

**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 June 30, 2019

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-10865



**AMAG Pharmaceuticals, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**1100 Winter Street, Waltham, Massachusetts**

(Address of Principal Executive Offices)

**04-2742593**

(I.R.S. Employer  
Identification No.)

**02451**

(Zip Code)

**(617) 498-3300**

(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
Common Stock, par value \$0.01 per share	AMAG	NASDAQ Global Select Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). **Yes**  **No**

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

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 Exchange Act). **Yes**  **No**

As of August 1, 2019, there were 33,900,681 shares of the registrant's Common Stock, par value \$0.01 per share, outstanding.

**AMAG PHARMACEUTICALS, INC.**  
**FORM 10-Q**  
**FOR THE QUARTER ENDED JUNE 30, 2019**  
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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)**

	June 30, 2019	December 31, 2018
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 150,461	\$ 253,256
Marketable securities	110,583	140,915
Accounts receivable, net	83,183	75,347
Inventories	25,179	26,691
Prepaid and other current assets	24,549	18,961
Note receivable	—	10,000
Total current assets	393,955	525,170
Property and equipment, net	8,224	7,521
Goodwill	422,513	422,513
Intangible assets, net	191,789	217,033
Operating lease right-of-use asset	6,582	—
Deferred tax assets	630	1,260
Restricted cash	495	495
Other long-term assets	12	1,467
Total assets	\$ 1,024,200	\$ 1,175,459
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 26,946	\$ 14,487
Accrued expenses	214,211	129,537
Current portion of convertible notes, net	—	21,276
Current portion of operating lease liability	3,889	—
Current portion of deferred revenue	1,128	—
Current portion of acquisition-related contingent consideration	128	144
Total current liabilities	246,302	165,444
Long-term liabilities:		
Convertible notes, net	269,305	261,933
Long-term operating lease liability	3,504	—
Long-term deferred revenue	5,171	—
Long-term acquisition-related contingent consideration	183	215
Other long-term liabilities	228	1,212
Total liabilities	524,693	428,804
Commitments and contingencies (Note P)		
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; 33,899,954 and 34,606,760 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	339	346
Additional paid-in capital	1,287,553	1,292,736
Accumulated other comprehensive loss	(3,032)	(3,985)
Accumulated deficit	(785,353)	(542,442)
Total stockholders' equity	499,507	746,655
Total liabilities and stockholders' equity	\$ 1,024,200	\$ 1,175,459

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
<b>Revenues:</b>				
Product sales, net	\$ 77,976	\$ 146,219	\$ 153,705	\$ 263,567
Other revenues	133	35	208	75
Total revenues	78,109	146,254	153,913	263,642
<b>Costs and expenses:</b>				
Cost of product sales	24,290	76,776	42,767	140,688
Research and development expenses	14,980	11,693	33,046	22,502
Acquired in-process research and development	—	—	74,856	20,000
Selling, general and administrative expenses	77,324	15,898	152,006	89,329
Impairment of intangible assets	77,358	—	77,358	—
Restructuring expenses	—	—	7,420	—
Total costs and expenses	193,952	104,367	387,453	272,519
Operating (loss) income	(115,843)	41,887	(233,540)	(8,877)
<b>Other income (expense):</b>				
Interest expense	(6,330)	(16,056)	(12,780)	(32,034)
Interest and dividend income	1,224	952	2,810	1,595
Other income (expense)	2	(44)	342	(44)
Total other expense, net	(5,104)	(15,148)	(9,628)	(30,483)
(Loss) income from continuing operations before income taxes	(120,947)	26,739	(243,168)	(39,360)
Income tax (benefit) expense	(120)	52,556	(257)	44,556
Net loss from continuing operations	\$ (120,827)	\$ (25,817)	\$ (242,911)	\$ (83,916)
<b>Discontinued operations:</b>				
Income from discontinued operations	\$ —	\$ 7,158	\$ —	\$ 13,036
Income tax expense	—	1,422	—	3,444
Net income from discontinued operations	\$ —	\$ 5,736	\$ —	\$ 9,592
Net loss	\$ (120,827)	\$ (20,081)	\$ (242,911)	\$ (74,324)
<b>Basic and diluted net (loss) income per share:</b>				
Loss from continuing operations	\$ (3.57)	\$ (0.75)	\$ (7.12)	\$ (2.45)
Income from discontinued operations	—	0.17	—	0.28
Basic and diluted net loss per share	\$ (3.57)	\$ (0.58)	\$ (7.12)	\$ (2.17)
<b>Weighted average shares outstanding used to compute net (loss) income per share (basic and diluted)</b>				
	33,807	34,358	34,136	34,261

