

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hydroxyprogesterone caproate, and (iii) how our contracts with former compounders do allow those compounders to continue to serve physicians and patients with respect to supplying medically necessary alternative/altered forms of hydroxyprogesterone caproate.

Feraheme Regulatory Developments

In March 2015, following discussions with the FDA, we updated our current U.S. Feraheme label to include (a) the addition of a boxed warning related to the risks of serious hypersensitivity reactions or anaphylaxis, which risks were previously described only in the Warnings and Precautions section; (b) revisions to the Dosing and Administration section to indicate that Feraheme should only be administered by IV infusion; and (c) modifications to the Warnings and Precautions section to include a statement that patients with a history of multiple drug allergies may have a greater risk of anaphylaxis with parenteral iron products. In addition to updating the Feraheme product label, we have communicated these changes to healthcare providers through a Dear Healthcare Provider Letter.

In December 2014, we entered into an agreement (the "Takeda Termination Agreement"), which terminated our License, Development and Commercialization Agreement with Takeda (as amended, the "Takeda Agreement"). Under the terms of the Takeda Agreement, Takeda had exclusive rights to develop and commercialize Feraheme as a therapeutic agent in certain agreed-upon territories outside of the U.S. Pursuant to the Takeda Termination Agreement, the termination of the Takeda Agreement was effective on a rolling basis, whereby the termination was effective for a particular geographic territory (i.e., countries under the regulatory jurisdictions of Health Canada, the European Medicines Agency and SwissMedic) upon the earlier of effectiveness of the transfer to us or a withdrawal of the marketing authorization for such territory, with the final effective termination date to be on the third such effective date. The marketing authorization for Rienso (the trade name for ferumoxytol in the EU and Switzerland) was withdrawn in the EU and Switzerland in April 2015, and on June 25, 2015, the transfer from Takeda to us of the Feraheme marketing authorization in Canada became effective and marked the final termination date of the Takeda Agreement. As a result, we have recognized all remaining deferred revenues related to Takeda into revenues during the nine months ended September 30, 2015. We continue to assess the commercial opportunity for Feraheme, including partnering opportunities, in Canada.

In December 2012, we submitted a supplemental new drug application ("sNDA") to the FDA seeking approval for Feraheme for the treatment of IDA in adult patients who had failed or could not use oral iron. In January 2014, 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. The FDA indicated that its decision was based on the cumulative ferumoxytol data, including the global Phase 3 IDA program and global post-marketing safety reports for the currently indicated CKD patient population. The FDA suggested, among other things, that we submit additional clinical trial data in the proposed broad IDA patient population with a primary composite safety endpoint of serious hypersensitivity/anaphylaxis, cardiovascular events and death, events that are included in the labels of Feraheme and other IV irons and that have been reported in the post-marketing environment for Feraheme. We have been working closely with the FDA and have recently commenced start-up activities on a new head-to-head Phase 3 clinical trial evaluating Feraheme in adults with IDA, excluding patients on hemodialysis. This new trial will be 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. 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 infusion. We currently expect to initiate the trial in the first quarter of 2016.

Recent Financings

On August 5, 2015, we sold approximately 3.6 million shares of our common stock at a public offering price of $63.75 per share (the "August 2015 Offering"), resulting in net proceeds to us of approximately $218.6 million.

On August 17, 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 and Jefferies Finance LLC ("Jefferies"), 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"). We

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borrowed the full $350.0 million available under the 2015 Term Loan Facility on August 17, 2015. We used the net proceeds from the August 2015 Offering, disclosed below, the offering of the 2023 Senior Notes and borrowings under the 2015 Term Loan Facility along with existing cash to fund the acquisition of CBR, to repay the remaining $323.0 million outstanding principal amount under our then existing five-year term loan facility (the "2014 Term Loan Facility"), and to pay prepayment premiums, fees and expenses in connection with the foregoing.

Results of Operations — Three Months Ended September 30, 2015 and 2014

Revenues

Total revenues for the three months ended September 30, 2015 and 2014 consisted of the following (in thousands):

	Three Months Ended September 30,				
	2015	2014	$ Change	% Change	
U.S. product sales, net					
Makena	$ 65,155	$ —	$ 65,155	N/A	
Feraheme	23,227	22,547	680	3	%
MuGard	535	462	73	16	%
Total	88,917	23,009	65,908	>100	%
Service revenues, net	7,177	—	7,177	N/A	
License fee, collaboration and other revenues	58	2,485	(2,427)	(98)	%
Total Revenues	$ 96,152	$ 25,494	$ 70,658	>100	%

Product Sales Revenues

Net U.S. product sales increased by $65.9 million during the three months ended September 30, 2015 as compared to the same period in 2014 primarily due to the addition of Makena to our product portfolio as a result of the November 2014 acquisition of Lumara Health. We anticipate that sales of Makena will increase for the remainder of 2015 as compared to the third quarter of 2015 as we continue to gain market share from compounded product through broader reimbursement of Makena, improved patient compliance and continued educational programs for patients and physicians regarding treatment with Makena. In addition, we anticipate that sales of Feraheme will remain relatively consistent for the remainder of the year.

Total gross U.S. product sales were offset by product sales allowances and accruals for the three months ended September 30, 2015 and 2014 as follows (in thousands):

	Three Months Ended September 30,				
	2015	2014	$ Change	% Change	
Gross U.S. product sales	$ 145,131	$ 41,396	$ 103,735	>100	%
Provision for U.S. product sales allowances and accruals:					
Contractual adjustments	41,851	18,179	23,672	>100	%
Governmental rebates	14,363	208	14,155	>100	%
Total provision for U.S product sales allowances and accruals	56,214	18,387	37,827	>100	%
U.S. product sales, net	$ 88,917	$ 23,009	$ 65,908	>100	%

The $103.7 million increase in gross U.S. product sales was due primarily to the addition of Makena to our product portfolio, which resulted in $100.3 million gross sales in the third quarter of 2015, and a $3.0 million increase in our U.S. Feraheme sales in the three months ended September 30, 2015 as compared to the same period in 2014. Of the $3.0 million increase in gross U.S. Feraheme sales, $5.7 million was due to price increases, partially offset by $2.7 million due to decreased units sold.

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, and volume-based and other commercial rebates. Governmental

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rebates relate to our reimbursement arrangements with state Medicaid programs. The increases in contractual adjustments and governmental rebates primarily relate to the addition of the Makena product to our portfolio.

Service Revenues

The $7.2 million in service revenues was due to the addition of the CBR Services in connection with the August 2015 acquisition of CBR. Revenues associated with the CBR Services are recorded net of discounts and include (i) processing fees for cord blood and cord tissue and (ii) storage fees for cord blood and cord tissue. We expect our service revenues to increase for the remainder of the year due to the recognition of a full quarter of CBR Services revenue in the fourth quarter of 2015.

For further details related to our revenue recognition and related sales allowances policy, please refer to our critical accounting policies included in Part II, Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report and Note B, “Basis of Presentation and Summary of Significant Accounting Policies”, to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Healthcare Reform Legislation

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “Healthcare Reform Act”) was enacted in the U.S. in March 2010 and includes certain cost containment measures including an increase to the minimum rebates for products covered by Medicaid programs and the extension of such rebates to drugs dispensed to Medicaid beneficiaries enrolled in Medicaid managed care organizations as well as the expansion of the 340B Drug Discount Program under the Public Health Service Act. This legislation contains provisions that can affect the operational results of companies in the pharmaceutical industry and healthcare related industries, including us, by imposing additional costs on such companies. The impact of this healthcare reform legislation has not had a material impact on our financial statements or results of operations.

Presently, we have not identified any provisions of the Healthcare Reform Act that could materially impact our business in 2015 and beyond, but we continue to monitor ongoing legislative developments and we are assessing what impact such healthcare reform legislation will have on our business going forward.

License Fee, Collaboration and Other Revenues

License fee, collaboration and other revenues include deferred license fee revenues from Takeda, Feraheme product sales to Takeda and royalties from Takeda. The $2.4 million decrease in license fee, collaboration and other revenues in the three months ended September 30, 2015 as compared to the same period in 2014 was primarily due to the termination of the Takeda Agreement and the resulting decrease of Takeda-related license fees, product sales and royalty revenue.

We expect our quarterly license fee, collaboration and other revenues will be immaterial for the remainder of 2015 due to the effective termination of the Takeda Agreement and the full recognition of the remaining deferred revenue balance.

