AMAG PHARMACEUTICALS INC.
Form 10-Q
November 06, 2017

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

FORM 10-Q
(Mark
One)

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

For the quarterly period ended September 30, 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 Incorporation or Organization)	(I.R.S. Employer Identification No.)
1100 Winter Street Waltham, Massachusetts (Address of Principal Executive Offices)	02451 (Zip Code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 October 31, 2017, there were 35,374,341 shares of the registrant's Common Stock, par value $0.01 per share, outstanding.

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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements:
AMAG PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)
(Unaudited)

	September 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$257,914	$274,305
Investments	136,186	304,781
Accounts receivable, net	97,762	92,375
Inventories	36,543	37,258
Prepaid and other current assets	11,430	9,839
Total current assets	539,835	718,558
Property, plant and equipment, net	24,833	24,460
Goodwill	639,484	639,484
Intangible assets, net	769,160	1,092,178
Restricted cash	2,653	2,593
Other long-term assets	801	1,153
Total assets	$1,976,766	$2,478,426
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$8,511	$3,684
Accrued expenses	190,457	156,008
Current portion of long-term debt	—	21,166
Current portion of acquisition-related contingent consideration	99,106	97,068
Deferred revenues	41,623	34,951
Total current liabilities	339,697	312,877
Long-term liabilities:		
Long-term debt, net	490,518	785,992
Convertible notes, net	264,899	179,363
Acquisition-related contingent consideration	1,582	50,927
Deferred tax liabilities	55,800	197,066
Deferred revenues	22,312	14,850
Other long-term liabilities	1,651	2,962
Total liabilities	1,176,459	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; 35,369,141 and 34,336,147 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	354	343
Additional paid-in capital	1,284,867	1,238,031
Accumulated other comprehensive loss	(3,637)	(3,838)
Accumulated deficit	(481,277)	(300,147)
Total stockholders' equity	800,307	934,389
Total liabilities and stockholders' equity	$1,976,766	$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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues:				
Product sales, net	$124,331	$115,777	$367,190	$308,324
Service revenues, net	29,410	27,965	84,365	71,863
License fee, collaboration and other revenues	—	40	53	313
Total revenues	153,741	143,782	451,608	380,500
Costs and expenses:				
Cost of product sales	31,085	25,706	90,761	65,942
Cost of services	5,559	4,984	16,130	15,705
Research and development expenses	16,274	17,116	63,021	45,579
Acquired in-process research and development	—	—	65,845	—
Selling, general and administrative expenses	31,307	57,216	182,719	172,314
Impairment charges of intangible assets	319,246	—	319,246	15,963
Restructuring expenses	—	—	—	712
Total costs and expenses	403,471	105,022	737,722	316,215
Operating (loss) income	(249,730)	38,760	(286,114)	64,285
Other (expense) income:				
Interest expense	(16,847)	(18,309)	(52,403)	(55,002)
Loss on debt extinguishment	(314)	—	(9,830)	—
Interest and dividend income	487	838	2,181	2,319
Other (expense) income	—	(24)	(43)	197
Total other (expense) income	(16,674)	(17,495)	(60,095)	(52,486)
(Loss) income before income taxes	(266,404)	21,265	(346,209)	11,799
Income tax (benefit) expense	(114,343)	5,069	(143,521)	3,725
Net (loss) income	$(152,061)	$16,196	$(202,688)	$8,074
Net (loss) income per share:				
Basic	$(4.31)	$0.47	$(5.80)	$0.23
Diluted	$(4.31)	$0.43	$(5.80)	$0.23
Weighted average shares outstanding used to compute net (loss) income per share:				
Basic	35,311	34,171	34,948	34,377
Diluted	35,311	42,111	34,948	34,764

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 (LOSS) INCOME
(IN THOUSANDS)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net (loss) income	$(152,061)	$16,196	$(202,688)	$8,074
Other comprehensive (loss) income:				
Holding (losses) gains arising during period, net of tax	(4)	(336)	201	811
Total comprehensive (loss) income	$(152,065)	$15,860	$(202,487)	$8,885

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

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

	Nine Months Ended September 30,	
	2017	2016
Cash flows from operating activities:		
Net (loss) income	$(202,688)	$8,074
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	88,941	68,960
Impairment of intangible assets	319,246	15,963
Provision for bad debt expense	3,503	2,209
Amortization of premium/discount on purchased securities	218	518
Non-cash equity-based compensation expense	18,058	16,809
Non-cash IPR&D expense	945	—
Loss on debt extinguishment	9,830	—
Amortization of debt discount and debt issuance costs	10,600	9,015
(Loss) gains on investments, net	(255)	24
Change in fair value of contingent consideration	(47,142)	5,106
Deferred income taxes	(146,682)	2,573
Changes in operating assets and liabilities:		
Accounts receivable, net	(8,889)	13,390
Inventories	(600)	(1,369)
Receivable from collaboration	—	428
Prepaid and other current assets	(1,409)	(1,293)
Accounts payable and accrued expenses	29,977	19,940
Deferred revenues	14,134	21,888
Other assets and liabilities	(1,139)	1,467
Net cash provided by operating activities	86,648	183,702
Cash flows from investing activities:		
Proceeds from sales or maturities of investments	279,526	71,733
Purchase of investments	(110,894)	(142,175)
Intrarosa developed technology	(55,800)	—
Change in restricted cash	(60)	—
Capital expenditures	(6,573)	(3,360)
Net cash provided by (used in) investing activities	106,199	(73,802)
Cash flows from financing activities:		
Long-term debt principal payments	(328,125)	(13,127)
Proceeds from 2022 Convertible Notes	320,000	—
Payment to repurchase 2019 Convertible Notes	(191,480)	—
Proceeds to settle warrants	323	—
Payment of convertible debt issuance costs	(9,553)	—
Payments of contingent consideration	(165)	(212)
Payments for repurchases of common stock	—	(20,000)
Proceeds from the issuance and exercise of common stock options	2,350	2,184
Payments of employee tax withholding related to equity-based compensation	(2,588)	(2,171)
Net cash used in financing activities	(209,238)	(33,326)
Net (decrease) increase in cash and cash equivalents	(16,391)	76,574

Cash and cash equivalents at beginning of the period	274,305	228,705
Cash and cash equivalents at end of the period	$257,914	$305,279
Supplemental data for cash flow information:		
Cash paid for taxes	$3,565	$4,611
Cash paid for interest	$50,892	$58,319
Non-cash investing and financing activities:		
Fair value of common stock issued in connection with the acquisition of the Intrarosa intangible asset	$12,555	$—
Contingent consideration accrued for the acquisition of the Intrarosa intangible asset	$9,300	$—

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

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

A. DESCRIPTION OF BUSINESS

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a 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 maternal and women's health, anemia management and cancer supportive care, including Makena® (hydroxyprogesterone caproate injection), Feraheme® (ferumoxytol) for intravenous use, MuGard® Mucoadhesive Oral Wound Rinse, and Intrarosa®(prasterone) vaginal inserts for the treatment of moderate-to-severe dyspareunia, a symptom of vulvar and vaginal atrophy ("VVA"), due to menopause. 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. Throughout this Quarterly Report on Form 10-Q, AMAG Pharmaceuticals, Inc. and our consolidated subsidiaries are collectively referred to as "the Company," "AMAG," "we," "us," or "our."

B. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

In accordance with GAAP for interim financial reports and the instructions for Form 10-Q and the rules of the Securities and Exchange Commission, certain information and footnote disclosures normally included in annual financial statements have been condensed or omitted. Our accounting policies are described in the Notes to the Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 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 funds, corporate debt securities, U.S. treasury and government agency securities, commercial paper and certificates of deposit. As of September 30, 2017, we did not have a material concentration in any single investment.

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Our operations are located entirely within the U.S. We focus primarily on developing, manufacturing, and commercializing our products and product candidates and marketing and selling the CBR Services. We perform ongoing credit evaluations of our product sales customers and generally do not require collateral. The following table sets forth customers who represented 10% or more of our total revenues for the three and nine months ended September 30, 2017 and 2016:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
AmerisourceBergen Corporation	22%	20 %	21%	22 %
McKesson Corporation	21%	<10%	19%	<10%
Caremark LLC (Specialty Pharmacy)	—%	10 %	—%	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 balances as of September 30, 2017 and December 31, 2016 were as follows:

	September 30, 2017	December 31, 2016
AmerisourceBergen Corporation	26 %	13 %
McKesson Corporation	23 %	32 %

We are currently dependent on a single supplier for Feraheme drug substance (produced in two separate facilities), Feraheme finished drug product and Intrarosa drug substance. 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 and nine months ended September 30, 2017 and 2016, were offset by provisions for allowances and accruals as follows (in thousands):

	Three Months Ended September	Nine Months Ended September 30,

	30,			
	2017	2016	2017	2016
Gross product sales	$235,299	$201,303	$676,377	$530,076
Provision for product sales allowances and accruals:				
Contractual adjustments	80,110	61,504	225,622	161,023
Governmental rebates	30,858	24,022	83,565	60,729
Total	110,968	85,526	309,187	221,752
Product sales, net	$124,331	$115,777	$367,190	$308,324

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 and nine months ended September 30, 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 September 30, 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. Available-for-sale securities are those securities which we view as available for use in current operations, if needed. We generally classify our available-for-sale securities as short-term investments even though the stated maturity date may be one year or more beyond the current balance sheet date.

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The following is a summary of our investments as of September 30, 2017 and December 31, 2016 (in thousands):

	September 30, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:*				
Corporate debt securities	$47,494	$ 21	$ (12)	$47,503
Commercial paper	3,990	—	—	3,990
Certificates of deposit	11,449	—	—	11,449
Total short-term investments	62,933	21	(12)	62,942
Long-term investments:**				
Corporate debt securities	63,918	45	(52)	63,911
U.S. treasury and government agency securities	9,378	—	(45)	9,333
Total long-term investments	73,296	45	(97)	73,244
Total investments	$136,229	$ 66	$ (109)	$136,186

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

	December 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:*				
Corporate debt securities	$106,430	$ 3	$ (69)	$106,364
U.S. treasury and government agency securities	1,021	—	—	1,021
Commercial paper	40,560	—	—	40,560
Certificates of deposit	6,000	—	—	6,000
Total short-term investments	154,011	3	(69)	153,945
Long-term investments:**				
Corporate debt securities	139,742	32	(281)	139,493
U.S. treasury and government agency securities	11,395	—	(52)	11,343
Total long-term investments	151,137	32	(333)	150,836
Total investments	$305,148	$ 35	$ (402)	$304,781

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

Impairments and Unrealized Gains and Losses on Investments

We did not recognize any other-than-temporary impairment losses in our condensed consolidated statements of operations related to our securities during the three or nine months ended September 30, 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. 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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D. FAIR VALUE MEASUREMENTS

The following tables represent the fair value hierarchy as of September 30, 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 September 30, 2017 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$4,826	$ 4,826	$ —	$ —
Corporate debt securities	111,414	—	111,414	—
U.S. treasury and government agency securities	9,333	—	9,333	—
Commercial paper	3,990	—	3,990	—
Certificates of deposit	11,449	—	11,449	—
Total Assets	$141,012	$ 4,826	$ 136,186	$ —
Liabilities:				
Contingent consideration - Lumara Health	$98,778	$ —	$ —	$ 98,778
Contingent consideration - MuGard	1,910	—	—	1,910
Total Liabilities	$100,688	$ —	$ —	$ 100,688

	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 analysis of prices received from third parties to determine whether prices are reasonable estimates of fair value. After completing our analysis, we did not adjust or override any fair value measurements provided by our pricing services as of September 30, 2017. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during the nine months ended September 30, 2017.

