

AMAG PHARMACEUTICALS INC.

Form 10-Q

May 03, 2017

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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 March 31, 2017

or

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

For the transition period from _____ to _____

Commission file number 001-10865

AMAG Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware 04-2742593

(State or Other Jurisdiction of (I.R.S. Employer
Incorporation or Organization) Identification No.)

1100 Winter Street 02451
Waltham, Massachusetts (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, a smaller reporting company, or an emerging growth company. See definition of "accelerated filer," "large accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of April 28, 2017, there were 35,045,394 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 MARCH 31, 2017

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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)

	March 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$252,854	\$274,305
Investments	305,541	304,781
Accounts receivable, net	85,233	92,375
Inventories	36,927	37,258
Prepaid and other current assets	8,316	9,839
Total current assets	688,871	718,558
Property, plant and equipment, net	22,708	24,460
Goodwill	639,484	639,484
Intangible assets, net	1,067,329	1,092,178
Restricted cash	2,493	2,593
Other long-term assets	1,025	1,153
Total assets	\$2,421,910	\$2,478,426
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$7,591	\$3,684
Accrued expenses	147,479	156,008
Current portion of long-term debt	20,455	21,166
Current portion of acquisition-related contingent consideration	97,515	97,068
Deferred revenues	34,899	34,951
Total current liabilities	307,939	312,877
Long-term liabilities:		
Long-term debt, net	783,333	785,992
Convertible 2.5% notes, net	181,566	179,363
Acquisition-related contingent consideration	51,440	50,927
Deferred tax liabilities	154,225	197,066
Deferred revenues	16,970	14,850
Other long-term liabilities	2,349	2,962
Total liabilities	1,497,822	1,544,037
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value \$0.01 per share, 2,000,000 shares authorized; none issued	—	—
Common stock, par value \$0.01 per share, 117,500,000 shares authorized; 34,445,394 and 34,336,147 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	344	343
Additional paid-in capital	1,242,640	1,238,031
Accumulated other comprehensive loss	(3,746)	(3,838)
Accumulated deficit	(315,150)	(300,147)
Total stockholders' equity	924,088	934,389
Total liabilities and stockholders' equity	\$2,421,910	\$2,478,426

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 March 31,	
	2017	2016
Revenues:		
Product sales, net	\$ 112,517	\$ 89,564
Service revenues, net	26,931	19,520
License fee, collaboration and other revenues	24	216
Total revenues	139,472	109,300
Costs and expenses:		
Cost of product sales	27,573	18,300
Cost of services	5,010	5,526
Research and development expenses	16,489	14,229
Acquired in-process research and development	60,000	—
Selling, general and administrative expenses	70,424	63,175
Restructuring expenses	—	622
Total costs and expenses	179,496	101,852
Operating income (loss)	(40,024)	7,448
Other income (expense):		
Interest expense	(18,300)	(18,443)
Interest and dividend income	1,031	708
Gains on investments, net	27	—
Other income (expense)	—	220
Total other income (expense)	(17,242)	(17,515)
Loss before income taxes	(57,266)	(10,067)
Income tax benefit	(20,706)	(2,540)
Net loss	\$(36,560)	\$(7,527)
Net loss per share:		
Basic	\$(1.06)	\$(0.22)
Diluted	\$(1.06)	\$(0.22)
Weighted average shares outstanding used to compute net loss per share:		
Basic	34,378	34,739
Diluted	34,378	34,739

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

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AMAG PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(IN THOUSANDS)

(Unaudited)

	Three Months	
	Ended March 31,	
	2017	2016
Net loss	\$(36,560)	\$(7,527)
Other comprehensive income (loss):		
Unrealized gains (losses) on securities:		
Holding gains arising during period, net of tax	92	932
Net unrealized gains on securities	92	932
Total comprehensive loss	\$(36,468)	\$(6,595)

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)

	Three Months Ended March 31,	
	2017	2016
Cash flows from operating activities:		
Net loss	\$(36,560)	\$(7,527)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	27,994	19,644
Provision for bad debt expense	590	2,209
Amortization of premium/discount on purchased securities	113	177
Non-cash equity-based compensation expense	5,778	6,160
Amortization of debt discount and debt issuance costs	3,209	2,937
Gains on investments, net	(143)	—
Change in fair value of contingent consideration	1,043	5,056
Deferred income taxes	(21,192)	(1,469)
Changes in operating assets and liabilities:		
Accounts receivable, net	6,553	715
Inventories	(403)	(2,157)
Receivable from collaboration	—	246
Prepaid and other current assets	1,523	(3,078)
Accounts payable and accrued expenses	(4,622)	(6,647)
Deferred revenues	2,067	9,717
Other assets and liabilities	(486)	593
Net cash (used in) provided by operating activities	(14,536)	26,576
Cash flows from investing activities:		
Proceeds from sales or maturities of investments	128,512	25,500
Purchase of investments	(129,241)	(63,413)
Change in restricted cash	100	—
Capital expenditures	(658)	(681)
Net cash used in investing activities	(1,287)	(38,594)
Cash flows from financing activities:		
Long-term debt principal payments	(4,375)	(4,375)
Payment of contingent consideration	(83)	(65)
Payments for repurchases of common stock	—	(7,562)
Proceeds from the exercise of stock options	152	400
Payments of employee tax withholding related to equity-based compensation	(1,322)	(1,696)
Net cash used in financing activities	(5,628)	(13,298)
Net decrease in cash and cash equivalents	(21,451)	(25,316)
Cash and cash equivalents at beginning of the period	274,305	228,705
Cash and cash equivalents at end of the period	\$252,854	\$203,389
Supplemental data for cash flow information:		
Cash paid for taxes	\$208	\$2,400
Cash paid for interest	\$26,195	\$27,964

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

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AMAG PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

A. DESCRIPTION OF BUSINESS

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a biopharmaceutical company focused on developing and delivering important therapeutics, conducting clinical research in areas of unmet need and creating education and support programs for the patients and families we serve. Our currently marketed products support the health of patients in the areas of women's and maternal health, anemia management and cancer supportive care, including Makena® (hydroxyprogesterone caproate injection), Feraheme® (ferumoxytol) for intravenous use and MuGard® Mucoadhesive Oral Wound Rinse. Through services related to the preservation of umbilical cord blood stem cell and cord tissue units (the "CBR Services") operated through Cord Blood Registry ("CBR"), we also help families to preserve newborn stem cells, which are used today in transplant medicine for certain cancers and blood, immune and metabolic disorders, and which we believe have the potential to play a valuable role in the ongoing development of regenerative medicine. In addition, in February 2017, we acquired the rights to research, develop and commercialize bremelanotide in North America, which is being developed for the treatment of hypoactive sexual desire disorder ("HSDD") in pre-menopausal women, and in April 2017, we acquired the rights to market Intraro™ (prasterone) in the U.S. for the treatment of moderate-to-severe dyspareunia, a common symptom of vulvar and vaginal atrophy ("VVA"), due to menopause.

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

B. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

In accordance with GAAP for interim financial reports and the instructions for Form 10-Q and the rules of the Securities and Exchange Commission, certain information and footnote disclosures normally included in annual financial statements have been condensed or omitted. Our accounting policies are described in the Notes to the Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2016 (our "Annual Report"). Interim results are not necessarily indicative of the results of operations for the full year. These interim financial statements should be read in conjunction with our Annual Report.

Principles of Consolidation

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

Use of Estimates and Assumptions

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. The most significant estimates and assumptions are used to determine amounts and values of, but are not limited to: revenue recognition related to product sales and services revenue; product sales allowances and accruals; allowance for doubtful accounts; investments; inventory; acquisition date fair value and subsequent fair value estimates used to assess impairment of long-lived assets, including goodwill, in-process research and development ("IPR&D") and other intangible assets; contingent consideration; debt obligations; certain accrued liabilities, including clinical trial accruals; income taxes and equity-based compensation expense. Actual results could differ materially from those estimates.

Concentrations and Significant Customer Information

Financial instruments which potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents, investments, and accounts receivable. We currently hold our excess cash primarily in institutional money market

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funds, corporate debt securities, U.S. treasury and government agency securities, commercial paper and certificates of deposit. As of March 31, 2017, we did not have a material concentration in any single investment.

Our operations are located entirely within the U.S. We focus primarily on developing, manufacturing, and commercializing our products and marketing and selling the CBR Services. We perform ongoing credit evaluations of our product sales customers and generally do not require collateral. The following table sets forth customers who represented 10% or more of our total revenues for the three months ended March 31, 2017 and 2016:

	Three Months Ended March 31, 2017	2016
AmerisourceBergen Drug Corporation	22 %	24 %
McKesson Corporation	14 %	<10 %

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

Customers which represented greater than 10% of our accounts receivable balance as of March 31, 2017 and December 31, 2016 were as follows:

	March 31, 2017	December 31, 2016
AmerisourceBergen Drug Corporation	31 %	13 %
McKesson Corporation	21 %	32 %

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

Revenue Recognition and Related Sales Allowances and Accruals

Our primary sources of revenue during the reporting periods were product revenues from Makena and Feraheme and service revenues associated with the CBR Services. Revenue is recognized when the following criteria are met:

• Persuasive evidence of an arrangement exists;

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

• The sales price charged is fixed or determinable; and

• Collection is reasonably assured.

Product Revenue

Our product sales, which primarily represented revenues from Makena and Feraheme for the three months ended March 31, 2017 and 2016, were offset by provisions for allowances and accruals as follows (in thousands):

Three Months
Ended March 31,

	2017	2016
Gross product sales	\$206,724	\$152,192
Provision for product sales allowances and accruals:		
Contractual adjustments	69,829	45,581
Governmental rebates	24,378	17,047
Total	94,207	62,628
Product sales, net	\$112,517	\$89,564

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We recognize product revenues net of certain allowances and accruals in our condensed consolidated statement of operations at the time of sale. Our contractual adjustments include provisions for returns, pricing and prompt payment discounts, as well as wholesaler distribution fees, rebates to hospitals that qualify for 340B pricing, and volume-based and other commercial rebates. Governmental rebates relate to our reimbursement arrangements with state Medicaid programs.

We did not materially adjust our product sales allowances and accruals during the three months ended March 31, 2017 or 2016. If we determine in future periods that our actual experience is not indicative of our expectations, if our actual experience changes, or if other factors affect our estimates, we may be required to adjust our allowances and accruals estimates, which would affect our net product sales in the period of the adjustment and could be significant.

Multiple Element Arrangements

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

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

Service Revenue

Our service revenues for the CBR Services include the following two deliverables: (a) enrollment, including the provision of a collection kit and cord blood and cord tissue unit processing, which are delivered at the beginning of the relationship (the “processing services”), with revenue for this deliverable recognized after the collection and successful processing of the cord blood and cord tissue; and (b) the storage of newborn cord blood and cord tissue units (the “storage services”), for either an annual fee or a prepayment of 18 years or the lifetime of the newborn donor (the “lifetime option”), with revenue for this deliverable recognized ratably over the applicable storage period. For the lifetime option, storage fees are not charged during the lifetime of the newborn donor. However, revenue is recognized based on the average of male and female life expectancies using lifetime actuarial tables published by the Social Security Administration in effect at the time of the newborn’s birth. As there are other vendors who provide processing services and storage services at separately stated list prices, the processing services and storage services, including the first year storage, each have standalone value to the customer, and therefore represent separate deliverables. The selling price for the processing services is estimated based on the best estimate of selling price because we do not have vendor specific objective evidence or third-party evidence of selling price for these elements. The selling price for the storage services is determined based on vendor specific objective evidence as we have standalone renewals to support the selling price.

C. INVESTMENTS

As of March 31, 2017 and December 31, 2016, our investments consisted of securities classified as available-for-sale in accordance with accounting standards which provide guidance related to accounting and classification of certain investments in debt and equity securities.