Costs and Expenses

Cost of Product Sales

Cost of product sales for the three months ended September 30, 2015 and 2014 were as follows (in thousands):

	Three Months Ended September 30,			
	2015	2014	$ Change	% Change
Cost of Product Sales	$ 19,088	$ 2,968	$ 16,120	>100 %
Percentage of Net Product Sales	21%	13%		

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 and the amortization of product related intangible assets and inventory step-up related to the November 2014 acquisition of

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Lumara Health. The $16.1 million increase in our cost of product sales for the three months ended September 30, 2015 as compared to the same period in 2014 was primarily attributable to $13.4 million of amortization expense recognized during the third quarter of 2015 related to the Makena intangible asset. In addition, the increase reflects $1.6 million recognized during the third quarter of 2015 for the step-up adjustment to the Makena inventory we acquired in November 2014.

We expect our cost of product sales as a percentage of net product sales, excluding any impact from the amortization of the Makena and MuGard Rights intangible assets and the amortization of inventory step-up of Makena inventory, to remain relatively consistent for the remainder of 2015 as compared to the third quarter of 2015.

Cost of Services

The $3.3 million in cost of services was due to the addition of the CBR Services in August 2015. Cost of services includes the transportation of the umbilical cord blood stem cells and cord tissue from the hospital, direct material plus labor costs for processing, cryogenic storage and collection kit materials. We expect our cost of services to increase for the remainder of the year due to the recognition of a full quarter of CBR Services revenue in the fourth quarter of 2015.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2015 and 2014 consisted of the following (in thousands):

	Three Months Ended September 30,				
	2015	2014	$ Change	% Change	
External Research and Development Expenses					
Feraheme-related costs	$ 1,878	$ 2,606	$ (728)	(28)	%
Makena-related costs	3,396	—	3,396	N/A	
Option rights to license orphan drug	10,000	—	10,000	N/A	
Other external costs	742	205	537	>100	%
Total	16,016	2,811	13,205	>100	%
Internal Research and Development Expenses	3,793	2,547	1,246	49	%
Total Research and Development Expenses	$ 19,809	$ 5,358	$ 14,451	>100	%

Total research and development expenses incurred in the three months ended September 30, 2015 increased by $14.5 million, or greater than 100%, as compared to the same period in 2014. The increase was primarily due to a $10.0 million upfront payment made to Velo in July 2015 for an option to acquire the rights to an orphan drug candidate in clinical development for the treatment of severe preeclampsia in pregnant women. In addition, the increase reflects new costs related to Makena clinical trials and related development costs in the third quarter of 2015.

We expect research and development expenses to decrease for the remainder of 2015 due to the one-time $10.0 million charge made in the third quarter of 2015 for the Velo option, partially offset by increased costs due to the timing of expenses for our current clinical trials related to Makena's next generation development program, our Feraheme trial to treat IDA regardless of the underlying cause, and our post approval commitments and expenses related to our clinical trial to determine the safety and efficacy of repeat doses of Feraheme for the treatment of IDA in patients with hemodialysis dependent CKD.

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 or applicable foreign regulatory body. 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 our fixed costs benefit multiple projects or our operations in general. The following major research and development projects were ongoing as of September 30, 2015:

· 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 as well as certain research and

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development expenses associated with our next generation development programs, 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; (c) a completed pharmacokinetic trial of women taking Makena; and (d) studies associated with our next generation development programs, including an auto-injector device and a longer-acting formulation of Makena.

- 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 to support the 2010 marketing authorization application ("MAA") submission; (b) an ongoing pediatric program as part of our post-approval Pediatric Research Equity Act ("PREA") requirement to support pediatric CKD labeling of Feraheme; and (c) an ongoing multi-center clinical trial to determine the safety and efficacy of repeat doses of Feraheme for the treatment of IDA in patients with hemodialysis dependent CKD, including a treatment arm with iron sucrose using a magnetic resonance imaging sub-analysis to evaluate the potential for iron to accumulate in the body following repeated IV iron administration ("FACT").

- 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, currently expected to be initiated in the first quarter of 2016.

From November 12, 2014 (the date of the Lumara Health acquisition) through September 30, 2015, we have incurred aggregate external research and development expenses of approximately $4.9 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 $25.0 million to $30.0 million over the next several years. Given the current early stage of our development of the longer-acting formulation of Makena, we are unable to estimate with any certainty the future costs we will incur for such formulation and have therefore not included an estimate in the expected range above.

Through September 30, 2015, we have incurred aggregate external research and development expenses of approximately $40.8 million related to our current program for the development of Feraheme to treat IDA in CKD patients, described above. We currently estimate that the total remaining external costs associated with this development project will be less than $5.0 million. This represents a decrease in the range from our expected range at June 30, 2015 due to the reduction of estimated costs primarily associated with changes in the time line for our FACT trial. In addition, in recent years, we have been unable to enroll sufficient patients in our pediatric studies. We are working with the FDA to modify or eliminate our obligations under our PREA requirements. We will continue to assess the potential future costs of these studies and modify our expected ranges as needed.

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, 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, based on feedback received from the FDA on a proposed clinical trial to address certain deficiencies noted by the FDA in our complete response letter, as described above, we commenced start up activities related to this program, including a head-to-head Phase 3 clinical trial, described above. We currently estimate that the total remaining external costs associated with this development project will be in the range of approximately $30.0 million to $35.0 million through the end of 2017.

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Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended September 30, 2015 and 2014 consisted of the following (in thousands):

	Three Months Ended September 30,				
	2015	2014	$ Change	% Change	
Compensation, payroll taxes and benefits	$ 16,273	$ 6,499	$ 9,774	>100	%
Professional, consulting and other outside services	23,281	6,723	16,558	>100	%
Fair value of contingent consideration liability	2,886	(3,712)	6,598	<(100)	%
Equity-based compensation expense	3,701	1,448	2,253	>100	%
Total	$ 46,141	$ 10,958	$ 35,183	>100	%

Total selling, general and administrative expenses incurred in the three months ended September 30, 2015 increased by $35.2 million as compared to the same period in 2014 primarily as the result of the November 2014 Lumara Health acquisition and the August 2015 CBR acquisition, including additional employee-related expenses primarily related to the addition of the Makena sales force and CBR employee base, and higher sales and marketing costs to support the Makena product and CBR Services.

We expect that total selling, general and administrative expenses will increase for the remainder of 2015 as compared to the three months ended September 30, 2015 due to the recognition of a full quarter of CBR expenses in the fourth quarter of 2015.

Acquisition-related Costs

Acquisition-related costs incurred in the three months ended September 30, 2015 and 2014 included $8.5 million and $1.9 million in costs for financial advising, legal fees, due diligence and other costs and expenses in connection with our acquisitions of CBR and Lumara Health, respectively.

Restructuring Expense

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, respectively. As a result of these restructurings, we recorded charges of approximately $0.7 million in the three

months ended September 30, 2015. We expect to pay substantially all of the restructuring costs by the end of 2016.

Other Income (Expense)

Other income (expense) for the three months ended September 30, 2015 decreased by $30.5 million as compared to the same period in 2014 primarily as the result of the following:

- an additional $11.1 million in interest expense in the third quarter of 2015, which was primarily comprised of the amortization of debt discount, contractual interest expense and amortization of debt issuance costs in connection with our current debt obligations as compared to the same quarter in 2014;

- $10.4 million loss on debt extinguishment as the result of the early repayment of the remaining $323.0 million outstanding principal amount of the 2014 Term Loan Facility; and

- $9.2 million of other expense, which includes a $6.8 million bridge loan commitment fee paid in the third quarter of 2015 as part of the planned financing for the CBR acquisition (and which was not utilized to fund the CBR acquisition) and $2.4 million in fees and expenses from the 2014 Term Loan Facility that were expensed in accordance with accounting guidance for the modification of debt arrangements.

We expect our net other income (expense) to increase for the remainder of 2015 as compared to the three months ended September 30, 2015 as the result of certain one-time charges incurred in the third quarter of 2015, partially offset by the interest expense associated with our additional borrowings in the third quarter of 2015.

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Income Tax Expense

The following table summarizes our effective tax rate and income tax expense for the three months ended September 30, 2015 and 2014 (in thousands except for percentages):

	Three Months Ended September 30,	
	2015	2014
Effective tax rate	41 %	— %
Income tax benefit (expense)	$ 14,130	$ —

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. We did not recognize any income tax benefit or expense for the three months ended September 30, 2014, as we were subject to a full valuation allowance due to our net operating loss position at the time.