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net loss	\$ (120,827)	\$ (20,081)	\$ (242,911)	\$ (74,324)
Other comprehensive loss:				
Holding gains (losses) arising during period, net of tax	344	67	953	(387)
Total comprehensive loss	\$ (120,483)	\$ (20,014)	\$ (241,958)	\$ (74,711)

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

**AMAG PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**(IN THOUSANDS, EXCEPT SHARES)**  
**(Unaudited)**

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at March 31, 2019	33,746,828	\$ 337	\$ 1,282,284	\$ (3,376)	\$ (664,526)	\$ 614,719
Net shares issued in connection with the exercise of stock options and vesting of restricted stock units, net of withholdings	48,051	1	(115)	—	—	(114)
Issuance of common stock under employee stock purchase plan	105,075	1	850	—	—	851
Non-cash equity based compensation	—	—	4,534	—	—	4,534
Unrealized losses on securities, net of tax	—	—	—	344	—	344
Net loss	—	—	—	—	(120,827)	(120,827)
Balance at June 30, 2019	33,899,954	\$ 339	\$ 1,287,553	\$ (3,032)	\$ (785,353)	\$ 499,507

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2018	34,606,760	\$ 346	\$ 1,292,736	\$ (3,985)	\$ (542,442)	\$ 746,655
Net shares issued in connection with the exercise of stock options and vesting of restricted stock units, net of withholdings	262,919	3	(1,721)	—	—	(1,718)
Issuance of common stock under employee stock purchase plan	105,075	1	850	—	—	851
Repurchase of common stock pursuant to the share repurchase program	(1,074,800)	(11)	(13,719)	—	—	(13,730)
Non-cash equity based compensation	—	—	9,407	—	—	9,407
Unrealized losses on securities, net of tax	—	—	—	953	—	953
Net loss	—	—	—	—	(242,911)	(242,911)
Balance at June 30, 2019	33,899,954	\$ 339	\$ 1,287,553	\$ (3,032)	\$ (785,353)	\$ 499,507

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

**AMAG PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (CONTINUED)**  
**(IN THOUSANDS, EXCEPT SHARES)**  
**(Unaudited)**

	<u>Common Stock</u>		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at March 31, 2018	34,322,193	\$ 343	\$ 1,274,935	\$ (4,362)	\$ (530,922)	\$ 739,994
Net shares issued in connection with the exercise of stock options and vesting of restricted stock units, net of withholdings	67,875	1	1,334	—	—	1,335
Non-cash equity based compensation	—	—	5,589	—	—	5,589
Unrealized losses on securities, net of tax	—	—	—	67	—	67
Net loss	—	—	—	—	(20,081)	(20,081)
Balance at June 30, 2018	<u>34,390,068</u>	<u>\$ 344</u>	<u>\$ 1,281,858</u>	<u>\$ (4,295)</u>	<u>\$ (551,003)</u>	<u>\$ 726,904</u>