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The following is a summary of our investments as of March 31, 2017 and December 31, 2016 (in thousands):

	March 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	\$137,390	\$ 8	\$ (86)	\$137,312
Due in one to three years	111,161	36	(135)	111,062
U.S. treasury and government agency securities				
Due in one year or less	2,513	—	(1)	2,512
Due in one to three years	14,373	4	(49)	14,328
Commercial paper				
Due in one year or less	26,875	—	—	26,875
Certificates of deposit				
Due in one year or less	12,000	—	—	12,000
Due in one to three years	1,452	—	—	1,452
Total investments	\$305,764	\$ 48	\$ (271)	\$305,541
	December 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	\$106,430	\$ 3	\$ (69)	\$106,364
Due in one to three years	139,742	32	(281)	139,493
U.S. treasury and government agency securities				
Due in one year or less	1,021	—	—	1,021
Due in one to three years	11,395	—	(52)	11,343
Commercial paper				
Due in one year or less	40,560	—	—	40,560
Certificates of deposit				
Due in one year or less	6,000	—	—	6,000
Total investments	\$305,148	\$ 35	\$ (402)	\$304,781

Impairments and Unrealized Gains and Losses on Investments

We did not recognize any other-than-temporary impairment losses in our condensed consolidated statements of operations related to our securities during the three months ended March 31, 2017 and 2016. We considered various factors, including the length of time that each security was in an unrealized loss position and our ability and intent to hold these securities until the recovery of their amortized cost basis occurs. As of March 31, 2017, none of our investments has been in an unrealized loss position for more than one year. Future events may occur, or additional information may become available, which may cause us to identify credit losses where we do not expect to receive cash flows sufficient to recover the entire amortized cost basis of a security and may necessitate the recording of future realized losses on securities in our portfolio. Significant losses in the estimated fair values of our investments could have a material adverse effect on our earnings in future periods.

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The following tables represent the fair value hierarchy as of March 31, 2017 and December 31, 2016, for those assets and liabilities that we measure at fair value on a recurring basis (in thousands):

Fair Value Measurements at March 31, 2017 Using:				
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	\$9,932	\$ 9,932	\$ —	\$ —
Corporate debt securities	248,374	—	248,374	—
U.S. treasury and government agency securities	16,840	—	16,840	—
Commercial paper	26,875	—	26,875	—
Certificates of deposit	13,452	—	13,452	—
Total Assets	\$315,473	\$ 9,932	\$ 305,541	\$ —
Liabilities:				
Contingent consideration - Lumara Health	\$146,973	\$ —	\$ —	\$ 146,973
Contingent consideration - MuGard	1,982	—	—	1,982
Total Liabilities	\$148,955	\$ —	\$ —	\$ 148,955

Fair Value Measurements at December 31, 2016 Using:				
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	\$9,951	\$ 9,951	\$ —	\$ —
Corporate debt securities	245,857	—	245,857	—
U.S. treasury and government agency securities	12,364	—	12,364	—
Commercial paper	40,560	—	40,560	—
Certificates of deposit	6,000	—	6,000	—
Total Assets	\$314,732	\$ 9,951	\$ 304,781	\$ —
Liabilities:				
Contingent consideration - Lumara Health	\$145,974	\$ —	\$ —	\$ 145,974
Contingent consideration - MuGard	2,021	—	—	2,021
Total Liabilities	\$147,995	\$ —	\$ —	\$ 147,995

Investments

Our cash equivalents are classified as Level 1 assets under the fair value hierarchy as these assets, which consist of money market funds, have been valued using quoted market prices in active markets and do not have any restrictions on redemption. Our investments are classified as Level 2 assets under the fair value hierarchy as these assets were primarily determined from independent pricing services, which normally derive security prices from recently reported trades for identical or similar securities, making adjustments based upon other significant observable market transactions. At the end of each reporting period, we perform quantitative and qualitative analyses of prices received from third parties to determine whether prices are reasonable estimates of fair value. After completing our analyses, we did not adjust or override any fair value measurements provided by our pricing services as of March 31, 2017. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during the three months ended March 31, 2017.

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Contingent consideration

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

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

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

Balance as of December 31, 2016	\$ 147,995
Payments made	(83)
Adjustments to fair value of contingent consideration	1,043
Balance as of March 31, 2017	\$ 148,955

The \$1.0 million of adjustments to the fair value of the contingent consideration liability during the three months ended March 31, 2017 were due to an approximately \$1.0 million increase to the Makena contingent consideration. We have classified \$97.2 million of the Makena contingent consideration and \$0.3 million of the MuGard contingent consideration as short-term liabilities in our condensed consolidated balance sheet as of March 31, 2017. The \$97.2 million Makena contingent consideration reflects a \$100.0 million sales milestone payment expected to be paid in the fourth quarter of 2017 to the former Lumara Health security holders based on the forecasted achievement of a net sales milestone of Makena in the fourth quarter of 2017.

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. As of March 31, 2017, the total undiscounted milestone payment amount we could pay in connection with the Lumara Health acquisition was \$250.0 million through December 31, 2019.

The fair value of the contingent royalty payments payable by us to Abeona under the MuGard License Agreement was determined based on various market factors, including an analysis of estimated sales using a discount rate of approximately 12%. As of March 31, 2017, we estimated that the undiscounted royalty amounts we could pay under the MuGard License Agreement, based on current projections, may range from approximately \$2.0 million to \$6.0 million over the remainder of the ten year period, which commenced on June 6, 2013, the acquisition date, which is our best estimate of the period over which we expect the majority of the asset’s cash flows to be derived.

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

Debt

We estimate the fair value of our debt obligations by using quoted market prices obtained from third-party pricing services, which is classified as a Level 2 input. As of March 31, 2017, the estimated fair value of our 2023 Senior Notes, Convertible Notes and 2015 Term Loan Facility (each as defined below) was \$473.8 million, \$219.3 million and \$323.5 million, respectively, which differed from their carrying values. See Note P, “Debt” for additional information on our debt obligations.

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Our major classes of inventories were as follows as of March 31, 2017 and December 31, 2016 (in thousands):

	March 31, 2017	December 31, 2016
Raw materials	\$ 14,721	\$ 14,382
Work in process	3,250	3,924
Finished goods	18,956	18,952
Total inventories	\$ 36,927	\$ 37,258

F. PROPERTY, PLANT AND EQUIPMENT, NET

Property, plant and equipment, net consisted of the following as of March 31, 2017 and December 31, 2016 (in thousands):

	March 31, 2017	December 31, 2016
Land	\$ 700	\$ 700
Land improvements	300	300
Building and improvements	9,500	9,500
Computer equipment and software	14,190	13,866
Furniture and fixtures	2,401	2,401
Leasehold improvements	3,718	3,718
Laboratory and production equipment	6,638	6,449
Construction in progress	1,765	1,619
	39,212	38,553
Less: accumulated depreciation	(16,504)	(14,093)
Property, plant and equipment, net	\$ 22,708	\$ 24,460

G. GOODWILL AND INTANGIBLE ASSETS, NET**Goodwill**

Our \$639.5 million goodwill balance consisted of \$198.1 million of goodwill acquired through the November 2014 Lumara Health acquisition and \$441.4 million acquired through the August 2015 CBR acquisition. As of March 31, 2017, we had no accumulated impairment losses related to goodwill.

Intangible Assets

As of March 31, 2017 and December 31, 2016, our identifiable intangible assets consisted of the following (in thousands):

	March 31, 2017				December 31, 2016			
	Cost	Accumulated Amortization	Impairment	Net	Cost	Accumulated Amortization	Impairment	Net
Amortizable intangible assets:								
Makena base technology	\$ 797,100	\$ 149,652	\$ —	\$ 647,448	\$ 797,100	\$ 128,732	\$ —	\$ 668,368
CBR customer relationships	297,000	17,519	—	279,481	297,000	13,590	—	283,410
	1,094,100	167,171	—	926,929	1,094,100	142,322	—	951,778
Indefinite-lived intangible assets:								
Makena IPR&D	79,100	—	—	79,100	79,100	—	—	79,100
	65,000	—	3,700	61,300	65,000	—	3,700	61,300

CBR trade names and
trademarks

Total intangible assets	\$ 1,238,200	\$ 167,171	\$ 3,700	\$ 1,067,329	\$ 1,238,200	\$ 142,322	\$ 3,700	\$ 1,092,178
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As of March 31, 2017, the weighted average remaining amortization period for our finite-lived intangible assets was approximately 8.5 years.

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

The CBR intangible assets (i.e., the CBR customer relationships and trade names and trademarks) were acquired in August 2015 in connection with our acquisition of CBR. Amortization of the CBR customer relationships is being recognized using an estimated useful life of 20 years from the acquisition date, which we believe is an appropriate amortization period due to the estimated economic lives of the CBR intangible assets. As part of our 2016 annual impairment test, we recorded an impairment charge of \$3.7 million in the fourth quarter of 2016 related to the impairment of a portion of the CBR trade names and trademarks indefinite-lived intangible asset based on a revised long-term revenue forecast for CBR.

Total amortization expense for the three months ended March 31, 2017 and 2016, was \$24.8 million and \$16.6 million, respectively. Amortization expense for the Makena base technology is recorded in cost of product sales in our condensed consolidated statements of operations. Amortization expense for the CBR customer relationships 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 Year Ending December 31, 2017	\$ 95,051
Year Ending December 31, 2018	81,433
Year Ending December 31, 2019	48,283
Year Ending December 31, 2020	46,845
Year Ending December 31, 2021	46,767
Thereafter	608,550
Total	\$ 926,929

H. CURRENT AND LONG-TERM LIABILITIES**Accrued Expenses**

Accrued expenses consisted of the following as of March 31, 2017 and December 31, 2016 (in thousands):

	March 31, 2017	December 31, 2016
Commercial rebates, fees and returns	\$96,280	\$89,466
Professional, license, and other fees and expenses	24,630	24,248
Research and development expenses	9,901	10,714
Interest expense	5,507	16,683
Salaries, bonuses, and other compensation	11,161	14,823
Restructuring expense	—	74
Total accrued expenses	\$147,479	\$156,008

Deferred Revenues

Our deferred revenue balances as of March 31, 2017 and December 31, 2016 were related to our CBR Services revenues and included: (a) amounts collected in advance of unit processing and (b) amounts associated with unearned storage fees collected at the beginning of the storage contract term, net of allocated discounts.

Table of Contents**I. INCOME TAXES**

The following table summarizes our effective tax rate and income tax benefit for the three months ended March 31, 2017 and 2016 (in thousands except for percentages):

	Three Months Ended			
	March 31,			
	2017		2016	
Effective tax rate	36	%	25	%
Income tax benefit	\$(20,706)		\$(2,540)	

For the three months ended March 31, 2017, we recognized an income tax benefit of \$20.7 million representing an effective tax rate of 36%. The difference between the expected statutory federal tax rate of 35% and the effective tax rate for the three months ended March 31, 2017, was primarily attributable to the impact of state income taxes and the federal research and development tax credit, partially offset by non-deductible stock compensation and other non-deductible expenses.

For the three months ended March 31, 2016, we recognized an income tax benefit of \$2.5 million representing an effective tax rate of 25%. The difference between the expected statutory federal tax rate of 35% and the 25% effective tax rate for the three months ended March 31, 2016, was primarily attributable to the impact of state income taxes, stock compensation, and federal research and development and orphan drug tax credits, partially offset by non-deductible contingent consideration expense associated with Lumara Health.

J. ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

The table below presents information about the effects of net income (loss) of significant amounts reclassified out of accumulated other comprehensive income (loss), net of tax, associated with unrealized gains (losses) on securities during the three months ended March 31, 2017 and 2016 (in thousands):

	Three Months	
	Ended March 31,	
	2017	2016
Beginning balance	\$(3,838)	\$(4,205)
Other comprehensive income before reclassifications	92	932
Ending balance	\$(3,746)	\$(3,273)

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

We compute basic net income (loss) per share by dividing net income (loss) by the weighted average number of common shares outstanding during the relevant period. Diluted net income (loss) per common share has been computed by dividing net income (loss) by the diluted number of common shares outstanding during the period. Except where the result would be antidilutive to net income (loss), diluted net income (loss) per common share would be computed assuming the impact of the conversion of the \$200.0 million of 2.5% convertible senior notes due February 15, 2019 (the "Convertible Notes"), the exercise of outstanding stock options, the vesting of restricted stock units ("RSUs"), and the exercise of warrants.

We have a choice to settle the conversion obligation under the Convertible Notes in cash, shares or any combination of the two. Pursuant to certain covenants in our six-year \$350.0 million term loan facility (the "2015 Term Loan Facility"), which we entered into in 2015 to partially fund the acquisition of CBR, we may be restricted from settling the conversion obligation in whole or in part with cash unless certain conditions in the 2015 Term Loan Facility are satisfied. We utilize the if-converted method to reflect the impact of the conversion of the Convertible Notes. This method assumes the conversion of the Convertible Notes into shares of our common stock and reflects the elimination of interest expense related to the Convertible Notes when dilutive.

The dilutive effect of the warrants, stock options and RSUs has been calculated using the treasury stock method.