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Contingent consideration

In accordance with GAAP, for asset acquisitions, such as Intrarosa, we record contingent consideration for obligations we consider to be probable and estimable and these liabilities are not adjusted to fair value. As of September 30, 2017, $10.0 million of contingent consideration was recorded in accrued expenses and is expected to be paid to Endoceutics in April 2018 on the first anniversary of the closing. We recorded 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	(165)
Adjustments to fair value of contingent consideration	(47,142)
Balance as of September 30, 2017	$100,688

During the nine months ended September 30, 2017, we adjusted the fair value of our contingent consideration liability by approximately $47.1 million, primarily due to a decrease of approximately $49.2 million to the Makena contingent consideration. During the third quarter of 2017, we revised our long-term forecast of total projected net sales for Makena, which impacted both the amount and timing of future milestone payments. As a result, during the third quarter of 2017, we reduced our Makena-related contingent consideration liability by $50.4 million. We have classified $98.8 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 September 30, 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 September 30, 2017, the total potential 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 11%. As of September 30, 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 September 30, 2017, the estimated fair value of our 2023 Senior Notes, 2022 Convertible Notes and 2019 Convertible Notes (each as defined below) was $502.5 million, $308.6 million and $22.2 million, respectively, which differed from their carrying values. See Note P, “Debt” for additional information on our debt obligations.

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E. INVENTORIES

Our major classes of inventories were as follows as of September 30, 2017 and December 31, 2016 (in thousands):

	September 30, 2017	December 31, 2016
Raw materials	$ 13,034	$ 14,382
Work in process	2,772	3,924
Finished goods	20,737	18,952
Total inventories	$ 36,543	$ 37,258

F. PROPERTY, PLANT AND EQUIPMENT, NET

Property, plant and equipment, net consisted of the following as of September 30, 2017 and December 31, 2016 (in thousands):

	September 30, 2017	December 31, 2016
Land	$ 700	$ 700
Land improvements	300	300
Building and improvements	9,534	9,500
Computer equipment and software	14,440	13,866
Furniture and fixtures	2,472	2,401
Leasehold improvements	3,804	3,718
Laboratory and production equipment	6,860	6,449
Construction in progress	7,016	1,619
	45,126	38,553
Less: accumulated depreciation	(20,293)	(14,093)
Property, plant and equipment, net	$ 24,833	$ 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 September 30, 2017, we had no accumulated impairment losses related to goodwill.

We test our goodwill balances during the fourth quarter of each year for impairment. An interim goodwill impairment test in advance of the annual impairment assessment may be required if events occur that indicate an impairment might be present. For example, a sustained substantial decline in our market capitalization, a material impairment charge related to other long-lived assets, unexpected adverse business conditions, economic factors and unanticipated competitive activities may signal that an interim impairment test is needed. Accordingly, among other factors, we monitor changes in our stock price between annual impairment tests. Our stock market capitalization has at times been, and as of September 30, 2017 is, lower than our stockholders' equity or book value. We believe that the current short-term decline in share price below book value does not necessarily reflect the underlying value of the Company. Management believes that the fair value of the Company exceeds book value and accordingly, has not recognized an impairment of its goodwill.

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Intangible Assets

As of September 30, 2017 and December 31, 2016, our identifiable intangible assets consisted of the following (in thousands):

	September 30, 2017				December 31, 2016			
	Cost	Accumulated Amortization	Impairments	Net	Cost	Accumulated Amortization	Impairments	Net
Amortizable intangible assets:								
Makena base technology	$797,100	$ 198,354	$ 319,246	$279,500	$797,100	$ 128,732	$ —	$668,368
CBR customer relationships	297,000	25,379	—	271,621	297,000	13,590	—	283,410
Intrarosa developed technology	77,655	16	—	77,639	—	—	—	—
	1,171,755	223,749	319,246	628,760	1,094,100	142,322	—	951,778
Indefinite-lived intangible assets:								
Makena IPR&D	79,100	—	—	79,100	79,100	—	—	79,100
CBR trade names and trademarks	65,000	—	3,700	61,300	65,000	—	3,700	61,300
Total intangible assets	$1,315,855	$ 223,749	$ 322,946	$769,160	$1,238,200	$ 142,322	$ 3,700	$1,092,178

Intangible assets are initially recorded at fair value and stated net of accumulated amortization and impairments. We amortize our intangible assets that have finite lives based on the pattern in which the economic benefit of the asset is expected to be utilized. Amortization is recorded over the estimated useful lives ranging from 7 to 20 years. We evaluate the realizability of our definite lived intangible assets whenever events or changes in circumstances or business conditions indicate that the carrying value of these assets may not be recoverable based on expectations of future undiscounted cash flows for each asset. If the carrying value of an asset exceeds its undiscounted cash flows, we estimate the fair value of the assets, generally utilizing a discounted cash flow analysis based on the present value of estimated future cash flows to be generated by the assets using a risk-adjusted discount rate. To estimate the fair value of the assets, we use market participant assumptions pursuant to Accounting Standards Codification ("ASC") Topic 820, Fair Value Measurements.

Indefinite lived intangible assets, such as IPR&D assets, are required to be tested for impairment annually, or more frequently if indicators of impairment are present. Our annual impairment test date is October 31st of each year.

During the third quarter of 2017, we received new information from a variety of sources, including from market research and our authorized generic partner, related to potential generic competitors to the intramuscular formulation of Makena. This information, combined with continued progress on our own authorized generic strategy, was incorporated into our revised long-range revenue forecasts for the Makena intramuscular formulation. We determined that this new information constituted a triggering event with respect to our Makena base technology intangible asset (the intramuscular formulation). We estimated that the sum of the undiscounted projected cash flows of the Makena intramuscular product was less than the carrying value of the corresponding intangible asset. In accordance with ASC Topic 350, Intangibles - Goodwill and Other we reassessed the fair value of the Makena base technology intangible asset using an income approach, a level three measurement technique. We determined that the fair value of the Makena base technology intangible asset was less than its carrying value and accordingly, we recorded an impairment charge of $319.2 million. The charge was recorded within a separate operating expense line item in our condensed consolidated statements of operations during the three months ended September 30, 2017. In addition, we reassessed the remaining useful life of the Makena base technology (the intramuscular formulation) and concluded that, as of

September 30, 2017, seven years is an appropriate amortization period based on the estimated remaining economic life of the intramuscular formulation of Makena. Further, we evaluated our Makena IPR&D intangible asset, which is related to the Makena auto-injector, for impairment and concluded that its fair value was greater than its carrying value, and therefore it was not impaired. Future events, such as the upcoming February 2018 PDUFA date, could cause us to reassess the realizability of the Makena IPR&D asset. Furthermore, additional information may become available, which may cause us to identify additional impairment charges. Such charges could have a material adverse effect on our earnings in future periods.

As of September 30, 2017, the weighted average remaining amortization period for our finite-lived intangible assets was approximately 11.62 years. Total amortization expense for the nine months ended September 30, 2017 and 2016, was $81.4 million and $58.3 million, respectively. We expect amortization expense related to our finite-lived intangible assets to be as

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follows (in thousands):

Period	Estimated Amortization Expense
Remainder of Year Ending December 31, 2017	$ 60,693
Year Ending December 31, 2018	186,356
Year Ending December 31, 2019	35,779
Year Ending December 31, 2020	30,068
Year Ending December 31, 2021	31,020
Thereafter	284,844
Total	$ 628,760

H. CURRENT AND LONG-TERM LIABILITIES

Accrued Expenses

Accrued expenses consisted of the following as of September 30, 2017 and December 31, 2016 (in thousands):

	September 30, 2017	December 31, 2016
Commercial rebates, fees and returns	$ 110,935	$ 89,466
Professional, license, and other fees and expenses	37,975	24,248
Research and development expenses	6,198	10,714
Intrarosa-related license fees	10,000	—
Interest expense	7,470	16,683
Salaries, bonuses, and other compensation	17,879	14,823
Restructuring expense	—	74
Total accrued expenses	$ 190,457	$ 156,008

Deferred Revenues

Our deferred revenue balances as of September 30, 2017 and December 31, 2016 of $63.9 million and $49.8 million, respectively, were primarily 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.

I. INCOME TAXES

The following table summarizes our effective tax rate and income tax (benefit) expense for the three and nine months ended September 30, 2017 and 2016 (in thousands except for percentages):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Effective tax rate	43 %	24 %	41 %	32 %
Income tax (benefit) expense	$ (114,343)	$ 5,069	$ (143,521)	$ 3,725

For the three and nine months ended September 30, 2017, we recognized an income tax benefit of $114.3 million and $143.5 million, respectively, representing an effective tax rate of 43% and 41%, respectively. The difference between the expected statutory federal tax rate of 35% and the effective tax rates for the three and nine months ended September 30, 2017, was primarily attributable to the impact of state income taxes, federal research and development and orphan drug tax credits, and contingent consideration associated with Lumara Health, partially offset by the establishment of a valuation allowance related to certain deferred tax assets. During the three months ended September 30, 2017, we entered into a three-year cumulative loss position and established a valuation allowance on certain deferred tax assets to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets.

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For the three and nine months ended September 30, 2016, we recognized an income tax expense of $5.1 million and $3.7 million, respectively, representing an effective tax rate of 24% and 32%, respectively. The difference between the expected statutory federal tax rate of 35% and the effective tax rates for the three and nine months ended September 30, 2016, was primarily attributable to contingent consideration associated with Lumara Health, including the tax deductible portion of the then anticipated 2016 milestone payment, and federal research and development and orphan drug tax credits, partially offset by the impact of state income taxes, non-deductible stock compensation, and other non-deductible expenses.