	<u>Common Stock</u>		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2017	34,083,112	\$ 341	\$ 1,271,628	\$ (3,908)	\$ (477,817)	\$ 790,244
ASC 606 adoption adjustment, net of tax	—	—	—	—	1,138	1,138
Net shares issued in connection with the exercise of stock options and vesting of restricted stock units, net of withholdings	306,956	3	(892)	—	—	(889)
Non-cash equity based compensation	—	—	11,122	—	—	11,122
Unrealized losses on securities, net of tax	—	—	—	(387)	—	(387)
Net loss	—	—	—	—	(74,324)	(74,324)
Balance at June 30, 2018	<u>34,390,068</u>	<u>\$ 344</u>	<u>\$ 1,281,858</u>	<u>\$ (4,295)</u>	<u>\$ (551,003)</u>	<u>\$ 726,904</u>

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



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

	<b>Six Months Ended June 30,</b>	
	<b>2019</b>	<b>2018</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (242,911)	\$ (74,324)
<b>Adjustments to reconcile net loss to net cash (used in) provided by operating activities:</b>		
Depreciation and amortization	9,089	126,183
Impairment of intangible assets	77,358	—
Provision for bad debt expense	(12)	856
Amortization of premium/discount on purchased securities	(51)	93
Write-down of inventory	4,836	—
Gain on disposal of fixed assets	—	(99)
Non-cash equity-based compensation expense	9,407	11,122
Non-cash IPR&D expense	18,029	—
Amortization of debt discount and debt issuance costs	7,513	7,851
Gains on marketable securities, net	(270)	—
Change in fair value of contingent consideration	(21)	(49,184)
Deferred income taxes	630	42,372
Prepaid transaction costs	—	(3,865)
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable, net	(7,825)	(11,265)
Inventories	(3,323)	1,223
Prepaid and other current assets	(5,562)	(756)
Accounts payable and accrued expenses	35,479	27,475
Deferred revenues	(101)	7,329
Other assets and liabilities	1,283	117
Net cash (used in) provided by operating activities	<u>(96,452)</u>	<u>85,128</u>
<b>Cash flows from investing activities:</b>		
Proceeds from sales or maturities of marketable securities	46,420	44,038
Purchase of marketable securities	(14,815)	(46,726)
Capital expenditures	(1,907)	(1,553)
Net cash provided by (used in) investing activities	<u>29,698</u>	<u>(4,241)</u>
<b>Cash flows from financing activities:</b>		
Payments to settle convertible notes	(21,417)	—
Payments of contingent consideration	(27)	(60)
Payments for repurchases of common stock	(13,730)	—
Proceeds from the issuance of common stock under the ESPP	851	—
Proceeds from the exercise of common stock options	30	1,473
Payments of employee tax withholding related to equity-based compensation	(1,748)	(2,362)
Net cash used in financing activities	<u>(36,041)</u>	<u>(949)</u>
Net (decrease) increase in cash, cash equivalents, and restricted cash	(102,795)	79,938
Cash, cash equivalents, and restricted cash related to discontinued operations	—	(59,714)
Cash, cash equivalents, and restricted cash at beginning of the period	253,751	192,770
Cash, cash equivalents, and restricted cash at end of the period	<u>\$ 150,956</u>	<u>\$ 212,994</u>
<b>Supplemental data for cash flow information:</b>		
Cash paid for taxes	\$ 433	\$ 4,181
Cash paid for interest	\$ 5,467	\$ 24,171
<b>Non-cash investing and financing activities:</b>		
Settlement of note receivable in connection with Perosphere acquisition	\$ 10,000	\$ —
Milestone payment accrued for FDA approval of Vyleesi	\$ 60,000	\$ —

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

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

**A. DESCRIPTION OF BUSINESS**

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a pharmaceutical company focused on bringing innovative products to patients with unmet medical needs by leveraging our development and commercial expertise to invest in and grow our pharmaceutical products across a range of therapeutic areas. 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 Feraheme® (ferumoxyl injection) for intravenous use, Makena® (hydroxyprogesterone caproate injection), Intrarosa® (prasterone) vaginal inserts and MuGard® Mucoadhesive Oral Wound Rinse. On June 21, 2019, Vyleesi™ (bremelanotide injection) was approved by the U.S. Food and Drug Administration (the "FDA") for the treatment of acquired, generalized hypoactive sexual desire disorder ("HSDD") in premenopausal women and is expected to be commercially available in September 2019. In addition to our approved products, our portfolio includes two product candidates, AMAG-423 (digoxin immune fab (ovine)), which is being studied for the treatment of severe preeclampsia, and ciraparantag, which is being studied as an anticoagulant reversal agent.