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The components of basic and diluted net loss per share for the three months ended March 31, 2017 and 2016, were as follows (in thousands, except per share data):

	Three Months Ended March 31,	
	2017	2016
Net loss	\$(36,560)	\$(7,527)
Weighted average shares outstanding used to compute net loss per share:		
Basic	34,378	34,739
Diluted	34,378	34,739
Net loss per share:		
Basic	\$(1.06)	\$(0.22)
Diluted	\$(1.06)	\$(0.22)

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

	Three Months Ended March 31,	
	2017	2016
Options to purchase shares of common stock	2,406	2,455
Shares of common stock issuable upon the vesting of RSUs	775	904
Warrants	7,382	7,382
Convertible 2.5% notes	7,382	7,382
Total	17,945	18,123

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.

L. 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 Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan and our 2015 Employee Stock Purchase Plan (“2015 ESPP”). All outstanding stock options granted under each of our equity compensation plans have an exercise price equal to the closing price of a share of our common stock on the grant date (excluding purchase rights under our 2015 ESPP).

Stock Options

The following table summarizes stock option activity for the three months ended March 31, 2017:

	2007 Equity Plan	2000 Equity Plan	2013 Lumara Equity Plan	Inducement Grants	Total
Outstanding at December 31, 2016	2,158,822	5,200	134,181	814,975	3,113,178
Granted	322,210	—	—	—	322,210
Exercised	(9,065)	—	—	—	(9,065)
Expired or terminated	(50,696)	—	(281)	(27,625)	(78,602)
Outstanding at March 31, 2017	2,421,271	5,200	133,900	787,350	3,347,721

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Restricted Stock Units

The following table summarizes RSU activity for the three months ended March 31, 2017:

	2007 Equity Plan	2000 Equity Plan	2013 Lumara Equity Plan	Inducement Grants	Total
Outstanding at December 31, 2016	773,804	—	27,694	135,456	936,954
Granted	732,956	—	—	—	732,956
Vested	(143,056)	—	(11,664)	(1,000)	(155,720)
Expired or terminated	(26,957)	—	(501)	(5,318)	(32,776)
Outstanding at March 31, 2017	1,336,747	—	15,529	129,138	1,481,414

In February 2017, we granted RSUs under our 2007 Plan to certain members of our senior management covering a maximum of 191,250 shares of common stock. These performance-based RSUs will vest, if at all, on February 22, 2020, based on our total shareholder return (“TSR”) performance measured against the median TSR of a defined comparator group of companies over a three-year period. The maximum aggregate total fair value of these RSUs is \$5.7 million, which is being recognized as expense over a period of three years from the date of grant, net of any estimated and actual forfeitures.

Equity-based compensation expense

Equity-based compensation expense for the three months ended March 31, 2017 and 2016 consisted of the following (in thousands):

	Three Months Ended March 31,	
	2017	2016
Cost of product sales	\$129	\$320
Research and development	756	756
Selling, general and administrative	4,893	5,084
Total equity-based compensation expense	5,778	6,160
Income tax effect	(1,605)	(1,674)
After-tax effect of equity-based compensation expense	\$4,173	\$4,486

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. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We adopted ASU No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (“ASU 2016-09”) during the first quarter of 2017. We will continue to use the current method of estimated forfeitures each period rather than accounting for forfeitures as they occur. For additional information, see Note R, “Recently Issued and Proposed Accounting Pronouncements,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

M. STOCKHOLDERS’ EQUITY

Share Repurchase Program

In January 2016, we announced that our board of directors authorized a program to repurchase up to \$60.0 million in shares of our common stock. The repurchase program does not have an expiration date and may be suspended for periods or discontinued at any time. Under the program, we may purchase our stock from time to time at the discretion of management in the open market or in privately negotiated transactions. The number of shares repurchased and the timing of the purchases will depend on a number of factors, including share price, trading volume and general market conditions, along with working capital requirements, general business conditions and other factors. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate

purchases of our shares under this program. As of March 31, 2017, we repurchased and retired 831,744 shares of common stock under this repurchase program for \$20.0 million at an average purchase price of \$24.05 per share. We did not repurchase any of our common stock during the first quarter of 2017.

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Change in Stockholders' Equity

Total stockholders' equity decreased by \$10.3 million during the three months ended March 31, 2017. This decrease was primarily driven by our net loss of \$36.6 million, partially offset by \$21.6 million related to the cumulative-effect adjustment to our accumulated deficit from previously unrecognized excess tax benefits upon our adoption of ASU No. 2016-09.

N. COMMITMENTS AND CONTINGENCIES

Commitments

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

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 \$4.6 million as of March 31, 2017.

Contingencies

Legal Proceedings

We accrue a liability for legal contingencies when we believe that it is both probable that a liability has been incurred and that we can reasonably estimate the amount of the loss. We review these accruals and adjust them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new information is obtained and our views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in our accrued liabilities would be recorded in the period in which such determination is made. For certain matters referenced below, the liability is not probable or the amount cannot be reasonably estimated and, therefore, accruals have not been made. In addition, in accordance with the relevant authoritative guidance, for any matters in which the likelihood of material loss is at least reasonably possible, we will provide disclosure of the possible loss or range of loss. If a reasonable estimate cannot be made, however, we will provide disclosure to that effect. We expense legal costs as they are incurred.

Sandoz Patent Infringement Lawsuit

On February 5, 2016, we received a Paragraph IV certification notice letter regarding an Abbreviated New Drug Application submitted to the U.S. Food and Drug Administration (the "FDA") by Sandoz Inc. ("Sandoz") requesting approval to engage in commercial manufacture, use and sale of a generic version of ferumoxytol. A generic version of Feraheme can be marketed only with the approval of the FDA of the respective application for such generic version. The Drug Price Competition and Patent Term Restoration Act of 1984, as amended, (the "Hatch-Waxman Act"), requires an ANDA applicant whose proposed drug is a generic version of a previously-approved drug listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the "Orange Book," to certify to any patents listed in the Orange Book for the previously-approved drug and, in the case of a Paragraph IV certification, to notify the owner of the approved application and the relevant patent-holder. The Paragraph IV certification notice is required to contain a detailed factual and legal statement explaining the basis for the applicant's opinion that the proposed product does not infringe the subject patents, that such patents are invalid or unenforceable, or both. If a patent infringement suit is filed within 45 days of receipt of the Paragraph IV notice, a so-called 30-month stay is triggered that generally prevents the FDA from approving the ANDA until the expiration of the 30-month stay period, conclusion of the litigation in the generic applicant's favor, or expiration of the patent, whichever is earlier. In its notice letter, Sandoz claims that our ferumoxytol patents are invalid, unenforceable and/or not infringed by Sandoz's manufacture, use, sale or offer for sale of the generic version. In March 2016, we initiated a patent infringement suit alleging that Sandoz's ANDA filing itself constituted an act of infringement and that if it is approved, the manufacture, use, offer for sale, sale or importation of Sandoz's ferumoxytol products would infringe our patents. By the filing of this complaint, we believe the 30 month stay was triggered and that Sandoz is prohibited

from marketing its ferumoxytol product, even if it receives conditional approval from the FDA until the earliest of 30 months from the date of receipt of the notice of certification by the patent owner or NDA holder, the conclusion of litigation in the generic's favor, or expiration of the patent(s). If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30 month stay period, the stay is lifted and the FDA may thereafter approve the application based on the applicable standards for approval. On May 2, 2016, Sandoz filed a response to our patent infringement suit and the trial is scheduled for March 12, 2018. Any future unfavorable outcome in this matter could negatively affect the magnitude and timing of future Feraheme revenues. We intend to vigorously enforce our intellectual property rights relating to ferumoxytol.

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Other

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

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

We may periodically become subject to other legal proceedings and claims arising in connection with ongoing business activities, including claims or disputes related to patents that have been issued or that are pending in the field of research on which we are focused. Other than the above actions, we are not aware of any material claims against us as of March 31, 2017.

O. COLLABORATION, LICENSE AND OTHER STRATEGIC AGREEMENTS

Our commercial strategy includes expanding our portfolio through the in-license or acquisition of additional pharmaceutical products or companies, including revenue-generating commercial products and late-stage development assets. As of March 31, 2017, we were a party to the following collaborations and license agreements:

Palatin

On January 8, 2017, we entered into a license agreement (the “Palatin License Agreement”) with Palatin Technologies, Inc. (“Palatin”) under which we acquired (a) an exclusive license in all countries of North America (the

“Palatin Territory”), with the right to grant sub-licenses, to research, develop and commercialize bremelanotide and any other products containing bremelanotide (collectively, the “Bremelanotide Products”), an investigational product designed to be an on-demand treatment for HSDD in pre-menopausal women, (b) a worldwide non-exclusive license, with the right to grant sub-licenses, to manufacture the Bremelanotide Products, and (c) a non-exclusive license in all countries outside the Palatin Territory, with the right to grant sub-licenses, to research, develop and manufacture (but not commercialize) the Bremelanotide Products. Following the satisfaction of the conditions to closing under the Palatin License Agreement, the transaction closed on February 2, 2017. We accounted for the Palatin License Agreement as an asset acquisition as a result of our early adoption of ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business.

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Under the terms of the Palatin License Agreement, in February 2017 we paid Palatin \$60.0 million as a one-time upfront payment and will reimburse Palatin up to an aggregate amount of \$25.0 million for all reasonable, documented, out-of-pocket expenses incurred by Palatin in connection with the development and regulatory activities necessary to submit a new drug application in the U.S. for brexelanotide for the treatment of HSDD in pre-menopausal women. The \$60.0 million upfront payment made in February 2017 to Palatin was recorded as in-process research and development expense as the product candidate had not received regulatory approval.

In addition, the Palatin License Agreement requires us to make future contingent payments of (a) up to \$80.0 million upon achievement of certain regulatory milestones, including FDA approval and (b) up to \$300.0 million of aggregate sales milestone payments upon the achievement of certain annual net sales milestones over the course of the license. The first sales milestone payment of \$25.0 million will be triggered when brexelanotide annual net sales exceed \$250.0 million. We are also obligated to pay Palatin tiered royalties on annual net sales of the Brexelanotide Products, on a product-by-product basis, in the Palatin Territory ranging from the high-single digits to the low double-digits. The royalties will expire on a product-by-product and country-by-country basis upon the latest to occur of (a) the earliest date on which there are no valid claims of Palatin patent rights covering such Brexelanotide Product in such country, (b) the expiration of the regulatory exclusivity period for such Brexelanotide Product in such country and (c) 10 years following the first commercial sale of such Brexelanotide Product in such country. These royalties are subject to reduction in the event that: (i) we must license additional third party intellectual property in order to develop, manufacture or commercialize a Brexelanotide Product or (ii) generic competition occurs with respect to a Brexelanotide Product in a given country, subject to an aggregate cap on such deductions of royalties otherwise payable to Palatin. After the expiration of the applicable royalties for any Brexelanotide Product in a given country, the license for such Brexelanotide Product in such country would become a fully paid-up, royalty-free, perpetual and irrevocable license.

Velo

In July 2015, we entered into an option agreement with Velo Bio, LLC (“Velo”), a privately held life-sciences company that granted us an option to acquire the rights (the “DIF Rights”) to an orphan drug candidate, digoxin immune fab (“DIF”), a polyclonal antibody in clinical development for the treatment of severe preeclampsia in pregnant women. We made an upfront payment of \$10.0 million in the third quarter of 2015 for the option to acquire the DIF Rights. DIF has been granted both orphan drug and fast-track review designations by the FDA for use in treating severe preeclampsia. Under the option agreement, Velo will complete a Phase 2b/3a clinical study, which we expect to begin in the second quarter of 2017. Following the conclusion of the DIF Phase 2b/3a study, we may terminate, or, for additional consideration, exercise or extend, our option to acquire the DIF Rights. If we exercise the option to acquire the DIF Rights, we would be responsible for additional costs in pursuing FDA approval, and would be obligated to pay to Velo certain milestone payments and single-digit royalties based on regulatory approval and commercial sales of the product. 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. In the event the royalty rate applicable to the quarter in which a milestone payment threshold is first achieved is zero, the applicable milestone payment amount will increase by 50%.