Results of Operations - Nine Months Ended September 30, 2015 and 2014

Revenues

Total revenues for the nine months ended September 30, 2015 and 2014 consisted of the following (in thousands):

	Nine Months Ended September 30,			
	2015	2014	$ Change	% Change
U.S. product sales, net				
Makena	$ 184,258	$ —	$ 184,258	N/A
Feraheme	65,235	62,147	3,088	5 %
MuGard	1,491	870	621	71 %
Total	250,984	63,017	187,967	>100 %

Service revenues, net	7,177	—	7,177	N/A	
License fee, collaboration and other revenues	51,380	8,114	43,266	>100	%
Total Revenues	$ 309,541	$ 71,131	$ 238,410	>100	%

Product Sales Revenues

Net U.S. product sales increased by $188.0 million during the nine months ended September 30, 2015 as compared to the same period in 2014 primarily due to the addition of Makena to our product portfolio as a result of the November 2014 acquisition of Lumara Health as well as a $3.1 million increase in Feraheme net product sales.

Total gross U.S. product sales were offset by product sales allowances and accruals for the nine months ended September 30, 2015 and 2014 as follows (in thousands):

	Nine Months Ended September 30,				
	2015	2014	$ Change	% Change	
Gross U.S. product sales	$ 407,238	$ 113,550	$ 293,688	>100	%
Provision for U.S. product sales allowances and accruals:					
Contractual adjustments	116,236	49,953	66,283	>100	%
Governmental rebates	40,018	580	39,438	>100	%
Total provision for U.S product sales allowances and accruals	156,254	50,533	105,721	>100	%
U.S. product sales, net	$ 250,984	$ 63,017	$ 187,967	>100	%

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The $293.7 million increase in gross U.S. product sales was due primarily to the addition of Makena to our product portfolio in November 2014, which resulted in $282.8 million gross sales in the first three quarters of 2015, and a $10.0 million increase in our gross U.S. Feraheme sales in the nine months ended September 30, 2015 as compared to the same period in 2014. Of the $10.0 million increase in gross U.S. Feraheme sales, $16.2 million was due to price increases, partially offset by $6.2 million due to decreased units sold.

During the nine months ended September 30, 2015, we reduced our Makena related Medicaid and other reserves, and chargeback reserves, which were initially recorded at the time of the Lumara acquisition, by $5.3 million and $1.9 million, respectively. These adjustments were recorded to goodwill during the nine months ended September 30, 2015, as they occurred within the acquisition measurement period. We did not materially adjust our product sales allowances and accruals during the nine months ended September 30, 2014. We may revise our estimated revenue reserves related to Makena as we continue to obtain additional experience. 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 $7.2 million in service revenues was due to the addition of the CBR Services in August 2015.

License Fee, Collaboration and Other Revenues

The $43.3 million increase in license fee, collaboration and other revenues in the nine months ended September 30, 2015 as compared to the same period in 2014 was primarily due to $44.4 million of deferred license fee revenues recognized in the nine months ended September 30, 2015 as the result of the effective termination of the Takeda Agreement on June 25, 2015, which resulted in the recognition of all remaining Takeda related deferred revenues. In addition, we recognized $5.2 million of additional revenues in the nine months ended September 30, 2015 related to payments made by Takeda upon the final termination date as required under the terms of the Takeda Termination Agreement.

Costs and Expenses

Cost of Product Sales

Cost of product sales for the nine months ended September 30, 2015 and 2014 were as follows (in thousands):

	Nine Months Ended September 30,			
	2015	2014	$ Change	% Change
Cost of Product Sales	$ 59,793	$ 8,548	$ 51,245	>100 %
Percentage of Net Product Sales	24%	14%		

The $51.2 million increase in our cost of product sales for the nine months ended September 30, 2015 as compared to the same period in 2014 was primarily attributable to $38.0 million of amortization expense recognized during the nine months ended September 30, 2015 related to the Makena intangible asset. In addition, the increase reflects $10.8 million recognized during the nine months ended September 30, 2015 for the step-up adjustment to the Makena inventory we acquired in November 2014, including $7.5 million related to product sales and $3.3 million related to inventory reserves.

Cost of Services

The $3.3 million in cost of services was due to the addition of the CBR Services in August 2015. Cost of services includes the transportation of the umbilical cord blood stem cells and cord tissue from the hospital, direct material plus labor costs for processing, cryogenic storage and collection kit materials.

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Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2015 and 2014 consisted of the following (in thousands):

	Nine Months Ended September 30,				
	2015	2014	$ Change	% Change	
External Research and Development Expenses					
Feraheme-related costs	$ 5,534	$ 7,798	$ (2,264)	(29)	%
Makena-related costs	8,158	—	8,158	N/A	
Option rights to license orphan drug	10,000	—	10,000	N/A	
Other external costs	1,250	738	512	69	%
Total	24,942	8,536	16,406	>100	%
Internal Research and Development Expenses	10,039	7,860	2,179	28	%
Total Research and Development Expenses	$ 34,981	$ 16,396	$ 18,585	>100	%

Total research and development expenses incurred in the nine months ended September 30, 2015 increased by $18.6 million as compared to the same period in 2014. The increase was primarily due to a $10.0 million upfront payment made to Velo in July 2015 for an option to acquire the rights to an orphan drug candidate in clinical development for the treatment of severe preeclampsia in pregnant women. In addition, the increase reflects new costs related to Makena clinical trials and related development costs in the nine months ended September 30, 2015, partially offset by a decrease in Feraheme clinical trial costs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the nine months ended September 30, 2015 and 2014 consisted of the following (in thousands):

	Nine Months Ended September 30,				
	2015	2014	$ Change	% Change	
Compensation, payroll taxes and benefits	$ 43,192	$ 20,162	$ 23,030	>100	%
Professional, consulting and other outside services	53,090	22,316	30,774	>100	%
Fair value of contingent consideration liability	4,525	(2,535)	7,060	<(100)	%
Equity-based compensation expense	9,247	4,790	4,457	93	%
Total	$ 110,054	$ 44,733	$ 65,321	>100	%

Total selling, general and administrative expenses incurred in the nine months ended September 30, 2015 increased by $65.3 million as compared to the same period in 2014 primarily as the result of the November 2014 Lumara Health

and August 2015 CBR acquisitions, including additional employee-related expenses primarily related to the addition of the Makena sales force and CBR employee base, an adjustment to the Makena contingent consideration expense, and higher sales and marketing costs to support the Makena product and the CBR Services, and an adjustment in the fair value of MuGard contingent consideration expense resulting from a revision to the estimated amounts and timing of cash flows related to the royalties we expect to pay to Abeona.

Acquisition-related Costs

Acquisition-related costs incurred in the nine months ended September 30, 2015 and 2014 included $11.2 million and $1.9 million of costs for financial advising, legal fees, due diligence and other costs and expenses in connection with our acquisitions of CBR and Lumara Health, respectively.

Restructuring Expense

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

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Other Income (Expense)

Other income (expense) for the nine months ended September 30, 2015 decreased by $46.7 million as compared to the same period in 2014 primarily as the result of the following:

- an additional $27.1 million in interest expense in 2015, which was comprised primarily of the amortization of debt discount, contractual interest expense and amortization of debt issuance costs in connection with our current debt obligations as compared to the same period in 2014;

- $10.4 million loss on debt extinguishment as the result of the early repayment of the remaining $323.0 million outstanding principal amount of the 2014 Term Loan Facility; and

- $9.2 million of other expense, which includes a $6.8 million bridge loan commitment fee paid in 2015 as part of the financing for the CBR acquisition (and which was not utilized to fund the CBR acquisition) and $2.4 million in fees and expenses from the 2014 Term Loan Facility that were expensed in accordance with accounting guidance for the modification of debt arrangements.

Income Tax Expense

The following table summarizes our effective tax rate and income tax expense for the nine months ended September 30, 2015 and 2014 (in thousands except for percentages):

	Nine Months Ended September 30,	
	2015	2014
Effective tax rate	27 %	— %
Income tax benefit (expense)	$ (9,513)	$ —

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 associated with Lumara Health. We did not recognize any income tax benefit or expense for the nine months ended September 30, 2014 as we were subject to a full valuation allowance due to our net operating loss position at the time.

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 and as we market and sell the CBR Services and MuGard, as we pursue next generation development programs for Makena and as we further develop and seek regulatory approval for Feraheme for the treatment of IDA in a broad range of patients in the U.S.