J. ACCUMULATED OTHER COMPREHENSIVE LOSS

The table below presents information about the effects of net income (loss) of significant amounts reclassified out of accumulated other comprehensive income (loss), net of tax, associated with unrealized gains (losses) on securities during the three and nine months ended September 30, 2017 and 2016 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Beginning balance	$(3,633)	$(3,058)	$(3,838)	$(4,205)
Other comprehensive (loss) income before reclassifications	(4)	(336)	201	811
Ending balance	$(3,637)	$(3,394)	$(3,637)	$(3,394)

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, diluted net income per common share would be computed assuming the impact of the conversion of the 2.50% convertible senior notes due 2019 (the “2019 Convertible Notes”) and the 3.25% convertible senior notes due 2022 (the “2022 Convertible Notes”), the exercise of outstanding stock options, the vesting of restricted stock units (“RSUs”), and the exercise of warrants.

We have a choice to settle the conversion obligation of our 2022 Convertible Notes and the 2019 Convertible Notes (together, the “Convertible Notes”) in cash, shares, or any combination of shares and cash. Our six-year $350.0 million term loan facility (the “2015 Term Loan Facility”), which was repaid in full in May 2017, contained certain covenants that, prior to May 2017, restricted us from settling the conversion obligation in whole or in part with cash unless certain conditions in the 2015 Term Loan Facility were satisfied. Prior to the repayment of the 2015 Term Loan Facility, we utilized the if-converted method to reflect the impact of the conversion of the Convertible Notes. Our current policy is to settle the principal balance of the Convertible Notes in cash. As such, subsequent to the repayment of the 2015 Term Loan Facility, we apply the treasury stock method to these securities and the dilution related to the conversion premium, if any, of the Convertible Notes is included in the calculation of diluted weighted-average shares outstanding to the extent each issuance is dilutive based on the average stock price during each reporting period being greater than the conversion price of the respective Convertible Notes.

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The components of basic and diluted net income (loss) per share for the three and nine months ended September 30, 2017 and 2016, were as follows (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net (loss) income	$(152,061)	$16,196	$(202,688)	$8,074
Weighted average common shares outstanding	35,311	34,171	34,948	34,377
Effect of dilutive securities:				
Stock options and RSUs	—	558	—	387
2019 Convertible Notes	—	7,382	—	—
Shares used in calculating dilutive net (loss) income per share	35,311	42,111	34,948	34,764
Net (loss) income per share:				
Basic	$(4.31)	$0.47	$(5.80)	$0.23
Diluted	$(4.31)	$0.43	$(5.80)	$0.23

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Options to purchase shares of common stock	3,145	2,218	3,389	2,778
Shares of common stock issuable upon the vesting of RSUs	932	249	1,140	654
Warrants	1,008	7,382	1,008	7,382
2022 Convertible Notes	11,695	—	11,695	—
2019 Convertible Notes	790	—	790	7,382
Total	17,570	9,849	18,022	18,196

In connection with the issuance of the 2019 Convertible Notes, in February 2014, we entered into convertible bond hedges. The convertible bond hedges are not included for purposes of calculating the number of diluted shares outstanding, as their effect would be anti-dilutive. The convertible bond hedges are generally expected, but not guaranteed, to reduce the potential dilution and/or offset the cash payments we are required to make upon conversion of the remaining 2019 Convertible Notes.

L. EQUITY BASED COMPENSATION

We currently maintain four equity compensation plans, namely our Fourth 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"). In May 2017 at our annual meeting of stockholders, our stockholders approved an amendment to our 2007 Plan to, among other things, increase the number of shares of our common stock available for issuance thereunder by 2,485,000 shares. 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).

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Stock Options

The following table summarizes stock option activity for the nine months ended September 30, 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	931,417	—	—	91,100	1,022,517
Exercised	(90,696)	—	—	—	(90,696)
Expired or terminated	(306,070)	—	(7,969)	(72,125)	(386,164)
Outstanding at September 30, 2017	2,693,473	5,200	126,212	833,950	3,658,835

Restricted Stock Units

The following table summarizes RSU activity for the nine months ended September 30, 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	790,476	—	—	24,300	814,776
Vested	(349,306)	—	(12,831)	(45,662)	(407,799)
Expired or terminated	(181,986)	—	(752)	(9,819)	(192,557)
Outstanding at September 30, 2017	1,032,988	—	14,111	104,275	1,151,374

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. As of September 30, 2017, the maximum shares of common stock that may be issued under these awards is 162,750. The maximum aggregate total fair value of these RSUs is $3.2 million, which is being recognized as expense over a period of three years from the date of grant.

Equity-based compensation expense

Equity-based compensation expense for the three and nine months ended September 30, 2017 and 2016 consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Cost of product sales and services	$566	$118	$892	$395
Research and development	799	858	2,651	2,583
Selling, general and administrative	5,024	4,492	14,515	13,831
Total equity-based compensation expense	6,389	5,468	18,058	16,809
Income tax effect	(1,805)	(1,568)	(5,127)	(4,637)
After-tax effect of equity-based compensation expense	$4,584	$3,900	$12,931	$12,172

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 Q, "Recently Issued and Proposed Accounting Pronouncements."

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M. STOCKHOLDERS' EQUITY

Preferred Stock and our 2017 NOL Rights Agreement

Our certificate of incorporation authorizes our board of directors (the "Board") to issue preferred stock from time to time in one or more series. The rights, preferences, restrictions, qualifications and limitations of such stock are determined by our Board. Following the expiration of our prior rights agreement and in an effort to protect stockholder value by continuing to help preserve our substantial tax assets associated with net operating loss carryforwards and certain other deferred tax assets ("NOLs"), our Board entered into a new shareholder rights plan with American Stock Transfer & Trust Company, LLC, as Rights Agent, in April 2017 (which was approved by our stockholders at our May 2017 annual meeting of stockholders and which is essentially a restatement of the prior rights agreement, but with an expiration date of April 6, 2018, subject to earlier expiration as described below) (the "2017 NOL Rights Agreement").

Our business operations have generated significant NOLs, and we may generate additional NOLs in future years. Under federal tax laws, we generally can use our NOLs and certain related tax credits to offset ordinary income tax paid in our prior two tax years or on our future taxable income for up to 20 years, when they "expire" for such purposes. Until they expire, we can "carry forward" NOLs and certain related tax credits that we do not use in any particular year to offset taxable income in future years. Our ability to utilize our NOLs to offset future taxable income may be significantly limited if we experience an "ownership change," as determined under Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"). Under Section 382, an "ownership change" occurs if a stockholder or a group of stockholders that is deemed to own at least 5% of our outstanding stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a rolling three-year period. If an ownership change occurs, Section 382 would impose an annual limit on the amount of our NOLs that we can use to offset taxable income equal to the product of the total value of our outstanding equity immediately prior to the ownership change (reduced by certain items specified in Section 382) and the federal long-term tax-exempt interest rate in effect for the month of the ownership change. The 2017 NOL Rights Agreement is intended to act as a deterrent to any person or group acquiring 4.99% or more of our outstanding common stock without the prior approval of our Board.

Under the 2017 NOL Rights Agreement, stockholders of record as of April 17, 2017 (the "Record Date") were issued one preferred share purchase right (a "Right") for each outstanding share of common stock, par value $0.01 per share (the "Common Shares"), outstanding as of the Record Date. The Rights will also attach to new Common Shares issued after the Record Date. Each Right entitles the registered holder to purchase from us one one-thousandth of a share of our Series A Junior Participating Preferred Stock, par value $0.01 per share (the "Preferred Shares") at a price of $80 per one one-thousandth of a Preferred Share (the "Purchase Price"), subject to adjustment. Each Preferred Share is designed to be the economic equivalent of 1,000 Common Shares.

The Rights will separate from the common stock and become exercisable on the earlier of (i) the tenth day after a public announcement that a person or group of affiliated or associated persons, has become an "Acquiring Person" (as such term is defined in the 2017 NOL Rights Agreement) or (ii) ten business days (or such later date as the Board may determine) following the commencement of, or announcement of an intention to make, a tender offer or exchange offer which would result in the beneficial ownership by an Acquiring Person of 4.99% (or, in the case of a Grandfathered Person, the Grandfathered Percentage applicable to such Grandfathered Person (as such terms are defined in the 2017 NOL Rights Agreement)) or more of the outstanding Common Shares (the earlier of such dates being called the "Distribution Date").

In the event that we are acquired in a merger or other business combination transaction or 50% or more of our consolidated assets or earning power are sold to an Acquiring Person, its affiliates or associates or certain other persons in which such persons have an interest, proper provision will be made so that each such holder of a Right will thereafter have the right to receive, upon the exercise thereof at the then current exercise price of the Right, that number of shares of common stock of the acquiring company which at the time of such transaction will have a market value of two times the exercise price of the Right.

The Rights will expire on the earliest of the close of business on (1) April 6, 2018, (2) the effective date of the repeal of Section 382 or any successor statute if the Board determines that the 2017 NOL Rights Agreement is no longer necessary or desirable for the preservation of tax benefits or (3) the first day of a taxable year of the Company to which the Board determines that no tax benefits may be carried forward (the “Final Expiration Date”), unless the Final Expiration Date is extended or unless the Rights are earlier redeemed or exchanged by us.

The terms of the Rights generally may be amended by the Board without the consent of the holders of the Rights, except that from and after the time that the Rights are no longer redeemable, no such amendment may adversely affect the interests of the holders of the Rights (excluding the interests of any Acquiring Person and any group of affiliated or associated persons).

There can be no assurance that the 2017 NOL Rights Agreement will result in us being able to preserve all or any of the substantial tax assets associated with NOLs and other tax benefits.

Share Repurchase Program

In January 2016, we announced that our Board authorized a program to repurchase up to $60.0 million in shares of our common stock. The repurchase program does not have an expiration date and may be suspended for periods or discontinued at any time. Under the program, we may purchase our stock from time to time at the discretion of management in the open market or in privately negotiated transactions. The number of shares repurchased and the timing of the purchases will depend on a number of factors, including share price, trading volume and general market conditions, along with working capital requirements, general business conditions and other factors. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate purchases of our shares under this program. As of September 30, 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 2017.

Change in Stockholders' Equity

Total stockholders' equity decreased by $134.1 million during the nine months ended September 30, 2017. This decrease was primarily driven by the following:

- $21.6 million increase related to the cumulative-effect adjustment to our accumulated deficit from previously unrecognized excess tax benefits upon our adoption of ASU No. 2016-09;
- $13.5 million increase related to net shares issued in connection with the Endoceutics License Agreement;
- $18.1 million increase related to equity-based compensation expense;
- $72.6 million increase related to the Equity Component of the 2022 Convertible Notes;
- $202.7 million reduction due to our net loss for the nine months ended September 30, 2017;
- $27.2 million reduction related to changes in deferred taxes associated with our debt transactions executed during the nine months ended September 30, 2017;
- $28.3 million reduction related to the Equity Component of the 2019 Convertible Notes repurchased; and
- $2.2 million reduction related to the Equity Component for debt issuance costs associated with the 2022 Convertible Notes.