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

Antares

In September 2014, Lumara Health entered into a development and license agreement (the “Antares Agreement”) with Antares Pharma, Inc. (“Antares”), which in connection with our acquisition of Lumara Health in November of 2014, grants us an exclusive, worldwide, royalty-bearing license, with the right to sublicense, to certain intellectual property rights, including know-how, patents and trademarks, to develop, use, sell, offer for sale and import and export the

Makena auto-injector. In consideration for the license, to support joint meetings and a development strategy with the FDA, and for initial tooling and process validation, Lumara Health paid Antares an up-front payment in October 2014. Under the Antares Agreement, we are responsible for the clinical development and preparation, submission and maintenance of all regulatory applications in each country where we desire to market and sell the Makena auto-injector, including the U.S. We are required to pay royalties to Antares on net sales of the Makena auto-injector for the life of the Antares Royalty Term. The royalty rates range from high single digit to low double digits and are tiered based on levels of net sales of the Makena auto-injector and decrease after the expiration of licensed patents or where there are generic equivalents to the Makena auto-injector being sold in a particular country. Antares is entitled to sales-based milestone payments. Antares is the exclusive supplier of the device components of the Makena auto-injector and Antares remains responsible for the manufacture and supply of the device components and assembly of the Makena auto-injector. We are responsible for the supply of the drug to be used in the assembly of the finished

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

P. DEBT

Our outstanding debt obligations as of March 31, 2017 and December 31, 2016 consisted of the following (in thousands):

	March 31, 2017	December 31, 2016
2023 Senior Notes	\$489,907	\$489,612
2015 Term Loan Facility	313,881	317,546
Convertible Notes	181,566	179,363
Total long-term debt	985,354	986,521
Less: current maturities	20,455	21,166
Long-term debt, net of current maturities	\$964,899	\$965,355

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 7.875% Senior Notes due 2023 (the “2023 Senior Notes”). The 2023 Senior Notes were issued pursuant to an Indenture, dated as of August 17, 2015 (the “Indenture”), by and among us, certain of our subsidiaries acting as guarantors of the 2023 Senior Notes and Wilmington Trust, National Association, as trustee. The Indenture contains certain customary negative covenants, which are subject to a number of limitations and exceptions. Certain of the covenants will be suspended during any period in which the 2023 Senior Notes receive investment grade ratings.

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

At March 31, 2017, the principal amount of the outstanding borrowings was \$500.0 million and the carrying value of the outstanding borrowings, net of issuance costs and other lender fees and expenses, was \$489.9 million.

2015 Term Loan Facility

On August 17, 2015, to fund a portion of the purchase price of CBR, we entered into a credit agreement with a group of lenders, including Jefferies Finance LLC as administrative and collateral agent, that provided us with, among other things, a six-year \$350.0 million term loan facility. We borrowed the full \$350.0 million available under the 2015 Term Loan Facility on August 17, 2015. The credit agreement also allows for the incurrence of incremental loans in an amount up to \$225.0 million. The unamortized original issue costs and other lender fees and expenses, including a

prepayment penalty, included \$6.8 million of the unamortized original issue costs and other lender fees and expenses from our then existing five-year term loan facility as a result of accounting guidance for the modification of debt arrangements.

The 2015 Term Loan Facility bears interest, at our option, at the London Interbank Offered Rate (“LIBOR”) plus a margin of 3.75% or the prime rate plus a margin of 2.75%. The LIBOR is subject to a 1.00% floor and the prime rate is subject to a 2.00% floor. As of March 31, 2017, the stated interest rate, based on the LIBOR, was 4.75%, and the effective interest rate was 5.65%.

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

The 2015 Term Loan Facility includes an annual mandatory prepayment of the debt in an amount equal to 50% of our excess cash flow (as defined in the 2015 Term Loan Facility) as measured on an annual basis, beginning with the year ended December 31, 2016. As a result, as of March 31, 2017, \$3.0 million was reclassified from long-term debt to current portion of long-term debt in our condensed consolidated balance sheet and paid in April 2017. On or after December 31, 2016, the applicable excess cash flow percentage shall be reduced based on the total net leverage ratio as of the last day of the period. Excess cash flow is generally defined as our adjusted Earnings Before Interest, Taxes, Depreciation and Amortization (“EBITDA”) less debt service costs, unfinanced capital expenditures, unfinanced acquisition expenditures, contingent consideration paid, and current income taxes as well as other adjustments specified in the credit agreement.

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

At March 31, 2017, the principal amount of the outstanding borrowings was \$323.8 million and the carrying value of the outstanding borrowings, net of issuance costs and other lender fees and expenses, was \$313.9 million.

2.5% Convertible Notes

On February 14, 2014, we issued \$200.0 million aggregate principal amount of the Convertible Notes. We received net proceeds of \$193.3 million from the sale of the Convertible Notes, after deducting fees and expenses of \$6.7 million. We used \$14.1 million of the net proceeds from the sale of the Convertible Notes to pay the cost of the convertible bond hedges, as described below (after such cost was partially offset by the proceeds to us from the sale of warrants in the warrant transactions described below).

The Convertible Notes are governed by the terms of an indenture between us, as issuer, and Wilmington Trust, National Association, as the trustee. The Convertible Notes are senior unsecured obligations and bear interest at a rate of 2.5% per year, payable semi-annually in arrears on February 15 and August 15 of each year. The Convertible Notes will mature on February 15, 2019, unless earlier repurchased or converted. Upon conversion of the Convertible Notes, at a holder’s election, such Convertible Notes will be convertible into cash, shares of our common stock, or a combination thereof, at our election (subject to certain limitations in the 2015 Term Loan Facility), at a conversion rate of approximately 36.9079 shares of common stock per \$1,000 principal amount of the Convertible Notes, which corresponds to an initial conversion price of approximately \$27.09 per share of our common stock.

The conversion rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the issuance of stock dividends and payment of cash dividends. At any time prior to the close of business on the business day immediately preceding May 15, 2018, holders may convert their Convertible Notes at their option only under the following circumstances:

- 1) during any calendar quarter (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;
- 2) during the five business day period after any five consecutive trading day period (the “measurement period”) in which the trading price per \$1,000 principal amount of the Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; or
- 3) upon the occurrence of specified corporate event.

On or after May 15, 2018 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert all or any portion of their Convertible Notes, in multiples of \$1,000 principal amount, at the 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 fourth quarter of 2016, the Convertible Notes were not convertible as of March 31, 2017.

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In accordance with accounting guidance for debt with conversion and other options, we separately account for the liability and equity components of the Convertible Notes by allocating the proceeds between the liability component and the embedded conversion option (“equity component”) due to our ability to settle the Convertible Notes in cash, common stock or a combination of cash and common stock, at our option (subject to certain limitations in the 2015 Term Loan Facility). The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected our non-convertible debt borrowing rate for similar debt. The equity component of the Convertible Notes was recognized as a debt discount and represents the difference between the proceeds from the issuance of the Convertible Notes and the fair value of the liability of the Convertible Notes on their respective dates of issuance. The excess of the principal amount of the liability component over its carrying amount (“debt discount”) is amortized to interest expense using the effective interest method over five years. The equity component is not remeasured as long as it continues to meet the conditions for equity classification.

Our outstanding Convertible Note balances as of March 31, 2017 consisted of the following (in thousands):

March 31,
2017

Liability component:

Principal	\$ 199,998
Less: debt discount and issuance costs, net	(18,432)
Net carrying amount	\$ 181,566

In connection with the issuance of the Convertible Notes, we incurred approximately \$6.7 million of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, and allocated these costs to the liability and equity components based on the allocation of the proceeds. Of the total \$6.7 million of debt issuance costs, \$1.3 million was allocated to the equity component and recorded as a reduction to additional paid-in capital and \$5.4 million was allocated to the liability component and is now recorded as a reduction of the Convertible Notes in our condensed consolidated balance sheets. The portion allocated to the liability component is amortized to interest expense using the effective interest method over five years.

We determined the expected life of the debt was equal to the five-year term on the Convertible Notes. The effective interest rate on the liability component was 7.23% for the period from the date of issuance through March 31, 2017. As of March 31, 2017, the “if-converted value” did not exceed the remaining principal amount of the Convertible Notes.

The following table sets forth total interest expense recognized related to the Convertible Notes during the three months ended March 31, 2017 and 2016 (in thousands):

	Three Months Ended March 31,	
	2017	2016
Contractual interest expense	\$ 1,250	\$ 1,250
Amortization of debt issuance costs	274	258
Amortization of debt discount	1,929	1,815
Total interest expense	\$ 3,453	\$ 3,323

As of March 31, 2017, the principal amount of the Convertible Notes was \$200.0 million and the carrying value of the Convertible Notes was \$181.6 million.

Convertible Bond Hedge and Warrant Transactions

In connection with the pricing of the Convertible Notes and in order to reduce the potential dilution to our common stock and/or offset cash payments due upon conversion of the Convertible Notes, in February 2014 we entered into convertible bond hedge transactions covering approximately 7.4 million shares of our common stock underlying the

\$200.0 million aggregate principal amount of the Convertible Notes with the call spread counterparties. The convertible bond hedges have an exercise price of approximately \$27.09 per share, subject to adjustment upon certain events, and are exercisable when and if the Convertible Notes are converted. If upon conversion of the Convertible Notes, the price of our common stock is above the exercise price of the convertible bond hedges, the call spread counterparties will deliver shares of our common stock and/or 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

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the convertible bond hedges. We paid \$39.8 million for these convertible bond hedges and recorded this amount as a reduction to additional paid-in capital, net of tax, in 2014.

In February 2014, we also entered into separate warrant transactions with each of the call spread counterparties relating to, in the aggregate, approximately 7.4 million shares of our common stock underlying the \$200.0 million aggregate principal amount of the Convertible Notes. The initial exercise price of the warrants is \$34.12 per share, subject to adjustment upon certain events, which is 70% above the last reported sale price of our common stock of \$20.07 on February 11, 2014. The warrants would separately have a dilutive effect to the extent that the market value per share of our common stock, as measured under the terms of the warrants, exceeds the applicable exercise price of the warrants. The warrants were issued to the call spread counterparties pursuant to the exemption from registration set forth in Section 4(a)(2) of the Securities Act of 1933, as amended. We received \$25.6 million for these warrants and recorded this amount to additional paid-in capital in 2014.

Aside from the initial payment of \$39.8 million to the call spread counterparties for the convertible bond hedges, which was partially offset by the receipt of \$25.6 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.

Q. RESTRUCTURING

In connection with the CBR and Lumara Health acquisitions, we initiated restructuring programs in the third quarter of 2015 and the fourth quarter of 2014, respectively, which included severance benefit expenses primarily related to certain former CBR and Lumara Health employees. As a result of these restructurings, we recorded charges of approximately \$0.6 million for the three months ended March 31, 2016. We recorded no additional restructuring charges for the three months ended March 31, 2017. All of the restructuring costs have been paid as of March 31, 2017.

The following table outlines the components of our restructuring expenses which were included in current liabilities for the three months ended March 31, 2017 and 2016 (in thousands):

	Three Months Ended March 31, 2017 2016	
Accrued restructuring, beginning of period	\$74	\$2,883
Employee severance, benefits and related costs	—	809
Payments	(74)	(1,599)
Accrued restructuring, end of period	\$—	\$2,093

R. 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 January 2017, the FASB issued ASU 2017-04, Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment (“ASU 2017-04”). This new standard eliminates Step 2 from the goodwill impairment test. ASU 2017-04 requires an entity to perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value. ASU 2017-04 still allows the option to perform a qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. ASU 2017-04 is effective for any annual or interim goodwill impairment tests performed in the fiscal years beginning after December 15, 2019 and must be applied prospectively. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. We have adopted ASU 2017-04 as of January 1, 2017, with prospective application for our interim or annual goodwill impairment tests.

In January 2017, the FASB issued ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business (“ASU 2017-01”). This standard clarifies the definition of a business and provides a screen to determine when an integrated set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. We have early adopted ASU 2017-01 as of January 1, 2017, with prospective application to any business development transaction. Depending upon individual facts and circumstances of future transactions, this guidance will likely result in more transactions being accounted for as asset acquisitions rather than business combinations.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (“ASU 2016-15”). This standard clarifies certain aspects of the statement of cash flows, including

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the classification of debt prepayment or debt extinguishment costs or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate owned life insurance policies, distributions received from equity method investees and beneficial interests in securitization transactions. This new standard also clarifies that an entity should determine each separately identifiable source of use within the cash receipts and payments on the basis of the nature of the underlying cash flows. In situations in which cash receipts and payments have aspects of more than one class of cash flows and cannot be separated by source or use, the appropriate classification should depend on the activity that is likely to be the predominant source or use of cash flows for the item. ASU 2016-15 will be effective for us on January 1, 2018. We are currently evaluating the impact of our adoption of ASU 2016-15 in our condensed consolidated financial statements.