On January 16, 2019, we acquired Perosphere Pharmaceuticals Inc. ("Perosphere") through the merger of our wholly-owned subsidiary, Magellan Merger Sub, Inc., a Delaware corporation, with and into Perosphere, with Perosphere continuing as the surviving entity and our wholly-owned subsidiary (the "Merger"). As a result of the acquisition of Perosphere, we acquired the global rights to ciraparantag, an anticoagulant reversal agent, which is being investigated for patients treated with novel oral anticoagulants or low molecular weight heparin when reversal of the anticoagulant effect of these products is needed for emergency surgery, urgent procedures or due to life-threatening or uncontrolled bleeding. See Note Q, "Acquisitions, Collaboration, License and Other Strategic Agreements" for further details on the Perosphere acquisition.

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 our financial position and results of operations 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, 2018 (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.

In August 2018, we completed the sale of our wholly-owned subsidiary, CBR Acquisition Holdings Corp, and the Cord Blood Registry® ("CBR") business to GI Partners ("GI"), a private equity investment firm, pursuant to the June 14, 2018 Stock Purchase Agreement between us and affiliates of GI. As of June 30, 2018, our CBR business met the criteria for classification as a discontinued operation. All historical operating results for CBR are therefore reflected within discontinued operations in the consolidated statements of operations for the three and six months ended June 30, 2018. For additional information, see Note C, "Discontinued Operations."

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

## Restricted Cash

We classified \$0.5 million of our cash as restricted cash, a non-current asset on the balance sheet, as of June 30, 2019 and December 31, 2018. This amount represented the security deposit delivered to the landlord of our Waltham, Massachusetts headquarters in the form of an irrevocable letter of credit.

## Concentrations and Significant Customer Information

Financial instruments which potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents, marketable securities, and accounts receivable. We currently hold our excess cash primarily in institutional money market funds, corporate debt securities, U.S. treasury and government agency securities, commercial paper and certificates of deposit. As of June 30, 2019, we did not have a material concentration in any single investment.

Our operations are located entirely within the U.S. We focus primarily on developing, manufacturing, and commercializing our products and product candidates. We perform ongoing credit evaluations of our customers and generally do not require collateral. The following table sets forth customers who represented 10% or more of our total revenues for the three and six months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
McKesson Corporation	35%	26%	36%	27%
AmerisourceBergen Drug Corporation	28%	27%	27%	27%
Cardinal Health	11%	<10%	12%	<10%

Our net accounts receivable primarily represent amounts due for products sold directly to wholesalers, distributors, specialty pharmacies, and our authorized generic partner. Accounts receivable for our products are recorded net of reserves for estimated chargeback obligations, prompt payment discounts and any allowance for doubtful accounts. At June 30, 2019 and December 31, 2018, two and three customers, respectively, accounted for 10% or more of our accounts receivable balances, representing approximately 65% and 73% in the aggregate of our total accounts receivable, respectively.

We are currently dependent on a single supplier for Feraheme drug substance (produced in two separate facilities) as well as a single supplier for our Makena auto-injector product. We have been and may continue to be exposed to a significant loss of revenue from the sale of our products in the event that our suppliers and/or manufacturers are not able to fulfill demand for any reason.

## Revenue Recognition

### Product revenues

Effective January 1, 2018, we adopted the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 606, *Revenue from Contracts with Customers* (“ASC 606”), using the modified retrospective transition method. Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps:

- a. Identify the contract(s) with a customer;
- b. Identify the performance obligations in the contract;
- c. Determine the transaction price;
- d. Allocate the transaction price to the performance obligations in the contract; and

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- e. Recognize revenue when (or as) the performance obligations are satisfied.