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. With the exception of the commitments described below, there have been no material changes in our contractual obligations since December 31, 2016.

Contingent Regulatory and Commercial Milestone Payments

In connection with the Endoceutics License Agreement, described below, we are required to pay Endoceutics $10.0 million in April 2018 on the first anniversary of the closing. In addition, we are required to pay Endoceutics certain sales milestone payments, including a first sales milestone payment of $15.0 million, which would be triggered when Intrarosa annual net U.S. sales exceed $150.0 million, and a second milestone payment of $30.0 million, which would be triggered when annual net U.S. sales of Intrarosa exceed $300.0 million. If annual net U.S. sales of Intrarosa exceed $500.0 million, there are additional sales milestone payments totaling up to $850.0 million, which would be triggered at various sales thresholds. We are also obligated to pay tiered royalties to Endoceutics equal to a percentage of net sales of Intrarosa in the U.S. ranging from mid-teens for calendar year net sales up to $150.0 million to mid twenty percent for any calendar year net sales that exceed $1.0 billion for the commercial life of Intrarosa, with deductions (a) after the later of (i) the expiration date of the last to expire of a licensed patent containing a valid patent claim or (ii) ten years after the first commercial sale of Intrarosa for the treatment of VVA or female sexual dysfunction ("FSD") in the U.S. (as applicable), (b) for generic competition and (c) for third party payments, subject to an aggregate cap on such deductions of royalties otherwise payable to Endoceutics.

In connection with the Palatin License Agreement, described below, we are required to pay Palatin up to $380.0 million in regulatory and commercial milestone payments including up to $80.0 million upon achievement of certain regulatory milestones, including $20.0 million upon the acceptance by the U.S. Food and Drug Administration (the "FDA") of our New Drug Application ("NDA") for bremelanotide and $60.0 million upon FDA approval, and up to $300.0 million of aggregate sales milestone payments upon the achievement of certain annual net sales milestones over the course of the license. We are also obligated to pay Palatin tiered royalties on annual net sales of the Bremelanotide Products (as defined below), on a product-by-product basis, in the Palatin Territory ranging from the high-single digits to the low double-digits.

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 ("ANDA") submitted to the FDA by Sandoz Inc. ("Sandoz") requesting approval to engage in commercial manufacture, use and sale of a generic version of ferumoxytol. A generic version of ferumoxytol 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 response 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 September 30, 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-state development assets. As of September 30, 2017, we were a party to the following collaborations and license agreements:

Endoceutics

In February 2017, we entered into the Endoceutics License Agreement with Endoceutics. Pursuant to the Endoceutics License Agreement, Endoceutics granted us the right to develop and commercialize pharmaceutical products containing dehydroepiandrosterone (“DHEA”), including Intrarosa, at dosage strengths of 13 mg or less per dose and formulated for intravaginal delivery, excluding any dosage strengths over 13 mg per dose and combinations with other active pharmaceutical ingredients, in the U.S. for the treatment of VVA and FSD. The transactions contemplated by the Endoceutics License Agreement closed on April 3, 2017. We accounted for the Endoceutics License Agreement as an asset acquisition under our early adoption of ASU No. 2017-01, described in Note Q, “Recently Issued and Proposed Accounting Pronouncements.”

Upon the closing of the Endoceutics License Agreement, we made an upfront payment of $50.0 million and issued 600,000 shares of unregistered common stock to Endoceutics, which had a value of $13.5 million, as measured on April 3, 2017, the date of closing. Of these 600,000 shares, 300,000 were subject to a 180-day lock-up provision, and the other 300,000 are

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subject to a one-year lock-up provision. In addition, we paid Endoceutics $10.0 million in the third quarter of 2017 upon the delivery by Endoceutics of Intrarosa launch quantities and have agreed to make a payment of $10.0 million in April 2018 on the first anniversary of the closing. The anniversary payment is reflected in accrued expenses at September 30, 2017. In the second quarter of 2017, we recorded a total of $83.5 million of consideration, of which $77.7 million was allocated to the Intrarosa developed technology intangible asset and $5.8 million was recorded as IPR&D expense based on their relative fair values.

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

Subject to the terms of the Endoceutics License Agreement, Endoceutics has agreed to conduct clinical studies for the use of Intrarosa in HSDD to support an application for regulatory approval for Intrarosa for the treatment of HSDD 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 and FSD in the U.S., subject to the terms of the Endoceutics License Agreement (which contains certain non-competition provisions agreed to by the parties), including having final decision making authority with respect to commercial strategy, pricing and reimbursement and other commercialization matters. We have agreed to use commercially reasonable efforts to market, promote and otherwise commercialize Intrarosa for the treatment of VVA and 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 and 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 intracinology, in each case, subject to our right to withhold approval in certain instances.

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 will be our exclusive supplier of Intrarosa in the U.S., subject to certain rights for us to manufacture and supply Intrarosa in the event of a cessation notice or supply failure (as such terms are defined in the 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.

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

Palatin

In January 2017, we entered into 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 a 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 in February 2017. We accounted for the Palatin License Agreement as an asset acquisition under our early adoption of ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business.
Under the terms of the Palatin License Agreement, in February 2017 we paid Palatin $60.0 million as a one-time upfront payment and agreed to 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 bremelanotide for the treatment of HSDD in pre-menopausal women. As of September 30, 2017, we have substantially fulfilled these payment obligations to Palatin. The $60.0 million upfront payment made in February 2017 to Palatin was recorded as IPR&D expense as the product candidate had not received regulatory approval.
In 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 $20.0 million upon the acceptance by the FDA of our NDA for bremelanotide and $60.0 million upon 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 bremelanotide annual net sales exceed $250.0 million. We are also obligated to pay Palatin tiered royalties on annual net sales of the Bremelanotide 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 Bremelanotide Product in such country, (b) the expiration of the regulatory exclusivity period for such Bremelanotide Product in such country and (c) 10 years following the first commercial sale of such Bremelanotide 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 Bremelanotide Product or (ii) generic competition occurs with respect to a Bremelanotide 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 Bremelanotide Product in a given country, the license for such Bremelanotide Product in such country would become a fully paid-up, royalty-free, perpetual and irrevocable license. The Palatin License Agreement expires on the date of expiration of all royalty obligations due thereunder, unless earlier terminated in accordance with the Palatin License Agreement.
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 began 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

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Antares on net sales of the Makena auto-injector commencing on the launch of the Makena auto-injector until it is no longer sold or offered for sale (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 auto-injector product. The Antares 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 September 30, 2017 and December 31, 2016 consisted of the following (in thousands):

	September 30, 2017	December 31, 2016
2023 Senior Notes	$490,518	$489,612
2022 Convertible Notes	244,958	—
2019 Convertible Notes	19,941	179,363
2015 Term Loan Facility	—	317,546
Total long-term debt	755,417	986,521
Less: current maturities	—	21,166
Long-term debt, net of current maturities	$755,417	$965,355

2023 Senior Notes

In August 2015, in connection with the CBR acquisition, we completed a private placement of $500.0 million aggregate principal amount of 7.875% Senior Notes due 2023 (the "2023 Senior Notes"). The 2023 Senior Notes were issued pursuant to an Indenture, dated as of August 17, 2015 (the "Indenture"), by and among us, certain of our subsidiaries acting as guarantors of the 2023 Senior Notes and Wilmington Trust, National Association, as trustee. 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. In October 2017, we repurchased $25.0 million of the 2023 Senior Notes in a privately negotiated transaction.

At September 30, 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 $490.5 million.

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Convertible Notes

The outstanding balances of our Convertible Notes as of September 30, 2017 consisted of the following (in thousands):

	2022 Convertible Notes	2019 Convertible Notes	Total
Liability component:			
Principal	$ 320,000	$ 21,417	$341,417
Less: debt discount and issuance costs, net	75,042	1,476	76,518
Net carrying amount	$ 244,958	$ 19,941	$264,899
Equity Component	$ 72,576	$ 9,905	$82,481

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

2022 Convertible Notes

On May 10, 2017, we issued $300.0 million aggregate principal amount of the 2022 Convertible Notes. We received net proceeds of $291.0 million from the sale of the 2022 Convertible Notes, after deducting fees and expenses of $9.0 million. In addition, on June 7, 2017, we issued an additional $20.0 million principal amount of 2022 Convertible Notes pursuant to the exercise of an over-allotment option granted to the underwriters in the offering. We received net proceeds of $19.4 million from the sale of the over-allotment option, after deducting fees and expenses of $0.6 million.

In connection with the issuance of the 2022 Convertible Notes, we incurred approximately $9.6 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 $9.6 million of debt issuance costs, $2.2 million was allocated to the Equity Component and recorded as a reduction to additional paid-in capital and $7.4 million was allocated to the liability component and is now recorded as a reduction of the 2022 Convertible Notes in our condensed consolidated balance sheet. The portion allocated to the liability component is amortized to interest expense using the effective interest method over five years.

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

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

1) during any calendar quarter (and only during such calendar quarter) commencing after the calendar quarter ending September 30, 2017, if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;

2) during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price per $1,000 principal amount of the 2022 Convertible Notes for each trading day of the measurement

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period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; or

3) upon the occurrence of specified corporate events.

On or after March 1, 2022, until the close of business on the business day immediately preceding the maturity date, holders may convert all or any portion of their 2022 Convertible Notes, in multiples of $1,000 principal amount, at the option of the holder regardless of the foregoing circumstances.

We determined the expected life of the debt was equal to the five-year term on the 2022 Convertible Notes. The effective interest rate on the liability component was 9.49% for the period from the date of issuance through September 30, 2017. As of September 30, 2017, the "if-converted value" did not exceed the remaining principal amount of the 2022 Convertible Notes.

2019 Convertible Notes

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

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

The conversion rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the issuance of stock dividends and payment of cash dividends. At any time prior to the close of business on the business day immediately preceding May 15, 2018, holders may convert their 2019 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 measurement period in which the trading price per $1,000 principal amount of the 2019 Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; or

3) upon the occurrence of specified corporate events.

On or after May 15, 2018 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert all or any portion of their 2019 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 third quarter of 2017, the 2019 Convertible Notes were not convertible as of October 1, 2017.

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We determined the expected life of the debt was equal to the five-year term of the 2019 Convertible Notes. The effective interest rate on the liability component was 7.79% for the period from the date of issuance through September 30, 2017. As of September 30, 2017, the "if-converted value" did not exceed the remaining principal amount of the 2019 Convertible Notes.