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Cash, cash equivalents, investments and certain financial obligations as of September 30, 2015 and December 31, 2014 consisted of the following (in thousands):

	September 30, 2015	December 31, 2014	$ Change	% Change	
Cash and cash equivalents	$ 167,530	$ 119,296	$ 48,234	40	%
Investments	275,343	24,890	250,453	>100	%
Total	$ 442,873	$ 144,186	$ 298,687	>100	%
Outstanding principal on 2023 Senior Notes	$ 500,000	$ —	$ 500,000	N/A	
Outstanding principal on Convertible Notes	200,000	200,000	—	—	%
Outstanding principal on 2015 Term Loan Facility	350,000	—	350,000	N/A	
Outstanding principal on 2014 Term Loan Facility	—	340,000	(340,000)	(100)	%
Total	$ 1,050,000	$ 540,000	$ 510,000	94	%

The $298.7 million increase in cash, cash equivalents and investments as of September 30, 2015, as compared to December 31, 2014, was primarily due to net proceeds of $188.8 million received in the first quarter of 2015 following the sale of approximately 4.6 million shares of our common stock in an underwritten public offering, net proceeds of $218.6 million received in the third quarter of 2015 following the sale of approximately 3.6 million shares of our common stock in an underwritten public offering and cash flow from product sales, partially offset by expenditures to fund our operations. The $510.0 million increase in our debt obligations as of September 30, 2015, as compared to December 31, 2014, was due to the 2023 Senior Notes and 2015 Term Loan Facility, as discussed in more detail below, partially offset by the repayment of our 2014 Term Loan Facility.

Business Developments

In August 2015, we acquired CBR for $700.0 million in cash, subject to estimated working capital, indebtedness and other adjustments.

In November 2014, we acquired Lumara Health for approximately $600.0 million in cash consideration, subject to net working capital, net debt and transaction expenses and issued approximately 3.2 million shares of our common stock having a fair value of approximately $112.0 million at the time of closing. The Lumara Agreement includes future contingent payments of up to $350.0 million in cash (or upon mutual agreement between us and the former Lumara Health security holders, future contingent payments may also be made in common stock or some combination thereof) payable by us to the former Lumara Health security holders based upon the achievement of certain sales milestones through calendar year 2019. See Note C, “Business Combinations,” to the Financial Statements in our Annual Report for

additional information.

On July 22, 2015, we entered into an option agreement with Velo that granted us an option to acquire the rights to 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. Under the option agreement, Velo will complete a dose ranging study and a Phase 2b/3a clinical study. 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 anticipate that results from the pivotal Phase 2b/3a study could be available as early as 2018.

Borrowings and Other Liabilities

On August 17, 2015, in connection with the CBR acquisition, we completed a private placement of the 2023 Senior Notes and entered into the 2015 Term Loan Facility. We borrowed the full $350.0 million available under the 2015 Term Loan Facility on August 17, 2015. The 2015 Term Loan Facility imposes restrictive covenants on us and obligates us to

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make certain payments of principal and interest over time. 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. 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 November 2014, we partially financed the $600.0 million cash portion of the Lumara Health acquisition through $327.5 million of net proceeds from borrowings under the 2014 Term Loan Facility. On August 17, 2015, we repaid the remaining $323.0 million outstanding principal amount and recognized a $10.4 million loss on debt extinguishment as a result of the early repayment.

In addition, on February 14, 2014, we issued $200.0 million aggregate principal amount of 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 calendar quarter ended September 30, 2015, the Convertible Notes are convertible for the calendar quarter ending September 30, 2015.

We expect that our cash, cash equivalents and investments balances, in the aggregate, may increase as the result of increased net sales for the remainder of 2015. 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, 2015, and the cash we currently expect to receive from sales of our products and services, earnings on our investments, will be sufficient to service our debt obligations and satisfy our cash flow needs for the foreseeable future.

Cash flows from operating activities

Net cash provided by operating activities for the nine months ended September 30, 2015 was $58.1 million as compared to net cash used in operating activities of $10.4 million for the same period in 2014. The increase in cash provided by (used in) operating activities is primarily due to increased product sales from the addition of Makena to our product portfolio. 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, 2015 was $934.1 million as compared to net cash used in investing activities in the nine months ended September 30, 2014 of $2.3 million. Cash used in investing activities increased during the nine months ended September 30, 2015 primarily attributable to the $682.2 million net cash used to fund the acquisition of CBR and $326.1 million of cash used to purchase investments with the proceeds we received from our March 2015 and August 2015 public equity offerings.

Cash flows from financing activities

Net cash provided by financing activities in the nine months ended September 30, 2015 and 2014 was $924.3 million and $181.9 million, respectively. Cash provided by financing activities increased during the nine months ended September 30, 2015 as compared to the same period in 2014 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, partially offset by the repayment of the 2014 Term Loan Facility. Cash provided by financing activities during the nine months ended September 30, 2014 was primarily attributable to $179.1 million in net proceeds received from the issuance of the Convertible Notes in February 2014.

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Contingent Consideration

In connection with certain of our acquisitions, we agreed to make contingent cash payments to the former shareholders of the acquired companies. In accordance with accounting for business combinations guidance, these contingent cash payments are recorded as contingent consideration liabilities on our condensed consolidated balance sheets at fair value. The aggregate, undiscounted amount of contingent consideration potentially payable for all contingent consideration arrangements ranges from zero to approximately $368.0 million.

As of September 30, 2015, the contingent consideration related to the Lumara Health acquisition and the MuGard Rights are our only financial liabilities measured and recorded using Level 3 inputs in accordance with accounting guidance for fair value measurements, and represent 100% of the total liabilities measured at fair value. See Note E, “Fair Value Measurements,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for additional information.

Off-Balance Sheet Arrangements

As of September 30, 2015, we did not have any off-balance sheet arrangements as defined in Regulation S-K, Item 303(a)(4)(ii).

Commitments

In connection with our acquisition of CBR, we have certain minimum purchase commitments associated with an agreement entered into by CBR prior to our acquisition. This agreement expires in December 2018, with the remaining amount of minimum purchase commitments totaling $7.9 million.

During the nine months ended September 30, 2015, we entered into an amendment of our lease agreement with BP Bay Colony LLC for additional space to use as our principal executive offices in Waltham, Massachusetts and to extend the term of our original lease from November 30, 2018 to November 30, 2019, with one five-year extension term at our option. The incremental impact of the amended lease is approximately $0.2 million per year.

Other than the issuance of the 2023 Senior Notes and the 2015 Term Loan Facility and the repayment of the 2014 Term Loan Facility, discussed above in Borrowings and Other Liabilities, there have been no other material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed in our

Annual Report.

Critical Accounting Policies

With the exception of the addition of service revenue to our critical accounting policies, there have been no material changes from the Critical Accounting Policies disclosed in Part II, Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report.

Service Revenue

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 (i) vendor specific objective evidence; (ii) third-party evidence of selling price and (iii) 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.

We have identified two deliverables contained in the revenue arrangements for the CBR Services, which involve the storage of umbilical cord blood and/or cord tissue products, namely: (i) enrollment, including the provision of a collection kit and unit processing, with revenue for this deliverable recognized after the collection and successful processing of a cord blood/cord tissue unit; and (ii) the storage of a specimen for either an annual fee or a prepayment of 18 years or the lifetime of the newborn donor (“lifetime option”). 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

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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 and in effect at the time of the newborn's birth and subtracting the age at death. We have allocated revenue between these two deliverables using the relative selling price method. The selling price for the enrollment, collection kit and processing deliverable and the lifetime option are estimated based on the published selling prices because we do not have vendor specific objective evidence or third-party evidence of selling price for these elements. The selling price for the annual storage option is determined based on vendor specific objective evidence as we have standalone renewals to support the selling price.

Deferred revenue includes (i) amounts collected in advance of unit processing and (ii) 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.

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, 2015 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

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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 factors below, there have been no material changes from the Risk Factors disclosed in Part I, Item 1A, of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

Our ability to successfully commercialize Makena is dependent upon a number of factors, including maintaining the benefits of Makena’s orphan drug exclusivity and the length of time before competitors begin selling generic versions of Makena.

Makena has been granted orphan drug exclusivity in the U.S. until February 3, 2018 for reducing the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, defined, in part, as a patient population of fewer than 200,000 in the U.S. In the U.S., the company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application for the “same drug” for the same orphan indication during the exclusivity period, except in very limited circumstances. In addition, orphan drug exclusivity marketing rights in the U.S. may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Finally, FDA may approve a subsequent drug that is otherwise the same as a currently approved orphan drug for the same orphan indication during the exclusivity period if the sponsor of the subsequent drug can demonstrate that the drug is clinically superior to the already approved drug. According to the FDA, clinical superiority may be demonstrated by showing that a drug is more effective in a clinical trial, safer in a substantial portion of the target population, or provides a major contribution to patient care relative to the currently approved drug.