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

### *Collaboration Revenues*

When we enter into collaboration agreements, we assess whether the agreements fall within the scope of ASC Topic 808, *Collaborative Arrangements* (“ASC 808”) based on whether the arrangements involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. To the extent that the arrangement falls within the scope of ASC 808, we assess whether the payments between us and our collaboration partner fall within the scope of other accounting literature. If we conclude that payments from the collaboration partner to us represent consideration from a customer, such as license fees and contract research and development activities, we account for those payments within the scope of ASC 606. However, if we conclude that our collaboration partner is not a customer for certain activities and associated payments, such as for certain collaborative research, development, manufacturing and commercial activities, we present such payments as a reduction of research and development expense or general and administrative expense, based on where we present the related underlying expense.

### **Leases**

Effective January 1, 2019, we adopted ASC Topic 842, *Leases* (“ASC 842”), and chose to apply the provisions of ASC 842 as of the effective date with no restatement of prior periods or cumulative adjustment to retained earnings. Upon adoption, we elected to utilize the package of transition practical expedients, which allowed us to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. We also made accounting policy elections to not separate lease and non-lease components for our real estate lease and to not recognize leases with an initial term of twelve months or less within our condensed consolidated balance sheets and to recognize those lease payments on a straight-line basis on our condensed consolidated statements of income over the lease term. We did not have any material short-term leases accounted for under this policy during the six months ended June 30, 2019.

We determine if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use (“ROU”) assets, current portion of operating lease liability, and long-term operating lease liability on our condensed consolidated balance sheets. ROU assets represent our right to use an underlying asset for the lease term and operating lease liabilities represent our obligation to make lease payments arising from the lease.

ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. As our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at the commencement date in determining the present value of future payments. Our incremental borrowing rate is determined based on an evaluation of our creditworthiness and the prevailing market rates for collateralized debt with maturity dates commensurate with the term of each lease. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise the option. Lease expense for operating leases is recognized on a straight-line basis over the lease term.

The lease payments used to determine our ROU assets may include lease incentives, stated rent increases, and escalation clauses linked to rates of inflation when determinable and are recognized in our ROU assets on our condensed consolidated balance sheet. In addition, certain lease agreements contain lease and non-lease components. With the exception of our real estate leases, we separate lease payments for the identified assets from any non-lease payments included in the agreement. For our real estate leases, we account for the lease and non-lease components as a single lease component. Additionally, for vehicle and certain equipment leases, we apply a portfolio approach to effectively account for the related ROU assets and operating lease liabilities.

### **Reclassifications**

Certain prior period amounts have been reclassified to conform to the current period presentation.

**C. DISCONTINUED OPERATIONS**

On August 6, 2018, we completed the sale of our CBR business to GI Partners pursuant to the CBR Purchase Agreement. We determined that the sale of CBR represented a strategic shift that would have a major effect on our business and therefore met the criteria for classification as discontinued operations at June 30, 2018. All historical operating results for CBR were reflected within discontinued operations in the condensed consolidated statement of operations for the three and six months ended June 30, 2018.

The following is a summary of net income from discontinued operations for the three and six months ended June 30, 2018:

	<b>Three Months Ended June 30, 2018</b>	<b>Six Months Ended June 30, 2018</b>
Service revenues, net	\$ 30,085	\$ 59,054
Costs and expenses:		
Cost of services	5,509	10,983
Selling, general and administrative expenses	17,531	35,150
Total costs and expenses	23,040	46,133
Operating income	7,045	12,921
Other income	113	115
Income from discontinued operations	7,158	13,036
Income tax expense	1,422	3,444
Net income from discontinued operations	<u>\$ 5,736</u>	<u>\$ 9,592</u>

The cash flows related to discontinued operations have not been segregated and are included in the Condensed Consolidated Statement of Cash Flows for the six months ended June 30, 2018. For the six months ended June 30, 2018, capital expenditures related to the CBR business were \$1.3 million. Depreciation and amortization expense related to the CBR business for the same period was \$8.4 million. There were no other significant operating or investing non-cash items related to the CBR business for the six months ended June 30, 2018.