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

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09"). The new standard involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. We adopted ASU 2016-09 during the first quarter of 2017 and will now record all excess tax benefits and deficiencies related to share-based compensation in our condensed consolidated statements of operations as discrete events in the interim reporting period in which the benefit or deficiency occurs. Such benefits and deficiencies will not be considered in the calculation of our annual estimated effective tax rate. Any excess tax benefits that were not previously recognized because the related tax deduction had not reduced current taxes payable (i.e. was not realized) are to be recorded using a modified retrospective transition method through a cumulative-effect adjustment to retained earnings as of the beginning of the period in which the new guidance is adopted. We recorded a cumulative-effect adjustment to our accumulated deficit from previously unrecognized excess tax benefits of \$21.6 million during the three months ended March 31, 2017. Lastly, we will continue to use the current method of estimated forfeitures each period rather than accounting for forfeitures as they occur.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"). This statement requires entities to recognize on its balance sheet assets and liabilities associated with the rights and obligations created by leases with terms greater than twelve months. This statement is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods and early adoption is permitted. We are currently evaluating the impact of ASU 2016-02 in our condensed consolidated financial statements and we currently expect that most of our operating lease commitments will be subject to the new standard and recognized as operating lease liabilities and right-of-use assets upon our adoption of ASU 2016-02.

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

effective for us on January 1, 2018. The adoption of ASU 2016-01 is not expected to 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 (“ASU 2015-11”). The new standard applies only to inventory for which cost is determined by methods other than last-in, first-out and the retail inventory method, which includes inventory that is measured using first-in, first-out or average cost. Inventory within the scope of ASU 2015-11 is required to be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. We adopted ASU 2015-11 during the first quarter of 2017, which did not have a material impact on our results of operations, cash flows or financial position.

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In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, as a new Topic, Accounting Standards Codification Topic 606 (“ASU 2014-09”). The new revenue recognition standard provides a five-step analysis of transactions to determine when and how revenue is recognized. The core principle is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customer Topic 606s, Principal versus Agent Considerations, which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU 2016-10, Revenue from Contracts with Customers Topic 606, Identifying Performance Obligations and Licensing, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU 2016-12, Revenue from Contracts with Customers Topic 606, Narrow-Scope Improvements and Practical Expedients, related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectibility, non-cash consideration and the presentation of sales and other similar taxes collected from customers. In December 2016, the FASB issued ASU No. 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers, which amends certain narrow aspects of the guidance issued in ASU 2014-09, including guidance related to the disclosure of remaining performance obligations and prior-period performance obligations, as well as other amendments to the guidance on loan guarantee fees, contract costs, refund liabilities, advertising costs and the clarification of certain examples. We are currently evaluating the method of adoption and the potential impact that Topic 606 may have on our financial position and results of operations. These ASUs are effective for entities for interim and annual reporting periods beginning after December 15, 2017, including interim periods within that year, which for us is the period beginning January 1, 2018. Early adoption is permitted any time after the original effective date, which for us was January 1, 2017. Entities have the choice to apply these ASUs either retrospectively to each reporting period presented or by recognizing the cumulative effect of applying these standards at the date of initial application and not adjusting comparative information. We have not yet selected a transition method and have initiated a revenue recognition task force to perform an assessment of our revenue contracts to determine what impact, if any, the adoption of ASU 2014-09 will have on our condensed consolidated financial statements.

S. SUBSEQUENT EVENTS

Endoceutics License Agreement

On April 3, 2017, we closed the license agreement (the “Endoceutics License Agreement”) with Endoceutics, Inc. (“Endoceutics”), which we entered into on February 13, 2017, pursuant to which Endoceutics has agreed to grant to us rights to Intrarosa, an FDA-approved product for the treatment of moderate-to-severe dyspareunia (pain during sexual intercourse), a symptom of VVA due to menopause. The Endoceutics License Agreement grants us the right to develop and commercialize pharmaceutical products containing dehydroepiandrosterone (“DHEA”), including Intrarosa, at dosage strengths of 13 mg or less per dose and formulated for intravaginal delivery, excluding any dosage strengths over 13 mg per dose and combinations with other active pharmaceutical ingredients, in the U.S. for the treatment of VVA and female sexual dysfunction (“FSD”). We will account for the Endoceutics License Agreement as an asset acquisition as a result of our early adoption of ASU No. 2017-01, described above.

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

We will have the exclusive right to commercialize Intrarosa for the treatment of VVA or FSD in the U.S., subject to the terms of the Endoceutics License Agreement, including having final decision making authority with respect to commercial strategy, pricing and reimbursement and other commercialization matters. We have agreed to use commercially reasonable efforts to market, promote and otherwise commercialize Intrarosa for the treatment of VVA or FSD in the U.S., including a commitment to a minimum marketing spend for Intrarosa in 2017. Endoceutics has the right to directly conduct, itself or through its affiliates or subcontractors, additional commercialization activities for Intrarosa for the treatment of VVA or FSD in the U.S., which scope of activities will be agreed to by the parties acting reasonably and in good faith, and has the right to conduct activities related generally to the field of intracrinology, in each case, subject to our right to withhold approval in certain instances.

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Upon the closing of the Endoceutics License Agreement, we made an upfront payment of \$50.0 million and issued 600,000 shares of unregistered common stock to Endoceutics, 300,000 of which are subject to a 180-day lock-up provision, and the other 300,000 of which are subject to a one-year lock-up provision. We have also agreed to make a payment to Endoceutics of up to \$10.0 million upon the delivery of launch quantities of Intrarosa and a payment of \$10.0 million on the first anniversary of the closing. In addition, we have also agreed to pay tiered royalties to Endoceutics equal to a percentage of net sales of Intrarosa in the U.S. ranging from mid-teens (for calendar year net sales up to \$150.0 million to mid twenty percent (for any calendar year net sales that exceed \$1 billion) (such royalty rate to be dependent on the aggregate annual net sales of Intrarosa) for the commercial life of Intrarosa, with deductions (a) after the later of (i) the expiration date of the last to expire of a licensed patent containing a valid patent claim or (ii) ten years after the first commercial sale of Intrarosa for the treatment of VVA or FSD in the U.S., (b) for generic competition and (c) for third party payments. Endoceutics is also eligible to receive certain sales milestone payments, including a first sales milestone payment of \$15.0 million, which would be triggered when Intrarosa annual net U.S. sales exceed \$150.0 million, and a second milestone payment of \$30.0 million, which would be triggered when annual net U.S. sales exceed \$300.0 million. If annual net U.S. sales exceed \$500.0 million, there are additional sales milestone payments totaling up to \$850.0 million, which would be triggered at various increasing sales thresholds.

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

Under the Endoceutics License Agreement, except as permitted under the Endoceutics License Agreement or the Supply Agreement, and except for any compounds or products affecting the melanocortin receptor pathway, including without limitation, bremelanotide (collectively, “Excluded Product”), we will not be permitted to research, develop, manufacture, or commercialize (i) DHEA for delivery by any route of administration anywhere in world, (ii) any compound (including DHEA) or product for use in VVA anywhere in the world, or (iii) commencing on the date of an approval of Intrarosa for the treatment of FSD in the U.S. and continuing for the remainder of the term of the Endoceutics License Agreement, any compound (including DHEA) for use in FSD (each, a “Competing Product”). Any compound or product for use in FSD that would be a Competing Product in the United States but that (i) does not contain DHEA and (ii) was acquired or licensed or for which the research, development, manufacture or commercialization of such compound or product is initiated by us or our affiliates, in each case, prior to the date of an approval of Intrarosa for the treatment of FSD in the U.S., will be an Excluded Product and will not be subject to the exclusivity obligations under the Endoceutics License Agreement in the treatment of FSD, subject to certain restrictions in the Endoceutics License Agreement. These noncompete restrictions are subject to certain exclusions relating to the acquisition of competing programs.

The Endoceutics License Agreement expires on the date of expiration of all royalty obligations due thereunder unless earlier terminated in accordance with the Endoceutics License Agreement. The Endoceutics License Agreement may be terminated by either Party for material breach that is either uncured after a 90-day notice period, or if such breach cannot be cured within such 90-day period, if the breaching party does not commence appropriate and material actions to cure such breach within the notice period and continue to diligently cure such breach for a period not to exceed 90

days, in either case, subject to tolling or determination of the arbitrators, if dispute resolution procedures are initiated within 30 days of the termination notice. We have the ability to elect not to terminate the Endoceutics License Agreement in the case of a material breach, in which case future milestone and royalty payments owed to Endoceutics would be reduced by a negotiated percentage or by an amount determined by arbitration. Either party may terminate under certain situations relating to the bankruptcy or insolvency of the other party. We may terminate the Endoceutics License Agreement for a valid business reason upon 365 days prior written notice to Endoceutics; or upon 60 days written notice in the event we reasonably determine in good faith, after due inquiry and after discussions with Endoceutics, that we cannot reasonably continue to develop or commercialize any Product as a result of a safety issue regarding the use of Intrarosa. We may also terminate the Endoceutics License Agreement upon 180 days notice if there is a change of control of AMAG and the acquiring entity (alone or with its affiliates) is engaged in a competing program (as defined in the Licensed Agreement) in the U.S. or in at least three countries within the European Union.

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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, 2016 (our "Annual Report").

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

Examples of forward-looking statements contained in this report include, without limitation, statements regarding the following: plans to continue to expand the impact of our current and future products and services for patients by delivering on our growth strategy; our expectation that we will launch Intrarosa in mid-2017; expectations regarding the timing of completion of the Palatin extension study in the second half of 2017 and the submission of an NDA for brexelanotide in early 2018; expectations that Velo will begin a Phase 2b/3a study in the second quarter of 2017; anticipated clinical, developmental, regulatory and other undertakings and cooperation efforts by our licensing parties; plans for the advancement of our next-generation development program for Makena, including anticipated FDA review timeline of the Makena auto-injector sNDA filing; expectations for our pursuit of the broader indication for Feraheme, including the expected timing of our sNDA submission; expectations as to the impacts of recent regulatory developments on our business and competition; expectations regarding our intellectual property, including patent protection and related litigation, and the impact generic and other competition could have on our business; beliefs regarding the intellectual property of our licensing and collaboration partners, and our rights to such property; the market opportunities for each of our products and services; plans regarding our sales and marketing initiatives, including our contracting and discounting strategy and efforts to increase patient compliance and continue educational programs for patients and physicians; our expectations that Makena sales and market share will increase for the remainder of 2017 as a result of the availability of the single-dose formulation, broader reimbursement, improved patient compliance and continued educational programs; our belief that the IV iron market will continue to grow and in turn increase Feraheme sales for the remainder of 2017; beliefs that our efforts to increase new enrollments for the CBR Services will increase services revenues for the remainder of 2017; the impact of our license and collaboration agreements on our results of operations; our expectation of costs to be incurred in connection with, and revenue sources to fund, our future operations; our expectations regarding the contribution of revenues from our products or services to the funding of our ongoing operations; expectations regarding the manufacture of all drug substance, drug products and key materials at our third-party manufacturers or suppliers; our expectations regarding customer returns and other revenue-related reserves and accruals; estimates regarding our effective tax rate and our ability to realize our net operating loss carryforwards and other tax attributes; the impact of accounting pronouncements; expected increases in research and development expenses, including as a result of the addition of our newly licensed products, and the timing of our planned research and development projects; plans to expand our commercial team and the impact on our business in connection with such efforts; 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 and the impact of our operations on our cash, cash equivalents and investments balances; our belief that our cash, cash equivalents and investments as of March 31, 2017, and the cash we currently expect to receive, will be sufficient to satisfy our cash flow needs for the foreseeable future; estimates and beliefs related to our debt, including our 2023 Senior Notes, Convertible Notes and the 2015 Term Loan Facility; the impact of volume-based and other rebates and incentives; the valuation of certain intangible assets, goodwill, contingent consideration, debt and other assets and liabilities, including our methodology and

assumptions regarding fair value measurements; the manner in which we intend or are required to settle the conversion of our Convertible Notes; and our expectations for our cash, revenue, cash equivalents, investments balances, capital needs and information with respect to any other plans and strategies for our business. Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements.