Additionally, in 1956, the FDA-approved the drug Delalutin, which contained the same active ingredient as Makena. Delalutin was approved for conditions other than reducing the risk of preterm birth and was marketed by

Bristol-Myers Squibb (“BMS”). BMS stopped marketing and manufacturing the FDA-approved product and it was withdrawn from the market in 1999. In 2010, in response to a citizen petition, the FDA determined that Delalutin was not withdrawn from sale for reasons of safety or effectiveness. As such, generic drug applications may reference the withdrawn Delalutin New Drug Application (an “NDA”). In August 2015, the FDA approved an abbreviated NDA (an “ANDA”) for hydroxyprogesterone caproate, which was submitted by McGuff Pharmaceuticals, Inc. (“McGuff”) in 2009. The ANDA label approved by the FDA is for the same patient population and indications as Delalutin (i.e., it is approved only for use in non-pregnant women with indications such as uterine cancer or abnormal uterine bleeding). Although the McGuff product is not indicated for pregnant women, is not therapeutically equivalent to Makena, and is thereby intended to serve a different patient population than Makena, if such generic version of hydroxyprogesterone caproate were to be made commercially available by McGuff or others, doctors may elect to prescribe McGuff’s approved drug off-label (i.e., outside of FDA-approved indications) for Makena’s orphan-protected indication, which could have an adverse impact on our business and results of operations. In addition, if such generic version is priced at a significant discount to Makena, it may be reimbursed by commercial or government insurers, and such insurers could encourage the use of the generic product prior to use of Makena.

Moreover, if one or more ANDA filers or a generic manufacturer were to receive approval to sell a generic or follow-on version of Makena for the orphan indication, those generic products could potentially be approved as early as February 3, 2018 (the date on which Makena's orphan exclusivity ends) and we would become subject to increased competition at that time.

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Further, our ability to successfully commercialize Makena depends on a number of additional factors, including but not limited to the following:

- The possibility that the benefit of the remaining exclusivity period resulting from the designation of Makena as an orphan drug may not be realized as a result of off-label use by physicians of current or future FDA-approved drugs in the market where Makena competes;

- The level of enforcement by the FDA to ensure compounded copies of commercially available FDA-approved products manufactured by compounding pharmacies, including compounded copies of Makena that are in violation of the federal Drug Quality and Security Act ("DQSA"), as well as other relevant provisions of the FDC Act, are not produced and dispensed to patients;

- The size of the pool of patients who meet the FDA-approved indication for Makena;

- Actual or perceived safety and efficacy of Makena;

- Our ability to increase patient compliance in line with the current label;

- The successful integration and retention of the Makena commercial sales team and any other key employees into our business structure;

- Our ability to gain or maintain insurance coverage for Makena for patients through both commercial insurance companies and government programs such as Medicaid, and that such insurance coverage does not create difficulties for physicians or patients to gain access to Makena, such as through prior authorizations to non-preferred status on hospital or insurance formularies; and

- Our ability to successfully leverage our commercial organization and distribution networks in marketing, selling and supplying Makena.

Failure to achieve any or all of these commercial objectives could have an adverse material effect on the growth of Makena and our ability to achieve our revenue forecasts which could impact our financial condition or results of operations.

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 is 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 instance, we are working to develop an auto-injector device for subcutaneous administration of Makena (the "auto-injector"), which may 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. Although our current timelines anticipate a launch of the auto-injector prior to the loss of current exclusivity in February 2018, this is only an estimate and we can make no assurances that the development work necessary to obtain approval, including the results of planned bioequivalence clinical studies, will yield the anticipated results or that the FDA will approve the auto-injector on the expected timelines, or at all. Further, we can make no assurances that clinical data or other information that we submit will be adequate for the FDA to grant new orphan drug exclusivity for the auto-injector. 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. In addition, there is 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.

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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.

Similarly, we are in the early stages of developing a longer-acting formulation of Makena, including conducting additional formulation work and pre-clinical studies to optimize the drug profile. Because this is a new formulation of Makena, our path to gaining regulatory approval in the U.S. will require us to perform additional clinical studies attempting to demonstrate clinical safety and efficacy of the new formulation, rather than gaining approval by demonstrating bioequivalence with the current form of Makena. Thus, pursuing the new formulation will require significant resources, financial and otherwise, over a considerable period of time. Despite our efforts, we may not be successful in developing the longer-acting formulation, including because the data obtained from any pre-clinical and clinical trials that we undertake may not generate anticipated results, may not demonstrate appropriate safety and efficacy, may be subject to varying interpretations and may not be deemed adequate by the FDA. Unexpected or unfavorable pre-clinical or clinical data can delay, limit or prevent regulatory approval.

Even if we succeed in gaining FDA approval for an auto-injector or the new formulation 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 our new formulation of Makena, physicians may choose to prescribe the generic, which could cause our 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 co-pays, 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, such as an oral hydroxyprogesterone caproate currently in development. 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 favorable insurance coverage or reimbursement, and could reduce our revenues and the value of our product development efforts.

In addition, in October 2014, we filed with the FDA a prior approval supplement to the original Makena NDA seeking approval of a single-dose (1 mL) preservative-free vial of Makena. In May 2015, we received a complete response letter from the FDA for the prior approval supplement requesting additional information related to manufacturing procedures for the single-dose preservative-free vial at our third-party manufacturer, Coldstream Laboratories, Inc. (“Coldstream”). We are currently working with Coldstream to develop the required information requested by the FDA in the complete response letter and are working to provide a response to the FDA. In July 2015, we filed a prior approval supplement to the original Makena NDA with the FDA seeking approval of Hospira, Inc. (“Hospira”), our current manufacturer of the multi-dose vial, to manufacture the single-dose preservative-free vial. Based on current expectations, we are planning for approval in the fourth quarter of 2015 and a commercial launch of the single-dose

preservative-free vial in the first quarter of 2016. We can make no assurance that our prior approval supplement for the single-dose preservative-free vial will be approved on the expected timeline, or at all, or that Coldstream or Hospira will be approved for its manufacture. Further, although we anticipate the single-dose preservative-free vial will increase market acceptance of Makena, it will not extend our current exclusivity period or grant new exclusivity or provide new patent protection.

We have limited experience in the development of an auto-injector and alternative formulations for Makena and in developing and implementing next generation development programs. If we are not successful in implementing Makena's next generation development programs, or if such activities cannot be completed on anticipated timelines, our business will suffer.

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We have undertaken efforts to expand our product portfolio with our recent acquisition of CBR. If we do not realize the expected benefits, including synergies, from the CBR acquisition, our business and results of operations will suffer.

On August 17, 2015, we acquired CBR Acquisition Holdings Corp. (“CBR Holdings”). CBR Holdings, through its wholly-owned subsidiary Cbr Systems, Inc., operated Cord Blood Registry (“CBR”), a provider of services for the collection, processing, and long-term cryopreservation of umbilical cord blood stem cell and cord tissue units for family use (the “CBR Services”), which we purchased for $700.0 million in cash consideration, subject to estimated working capital, indebtedness and other adjustments as set forth in the stock purchase agreement (the “CBR Agreement”).

With the acquisition of CBR, our business is significantly larger and more complex than it had been prior to the acquisition. Our future success will significantly depend upon our ability to manage our expanded enterprise, including multiple locations, which will pose substantial challenges for management, including challenges related to the management and monitoring of new operations and associated increased costs and complexity. In order to support this expanded enterprise, we will need to achieve revenues from the CBR business and synergies consistent with our business expectations, which may prove more difficult than initially and currently expected. For example, with the announcement of the acquisition of CBR, we indicated that we believe we could achieve annual synergies of approximately $15.0 million. Any failure to achieve this level of synergies could affect our profitability and our ability to service the debt that we incurred to fund this acquisition.

Further, we have no experience with providing the CBR Services and will be dependent upon the contributions of the CBR commercial organization and sales force, CBR's relationships and other key CBR personnel to drive CBR revenues, and we may be unable to retain and motivate the commercial organization, sales force and key personnel or successfully maintain the relationships CBR had in place at the time of the closing. The integration of the Makena and CBR sales forces into one could cause further disruption to our business because the sales force will need to be taken out of the field for training on our products and compliance programs and many of them will be given new territories and new health care professionals to call on where they might not have existing relationships and it will take them time to become efficient promoting a new product and covering a new territory. Different skills and training are required for the promotion of a therapeutic compared to a service business, and our revenues could suffer if this integrated sales force is unable to successfully promote a portfolio of products, especially since not only do they have limited experience with promoting multiple products, but also no experience promoting both a therapeutic and a service business.

Our post-closing recourse from the CBR Seller is limited under the CBR Agreement.

The CBR Seller’s obligation to indemnify us is limited to breaches of specified representations and warranties and covenants included in the CBR Agreement, certain pre-closing tax liabilities, and certain claims related to the reimbursements of engagement and retainer fees, and we have agreed to indemnify the CBR Seller for certain matters,

including breaches of specified representations and warranties and covenants included in the CBR Agreement. The maximum liability of each of the CBR Seller and us for indemnification claims is capped at $20.0 million. If any issues arise post-closing, we may not be entitled to sufficient, or any, indemnification or recourse from the CBR Seller, which could have a materially adverse impact on our business and results of operations.