**D. REVENUE RECOGNITION**

Our major sources of revenue during the reporting periods were product revenues from Makena, Feraheme, and Intrarosa.

**Product Revenue and Allowances and Accruals**

The following table provides information about disaggregated revenue by products for the three and six months ended June 30, 2019 and 2018 (in thousands):

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
Product sales, net				
Makena	\$ 30,935	\$ 105,172	\$ 62,192	\$ 195,156
Feraheme	42,074	37,699	82,089	62,833
Intrarosa	4,877	3,241	9,291	5,406
MuGard	90	107	133	172
Total product sales, net	<u>\$ 77,976</u>	<u>\$ 146,219</u>	<u>\$ 153,705</u>	<u>\$ 263,567</u>

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Total gross product sales were offset by product sales allowances and accruals for the three and six months ended June 30, 2019 and 2018 as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Gross product sales	\$ 239,185	\$ 297,732	\$ 450,904	\$ 537,602
Provision for product sales allowances and accruals:				
Contractual adjustments	128,641	111,539	237,526	197,683
Governmental rebates	32,568	39,974	59,673	76,352
Total	161,209	151,513	297,199	274,035
Product sales, net	\$ 77,976	\$ 146,219	\$ 153,705	\$ 263,567

The following table summarizes the product revenue allowance and accrual activity for the three and six months ended June 30, 2019 (in thousands):

	Contractual Adjustments	Governmental Rebates	Total
Balance at December 31, 2018	\$ 57,199	\$ 29,114	\$ 86,313
Provisions related to current period sales	107,388	18,502	125,890
Adjustments related to prior period sales	1,540	8,603	10,143
Payments/returns relating to current period sales	(65,839)	—	(65,839)
Payments/returns relating to prior period sales	(27,275)	(14,292)	(41,567)
Balance at March 31, 2019	\$ 73,013	\$ 41,927	\$ 114,940
Provisions related to current period sales	125,917	26,037	151,954
Adjustments related to prior period sales	2,660	6,531	9,191
Payments/returns relating to current period sales	(110,553)	(11,909)	(122,462)
Payments/returns relating to prior period sales	(13,263)	(22,070)	(35,333)
Balance at June 30, 2019	\$ 77,774	\$ 40,516	\$ 118,290

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

During the three and six months ended June 30, 2019, we recorded adjustments of \$6.5 million and \$15.1 million, respectively, for Medicaid rebates received that related to prior period sales and \$2.7 million and \$4.2 million, respectively, for contractual adjustments related to prior period sales. We concluded that these adjustments represented changes in estimate during the three and six months ended June 30, 2019 due to higher Medicaid utilization and payer rebate submissions than anticipated based on our historical experience.

*Variable Consideration*

Under ASC 606, we are required to make estimates of the net sales price, including estimates of variable consideration (such as rebates, chargebacks, discounts, copay assistance and other deductions), and recognize the estimated amount as revenue, when we transfer control of the product to our customers. In addition, we estimate variable consideration related to our share of net distributable profits from our authorized generic partner. We estimate variable consideration for our product revenues using an “expected value” method. No amounts recognized as part of our product revenues were constrained as of June 30, 2019.

**Collaboration Revenue**

During the first quarter of 2019, in conjunction with the Perosphere transaction, we assumed responsibility for a clinical trial collaboration agreement with a pharmaceutical company. This agreement provides for milestone payments to us, provided we meet certain clinical obligations in connection with our ciraparantag program. We also acquired \$6.4 million of deferred revenue related to this agreement, which represents the fair value of upfront milestone payments received by Perosphere under this agreement prior to acquisition. We may receive additional milestone payments throughout the remainder of the development program of up to a total of \$34.8 million based on completion of certain research and development activities.