Any forward-looking statement should be considered in light of the factors discussed in Part II, Item 1A below under “Risk Factors” in this Quarterly Report on Form 10-Q and in Part I, Item 1A in our Annual Report. We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the U.S. Securities and Exchange Commission, to publicly update or revise any such statements to reflect any change in company expectations or in events, conditions or circumstances 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 are a biopharmaceutical company focused on developing and delivering important therapeutics, conducting clinical research in areas of unmet need and creating education and support programs for the patients and families we serve. Our currently marketed products support the health of patients in the areas of women's and maternal health, anemia management and cancer supportive care, including Makena® (hydroxyprogesterone caproate injection), Feraheme® (ferumoxytol) for intravenous ("IV") use and MuGard® Mucoadhesive Oral Wound Rinse. Through services related to the preservation of umbilical cord blood stem cell and cord tissue units (the "CBR Services") operated through Cord Blood Registry ("CBR"), we also help families to preserve newborn stem cells, which are used today in transplant medicine for certain cancers and blood, immune and metabolic disorders, and which we believe have the potential to play a valuable role in the ongoing development of regenerative medicine. In addition, in February 2017, we acquired the rights to research, develop and commercializebremelanotide in North America, which is being developed for the treatment of hypoactive sexual desire disorder ("HSDD") in pre-menopausal women, and in April 2017, we acquired the rights to market Intrarosa™ (prasterone) in the U.S. for the treatment of moderate-to-severe dyspareunia, a common symptom of vulvar and vaginal atrophy ("VVA"), due to menopause.

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

AMAG's Portfolio of Products, Product Candidates and Services

Makena is the only FDA-approved drug indicated to reduce the risk of preterm birth in women pregnant with a single baby who have a history of singleton spontaneous preterm birth. We acquired the rights to Makena in connection with our acquisition of Lumara Health Inc. ("Lumara Health") in November 2014. Makena was approved by the U.S. Food and Drug Administration (the "FDA") in February 2011 and granted orphan drug exclusivity through February 3, 2018. We sell Makena primarily to specialty pharmacies, specialty distributors, home infusion companies and pharmacies which, in turn, sell Makena to healthcare providers, hospitals, government agencies and integrated delivery systems.

CBR is the largest private newborn stem cell bank in the world and offers pregnant women and their families the ability to preserve their newborns' umbilical cord blood and cord tissue for potential future use. We market and sell the CBR Services directly to consumers, who pay for the services directly, as third-party insurance and reimbursement are not available.

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

In April 2017, we acquired the rights from Endoceutics, Inc. ("Endoceutics") to develop and commercialize certain pharmaceutical products containing dehydroepiandrosterone ("DHEA"), including Intrarosa, in the U.S. for the treatment of VVA and female sexual dysfunction ("FSD"). Intrarosa was approved by the FDA in November 2016 for the treatment of moderate-to-severe dyspareunia, a common symptom of VVA, due to menopause. In addition, Endoceutics has agreed to conduct clinical studies for the use of Intrarosa in FSD to support an application for regulatory approval for Intrarosa for the treatment of FSD in the U.S. We and Endoceutics have agreed to share the direct costs related to such studies based upon a negotiated allocation with us funding up to \$20.0 million. We expect to launch Intrarosa in mid-2017. Additional details regarding the Endoceutics License Agreement can be found in

Note S, “Subsequent Events,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

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In February 2017, we acquired the rights from Palatin Technologies, Inc. (“Palatin”) to research, develop and commercializebremelanotide, which is being developed for the on-demand treatment of HSDD in pre-menopausal women. Bremelanotide is designed to be an on-demand therapy given prior to anticipated sexual activity and is self-administrated by the patient in the thigh or abdomen via a single-use subcutaneous auto-injector. Two recently completed Phase 3 bremelanotide studies conducted by Palatin for the treatment of HSDD in pre-menopausal women met the pre-specified co-primary efficacy endpoints of median improvement in desire and decrease in distress associated with low sexual desire as measured using validated patient-reported outcome instruments. Women in the trials had the option, after completion of the randomized trial, to continue in an ongoing open-label safety extension study for an additional 52 weeks, which is intended to gather additional data on the safety of long-term and repeated use of bremelanotide. Nearly 80% of patients who completed the randomized portion of the study elected to remain in the ongoing open-label portion of the study. All of the patients in the extension study are receiving bremelanotide. Palatin is continuing to oversee the conduct of the extension study, which we expect to be completed in the second half of 2017. We currently expect to submit an NDA in early 2018 following completion of multiple pharmacokinetic (“PK”) and safety pharmacology studies, including an abuse-liability study and drug-to-drug interaction studies with anti-hypertensive and anti-arrhythmic therapies, as well as certain chemistry, manufacturing and controls (“CMC”) activities, including drug product process validation studies. Palatin will continue to conduct the remaining studies through clinical research organizations, and we will oversee such development work to support our filing of an NDA for bremelanotide for the treatment of HSDD. Previously we referred to bremelanotide by the trade name Rekynda™. The FDA did not accept the product name Rekynda and we expect to pursue an alternative product name for bremelanotide. Additional details regarding the license with Palatin (the “Palatin License Agreement”) can be found in Note O, “Collaboration, License and Other Strategic Agreements,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

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

In June 2013, we entered into a license agreement with Abeona Therapeutics, Inc., under which we acquired the U.S. commercial rights to MuGard for the management of oral mucositis and stomatitis.

Makena Developments

We continue to advance our next-generation development program for Makena, seeking to enhance the product profile for patients and their healthcare providers. As part of this program, we are developing an auto-injector device for subcutaneous administration of Makena (the “Makena auto-injector”), including CMC development with Antares Pharma, Inc. In October 2016, we initiated an open label parallel study which enrolled approximately 120 healthy post-menopausal women in a 1:1 randomization. In February 2017, we announced topline results from this definitive PK study. Makena administered subcutaneously demonstrated bioequivalence to the IM injection on area under the curve (“AUC”) (AUC_{0-12h} 2,386 ng/mL compared to 2,086 ng/mL) with the 90% confidence interval for the ratio of AUC (105.17 to 124.39) falling within the 80% to 125% range, which the FDA uses to define bioequivalence. The mean maximum or peak plasma concentration (“C_{max}”) for Makena administered subcutaneously was slightly higher than for the IM (7.3 ng/mL compared to 6.3 ng/mL) with the 90% confidence interval for the ratio of C_{max} (96.6% to 138.7%) falling outside of the bioequivalence range of 80% to 125%. No serious adverse events were reported and the drug was generally well tolerated, although there was a higher reporting rate of injection site related adverse events

(e.g. transient burning/stinging sensation), in the subcutaneous injection arm of the study. In April 2017, we filed an sNDA with the FDA for the Makena subcutaneous auto-injector and anticipate a six-month FDA review time.

Feraheme Developments

In pursuit of a broader indication for Feraheme to include the treatment of IDA in adult patients who had failed or could not tolerate oral iron or in whom oral iron was contraindicated, we conducted a new head-to-head Phase 3 clinical trial in 2016 evaluating Feraheme in adults with IDA, excluding patients on hemodialysis. This trial was a randomized, double-blind multicenter non-inferiority trial that evaluated the incidence of moderate-to-severe hypersensitivity reactions (including anaphylaxis) and moderate-to-severe hypotension with Feraheme compared to Injectafer®(ferric carboxymaltose infusion). Approximately two thousand patients were 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 Injectafer® IV infusion.

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In May 2017, we announced positive topline data from this trial, which demonstrated that Feraheme met the study's primary composite endpoint demonstrating non-inferiority ("NI") to Injectafer® (based on an NI margin of 2.64%) with respect to the percentage of patients who experienced moderate-to-severe hypersensitivity reactions (including anaphylaxis) and/or moderate-to-severe hypotension (Feraheme: 0.6%; Injectafer®: 0.7%; treatment difference: -0.1%; 95% confidence interval: -0.80% to +0.61%; NI p=<0.0001). Feraheme also demonstrated non-inferiority to Injectafer® (based on an NI margin of 3.6%) for a secondary composite safety endpoint assessing incidence of moderate-to-severe hypersensitivity reactions (including anaphylaxis), serious cardiovascular events and death (Feraheme: 1.3%; Injectafer®: 2.0%; treatment difference: -0.7%; 95% confidence interval: -1.81% to +0.42%; NI p=<0.0001). With regards to secondary composite efficacy endpoints, Feraheme demonstrated superiority to Injectafer® in mean increase from baseline to week 5 in hemoglobin per gram of iron administered (Feraheme: 1.36 g/dL per gram of iron; Injectafer®: 1.09 g/dL per gram of iron; treatment difference: 0.27 g/dL per gram of iron; 95% confidence interval: +0.17 g/dL per gram of iron to +0.36 g/dL per gram of iron; superiority p-value =<0.0001). Feraheme also successfully demonstrated non-inferiority to Injectafer® (based on an NI margin of 0.5 g/dL) comparing mean improvement in hemoglobin from baseline to week 5 (Feraheme: 1.38 g/dL; Injectafer®: 1.62 g/dL; treatment difference: -0.24 g/dL; 95% confidence interval: -0.35 g/dL to -0.12 g/dL; NI p=<0.0001). The study also showed a markedly greater incidence of hypophosphatemia (defined by blood phosphorous of <0.6 mmol/L from baseline to week 2), an exploratory endpoint, in the patients dosed with Injectafer® versus those dosed with Feraheme (Feraheme: 0.4% of patients; Injectafer®: 38.6% of patients; treatment difference: 38.2%; 95% confidence interval: -41.31% to -35.06%; superiority p-value =<0.0001). We expect to file an sNDA for this broader indication in mid-2017.

Results of Operations - Three Months Ended March 31, 2017 and 2016

Revenues

Total revenues for the three months ended March 31, 2017 and 2016 consisted of the following (in thousands except for percentages):

	Three Months Ended March 31,		2017 to 2016		
	2017	2016	\$ Change	% Change	
Product sales, net					
Makena	\$86,455	\$65,032	\$21,423	33	%
Feraheme	25,922	24,195	1,727	7	%
MuGard	140	337	(197)	(58)	%
Total	112,517	89,564	22,953	26	%
Service revenues, net	26,931	19,520	7,411	38	%
License fee, collaboration and other revenues	24	216	(192)	(89)	%
Total Revenues	\$139,472	\$109,300	\$30,172	28	%

Our total revenues for the three months ended March 31, 2017 increased by \$30.2 million as compared to the same period in 2016, primarily as the result of a \$21.4 million increase in our net Makena sales and a \$7.4 million increase of CBR Services revenue.

Product Sales

Total gross product sales were offset by product sales allowances and accruals for the three months ended March 31, 2017 and 2016 as follows (in thousands except for percentages):

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	Three Months Ended March 31,						2017 to 2016			
	2017	Percent of gross product sales			2016	Percent of gross product sales		\$ Change	% Change	
Gross product sales	\$206,724				\$152,192			\$54,532	36	%
Provision for product sales allowances and accruals:										
Contractual adjustments	69,829	34	%		45,581	30	%			
Governmental rebates	24,378	12	%		17,047	11	%			
Total	94,207	46	%		62,628	41	%			
Product sales, net	\$112,517				\$89,564			\$22,953	26	%

We expect gross product sales to increase for the remainder of 2017 primarily based on increased units sold of our currently marketed products and the addition of Intrarosa sales following its anticipated launch in mid-2017.

Gross product sales increased by \$54.5 million, or approximately 36%, during the three months ended March 31, 2017 as compared to the same period in 2016 primarily due to increases of \$44.7 million and \$10.3 million of Makena and Feraheme gross sales for the three months ended March 31, 2017 as compared to the same period in 2016. The \$44.7 million increase in gross Makena sales was due to increased volume sold. Of the \$10.3 million increase in gross Feraheme sales, \$6.3 million was due to price increases and \$4.0 million was due to increased volume sold. This total increase in gross product sales was partially offset by \$31.6 million of additional allowances and accruals for the three months ended March 31, 2017 as compared to the same period in 2016.

Net product sales increased by \$23.0 million, or approximately 26%, during the three months ended March 31, 2017 as compared to the same period in 2016 primarily due a \$21.4 million increase in net Makena sales and a \$1.7 million increase in net Feraheme sales. We anticipate that net sales of Makena will continue to increase for the remainder of 2017 as compared to the first quarter of 2017 as we continue to gain market share from compounded product due to the availability of the single-dose, preservative-free formulation of Makena, which was approved in February 2016. We anticipate that we will also continue to gain market share through broader reimbursement of Makena, improved patient compliance and continued educational programs for patients and physicians regarding treatment with Makena. We anticipate that sales of Feraheme will increase for the remainder of 2017 as compared to the first quarter of 2017 due primarily to our expectation of continued growth of the IV iron market.

Product Sales Allowances and Accruals

We recognize product sales net of certain allowances and accruals in our condensed consolidated statement of operations at the time of sale. Our contractual adjustments include provisions for returns, pricing and prompt payment discounts, as well as wholesaler distribution fees, rebates to hospitals that qualify for 340B pricing, and volume-based and other commercial rebates. Governmental rebates relate to our reimbursement arrangements with state Medicaid programs. The increases in contractual adjustments and governmental rebates as a percentage of gross product sales primarily related to higher than expected costs associated with our co-pay assistance program, distribution fees and commercial rebates. We expect these costs to decrease as a percentage of sales in the remaining quarters of 2017 as our overall net pricing returns to more closely approximated historical levels.