CBR is subject to data security and privacy obligations. With the addition of the CBR Services to our portfolio, our existing data security and privacy obligations have expanded and the failure to comply with these obligations could adversely affect our financial condition and operating results.

CBR is subject to data security and privacy obligations. Through April 29, 2033, CBR is required to comply with a Federal Trade Commission (“FTC”) Order (the “FTC Order”). The FTC Order requires CBR, among other things, to implement and maintain a comprehensive information security program and conduct a biennial assessment of its information security program. CBR is also required not to make any misrepresentations regarding its information security program. The costs of compliance with, and other burdens imposed by, these obligations are substantial and may impede our performance and our ability to develop the CBR Services, or lead to significant fines, penalties or liabilities for noncompliance. The integration of CBR into our operations may also be limited by the FTC Order. Full integration of CBR’s information technology systems into our systems, for example, would result in a requirement that we also comply with the FTC Order. These limitations on our efforts to integrate CBR may impede our ability to operate and deploy our systems in the most efficient and cost effective manner.

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The CBR Services involve the collection, processing, and storage of health-related and other personal information. CBR may be subject to a number of federal, state and foreign laws and regulations regarding the privacy and protection of such information, some of which may already apply in our existing business, including state data breach notification laws, state data security laws, state health information privacy laws and federal and state consumer protection laws. Although CBR may not be directly subject to the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act ("HIPAA"), our combined business could potentially be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. The costs of compliance with, and other burdens imposed by, these laws may become substantial and may limit the use and adoption of CBR Services, impede the performance and development of future CBR Services, or lead to significant fines, penalties or liabilities for noncompliance with such laws or regulations. In addition, a security breach affecting this information could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. Because the techniques used to obtain unauthorized access change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or otherwise may fail to implement adequate preventative measures.

With the acquisition of CBR, we are exposed to numerous risks and uncertainties which could adversely affect our financial condition and operating results.

Strategic and transformative transactions like our recent acquisition of CBR create numerous uncertainties and risks. With the consummation of the acquisition, CBR became a wholly-owned subsidiary of AMAG and has significantly broadened our operations. This addition to our business will entail many changes, including the integration of CBR and its personnel, changes in systems and employee benefit plans and management of multiple geographic locations across the U.S. These transition activities are complex and we may encounter unexpected difficulties, incur unexpected costs or experience business disruptions, including as a result of:

- increased commitments for the management team, including the need to divert management's attention to integration matters, particularly if we are unable to retain key personnel;

- difficulties realizing the revenue projections, financial benefits, synergies and other strategic opportunities anticipated in connection with the transaction;

- our inexperience with maintaining multiple geographic locations spread out across the U.S.;

- challenges in leveraging our commercial expertise, which could result in unforeseen expenses and disrupt our business operations; and

- difficulties in the assimilation and retention of employees, including key personnel responsible for the success of the CBR Services, as well as the integration of the Makena and CBR sales forces and our ability to successfully train members of the integrated sales force to successfully sell both products and services.

If any of these factors limits our ability to integrate CBR into our operations successfully or on a timely basis, the expectations of future results of operations, including certain synergies expected to result from the acquisition, might not be met. As a result, we may not be able to realize the expected benefits that we seek to achieve from the acquisition, which could also affect our ability to service our debt obligations. In addition, we may be required to spend additional time or money on integration that otherwise would be spent on the development and expansion of our business, including efforts to further expand our product portfolio.

Further, the market price of our stock may decline in light of our recently completed acquisition, including if our integration of CBR is unsuccessful, takes longer than expected or fails to achieve financial benefits to the extent anticipated by us, financial analysts or investors, or the effect of the acquisition on our post-closing financial results is otherwise not consistent with our expectations or those of our financial analysts or investors.

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The success of the CBR Services in our portfolio will face considerable risks and uncertainties, any of which could have a materially adverse impact on our revenues and results of operations.

Our success with the CBR Services will be faced with certain risks and uncertainties, including:

- demand for the CBR Services and our ability to gain widespread market acceptance of cryopreservation of cord blood and cord tissue, including the success of efforts to educate and increase awareness among potential customers and medical practitioners, which will require significant marketing and promotional expenditures;

- the potential for stem cell science and its recognition, adoption and utility among the medical community and the continued viability of and actionable use of stem cells in the treatment of disease, especially given (a) this is a relatively new technology and is subject to potentially revolutionary technological, medical, therapeutic and regulatory changes and (b) future technological and medical developments could render the use of stem cells obsolete;

- controversy surrounding private versus public cord blood banks, and any erosion of market share for private banking of cord blood and cord tissue;

- our inexperience with CBR's service-based business model and our ability to meet or exceed customers' service level expectations and CBR's contractual obligations with respect to the CBR Services;

- the need for strategic pricing skills to optimize the forward looking CBR Services business;

- the ethical, legal, regulatory, and social implications of stem cell research, and the possibility that negative public opinion about stem cell therapy may damage perception of our overall business among the medical community and the public generally;

- complaints or perception that the benefits of private cord blood banking have been overstated, or legal challenges to the marketing and promotion of cord blood and/or cord tissue banking;

- reliance upon third party contractors to assist in providing the CBR Services, including reliance upon current suppliers for proprietary materials, which could lead to operational delays and lost revenue and the need to reconfigure machinery and/or systems if current suppliers need to be changed or are disrupted;

- legal, regulatory, and compliance risks we may face as a result of CBR's pre-acquisition business practices, including if CBR were alleged to have (a) participated in collusive or other anticompetitive conduct or utilized marketing and sales tactics with referring physicians that are in violation of applicable anti-kickback or self-referral provisions,

(b) violated any privacy, data security, or other healthcare compliance laws, or (c) failed to comply with all applicable FDA laws and requirements;

- the impact of any material disruption in our ability to maintain continued, uninterrupted and fully operating storage systems, or the loss or deterioration of cord blood and cord tissue stored in our storage systems, in the event of any damage or interruption from fire, earthquake, flood, break-ins, tornadoes and similar events, especially given that all storage systems are maintained in one location;

- our ability to maintain compliance with all applicable FDA regulations, including those regarding cord blood and cord tissue banking services, as well as tissue procurement services, especially in light of the fact that many of our competitors in the cord blood banking business do not adhere to FDA rules for pharmaceutical products;

- any new regulatory restrictions on cord blood and cord tissue banking;

- the application and implications to CBR's operations of certain healthcare laws, regulations and industry guidelines relating to pharmaceutical companies;

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- increased competition in the cord blood stem cell and cord tissue banking processing and storage business, especially pricing pressure from competitors offering reduced prices for the initial fee to entice customers to store cord blood and cord tissue with the competitor;

- unexpected increases in expenses, which will be difficult to pass on to the CBR customers who prepay for CBR Services far into the future;

- significant increases in costs due to large payments ($50,000) that may be made in the event a customer's stored cord blood is used in a hematopoietic reconstitution and fails to engraft, and such offerings could significantly increase costs in the event such failures begin to occur; and

- the increased financial burden of long-term commitments to pay fixed commissions to certain of CBR's marketing vendors if the CBR Services' profit margins fall.

If the success of the CBR Services is negatively impacted by any of the foregoing risks and uncertainties, our business and stock price could suffer as a result of a materially adverse impact on our revenues or results of operations. In addition, as we integrate the CBR business and pursue the CBR Services, we may identify additional risks and uncertainties not yet known to us, which we will identify in our subsequent SEC filings.

Should the FDA determine that CBR does not meet the regulatory requirements for a private cord blood and cord tissue bank that screens, processes, stores, labels and distributes human cells, tissues and cellular and tissue-based products without pre-marketing approval, we may be subject to FDA enforcement action and may be forced to change or halt CBR Service operations in a manner that materially harms our business.

Human tissues intended for transplantation, including umbilical cord blood stem cell and cord tissue, are subject to comprehensive regulations that address activities associated with human cells, tissues and cellular and tissue-based products ("HCT/Ps"). One set of regulations requires that companies that engage in the recovery, processing, storage, labeling, packaging, or distribution of any HCT/Ps, or the screening or testing of a cell or tissue donor, register with the FDA. This set of regulations also includes the criteria that must be met in order for the HCT/P to be eligible for distribution solely under Section 361 of the Public Health Service Act (the "PHSA"), and the regulations in 21 CFR Part 1271, rather than under the drug or device provisions of the Federal Food, Drug, and Cosmetic Act or the biological product licensing provisions of the PHSA. Another set of regulations provides criteria that must be met for donors to be eligible to donate HCT/Ps and is referred to as the "Donor Eligibility" rule. A third set of provisions governs the processing and distribution of the tissues and is often referred to as the "Current Good Tissue Practices" rule. The Current Good Tissue Practices rule covers all stages of HCT/P processing, from procurement to distribution of final allografts. Together these regulations are designed to ensure that sound, high quality practices are followed to reduce the risk of tissue contamination and of communicable disease transmission to recipients.