Convertible Notes Interest Expense

The following table sets forth total interest expense recognized related to the Convertible Notes during the three and nine months ended September 30, 2017 and 2016 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Contractual interest expense	$2,840	$1,250	$6,033	$3,750
Amortization of debt issuance costs	348	273	944	797
Amortization of debt discount	3,264	1,920	7,909	5,602
Total interest expense	$6,452	$3,443	$14,886	$10,149

Convertible Bond Hedge and Warrant Transactions

In connection with the pricing of the 2019 Convertible Notes and in order to reduce the potential dilution to our common stock and/or offset cash payments due upon conversion of the 2019 Convertible Notes, in February 2014 we entered into convertible bond hedge transactions and separate warrant transactions of our common stock underlying the aggregate principal amount of the 2019 Convertible Notes with the call spread counterparties. In connection with the May 2017 and September 2017 repurchases of the 2019 Convertible Notes, as discussed above, we entered into agreements with the call spread counterparties to terminate a portion of the then existing convertible bond hedge transactions in an amount corresponding to the amount of such 2019 Convertible Notes repurchased and to terminate a portion of the then-existing warrant transactions.

As of September 30, 2017, the remaining bond hedge transactions covered approximately 0.8 million shares of our common stock underlying the remaining $21.4 million principal amount of the 2019 Convertible Notes. The convertible bond hedges have an exercise price of approximately $27.09 per share, subject to adjustment upon certain events, and are exercisable when and if the 2019 Convertible Notes are converted. If upon conversion of the 2019 Convertible Notes, the price of our common stock is above the exercise price of the convertible bond hedges, the call spread counterparties will deliver shares of our common stock and/or cash with an aggregate value 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 were separate transactions entered into by us and were not part of the terms of the 2019 Convertible Notes or the warrants, discussed below. Holders of the 2019 Convertible Notes will not have any rights with respect to the convertible bond hedges.

As of September 30, 2017, the remaining warrant transactions covered approximately 1.0 million shares of our common stock underlying the remaining $21.4 million principal amount of the 2019 Convertible Notes. The initial exercise price of the warrants is $34.12 per share, subject to adjustment upon certain events, which was 70% above the last reported sale price of our common stock of $20.07 on February 11, 2014. The warrants would separately have a dilutive effect to the extent that the market value per share of our common stock, as measured under the terms of the warrants, exceeds the applicable exercise price of the warrants. The warrants were issued to the call spread counterparties pursuant to the exemption from registration set forth in Section 4(a)(2) of the Securities Act of 1933, as amended.

As part of the May 2017 agreements to partially terminate the bond hedge and warrant transactions, we received approximately $0.3 million, which we recorded as a net increase to additional paid-in capital during the nine months ended September 30, 2017.

2015 Term Loan Facility

In August 2015, 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, under which we borrowed the full amount.
The 2015 Term Loan Facility included 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, we prepaid $3.0 million of the debt in April 2017.

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In May 2017, we repaid the remaining $321.8 million of outstanding borrowings and accrued interest of the 2015 Term Loan Facility and, in accordance with ASC 470, recognized a $9.7 million loss on debt extinguishment.

Future Payments

Future annual principal payments on our long-term debt as of September 30, 2017 were as follows (in thousands):

Period	Future Annual Principal Payments
Remainder of Year Ending December 31, 2017	$ —
Year Ending December 31, 2018	—
Year Ending December 31, 2019	21,417
Year Ending December 31, 2020	—
Year Ending December 31, 2021	—
Thereafter	820,000
Total	$ 841,417

Q. 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 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 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.

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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 first quarter of 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.

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 collectability, 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. 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 reached conclusions on our key accounting assessments related to the standard for service revenue and are finalizing our accounting policies. We do not expect that our revenue recognition will be materially impacted by this new guidance as it relates to service revenue. We are currently performing an assessment of our revenue contracts to determine what impact, if any, the adoption of ASU 2014-09 will have on our product revenue, and we expect to complete this impact assessment in the fourth quarter of 2017. We currently plan to adopt the standard using the "modified retrospective method." Under that method, we will apply the rules to contracts that are not completed as of January 1, 2018, and recognize the cumulative effect of initially applying the standard as an adjustment to the opening balance of retained earnings. There are also certain considerations related to internal control over financial reporting that are associated with implementing Topic 606. We are evaluating our internal control framework over revenue recognition to identify any changes that may need to be made in response to the new guidance. In addition, disclosure requirements under the new guidance in Topic 606 have been significantly expanded in comparison to the disclosure requirements under the current guidance. Our next phase of implementation will include designing and implementing the appropriate controls to obtain and disclose the information required under Topic 606.

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 ot words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Examples of forward-looking statements contained in this report include, without limitation, statements regarding the following: plans to continue to expand the impact of our current and future products and services for patients by delivering on our growth strategy; our expectations regarding the submission of an NDA for bremelanotide in early 2018; 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; expectations for our pursuit of the broader indication for Feraheme; 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 and timing 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 product sales of Makena and Feraheme will increase in the fourth quarter of 2017; beliefs that our efforts to increase new enrollments for the CBR Services will increase services revenues in the fourth quarter 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; the impact on our business in connection with the expansion of our commercial team; expectations regarding our financial results, including revenues, product sales allowances and accruals, cost of product sales and services, research and development expenses, selling, general and administrative expenses, amortization and other income (expense); beliefs that the longer-term sustainability of the Makena franchise is dependent on a successful approval and launch of the auto-injector formulation of the product; 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 September 30, 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, and the Convertible Notes; 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.

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 maternal and women's health, anemia management and cancer supportive care, including Makena® (hydroxyprogesterone caproate injection), Feraheme® (ferumoxytol) for intravenous ("IV") use, MuGard® Mucoadhesive Oral Wound Rinse, and Intrarosa™ (prasterone) vaginal inserts, for the treatment of moderate-to-severe dyspareunia, a symptom of vulvar and vaginal atrophy ("VVA"), due to menopause. 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.

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

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. 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 healthcare companies and pharmacies which, in turn, sell Makena to healthcare providers, hospitals, government agencies and integrated delivery systems.

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 have developed an auto-injector device for subcutaneous administration of Makena (the "Makena auto-injector"), including chemistry, manufacturing and controls ("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 pharmacokinetic ("PK") study. Makena administered subcutaneously demonstrated bioequivalence to the intramuscular injection on area under the curve ("AUC") ($AUC_{0\text{-to-inf}}$ 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 ("Cmax") for Makena administered subcutaneously was slightly higher than for the intramuscular (7.3 ng/mL compared to 6.3 ng/mL) with the 90% confidence interval for the ratio of Cmax (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 June 2017, the FDA accepted our NDA supplement ("sNDA") for the Makena auto-injector and has granted a PDUFA action date of February 14, 2018.

Feraheme

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 pursuit of a broader indication for Feraheme to include the treatment of IDA in adult patients who have failed or cannot tolerate oral iron or in whom oral iron is contraindicated, we conducted a head-to-head Phase 3 clinical trial in 2016 evaluating Feraheme in adults with IDA regardless of cause, including adults with CKD but excluding dialysis dependent CKD patients. This trial was a randomized, double-blind multicenter non-inferiority trial that evaluated the incidence of moderate-to-severe hypersensitivity reactions (including anaphylaxis) or moderate-to-severe hypotension with Feraheme compared to Injectafer®(ferric carboxymaltose injection). 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.

In August 2017, we announced that we completed the Feraheme submission to the FDA, which is, in part, supported by data from this Phase 3 trial. The data 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) 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 or 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 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®: 1.10 g/dL per gram of iron; treatment difference: 0.26 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 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 -0.13 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®: 38.7% of patients; rate difference: 38.3%; 95% confidence interval: -41.46% to -35.15%). In August 2017, the FDA accepted our submission to broaden the existing label for Feraheme and has granted a PDUFA action date of February 2, 2018.

Intrarosa

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 symptom of VVA, due to menopause. In addition, Endoceutics has agreed to conduct clinical studies for the use of Intrarosa in HSDD to support an application for regulatory approval for Intrarosa for the treatment of HSDD in the U.S, which studies were initiated in the third quarter of 2017. 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. In July 2017, we announced the commercial availability of Intrarosa at pharmacies throughout the U.S. Additional details regarding the license agreement with Endoceutics (the "Endoceutics 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.

Bremelanotide

In February 2017, we acquired the rights from Palatin Technologies, Inc. ("Palatin") to research, develop and commercialize bremelanotide, which is being developed for the treatment of HSDD in pre-menopausal women.

Bremelanotide is designed to be self-administered prior to anticipated sexual activity 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 from baseline in desire and decrease in distress associated with low sexual desire as measured using validated patient-reported outcome instruments. We currently expect to submit a New Drug Application ("NDA") in the first quarter of 2018 for the treatment of HSDD in pre-menopausal women following the completion of certain safety pharmacology and CMC studies. Additional

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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.

CBR

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.

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. Under the option agreement, Velo will complete a Phase 2b/3a clinical study, which began in the second quarter of 2017. Approximately 200 antepartum women with severe preeclampsia will be enrolled in the multi-center, randomized, double-blind, placebo-controlled, parallel-group Phase 2b/3a study. Following the conclusion of the DIF Phase 2b/3a study, we may terminate, or, for additional consideration, exercise or extend, our option to acquire the DIF Rights. 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.

MuGard

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.

Results of Operations - Three Months Ended September 30, 2017 and 2016

Revenues

Total revenues for the three months ended September 30, 2017 and 2016 consisted of the following (in thousands except for percentages):

	Three Months Ended September 30,		2017 to 2016	
	2017	2016	$ Change	% Change
Product sales, net				
Makena	$97,635	$93,387	$4,248	5 %
Feraheme	26,095	22,256	3,839	17 %
MuGard	241	134	107	80 %
Intrarosa	360	—	360	N/A
Total	124,331	115,777	8,554	7 %
Service revenues, net	29,410	27,965	1,445	5 %
License fee, collaboration and other revenues	—	40	(40)	(100)%
Total Revenues	$153,741	$143,782	$9,959	7 %

Our total revenues for the three months ended September 30, 2017 increased by $10.0 million as compared to the same period in 2016, primarily as the result of a $4.2 million increase in our net Makena sales, a $3.8 million increase in our net Feraheme revenue, and a $1.4 million increase in net service revenue from CBR.