We did not materially adjust our product sales allowances and accruals during the three months ended March 31, 2017 or 2016. 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 \$7.4 million increase in service revenues recorded in the three months ended March 31, 2017 as compared to the same period in 2016 primarily due to a higher purchase accounting adjustment to the CBR deferred revenue balance in the first quarter of 2016 as compared to first quarter of 2017. We expect service revenues to increase for the remainder of 2017 as compared to the first quarter of 2017 due to continued efforts to increase new enrollments of cord blood and cord tissue units in our storage facility and recurring revenue from our growing base of stored units.

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Costs and Expenses

Cost of Product Sales

Cost of product sales for the three months ended March 31, 2017 and 2016 were as follows (in thousands except for percentages):

	Three Months Ended March 31,		2017 to 2016	
	2017	2016	\$ Change	% Change
Cost of product sales	\$27,573	\$18,300	\$9,273	51 %
Percentage of net product sales	25 %	20 %		

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 product sales, the amortization of product-related intangible assets and the inventory step-up in connection with the November 2014 acquisition of Lumara Health. The \$9.3 million increase in our cost of product sales for the three months ended March 31, 2017 as compared to the same period in 2016 was primarily attributable to a \$7.4 million increase in amortization expense of the Makena product intangible asset and a \$1.9 million increase in production costs and overhead.

We expect our cost of product sales as a percentage of net product sales excluding any impact from the amortization of the Makena intangible asset and the amortization of inventory step-up of Makena inventory to continue to increase slightly for the remainder of 2017 as compared to the first quarter of 2017 primarily due to increased sales of the single-dose preservative-free formulation of Makena, which we began promoting to physicians in the second quarter of 2016, compared to sales of the multidose vial of Makena.

Cost of Services

Cost of services for the three months ended March 31, 2017 and 2016 were as follows (in thousands except for percentages):

	Three Months Ended March 31,		2017 to 2016	
	2017	2016	\$ Change	% Change
Cost of services	\$5,010	\$5,526	\$(516)	(9 %) %
Percentage of service revenues	19 %	28 %		

Cost of services includes the transportation of the umbilical cord blood stem cells and cord tissue from the hospital and direct material plus labor costs for processing, cryogenic storage and collection kit materials. The 9% decrease in cost of services recorded in the three months ended March 31, 2017 as compared to the same period in 2016 was primarily due to a higher purchase accounting adjustment to the CBR deferred revenue balance in the first quarter of 2016 as compared to first quarter of 2017.

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

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Research and Development Expenses

Research and development expenses for the three months ended March 31, 2017 and 2016 consisted of the following (in thousands except for percentages):

	Three Months Ended March 31,		2017 to 2016		
	2017	2016	\$ Change	% Change	
External research and development expenses					
Feraheme-related costs	\$2,492	\$5,891	\$(3,399)	(58)	%
Makena-related costs	4,365	3,608	757	21	%
Bremelanotide-related costs	4,369	—	4,369	N/A	
Other external costs	972	844	128	15	%
Total	12,198	10,343	1,855	18	%
Internal research and development expenses	4,291	3,886	405	10	%
Total research and development expenses	\$16,489	\$14,229	\$2,260	16	%

Total research and development expenses incurred in the three months ended March 31, 2017 increased by \$2.3 million, or 16%, as compared to the same period in 2016. The increase was primarily due to \$4.4 million that we accrued in connection with our obligation to reimburse Palatin for up to \$25.0 million in costs associated with filing the NDA for bremlanotide. These increases were partially offset by a decrease of \$3.4 million in spending for the Feraheme IDA trial, which was completed in December 2016.

We expect our research and development expenses, excluding the impact of one-time payments, to continue to increase during the remainder of 2017, consistent with our stated plan to invest in our expanding portfolio. We expect the primary areas of our increased investment to include clinical development, CMC preparation and regulatory filing costs associated with our plan to file an NDA for bremlanotide in early 2018 as well as additional studies that we may conduct to potentially expand the labels of Intrarosa and/or bremlanotide.

Research and Development Activities

We track our external costs on a major project basis, in most cases through the later of the completion of the last trial in the project or the last submission of a regulatory filing to the FDA. We do not track our internal costs by project since our research and development personnel work on a number of projects concurrently and much of these costs benefit multiple projects or our operations in general. The following major research and development projects were ongoing as of March 31, 2017:

Bremelanotide: Under the terms of the Palatin License Agreement we will reimburse Palatin up to an aggregate amount of \$25.0 million for all reasonable, documented, out-of-pocket expenses incurred by Palatin in connection with the development and regulatory activities necessary to submit an NDA in the U.S. for bremlanotide for the treatment of HSDD in pre-menopausal women. In addition, we expect to incur supply chain costs to support the ultimate commercialization of bremlanotide;

Makena: This project currently includes studies conducted as part of the post-approval commitments under the provisions of the FDA's "Subpart H" Accelerated Approval regulations including: (a) an ongoing efficacy and safety clinical study of Makena; (b) an ongoing follow-up study of the children born to mothers from the efficacy and safety clinical study; and (c) a completed PK trial of women taking Makena. In addition, this project includes studies conducted as part of our Makena auto-injector development program, including completion of the definitive PK study in support of the sNDA we filed with the FDA in April 2017;

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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 and (b) a completed global multi-center randomized clinical trial to determine the safety and efficacy of repeat doses of Feraheme as compared to iron sucrose for the treatment of IDA in patients with hemodialysis dependent CKD. This project also includes a pediatric program as part of our post-approval Pediatric Research Equity Act requirement to support pediatric CKD labeling of Feraheme, which we suspended in 2015 due to difficulty in enrollment. In December 2016, we met with the FDA to advance our development of a plan forward in order to satisfy this post-approval commitment for Feraheme and recently proposed a protocol to the FDA for a new pediatric study; and

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Feraheme to treat IDA regardless of the underlying cause: This project currently includes the randomized, double-blind multicenter non-inferiority trial evaluating the incidences of moderate-to-severe hypersensitivity reactions (including anaphylaxis) and moderate-to-severe hypotension with Feraheme compared to Injectafer® (ferric carboxymaltose infusion) in adults with IDA, which was completed in December 2016. We announced positive topline data in May 2017 and expect to file an sNDA for this broader indication in mid-2017.

From February 2, 2017 (the date of the Palatin License Agreement) through March 31, 2017, we have incurred aggregate external research and development expenses of approximately \$4.4 million related to our current program forbremelanotide, described above. We are finalizing our long-term development plans for this product as we evaluate possible label expansion opportunities that would require additional investment. We are therefore currently unable to estimate the total remaining external costs associated with this development project.

From November 12, 2014 (the date of the Lumara Health acquisition) through March 31, 2017, we have incurred aggregate external research and development expenses of approximately \$30.8 million related to our current program for Makena, described above. We currently estimate that the total remaining external costs associated with this development project, which relate solely to the Subpart H post-approval commitments, will be in the range of approximately \$8.1 million to \$12.5 million over the next several years.

Through March 31, 2017, we have incurred aggregate external research and development expenses of approximately \$41.8 million related to our current program for the development of Feraheme to treat IDA in CKD patients, described above. We currently estimate that the total remaining external costs associated with the new pediatric study will be in the range of approximately \$4.0 million to \$7.0 million over the next several years.

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. We began enrolling patients in the head-to-head trial in the first quarter of 2016 and have spent approximately \$30.1 million since the first quarter of 2016. We currently estimate that the total remaining external costs associated with this development project will be in the range of approximately \$3.5 million to \$5.5 million through mid-2017, the expected time of our sNDA submission to the FDA.

In-Process Research and Development

During the three months ended March 31, 2017, we recorded acquired in-process research and development (“IPR&D”) expense of \$60.0 million related to the one-time upfront payment under the terms of the Palatin License Agreement, which closed on February 2, 2017. The upfront payment made to Palatin was recorded as IPR&D expense as the product candidate has not received regulatory approval. We did not record any IPR&D expenses during the three months ended March 31, 2016.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended March 31, 2017 and 2016 consisted of the following (in thousands except for percentages):

	Three Months Ended March 31,					2017 to 2016
	2017	2016	\$ Change	% Change		%
Compensation, payroll taxes and benefits	\$21,694	\$20,760	\$934	4		%

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Professional, consulting and other outside services	38,864	29,137	9,727	33	%
Fair value of contingent consideration liability	1,043	5,056	(4,013)	(79)	%
Amortization expense related to customer relationship intangible	3,930	3,132	798	25	%
Equity-based compensation expense	4,893	5,090	(197)	(4)	%
Total selling, general and administrative expenses	\$70,424	\$63,175	\$7,249	11	%

Total selling, general and administrative expenses incurred in the three months ended March 31, 2017 increased by \$7.2 million, or approximately 11%, as compared to the same period in 2016 for the following reasons:

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\$10.6 million increase in sales and marketing, consulting, professional fees, and other expenses due to marketing and other activities related to Makena, CBR and Feraheme, partially offset by an \$0.8 million decrease in general and administrative, consulting, professional fees and other expenses; and

\$4.0 million decrease to the contingent consideration liability expense primarily as a result of the reduction in the remaining contingent consideration balance related to Makena following the \$100.0 million milestone payment made in 2016 and a revision of the expected timing for the next milestone payment.

We expect that total selling, general and administrative expenses will increase substantially for the remainder of 2017 as compared to the first quarter of 2017 due to increased costs associated with the planned launch of Intrarosa in mid-2017. These costs include the expansion of our commercial team, including plans to hire a new sales force of approximately 150 employees and certain marketing spend required to support a new product launch.

Restructuring Expenses

In connection with the August 2015 CBR acquisition and the November 2014 Lumara Health acquisition, we initiated restructuring programs, which included severance benefits related to former CBR and Lumara Health employees. We did not record any charges in the three months ended March 31, 2017 and recorded charges of approximately \$0.6 million in the three months ended March 31, 2016. All of the restructuring costs have been paid as of March 31, 2017.

Other Income (Expense)

Other expense for the three months ended March 31, 2017 decreased by \$0.3 million as compared to the same period in 2016 primarily as the result of increased interest and dividend income related to our investments.

We expect our net other income (expense) to remain relatively constant for the remainder of 2017 as compared to the first quarter of 2017.

Income Tax Benefit

The following table summarizes our effective tax rate and income tax benefit for the three months ended March 31, 2017 and 2016 (in thousands except for percentages):

	Three Months Ended			
	March 31,			
	2017		2016	
Effective tax rate	36	%	25	%
Income tax benefit	\$(20,706) \$(2,540)			

For the three months ended March 31, 2017, we recognized an income tax benefit of \$20.7 million, representing an effective tax rate of 36%. The difference between the expected statutory federal tax rate of 35% and the 36% effective tax rate for the three months ended March 31, 2017, was primarily attributable to the impact of state income taxes and the federal research and development tax credit, partially offset by non-deductible stock compensation and other non-deductible expenses.

For the three months ended March 31, 2016, we recognized an income tax benefit of \$2.5 million, representing an effective tax rate of 25%. The difference between the expected statutory federal tax rate of 35% and the 25% effective tax rate for the three months ended March 31, 2016, was primarily attributable to the impact of state income taxes, stock compensation, and federal research and development and orphan drug tax credits, partially offset by non-deductible contingent consideration expense associated with the Lumara Health acquisition.

Liquidity and Capital Resources

General

We currently finance our operations primarily from the sale of our products and services and cash generated from our investing and financing activities. We expect to continue to incur significant expenses as we continue to market, sell

and contract for the manufacture of Makena and Feraheme, market and sell the CBR Services, launch and commercialize Intrarosa, pursue the next-generation development program for Makena, and further develop and seek U.S. regulatory approval for Feraheme for the treatment of IDA in a broad range of patients and forbremelanotide for the treatment of HSDD. For a detailed

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

Cash, cash equivalents, investments and certain financial obligations as of March 31, 2017 and December 31, 2016 consisted of the following (in thousands except for percentages):

	March 31, 2017	December 31, 2016	\$ Change	% Change
Cash and cash equivalents	\$252,854	\$ 274,305	\$(21,451)	(8)%
Investments	305,541	304,781	760	—%
Total	\$558,395	\$ 579,086	\$(20,691)	(4)%
Outstanding principal on 2023 Senior Notes	\$500,000	\$ 500,000	\$—	—%
Outstanding principal on Convertible Notes	199,998	199,998	—	—%
Outstanding principal on 2015 Term Loan Facility	323,750	328,125	(4,375)	(1)%
Total	\$1,023,748	\$ 1,028,123	\$(4,375)	—%

The \$20.7 million decrease in cash, cash equivalents and investments as of March 31, 2017, as compared to December 31, 2016, was primarily due to the one-time \$60.0 million payment made to Palatin under the terms of the Palatin License Agreement in February 2017, expenditures to fund our operations, and service our debt, partially offset by cash flows from our operations during the first quarter of 2017.