CBR is registered with the FDA as an HCT/P establishment that screens, processes, stores, labels and distributes umbilical cord blood stem cell and cord tissue by virtue of the services it provides to expectant parents as a private cord blood and cord tissue bank. The FDA periodically inspects such registered establishments to determine compliance with HCT/P requirements. Violations of applicable regulations noted by the FDA during facility inspections could adversely affect the continued marketing of the CBR Services. Further, in the future, the FDA may promulgate new regulatory requirements and standards for HCT/Ps. We may not be able to comply with any such future regulatory requirements or product standards. If the FDA determines that we have failed to comply with applicable regulatory requirements or any future regulatory requirements or standards, it can impose or initiate a variety of enforcement actions, including but not limited to, public warning or untitled letters, written recall or destruction orders, written cease manufacturing orders, court-ordered seizures, injunctions, consent decrees, civil penalties, or criminal prosecutions. If any of these events were to occur, our business could be materially and adversely affected.

In addition, the FDA could conclude that CBR cord blood and cord tissue do not meet the criteria for distribution solely under Section 361 of the PHSA, and therefore, CBR’s banked HCT/Ps would require the submission and approval or clearance of a marketing application in order for us to continue to process and distribute the product. Such an action by the FDA could cause negative publicity, decreased or discontinued sales of CBR cord blood and cord tissue banking

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services, and significant expense in obtaining required marketing approval or clearance, or in conforming our marketing approach to the FDA's expectations.

If third parties who provide cord blood and cord tissue to CBR fail to comply with ongoing FDA requirements for HCT/P recovery and testing, CBR cord blood and cord tissue could be subject to restrictions that will cause a materially adverse effect on our business.

Healthcare providers and other entities who collect and test the cord blood and cord tissue that CBR processes and stores are responsible for performing donor recovery and donor testing in compliance with the FDA regulations that govern those functions. CBR is dependent upon the actions of these third parties with whom CBR contracts. If these third parties fail to comply with applicable requirements, the cord blood and cord tissue that CBR processes and stores will be negatively affected and at risk of FDA enforcement action, and our business could be negatively affected.

It is likely that the FDA's regulation of HCT/Ps will continue to evolve in the future. Complying with any such new regulatory requirements may entail significant time delays and expense, which could have a material adverse effect on our business.

In the future, the FDA may promulgate new regulatory requirements and standards for HCT/Ps. We may not be able to comply with any such future regulatory requirements or product standards. Failure to comply with future applicable regulatory requirements and standards may result in, among other things, public warning or untitled letters, written recall or destruction orders, court-ordered seizures, injunctions, consent decrees, civil penalties, or criminal prosecutions. Moreover, the cost of compliance with future government regulations may adversely affect revenue and profitability.

State and other requirements and standards may impact our ability to conduct a profitable collection, processing and storage business for cord blood and cord tissue.

Some states impose additional regulation and oversight of cord blood and cord tissue banks and of clinical laboratories operating within their borders and impose regulatory compliance obligations on out-of-state laboratories providing services to their residents. Many of the states in which we and our business partners operate, have licensing requirements that must be complied with. If current state law regulations change, there can be no assurance that we, our business partners, or members of our collection center network will be able to obtain or maintain any necessary licenses required to conduct business in any states. Further, if such laws change the cost of compliance could materially and adversely affect our ability to market or perform our services or our ability to do so profitably.

Our level of indebtedness and the terms of the 2015 Term Loan Facility, 2023 Senior Notes and Convertible Notes could adversely affect our operations and limit our ability to plan for or respond to changes in our business or acquire additional products for our portfolio. If we are unable to comply with restrictions in the 2015 Term Loan Facility or cannot repay or refinance the 2023 Senior Notes or Convertible Notes, the repayment of our indebtedness could be accelerated.

In order to consummate the CBR acquisition, we incurred a substantial amount of additional debt, which could adversely affect our business. As of September 30, 2015, we had $1.05 billion of total debt outstanding. In August 2015, we entered into a $350.0 million term loan facility (the "2015 Term Loan Facility"), with a floating annual interest rate (currently 4.75%), and issued $500.0 million in aggregate principal Senior Notes due 2023 bearing interest at 7.875% annually (the "2023 Senior Notes") to help fund our acquisition of CBR and potential expansion and diversification of our product portfolio through the in-license or purchase of additional pharmaceutical products or companies, among other things. We also incurred indebtedness in February 2014 in the amount of $200.0 million in aggregate principal convertible notes due February 15, 2019 bearing interest at 2.5% annually (the "Convertible Notes"). Our high level of indebtedness could adversely affect our business in the following ways, among other things:

· make it more difficult for us to satisfy our financial obligations under our current debt obligations, or other indebtedness, as well as our contractual and commercial commitments, and could increase the risk that we may default on our debt obligations;

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- prevent us from raising the funds necessary to repurchase 2023 Senior Notes tendered to us if there is a change of control, which would constitute a default under the indenture governing the 2023 Senior Notes, the Convertible Notes and the 2015 Term Loan Facility;

- require us to use a substantial portion of our cash flow from operations to pay interest and principal on our current debt obligations, or other indebtedness, which would reduce the funds available for working capital, capital expenditures and other general corporate purposes;

- limit our ability to obtain additional financing for working capital, capital expenditures, acquisitions and other investments, or general corporate purposes, which may limit the ability to execute our business strategy;

- heighten our vulnerability to downturns in our business, our industry or in the general economy and restrict us from exploiting business opportunities or making acquisitions;

- place us at a competitive disadvantage compared to those of our competitors that may have proportionately less debt;

- limit management's discretion in operating our business;

- limit our flexibility in planning for, or reacting to, changes in our business, the industry in which we operate or the general economy; and

- result in higher interest expense if interest rates increase and we have outstanding floating rate borrowings such as our 2015 Term Loan Facility.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the 2015 Term Loan Facility, the 2023 Senior Notes and the Convertible Notes ("our current debt obligations"), depends on our future performance, which is subject to economic, financial, competitive and other factors that may be beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and support our growth strategies. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, including under our current debt obligations. In addition, if for any reason we are unable to meet our debt service and repayment obligations, we would be in default under the terms of the agreements governing our indebtedness, which would allow our creditors at that time to declare all outstanding indebtedness to be due and payable. This would likely in turn trigger cross-acceleration or cross-default rights between our applicable debt agreements. Under these circumstances, our lenders could compel us to apply all of our available cash to repay our indebtedness or they could prevent us from making payments on the notes.

The 2015 Term Loan Facility requires us to make certain payments of principal and interest over time and contains a number of other restrictive covenants. The 2015 Term Loan Facility also contains covenants and terms limiting our ability to enter into new acquisitions, licenses, mergers, foreign investments, to take on new debt and sell assets, and requiring us to pay penalties in the event we want to prepay the 2015 Term Loan Facility early. The maturity date of the 2015 Term Loan Facility could also be accelerated in certain circumstances, including in the event of an uncured event of default as outlined in the 2015 Term Loan Facility. The 2015 Term Loan Facility has a floating interest rate based on the prevailing London Interbank Offered Rate ("LIBOR") rate, making interest payments subject to adjustment depending on the interest rate environment. These and other terms in the 2015 Term Loan Facility have to be monitored closely for compliance and could restrict our ability to grow our business or enter into transactions that we believe will be beneficial to our business.

Also, upon the occurrence of specific types of change of control events, we will be required to offer to repurchase all of the outstanding 2023 Senior Notes at a price equal to 101% of the aggregate principal amount of the 2023 Senior Notes repurchased, plus accrued and unpaid interest up to, but not including, the date of repurchase. In addition, in connection with certain asset sales, we may be required to offer to repurchase a portion of the 2023 Senior Notes at a

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price equal to 100% of the principal amount, plus accrued and unpaid interest and additional interest up to, but not including, the date of repurchase. We may not have sufficient funds available to repurchase all of the 2023 Senior Notes tendered pursuant to any such offer and any other debt that would become payable upon a change of control or in connection with such an asset sale offer. The 2015 Term Loan Facility also limits our ability to repurchase the 2023 Senior Notes. Our failure to purchase the 2023 Senior Notes upon the occurrence of specific types of change of control events would be a default under the indenture governing the 2023 Senior Notes, which would in turn trigger a default under our 2015 Term Loan Facility, the indenture governing the Convertible Notes and may trigger a default under any future credit facility and the terms of our other indebtedness outstanding at such time.