Product Sales

Total gross product sales were offset by product sales allowances and accruals for the three months ended September 30, 2017 and 2016 as follows (in thousands except for percentages):

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	Three Months Ended September 30,				2017 to 2016	
	2017	Percent of gross product sales	2016	Percent of gross product sales	$ Change	% Change
Gross product sales	$235,299		$201,303		$33,996	17 %
Provision for product sales allowances and accruals:						
Contractual adjustments	80,110	34 %	61,504	31 %		
Governmental rebates	30,858	13 %	24,022	12 %		
Total	110,968	47 %	85,526	43 %		
Product sales, net	$124,331		$115,777		$8,554	7 %

We expect gross product sales to increase in the fourth quarter of 2017 as compared the third quarter of 2017, primarily based on increased units sold of our currently marketed products and the addition of Intrarosa sales following its July 2017 launch.

Gross product sales increased by $34.0 million, or approximately 17%, during the three months ended September 30, 2017 as compared to the same period in 2016 primarily due to increases of $19.3 million and $13.0 million of Makena and Feraheme gross sales, respectively. Of the $19.3 million increase in gross Makena sales, $7.0 million was due to pricing and $12.3 million was due to increased quantities sold. Of the $13.0 million increase in gross Feraheme sales, $6.6 million was due to pricing and $6.4 million was due to increased quantities sold. The total increase in gross product sales was partially offset by $25.4 million of additional allowances and accruals for the three months ended September 30, 2017, as compared to the same period in 2016, as discussed below.

Net product sales increased by $8.6 million, or approximately 7%, during the three months ended September 30, 2017 as compared to the same period in 2016 primarily due to a $4.2 million increase in net Makena sales and a $3.8 million increase in net Feraheme sales. We anticipate that net sales of Makena will increase in the fourth quarter as compared to the third quarter of 2017, driven primarily by increased quantities sold. Over the long-term, dependent on the number and commercial success of potential generic competitors, we anticipate revenues from the intramuscular Makena product to decline. Any revenues from the Makena subcutaneous auto-injector, if approved, could partially alleviate the expected decline in Makena revenue. We anticipate that sales of Feraheme will increase in the fourth quarter of 2017 as compared to the third quarter of 2017 due to a combination of price and quantities sold.

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 greater distribution fees and higher mix of business through commercial and Medicaid rebates than historically realized. We expect these allowances to decrease slightly for Makena as a percentage of gross sales in the fourth quarter of 2017.

We did not materially adjust our product sales allowances and accruals during the three months ended September 30, 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 $1.4 million increase in service revenues recorded in the three months ended September 30, 2017 as compared to the same period in 2016 was partially due to increased recurring revenue from new enrollments as well as a lower purchase accounting adjustment to the CBR deferred revenue balance in the third quarter of 2017 as compared to third quarter of 2016. We expect service revenues to increase slightly in the fourth quarter of 2017 as compared to the third 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 September 30, 2017 and 2016 were as follows (in thousands except for percentages):

	Three Months Ended September 30,		2017 to 2016	
	2017	2016	$ Change	% Change
Cost of product sales	$31,085	$25,706	$5,379	21 %
Percentage of net product sales	25 %	22 %		

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, Inc. (“Lumara Health”). The $5.4 million increase in our cost of product sales for the three months ended September 30, 2017 as compared to the same period in 2016 was primarily attributable to a $4.5 million increase in amortization expense of the Makena product intangible asset and a $2.1 million increase in production costs and overhead, partially offset by a $1.3 million decrease in the amortization of inventory step-up.

We expect our cost of product sales as a percentage of net product sales to increase significantly in the fourth quarter of 2017 as well as 2018, as compared to previous levels, primarily due to the amortization of the Makena base technology intangible asset over its remaining estimated useful life, which was shortened during the third quarter of 2017.

Cost of Services

Cost of services for the three months ended September 30, 2017 and 2016 were as follows (in thousands except for percentages):

	Three Months Ended September 30,		2017 to 2016	
	2017	2016	$ Change	% Change
Cost of services	$5,559	$4,984	$575	12 %
Percentage of service revenues	19 %	18 %		

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.

We expect our cost of services as a percentage of service revenues to remain relatively constant in the fourth quarter of 2017 as compared to the third quarter of 2017 as the deferred revenues adjustment associated with the CBR Services revenues becomes more consistent on an annual basis going forward.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2017 and 2016 consisted of the following (in thousands except for percentages):

	Three Months Ended September 30,		2017 to 2016	
	2017	2016	$ Change	% Change
External research and development expenses				
Feraheme-related costs	$(370)	$7,159	$(7,529)	<(100 %)
Makena-related costs	3,616	5,464	(1,848)	(34)%
Bremelanotide-related costs	6,516	—	6,516	N/A
Intrarosa-related costs	336	—	336	N/A

Other external costs	824	602	222	37 %
Total	10,922	13,225	(2,303)	(17)%
Internal research and development expenses	5,352	3,891	1,461	38 %
Total research and development expenses	$16,274	$17,116	$(842)	(5)%

Total research and development expenses incurred in the three months ended September 30, 2017 decreased by $0.8 million, or 5%, as compared to the same period in 2016. The decrease was primarily due to a $7.5 million and $1.8 million

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decrease in spending for the Feraheme IDA program and Makena auto-injector program, respectively. These decreases were partially offset by $6.5 million incurred primarily in connection with our reimbursement of costs to Palatin associated with development and regulatory activities for the bremelanotide regulatory submission (our reimbursement obligation was capped at $25.0 million).

We expect that our research and development expenses in the fourth quarter of 2017 will remain consistent with the third quarter of 2017 due to continued costs to advance bremelanotide toward our expected NDA filing in early 2018, potential label expansion opportunities for bremelanotide and Intrarosa, and start-up costs related to a new Feraheme pediatric trial, partially offset by decreased Makena-related costs due to the completion of the related clinical trial.

Research and Development Activities

We track our external costs on a major project basis, in most cases through the later of the completion of the last trial in the project or the last submission of a regulatory filing to the FDA. We do not track our internal costs by project since our research and development personnel work on a number of projects concurrently and much of these costs benefit multiple projects or our operations in general. The following major research and development projects were ongoing as of September 30, 2017:

- Bremelanotide: Under the terms of the Palatin License Agreement we agreed to 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 bremelanotide for the treatment of HSDD in pre-menopausal women. In addition, we expect to incur supply chain costs to support the ultimate commercialization of bremelanotide;
- Makena: This project 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 for the Makena auto-injector submitted to the FDA in April 2017;
- Feraheme to treat IDA in CKD patients: This project 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 evaluate 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 the development of a plan forward in order to satisfy this post-approval commitment for Feraheme and subsequently proposed a protocol to the FDA for a new pediatric study. Following recent interactions with the FDA regarding the adequacy of our proposed protocol, we amended the protocol and intend to initiate a new pediatric study in the near future; and
- Feraheme to treat IDA regardless of the underlying cause: This project includes the randomized, double-blind multicenter non-inferiority trial evaluating the incidences of moderate-to-severe hypersensitivity reactions (including anaphylaxis) or moderate-to-severe hypotension with Feraheme compared to Injectafer®(ferric carboxymaltose infusion) in adults with IDA, which was completed in December 2016. In August 2017, the FDA accepted our submission to broaden the existing label for Feraheme and has granted a PDUFA action date of February 2, 2018.

From February 2, 2017 (the date of the Palatin License Agreement) through September 30, 2017, we have incurred aggregate external research and development expenses of approximately $26.5 million related to our current program for bremelanotide, 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 currently estimate that the total remaining external costs associated with this development program, including costs related to our expected NDA submission to the FDA planned for the first quarter of 2018 and planned label expansion projects, will be in the range of approximately $15.0 million to $25.0 million over the next several years.

From November 12, 2014 (the date of the Lumara Health acquisition) through September 30, 2017, we have incurred aggregate external research and development expenses of approximately $37.1 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 $4.5 million to $7.0 million over the next several years.

Through September 30, 2017, we have incurred aggregate external research and development expenses of approximately $41.4 million related to our current program for the development of Feraheme to treat IDA in CKD patients, described above.

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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 $34.2 million since the first quarter of 2016. In light of our August 2017 submission to the FDA, we do not currently expect to incur any further external costs associated with this development project.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended September 30, 2017 and 2016 consisted of the following (in thousands except for percentages):

	Three Months Ended September 30,		2017 to 2016	
	2017	2016	$ Change	% Change
Compensation, payroll taxes and benefits	$37,079	$19,940	$17,139	86 %
Professional, consulting and other outside services	35,203	25,944	9,259	36 %
Fair value of contingent consideration liability	(49,929)	3,708	(53,637)	>(100%)
Amortization expense related to customer relationship intangible	3,930	3,132	798	25 %
Equity-based compensation expense	5,024	4,492	532	12 %
Total selling, general and administrative expenses	$31,307	$57,216	$(25,909)	(45)%

Total selling, general and administrative expenses, excluding the $53.6 million decrease to the contingent consideration liability expense, described below, increased by $27.7 million, or approximately 52%, in the three months ended September 30, 2017 as compared to the same period in 2016 for the following reasons:

- $17.1 million increase in compensation, payroll taxes and benefits primarily due to increased costs associated with the expansion of our women's health sales force and related organizational growth; and
- $9.3 million increase in sales and marketing, consulting, professional fees, and other expenses primarily due to costs related to the July 2017 launch of Intrarosa.

In addition, total selling, general and administrative expenses for the three months ended September 30, 2017 reflects a $49.9 million decrease to the fair value of contingent consideration liability expense due to a change in our estimated Makena revenues and associated milestone payments, as discussed in more detail in Note D "Fair Value Measurements" to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

We expect that total selling, general and administrative expenses, excluding any impact from the Makena contingent consideration liability expense, will remain relatively consistent in the fourth quarter of 2017 as compared to the third quarter of 2017.

Impairment of Intangible Assets

During the third quarter of 2017, we updated our long-range revenue forecasts for the intramuscular formulation of Makena and incorporated new information about potential generic competitors. Based on these revised expectations, we determined that indicators of impairment existed for our Makena base technology intangible asset (the intramuscular formulation). As a result, we concluded that the fair value of this asset was less than its carrying value and accordingly, recorded an impairment charge of $319.2 million. We also assessed our IPR&D intangible asset, which is associated with the Makena subcutaneous auto-injector and concluded that this asset's fair value was greater than its carrying value, and was therefore not impaired. For additional information, refer to Note G, "Goodwill and Intangible Assets, Net" to the condensed consolidated financial statements included in this quarterly report on Form 10-Q. Management believes that the longer-term sustainability of the Makena franchise is dependent on a successful approval and launch of the auto-injector formulation of the product.

There were no impairments of intangible assets for the three months ended September 30, 2016.

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Other Income (Expense), net

Other income (expense), net for the three months ended September 30, 2017 remained relatively constant as compared to the same period in 2016.