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Subsequent to June 30, 2019, we were informed by the pharmaceutical company of its intention to terminate the clinical trial collaboration agreement. See Note V, "Subsequent Events."

In accordance with ASC 808, we considered the nature and contractual terms of the arrangement and the nature of our business operations to determine the classification of payments under this agreement and concluded that the pharmaceutical company meets the definition of a customer. As a result, this agreement was accounted for under ASC 606. We determined that the promises to perform various research and development activities related to our ciraparantag program are not distinct because they are all necessary and highly interdependent with one another for the purpose of pursuing regulatory approval of ciraparantag. As such, these promises are combined into a single performance obligation, which is the submission for regulatory approval of ciraparantag in the U.S. and the European Union.

In order to evaluate the appropriate transaction price, we considered that the remaining \$34.8 million of potential milestone payments relate to activities which cannot progress until FDA clearance is received for a device needed to conduct the future clinical trials. As a result, these amounts were excluded from the transaction price and fully constrained based on the probability of achievement, which is outside of our control. Therefore, as of June 30, 2019, the transaction price is limited to the \$6.4 million of deferred revenue acquired. We will reevaluate the transaction price, including all constrained amounts, at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust our estimate of the transaction price.

We will recognize revenue from the \$6.4 million of acquired deferred revenue and any future milestone payments received or considered probable based on an input method in the form of research effort relative to expected research effort at the completion of the performance obligation. This is based on the relative costs of the research and development activities incurred and expected to be incurred in the future to satisfy the performance obligation, which is estimated to be completed over approximately two years. The estimated period of performance to satisfy the performance obligation and project cost is reviewed quarterly and adjusted, as needed, to reflect our current expectations regarding the costs and timing of the deliverable. These estimates are subject to a number of assumptions and actual results could differ materially from our assumptions in future periods.

As of June 30, 2019, deferred revenue related to the agreement amounted to \$6.3 million, of which \$1.1 million was included in current liabilities. No milestone payments were received during the six months ended June 30, 2019.

#### E. MARKETABLE SECURITIES

As of June 30, 2019 and December 31, 2018, our marketable securities were classified as available-for-sale in accordance with accounting standards which provide guidance related to accounting and classification of certain investments in marketable securities. Available-for-sale marketable securities are those securities which we view as available for use in current operations, if needed. We generally classify our available-for-sale marketable securities as short-term investments on our condensed consolidated balance sheets even though the stated maturity date may be one year or more beyond the current balance sheet date.

The following is a summary of our marketable securities as of June 30, 2019 and December 31, 2018 (in thousands):

	June 30, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term marketable securities:*				
Corporate debt securities	\$ 47,410	\$ 122	\$ (52)	\$ 47,480
Certificates of deposit	8,000	—	—	8,000
U.S. treasury and government agency securities	6,394	—	(11)	6,383
Commercial paper	1,500	—	—	1,500
Total short-term marketable securities	\$ 63,304	\$ 122	\$ (63)	\$ 63,363
Long-term marketable securities:**				
Corporate debt securities	\$ 46,739	\$ 500	\$ (19)	\$ 47,220
Total long-term marketable securities	46,739	500	(19)	47,220
Total marketable securities	\$ 110,043	\$ 622	\$ (82)	\$ 110,583

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\* Represents marketable securities with a remaining maturity of less than one year.

\*\* Represents marketable securities with a remaining maturity of one to three years classified as short-term on our condensed consolidated balance sheets.