Further, holders of the Convertible Notes have the right to require us to repurchase their notes upon the occurrence of a fundamental change at a repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest. Upon conversion of the Convertible Notes (which are currently convertible), unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the notes being converted. We may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Convertible Notes surrendered therefor or at the time Convertible Notes are being converted. Our failure to repurchase Convertible Notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the Convertible Notes would constitute an event of default. Moreover, if our stock price increases, the parties with whom we entered into warrant transactions in connection with the pricing of the Convertible Notes (the “Warrants”) could exercise such warrants, thereby causing substantial dilution to our stockholders. The Convertible Notes are, the Warrants may be, and any additional equity or equity-linked financings or alternative strategic arrangements would be, dilutive to our stockholders.

Our 2015 Term Loan Facility and the indenture governing the 2023 Senior Notes impose operating and financial restrictions on us and our subsidiaries that may prevent us from pursuing certain business opportunities and restrict our ability to operate our business.

The terms of our current debt instruments or any additional debt financing could greatly restrict our ability to raise additional capital and may provide rights and preferences to the investors in any such financing which are senior to those of, and not available to, current stockholders, impose restrictions on our day-to-day operations or place limitations on our ability to enter into combination transactions with other entities. Our inability to raise additional capital on terms and within a timeframe acceptable to us when needed could force us to dramatically reduce our expenses and delay, scale back or eliminate certain of our activities and operations, including our commercialization and development activities, any of which would have a material adverse effect on our business, financial condition and future business prospects.

Our 2015 Term Loan Facility and the indenture governing the 2023 Senior Notes contain covenants that restrict our and our restricted subsidiaries’ ability to take various actions, such as:

- paying dividends, redeeming subordinated indebtedness or making other restricted payments, including certain investments;

- incurring or guaranteeing additional indebtedness or issuing preferred stock;

- creating or incurring liens;

- consummating a merger;

- consolidation or sale of all or substantially all of our or our subsidiaries' assets;

- entering into transactions with affiliates;

- transferring or selling assets;

- engaging in businesses other than our current businesses and reasonably related extensions thereof;

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- designating subsidiaries as unrestricted subsidiaries; and

- allowing to exist certain restrictions on the ability of restricted subsidiaries to pay dividends or make other payments to us.

We cannot make any assurances that our future operating results will be sufficient to ensure compliance with the covenants in these arrangements or to remedy any such default. In the event of an acceleration of this indebtedness, we may not have or be able to obtain sufficient funds to make any accelerated payments. Any of the factors discussed above could materially and adversely affect our business, financial condition and results of operations. In addition, if we incur additional indebtedness, the risks related to our business and our ability to service or repay our indebtedness would increase.

Our variable rate indebtedness subjects us to interest rate risk, which could cause our debt service obligations to increase significantly.

Borrowings under our 2015 Term Loan Facility will, and other indebtedness we incur in the future may, bear interest at variable rates exposing us to interest rate risk. If interest rates increase, our debt service obligations on the variable rate indebtedness would increase even though the amount borrowed remained the same, and our net income and cash available for servicing our indebtedness would decrease.

We may need additional capital to achieve our business objectives and to service our debt obligations, including the 2015 Term Loan Facility, our Convertible Notes, our 2023 Senior Notes and contingent payments that may become due under the Lumara Agreement, which could cause significant dilution to our stockholders.

We estimate that our cash resources as of September 30, 2015, combined with cash we currently expect to receive from product sales and earnings on our investments will be sufficient to finance our currently planned operations for at least the foreseeable future. We may require additional funds or need to establish additional alternative strategic arrangements to execute a business development transaction. We may at any time seek funding through additional arrangements with collaborators through public or private equity or debt financings, subject to the covenants in the documents governing our debt obligations. We may not be able to obtain financing or to secure alternative strategic arrangements on acceptable terms or within an acceptable timeframe, if at all, which would limit our ability to execute on our strategic plan. Moreover, the condition of the credit markets can be unpredictable and we may experience a reduction in value or loss of liquidity with respect to our investments, which would put further strain on our cash resources. For example, as of September 30, 2015, our 2023 Senior Notes are trading at 95.5 (a discount to par) from the time they were issued in August 2015. The yields on debt of comparable credit quality have risen significantly since the time we issued the 2023 Senior Notes implying that our cost of capital could be higher in the future.

In August 2015, we completed the acquisition of CBR, which required us to pay $700.0 million in cash consideration, subject to estimated working capital, indebtedness and other adjustments. We used a combination of cash on hand, the $500.0 million in gross proceeds from the sale of the 2023 Senior Notes and the $350.0 million 2015 Term Loan Facility to pay the cash consideration, to retire our 2014 Term Loan and to pay related transaction expenses on the acquisition of CBR and related financings. Further, in November 2014, we completed the acquisition of Lumara Health, which required us to pay $600.0 million in cash consideration and approximately 3.2 million shares of newly issued common stock. We used a combination of cash on hand and a $340.0 million term loan facility to pay the cash consideration. In addition to the consideration paid at closing, our definitive merger agreement with Lumara Health provides for contingent consideration of up to an additional $350.0 million based on the achievement of various sales milestones for Makena, which could be paid in all cash. We also incurred substantial costs and expenses associated with the transaction. As a result, our current level of cash on hand may limit our ability to take advantage of attractive business development opportunities and execute on our strategic plan. In addition, our cash on hand may not be sufficient to service the principal and interest payments under our current debt obligations or any cash milestone payments to the former Lumara Health security holders upon the achievement of sales milestones. Our ability to make these required payments could be adversely affected if we do not achieve expected revenue and cash flow forecasts or if we are unable to find other sources of cash in the future and we may need to offer the former Lumara Health security holders shares of our common stock or issue shares of our common stock to raise cash resulting in dilution to our stockholders.

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Our long-term capital requirements will depend on many other factors, including, but not limited to the commercial success of our products and efforts we make in connection with commercialization and development, our ability to realize synergies and opportunities in connection with our acquisitions and portfolio expansion, the outcome of and costs associated with any material litigation or patent challenges to which we are or may become a party, the timing and magnitude of costs associated with qualifying additional manufacturing capacities and alternative suppliers, and our ability to raise additional capital on terms and within a timeframe acceptable to us, if necessary.

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, 2015:

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 that May Yet Be Purchased Under the Plans or Programs(2)
July 1, 2015 through July 31, 2015	1,225	$ 70.44	—	—
August 1, 2015 through August 31, 2015	5,219	61.71	—	—
September 1, 2015 through September 30, 2015	—	—	—	—
Total	6,444	$ 63.37	—	—

(1) Represents 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 do not currently have any publicly announced purchase programs or plans.

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Item 6. Exhibits

(a)List of Exhibits

2.1		Stock Purchase Agreement, dated as of June 29, 2015, by and among CBR Holdco, LLC, CBR Acquisition Holdings Corp. and AMAG Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed June 29, 2015, File No. 001-10865)
4.1		Indenture, dated as of August 17, 2015, by and among AMAG Pharmaceuticals, Inc., the Guarantors party thereto and Wilmington Trust, National Association, as trustee (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed August 17, 2015, File No. 001-10865)
4.2		Form of 7.875% Senior Note due 2023 (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed August 17, 2015, File No. 001-10865)
10.1	+	Amendment No. 2 to Pharmaceutical Manufacturing and Supply Agreement, effective as of September 25, 2015, by and between the Company and Patheon Manufacturing Services LLC (as assignee from DPI Newco LLC as assignee from DSM Pharmaceuticals, Inc.) (Certain confidential information contained in this exhibit was omitted by means of redacting a portion of the text and replacing it with [***]. This exhibit has been filed separately with the SEC without any redactions pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended)
10.2		Underwriting Agreement, dated as of July 30, 2015, among AMAG Pharmaceuticals, Inc., Jefferies LLC and Barclays Capital Inc., as representatives of the underwriters named therein (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed July 31, 2015, File No. 001-10865)
10.3		Credit Agreement, dated as of August 17, 2015, by and among AMAG Pharmaceuticals, Inc., the financial institutions and agents listed therein, and Jefferies Finance LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 17, 2015, File No. 001-10865)
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

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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
(Authorized Officer)

Date: November 6, 2015

AMAG PHARMACEUTICALS, INC.

By: /s/ Frank E. Thomas
Frank E. Thomas
President and Chief Operating Officer (Principal Financial Officer)

Date: November 6, 2015

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