We expect that our cash, cash equivalents and investments balances will decrease for the remainder of 2017 primarily as a result of the upfront payment due in connection with the Endoceutics License Agreement, milestone payments and other commitments related to our license and collaboration agreements, partially offset by our operating profits. Our expectation takes into consideration our commitments under these license agreements and assumes our continued investment in the development and commercialization of our products and services, including: the \$50.0 million upfront payment made to Endoceutics upon the close of the transaction in April 2017, \$10.0 million to be paid to Endoceutics for commercial supply of Intrarosa in preparation for its 2017 launch, as well as clinical development and regulatory costs associated with our obligations under the Palatin License Agreement and the related anticipated increase in expenses in our regulatory and clinical functions, supply chain costs to support the ultimate commercialization of bremelanotide, significant costs associated with our new women's health commercial team and certain marketing commitments to support the commercialization of Intrarosa and a potential \$100.0 million milestone payment expected to be paid in the fourth quarter of 2017 to the former Lumara Health security holders based on the achievement of a net sales milestone of Makena. We believe that our cash, cash equivalents and investments as of March 31, 2017, and the cash we currently expect to generate from our operations and earnings on our investments, will be sufficient to satisfy our cash flow needs for the foreseeable future.

Borrowings and Other Liabilities

In August 2015, in connection with the CBR acquisition, we completed a private placement of \$500.0 million aggregate principal amount of 7.875% Senior Notes due 2023 (the "2023 Senior Notes") and entered into a credit agreement with a group of lenders, including Jefferies Finance LLC, who acted as administrative and collateral agent, that provided us with, among other things, a six-year \$350.0 million term loan facility (the "2015 Term Loan Facility"). The 2023 Senior Notes, which are senior unsecured obligations, will mature on September 1, 2023 and will bear interest at a rate of 7.875% per year, with interest payable semi-annually on September 1 and March 1 of each year, beginning on March 1, 2016. We borrowed the full \$350.0 million available under the 2015 Term Loan Facility in August 2015. In addition, the 2015 Term Loan Facility includes an annual mandatory prepayment of the debt in an amount equal to 50% of our excess cash flow (as defined in the 2015 Term Loan Facility) as measured on an annual basis, beginning with the year ended December 31, 2016. As a result, as of March 31, 2017, \$3.0 million was reclassified from long-term debt to current portion of long-term debt in our condensed consolidated balance sheet and paid in April 2017. On or after December 31, 2016, the applicable excess cash flow percentage shall be reduced based

on the total net leverage ratio as of the last day of the period. For additional information, see Note P, “Debt,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

In February 2014, we issued \$200.0 million aggregate principal amount of 2.5% convertible senior notes due February 15, 2019 (the “Convertible Notes”), as discussed in more detail in Note P, “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

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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 fourth quarter of 2016, the Convertible Notes were not convertible as of March 31, 2017.

Share Repurchase Program

In January 2016, we announced that our board of directors had authorized a program to repurchase up to \$60.0 million in shares of our common stock. The repurchase program does not have an expiration date and may be suspended for periods or discontinued at any time. Under the program, we may purchase our stock from time to time at the discretion of management in the open market or in privately negotiated transactions. The number of shares repurchased and the timing of the purchases will depend on a number of factors, including share price, trading volume and general market conditions, along with working capital requirements, general business conditions and other factors. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate purchases of our shares under this program. As of March 31, 2017, we repurchased and retired 831,744 shares of common stock, respectively, under this repurchase program for \$20.0 million at an average purchase price of \$24.05 per share. We did not repurchase any of our common stock during the first quarter of 2017.

Cash flows from operating activities

Net cash used in operating activities for the three months ended March 31, 2017 was \$14.5 million as compared to cash provided by operating activities of \$26.6 million for the same period in 2016. The decrease in net cash provided by operating activities was primarily due to a decrease in net income of approximately \$29.0 million, partially offset by an increase in accounts receivable of \$5.8 million and the net increase in CBR deferred revenues of \$7.7 million. We expect to generate cash from operations as we continue to grow our business, partially offset by increased expenditures to support our growth.

Cash flows from investing activities

Net cash used in investing activities in the three months ended March 31, 2017 was \$1.3 million as compared to \$38.6 million for the same period in 2016. Cash used in investing activities decreased during the three months ended March 31, 2017 by \$37.3 million, which primarily reflects net cash used for the purchase and sale of our investments.

Cash flows from financing activities

Net cash used in financing activities in the three months ended March 31, 2017 was \$5.6 million as compared to \$13.3 million for the same period in 2016. Cash used in financing activities decreased during the three months ended March 31, 2017 as compared to the same period in 2016 primarily due to \$7.6 million of cash used to repurchase shares of our common stock under our share repurchase program during 2016.

Off-Balance Sheet Arrangements

As of March 31, 2017, we did not have any off-balance sheet arrangements as defined in Regulation S-K, Item 303(a)(4)(ii).

Impact of Recently Issued and Proposed Accounting Pronouncements

See Note R, “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,

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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 March 31, 2017 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings:

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

Item 1A. Risk Factors:

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

Bremelanotide is not approved for sale by the FDA and we cannot guarantee that bremelanotide will receive regulatory approval on a timely basis, or at all, or that such approval, if obtained, will not contain restrictions that the FDA may impose on the use or distribution of bremelanotide.

In January 2017, we entered into the Palatin License Agreement under which we acquired an exclusive license from Palatin to research, develop and commercialize bremelanotide in North America. Palatin recently completed two Phase 3 clinical trials to treat HSDD in pre-menopausal women. The trials consisted of double-blind placebo-controlled, randomized parallel group studies comparing a subcutaneous dose of 1.75 mg bremelanotide versus placebo, in each case, delivered via an auto-injector. In both clinical trials, bremelanotide met the pre-specified co-primary efficacy endpoints of median improvement in desire and decrease in distress associated with low sexual desire as measured using validated patient-reported outcome instruments; however, the change in the number of satisfying sexual events, a key secondary endpoint, was not significantly different from placebo in either clinical trial. The most frequent adverse events were nausea, flushing and headache, which were generally mild-to-moderate in severity. Approximately 18% of patients discontinued participation in the bremelanotide arm due to adverse events in both studies. Palatin is conducting multiple PK and safety pharmacology studies, including an abuse-liability study and drug-drug interaction studies with anti-hypertensive and anti-arrhythmic therapies, as well as certain chemistry, manufacturing and controls activities, including drug product process validation studies to support the NDA for bremelanotide for the treatment of HSDD. We currently expect to submit the bremelanotide NDA in early 2018, subject to the successful and timely completion of the ongoing studies and activities.

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

The FDA may determine that bremelanotide does not demonstrate safety and efficacy in accordance with regulatory agency standards based on the results of the Phase 3 trial, including the co-primary and secondary endpoints and safety results;

The FDA may determine that the magnitude of efficacy demonstrated in the bremelanotide studies does not amount to a clinically meaningful benefit to pre-menopausal women with HSDD and thus that the product cannot be approved despite statically significant efficacy results;

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The FDA could analyze and/or interpret data from pre-clinical testing and clinical trials in different ways than we or Palatin interpret it, such as the calculation of effect size in our Phase 3 studies or the sufficiency of data to determine the timing of onset and the dosing of the product;

The initiation, conduct or results of the remaining drug interaction, safety pharmacology and other ancillary studies may be delayed or unsuccessful;

The auto-injector device, supplied by an unaffiliated third party, that we plan to use to administer bremelanotide may not be adequate or may not be approved by the FDA;

Palatin or we may be unable to establish, and obtain FDA approval for, a commercially viable manufacturing process for bremelanotide in a timely manner, or at all;

Adverse medical events reported during the trials, including increases in blood pressure noted in prior clinical trials and a serious adverse event of hepatitis of unknown etiology;

The failure of clinical investigational sites and the records kept at such sites, including the clinical trial data, to be in compliance with the FDA's GCP, including the failure to pass FDA inspections of clinical trial sites; and

The FDA may change their approval policies or adopt new regulations.

Any delay in obtaining regulatory approval for bremelanotide could adversely affect our ability to successfully commercialize such product. In addition, share prices have declined significantly in certain instances where companies have failed to obtain FDA approval of a product or where the timing of FDA approval is delayed. If the remaining drug interaction, safety pharmacology or other ancillary studies or the FDA's response to any application for approval are delayed or not favorable for bremelanotide, or if we are required to conduct additional studies, our share price could decline significantly. In such circumstances, Palatin's share price could also decline and Palatin may be unable to perform its obligations under the Palatin License Agreement.

Even if regulatory approval to market bremelanotide is granted by the FDA, the approval may impose limitations on the indicated use for which the drug product may be marketed and additional post-approval requirements with which we and Palatin would need to comply in order to maintain bremelanotide's approval. For example, demonstration of clinically important drug-drug interactions in the ongoing studies may reduce the population for which bremelanotide may be approved. In addition, unexpected adverse findings in the safety pharmacology studies may cause FDA to impose restrictions on the distribution of bremelanotide, which may limit its commercial potential. Similarly, chemistry, manufacturing and control efforts for the drug product are still ongoing, and based on the results of those efforts, including stability studies, FDA approval may require that the product be kept refrigerated in the supply chain prior to being dispensed to the patient, in order to lengthen the shelf life, which could affect the cost of goods, or the market acceptance of the product. Our business could be seriously harmed if we and/or Palatin do not complete any post-approval requirements and the FDA, as a result, requires us to change sections of the labeling.

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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 March 31, 2017.

Period	Total Number of Shares Purchased(1)	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (2)	Maximum Number of Shares (or approximate dollar value) That May Yet Be Purchased Under the Plans or Programs (2)
January 1, 2017 through January 31, 2017	949	\$ 34.80	—	1,659,751
February 1, 2017 through February 28, 2017	38,386	23.74	—	1,781,737
March 1, 2017 through March 31, 2017	16,203	23.27	—	1,773,836
Total	55,538	\$ 23.79	—	

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

- (2) We did not repurchase any of our common stock during the first quarter of 2017. We have repurchased and retired \$20.0 million of our common stock under the share repurchase program through March 31, 2017. These shares were purchased pursuant to a repurchase program authorized by our board of directors that was announced in January 2016 to repurchase up to \$60.0 million of our common stock, of which \$40.0 million remains outstanding as of March 31, 2017. The repurchase program does not have an expiration date and may be suspended for periods or discontinued at any time.

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Item 6. Exhibits:

Exhibit Number	Description
10.1	License Agreement, by and between AMAG Pharmaceuticals, Inc. and Palatin Technologies, Inc., dated January 8, 2017 (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 3, 2017, File No. 001-10865) (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	License Agreement, by and between AMAG Pharmaceuticals, Inc. and Endoceutics, Inc., dated February 13, 2017 (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 5, 2017, File No. 001-10865) (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)
10.3	Manufacturing and Supply Agreement, by and between AMAG Pharmaceuticals, Inc. and Endoceutics, Inc., dated April 5, 2017 (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed April 5, 2017, File No. 001-10865) (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)
10.4+	AMAG Pharmaceuticals, Inc. Long-Term Incentive Plan (included as Exhibit A to the Form of Award Notice under the AMAG Pharmaceuticals, Inc. Long-term Incentive Plan filed as Exhibit 10.5 to this Quarterly Report on Form 10-Q)
10.5+	Form of Award Notice under the AMAG Pharmaceuticals, Inc. Long-term Incentive Plan
10.6+	AMAG Pharmaceuticals, Inc.'s Non-Employee Director Compensation Policy
31.1+	Certification Pursuant to Rule 13a 14(a)/15d 14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2+	Certification Pursuant to Rule 13a 14(a)/15d 14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS+	XBRL Instance Document
101.SCH+	XBRL Taxonomy Extension Schema Document
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+	XBRL Taxonomy Extension Label Linkbase Document
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document

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

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

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SIGNATURES

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

AMAG
PHARMACEUTICALS, INC.

By: /s/ William
K. Heiden
William K.
Heiden
President
and Chief
Executive
Officer
(Principal
Executive
Officer)

Date: May 3,
2017

AMAG
PHARMACEUTICALS, INC.

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

Date: May 3,
2017

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