We expect our net other income (expense) to remain relatively consistent in the fourth quarter of 2017 as compared to the third quarter of 2017.

Income Tax (Benefit) Expense

The following table summarizes our effective tax rate and income tax (benefit) expense for the three months ended September 30, 2017 and 2016 (in thousands except for percentages):

	Three Months Ended September 30,	
	2017	2016
Effective tax rate	43 %	24 %
Income tax (benefit) expense	$(114,343)	$5,069

For the three months ended September 30, 2017, we recognized an income tax benefit of $114.3 million, representing an effective tax rate of 43%. The difference between the expected statutory federal tax rate of 35% and the 43% effective tax rate for the three months ended September 30, 2017, was primarily attributable to the impact of state income taxes, federal research and development and orphan drug tax credits, and contingent consideration associated with Lumara Health, partially offset by the establishment of a valuation allowance related to certain deferred tax assets. During the three months ended September 30, 2017, we entered into a three-year cumulative loss position and established a valuation allowance on certain deferred tax assets to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets.

For the three months ended September 30, 2016, we recognized an income tax expense of $5.1 million, representing an effective tax rate of 24%. The difference between the expected statutory federal tax rate of 35% and the 24% effective tax rate for the three months ended September 30, 2016 was primarily attributable to contingent consideration associated with Lumara Health, including the tax deductible portion of the then anticipated 2016 milestone payment, and federal research and development and orphan drug tax credits, partially offset by the impact of state income taxes, non-deductible stock compensation, and other non-deductible expenses.

Results of Operations - Nine Months Ended September 30, 2017 and 2016

Revenues

Total revenues for the nine months ended September 30, 2017 and 2016 consisted of the following (in thousands except for percentages):

	Nine Months Ended September 30,		2017 to 2016	
	2017	2016	$ Change	% Change
Product sales, net				
Makena	$286,771	$236,824	$49,947	21 %
Feraheme	79,492	70,774	8,718	12 %
MuGard	567	726	(159)	(22)%
Intrarosa	360	—	360	N/A
Total	367,190	308,324	58,866	19 %
Service revenues, net	84,365	71,863	12,502	17 %
License fee, collaboration and other revenues	53	313	(260)	(83)%
Total Revenues	$451,608	$380,500	$71,108	19 %

Our total revenues for the nine months ended September 30, 2017 increased by $71.1 million as compared to the same period in 2016, primarily as the result of a $49.9 million increase in our net Makena sales, a $12.5 million increase of net CBR Services revenue and a $8.7 million increase in our net Feraheme sales.

Product Sales

Total gross product sales were offset by product sales allowances and accruals for the nine months ended September 30, 2017 and 2016 as follows (in thousands except for percentages):

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	Nine Months Ended September 30,				2017 to 2016	
	2017	Percent of gross product sales	2016	Percent of gross product sales	$ Change	% Change
Gross product sales	$676,377		$530,076		$146,301	28 %
Provision for product sales allowances and accruals:						
Contractual adjustments	225,622	33 %	161,023	30 %		
Governmental rebates	83,565	12 %	60,729	11 %		
Total	309,187	45 %	221,752	41 %		
Product sales, net	$367,190		$308,324		$58,866	19 %

Gross product sales increased by $146.3 million, or approximately 28%, during the nine months ended September 30, 2017 as compared to the same period in 2016 primarily due to increases of $111.9 million and $33.2 million of Makena and Feraheme sales, respectively. Of the $111.9 million increase in gross Makena sales, $6.0 million was due to pricing and $105.9 million was due to increased quantities sold. Of the $33.2 million increase in gross Feraheme sales, $19.6 million was due to pricing and $13.6 million was due to increased quantities sold. The total increase in gross product sales was partially offset by $87.4 million of additional allowances and accruals for the nine months ended September 30, 2017 as compared to the same period in 2016.

Net product sales increased by $58.9 million, or approximately 19%, during the nine months ended September 30, 2017 as compared to the same period in 2016 primarily due to a $49.9 million increase in net Makena sales and a $8.7 million increase in net Feraheme sales.

We did not materially adjust our product sales allowances and accruals during the nine months ended September 30, 2017 or 2016.

Service Revenues

The $12.5 million increase in service revenues recorded in the nine months ended September 30, 2017 as compared to the same period in 2016 was primarily due to a lower purchase accounting adjustment to the CBR deferred revenue balance in the first three quarters of 2017 as compared to first three quarters of 2016.

Costs and Expenses

Cost of Product Sales

Cost of product sales for the nine months ended September 30, 2017 and 2016 were as follows (in thousands except for percentages):

	Nine Months Ended September 30,		2017 to 2016	
	2017	2016	$ Change	% Change
Cost of product sales	$90,761	$65,942	$24,819	38 %
Percentage of net product sales	25 %	21 %		

The $24.8 million increase in our cost of product sales for the nine months ended September 30, 2017 as compared to the same period in 2016 was primarily attributable to a $20.8 million increase in amortization expense of the Makena product intangible asset and a $6.6 million increase in product costs and overhead, partially offset by a $2.6 million decrease in the amortization of inventory step-up of Makena inventory.

Cost of Services

Cost of services for the nine months ended September 30, 2017 and 2016 were as follows (in thousands except for percentages):

	Nine Months Ended September 30,		2017 to 2016	
	2017	2016	$ Change	% Change
Cost of services	$16,130	$15,705	$425	3 %

Percentage of service revenues	19	%	22	%

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The decrease of three percentage points in cost of service revenue as a percentage of service revenues was primarily due to a lower deferred revenue adjustment (as a result of purchase accounting) to the CBR deferred revenue balance in the nine months ended September 30, 2017 as compared to the same period in 2016.

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2017 and 2016 consisted of the following (in thousands except for percentages):

	Nine Months Ended September 30,		2017 to 2016	
	2017	2016	$ Change	% Change
External research and development expenses				
Feraheme-related costs	$7,046	$18,661	$(11,615)	(62)%
Makena-related costs	10,736	13,364	(2,628)	(20)%
Bremelanotide-related costs	26,521	—	26,521	N/A
Intrarosa-related costs	498	—	498	N/A
Other external costs	3,516	1,943	1,573	81%
Total	48,317	33,968	14,349	42%
Internal research and development expenses	14,704	11,611	3,093	27%
Total research and development expenses	$63,021	$45,579	$17,442	38%

Total research and development expenses incurred in the nine months ended September 30, 2017 increased by $17.4 million, or 38%, as compared to the same period in 2016. The increase was due to $26.5 million incurred primarily in connection with our reimbursement of costs to Palatin associated with development and regulatory activities for the bremelanotide regulatory submission (our reimbursement obligation was capped at $25.0 million). This increase was partially offset by a decrease of $11.6 million in spending for the Feraheme clinical trial, which was completed in December 2016.

In-Process Research and Development

During the nine months ended September 30, 2017, we recorded acquired in-process research and development (“IPR&D”) expense of $65.8 million related primarily to the $60.0 million one-time upfront payment under the terms of the Palatin License Agreement, which closed in February 2017, and which we characterized as acquired IPR&D because the product candidate had not received regulatory approval. In addition, during the nine months ended September 30, 2017, we recorded IPR&D expense of $5.8 million, which represented a portion of the $83.5 million of consideration recorded to date under the terms of the Endoceutics License Agreement, based on our determination that this portion of the total consideration did not have an alternative future use. The $83.5 million consideration for Intrarosa reflects the $50.0 million upfront payment, 600,000 shares of our common stock, having a value of $13.5 million, as measured on April 3, 2017, the date of closing, a $10.0 million payment made in the third quarter of 2017 upon delivery of the initial Intrarosa commercial launch supply, and a $10.0 million payment to be made in April 2018 on the first anniversary of the closing.We did not record any IPR&D expenses during the nine months ended September 30, 2016.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the nine months ended September 30, 2017 and 2016 consisted of the following (in thousands except for percentages):

	Nine Months Ended September 30,		2017 to 2016	
	2017	2016	$ Change	% Change
Compensation, payroll taxes and benefits	$96,437	$59,615	$36,822	62%
Professional, consulting and other outside services	107,120	84,365	22,755	27%
Fair value of contingent consideration liability	(47,142)	5,106	(52,248)	>(100%)
Amortization expense related to customer relationship intangible	11,789	9,397	2,392	25%

Equity-based compensation expense	14,515	13,831	684	5	%
Total selling, general and administrative expenses	$182,719	$172,314	$10,405	6	%

Total selling, general and administrative expenses, excluding the $52.2 million decrease to the contingent consideration liability expense, described below, increased by $62.7 million, or approximately 37%, as compared to the same period in 2016 for the following reasons:

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- $36.8 million increase in compensation, payroll taxes and benefits primarily due to increased costs associated with personnel from the expansion of our women's health sales force and related organizational growth;
- $22.8 million increase in sales and marketing, consulting, professional fees, and other expenses primarily due to costs related to the July 2017 launch of Intrarosa, increased costs associated with the expansion of our women's health sales force and litigation expense related to our ongoing Sandoz patent infringement litigation; and
- $2.4 million increase in amortization expense related to the CBR customer relationship intangible.

In addition, total selling, general and administrative expenses, for the nine months ended September 30, 2017, reflects a $47.1 million decrease to the fair value of contingent consideration liability expense due to a change in our estimated Makena revenues and associated milestone payments, as discussed in more detail in Note D "Fair Value Measurements" to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Impairment of Intangible Assets

During the third quarter of 2017, we updated our long-range revenue forecasts for the intramuscular formulation of Makena and incorporated new information about potential generic competitors. Based on these revised expectations, we determined that indicators of impairment existed for our Makena base technology intangible asset (the intramuscular formulation). As a result, we concluded that the fair value of this asset was less than its carrying value and accordingly, recorded an impairment charge of $319.2 million. We also assessed our IPR&D intangible asset, which is associated with the Makena subcutaneous auto-injector and concluded that this asset's fair value was greater than its carrying value, and was therefore not impaired. For additional information, refer to Note G, "Goodwill and Intangible Assets, Net" to the condensed consolidated financial statements included in this quarterly report on Form 10-Q. Management believes that the longer-term sustainability of the Makena franchise is dependent on a successful approval and launch of the auto-injector formulation of the product.

Impairments of finite-lived intangible assets was $16.0 million for the nine months ended September 30, 2016, due to an impairment charge of $15.7 million in the nine months ended September 30, 2016 related to the impairment of the remaining net intangible asset for the MuGard Rights based on the lack of broad reimbursement and insurance coverage for MuGard and the impairment of the remaining $0.2 million net CBR favorable lease intangible asset due to the subleasing of a portion of our CBR office space in San Bruno, California at a rate below the market rate used to determine the favorable lease intangible asset.

Other Income (Expense), net

Other income (expense), net for the nine months ended September 30, 2017 increased by $7.6 million as compared to the same period in 2016 primarily due to a $9.8 million loss on extinguishment of debt as the result of the early repayment in May 2017 of the then remaining $321.8 million outstanding principal amount of the 2015 Term Loan Facility, partially offset by a decrease in interest expense as the result of the termination of the 2015 Term Loan Facility.

Income Tax (Benefit) Expense

The following table summarizes our effective tax rate and income tax (benefit) expense for the nine months ended September 30, 2017 and 2016 (in thousands except for percentages):

	Nine Months Ended September 30,	
	2017	2016
Effective tax rate	41 %	32 %
Income tax (benefit) expense	$(143,521)	$3,725

For the nine months ended September 30, 2017, we recognized an income tax benefit of $143.5 million, representing an effective tax rate of 41%. The difference between the expected statutory federal tax rate of 35% and the 41% effective tax rate for the nine months ended September 30, 2017, was primarily attributable to the impact of state income taxes, federal research and development and orphan drug tax credits, and contingent consideration associated with Lumara Health, partially offset by the establishment of a valuation allowance related to certain deferred tax assets. During the nine months ended September 30, 2017, we entered into a three-year cumulative loss position and established a valuation allowance on certain deferred tax assets to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets.

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

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, Feraheme and Intrarosa, market and sell the CBR Services, pursue the next-generation development program for Makena, and develop and seek U.S. regulatory approval for bremelanotide for the treatment of HSDD. For a detailed discussion regarding the risks and uncertainties related to our liquidity and capital resources, please refer to our Risk Factors in Part I, Item 1A of our Annual Report and in Part II, Item IA of this Quarterly Report on Form 10-Q.

Cash, cash equivalents, investments and certain financial obligations as of September 30, 2017 and December 31, 2016 consisted of the following (in thousands except for percentages):

	September 30, 2017	December 31, 2016	$ Change	% Change
Cash and cash equivalents	$ 257,914	$ 274,305	$(16,391)	(6)%
Investments	136,186	304,781	(168,595)	(55)%
Total	$ 394,100	$ 579,086	$(184,986)	(32)%
Outstanding principal on 2023 Senior Notes	$ 500,000	$ 500,000	$—	—%
Outstanding principal on 2022 Convertible Notes	320,000	—	320,000	N/A
Outstanding principal on 2019 Convertible Notes	21,417	199,998	(178,581)	(89)%
Outstanding principal on 2015 Term Loan Facility	—	328,125	(328,125)	(100)%
Total	$ 841,417	$ 1,028,123	$(186,706)	(18)%

The $185.0 million decrease in cash, cash equivalents and investments as of September 30, 2017, as compared to December 31, 2016, was primarily due to the following factors:

- Decrease of $328.1 million for principal repayments made during 2017 and the full repayment of the remaining balance of our 2015 Term Loan Facility, described below;
- Decrease of $191.5 million related to the repurchase of a portion of our 2019 Convertible Notes, described below;
- Decrease of $60.0 million due to a one-time up-front payment made to Palatin in February 2017 under the terms of the Palatin License Agreement;
- Decrease of $50.0 million due to a one-time up-front payment and a one-time $10.0 million payment for the delivery of commercial supply of Intrarosa made to Endoceutics in April 2017 and August 2017, respectively, under the terms of the Endoceutics License Agreement;
- Increase of $310.4 million net proceeds related to the issuance of our 2022 Convertible Notes, described below; and
- Positive net cash flows from our operations during the first three quarters of 2017.

We expect that our cash, cash equivalents and investments balances will decrease in the fourth quarter of 2017 relative to the $394.1 million balance as of September 30, 2017. This expected decrease is primarily as a result of a $50.0 million milestone payment that we expect to pay in the fourth quarter of 2017 to the former Lumara Health security holders based on the achievement of a Makena net sales milestone. Also contributing to our expected decrease in cash is our October 2017 repurchase of $25.0 million of the 2023 Senior Notes, as defined below, partially offset by our operating profits. In addition, we expect to pay a second $50.0 million milestone payment in the first half of 2018 to the former Lumara Health security holders based on the achievement of a Makena net sales milestone. Further, under the terms of the Palatin License Agreement, we are required to pay Palatin up to $80.0 million upon the achievement of certain regulatory milestones. In the first half of 2018, we expect to pay $20.0 million, of the $80.0 million in regulatory milestone payments, upon the acceptance by the FDA of our

NDA for bremelanotide. We believe that our cash, cash equivalents and investments as of September 30, 2017, and the cash we 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 May 2017, we issued $300.0 million aggregate principal amount of the 3.25% convertible senior notes due 2022 (the “2022 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. We received net proceeds of $291.0 million from the sale of the 2022 Convertible Notes, after deducting fees and expenses of $9.0 million. In addition, on June 7, 2017, we issued an additional $20.0 million principal amount of 2022 Convertible Notes pursuant to the exercise of an over-allotment option granted to the underwriters in the offering. We received net proceeds of $19.4 million from the sale of the over-allotment option, after deducting fees and expenses of $0.6 million.

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

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, which began in March 2016. On May 11, 2017, we repaid the remaining $321.8 million of outstanding borrowings and accrued interest of, and terminated, the 2015 Term Loan Facility and recognized a $9.7 million loss on debt extinguishment. For additional information, see Note P, “Debt,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. In October 2017, we repurchased $25.0 million principal of the 2023 Senior Notes in a privately negotiated transaction with cash on hand.

In February 2014, we issued $200.0 million aggregate principal amount of 2.5% convertible senior notes due February 15, 2019 (the “2019 Convertible Notes”). In May 2017 and September 2017, we entered into privately negotiated transactions with certain investors to repurchase approximately $158.9 million and $19.6 million, respectively, aggregate principal amount of the 2019 Convertible Notes for an aggregate repurchase price of approximately $171.3 million and $21.4 million, respectively, including accrued interest, as discussed in more detail in Note P, “Debt,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. The remaining 2019 Convertible Notes are senior unsecured obligations and bear interest at a rate of 2.5% per year, payable semi-annually in arrears on February 15 and August 15 of each year. The 2019 Convertible Notes will mature on February 15, 2019, unless repurchased or converted earlier. The 2019 Convertible Notes will be convertible into cash, shares of our common stock, or a combination thereof, at our election, at a conversion rate of 36.9079 shares of common stock per $1,000 principal amount of the 2019 Convertible Notes, which corresponds to a conversion price of approximately $27.09 per share of our common stock. The conversion rate is subject to adjustment from time to time. Based on the last reported sale price of our common stock during the last 30 trading days of the third quarter of 2017, the 2019 Convertible Notes were not convertible as of October 1, 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 September 30, 2017, we have 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 nine months ended September 30, 2017.

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Cash flows from operating activities

Net cash provided by operating activities for the nine months ended September 30, 2017 was $86.6 million as compared to net cash provided by operating activities of $183.7 million for the same period in 2016. The $97.1 million decrease in net cash provided by operating activities was primarily due to an increase in net loss of $210.8 million, a decrease of $149.3 million in deferred income taxes, a $52.2 million decrease in the fair value of contingent consideration, a $17.9 million decrease due to changes in operating assets and liabilities and other non-cash charges, partially offset by an increase of $319.2 million due to a non-cash impairment of intangible assets reflected in the nine months ended September 30, 2017, $20.0 million of increased depreciation and amortization and a $9.8 million increase in loss on debt extinguishment.

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 provided by investing activities in the nine months ended September 30, 2017 was $106.2 million as compared to $73.8 million net cash used in investing activities for the same period in 2016. Cash flows from investing activities increased during the nine months ended September 30, 2017 by $180.0 million, which primarily reflects a $239.1 million increase in net cash provided by the sale of our investments, partially offset by the $55.8 million cash portion of our investment in the Intrarosa asset.

Cash flows from financing activities

Net cash used in financing activities in the nine months ended September 30, 2017 was $209.2 million as compared to $33.3 million for the same period in 2016. Cash used in financing activities increased during the nine months ended September 30, 2017 as compared to the same period in 2016 primarily due to $328.1 million of principal repayments made during 2017 and the full repayment of the remaining balance of our 2015 Term Loan Facility, $191.5 million for the repurchase of a portion of our 2019 Convertible Notes and $9.6 million of convertible debt issuance costs, partially offset by $320.0 million net proceeds related to the issuance of our 2022 Convertible Notes and $20.0 million of cash used to repurchase shares of our common stock under our share repurchase program during the first half of 2016.

Off-Balance Sheet Arrangements

As of September 30, 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 Q, “Recently Issued and Proposed Accounting Pronouncements,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for information regarding new accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk:

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

Item 4. Controls and Procedures:

Managements’ Evaluation of our Disclosure Controls and Procedures

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

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Changes in Internal Control Over Financial Reporting

During the third quarter of 2017, we completed the migration of our legacy accounting system for the majority of our legal entities to an Oracle platform. In connection with this implementation, we have updated the processes that constitute our internal control over financial reporting, as necessary, to accommodate related changes in our business processes. There were no other changes in our internal control over financial reporting (as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) that occurred during the three months ended September 30, 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, the key secondary endpoint, was not significantly different from placebo in either clinical trial. The most frequent adverse events were nausea, flushing and headache, which were generally mild-to-moderate in severity. Approximately 18% of patients discontinued participation in the bremelanotide arm due to adverse events in both studies. We currently expect to submit the bremelanotide NDA in the first quarter of 2018, subject to the successful and timely completion of certain safety pharmacology and chemistry, manufacturing and controls studies.

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 statistically significant efficacy results;

- 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 results of the safety pharmacology and other ancillary studies;

- 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;

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- 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 safety pharmacology or other ancillary studies or the FDA's response to any application for approval are 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.

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

The following table provides certain information with respect to our purchases of shares of our stock during the three months ended September 30, 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)
July1, 2017 through July 31, 2017	—	$ —	—	2,035,624
August 1, 2017 through August 31, 2017	7,081	17.60	—	2,395,210
September 1, 2017 through September 30, 2017	1,320	18.31	—	2,168,022
Total	8,401	$ 17.71	—	

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

(2)

We did not repurchase any of our common stock during the third quarter of 2017. We have repurchased and retired $20.0 million of our common stock under the share repurchase program through September 30, 2017. These shares were purchased pursuant to a repurchase program authorized by our Board that was announced in January 2016 to repurchase up to $60.0 million of our common stock, of which $40.0 million remains authorized for repurchase as of September 30, 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
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:	November 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:	November 3, 2017

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Exhibit Number	Description
31.1+	Certification Pursuant to Rule 13a 14(a)/15d 14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes Oxley Act of 2002
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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.