	December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<b>Short-term marketable securities:*</b>				
Corporate debt securities	\$ 51,184	\$ —	\$ (236)	\$ 50,948
Certificates of deposit	7,647	—	(34)	7,613
U.S. treasury and government agency securities	3,995	—	—	3,995
Commercial paper	12,000	—	—	12,000
Total short-term marketable securities	<u>\$ 74,826</u>	<u>\$ —</u>	<u>\$ (270)</u>	<u>\$ 74,556</u>
<b>Long-term marketable securities:**</b>				
Corporate debt securities	\$ 62,530	\$ 52	\$ (433)	\$ 62,149
U.S. treasury and government agency securities	2,742	—	(32)	2,710
Certificates of deposit	1,500	—	—	1,500
Total long-term marketable securities	<u>66,772</u>	<u>52</u>	<u>(465)</u>	<u>66,359</u>
Total marketable securities	<u>\$ 141,598</u>	<u>\$ 52</u>	<u>\$ (735)</u>	<u>\$ 140,915</u>

\* Represents marketable securities with a remaining maturity of less than one year.

\*\* Represents marketable securities with a remaining maturity of one to three years classified as short-term on our condensed consolidated balance sheets.

**Impairments and Unrealized Gains and Losses on Marketable Securities**

We did not recognize any other-than-temporary impairment losses on our condensed consolidated statements of operations related to our marketable securities during the three and six months ended June 30, 2019 and 2018. We considered various factors, including the length of time that each security was in an unrealized loss position and our ability and intent to hold these securities until the recovery of their amortized cost basis occurs. As of June 30, 2019, we had no material losses in an unrealized loss position for more than one year. Future events may occur, or additional information may become available, which may cause us to identify credit losses where we do not expect to receive cash flows sufficient to recover the entire amortized cost basis of a security and may necessitate the recording of future realized losses on securities in our portfolio. Significant losses in the estimated fair values of our marketable securities could have a material adverse effect on our earnings in future periods.



**F. FAIR VALUE MEASUREMENTS**

The following tables represent the fair value hierarchy as of June 30, 2019 and December 31, 2018, for those assets and liabilities that we measure at fair value on a recurring basis (in thousands):

	Fair Value Measurements at June 30, 2019 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash equivalents	\$ 35,437	\$ 7,242	\$ 28,195	\$ —
<b>Marketable securities:</b>				
Corporate debt securities	94,700	—	94,700	—
U.S. treasury and government agency securities	6,383	—	6,383	—
Certificates of deposit	8,000	—	8,000	—
Commercial paper	1,500	—	1,500	—
Total marketable securities	\$ 110,583	\$ —	\$ 110,583	\$ —
Total assets	\$ 146,020	\$ 7,242	\$ 138,778	\$ —
<b>Liabilities:</b>				
Contingent consideration - MuGard	\$ 311	\$ —	\$ —	\$ 311
Total liabilities	\$ 311	\$ —	\$ —	\$ 311

	Fair Value Measurements at December 31, 2018 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash equivalents	\$ 71,568	\$ 71,568	\$ —	\$ —
Corporate debt securities	113,097	—	113,097	—
U.S. treasury and government agency securities	10,323	—	10,323	—
Certificates of deposit	13,500	—	13,500	—
Commercial paper	3,995	—	3,995	—
Total assets	\$ 212,483	\$ 71,568	\$ 140,915	\$ —
<b>Liabilities:</b>				
Contingent consideration - MuGard	359	—	—	359
Total liabilities	\$ 359	\$ —	\$ —	\$ 359

**Cash Equivalents**

Our cash equivalents are classified as Level 1 and Level 2 assets under the fair value hierarchy. Assets classified as Level 1 have been valued using quoted market prices in active markets and do not have any restrictions on redemption. Cash equivalents classified as Level 2 have been valued using the techniques described in the Marketable Securities section below. As of June 30, 2019, cash equivalents were comprised of funds in money market accounts, commercial paper and certificates of deposit. As of December 31, 2018, cash equivalents were primarily comprised of funds in money market accounts.

**Marketable Securities**

Our marketable securities are classified as Level 2 assets under the fair value hierarchy as the values of these assets are primarily determined from independent pricing services, which normally derive security prices from recently reported trades for identical or similar securities, making adjustments based upon other significant observable market transactions. At the end of each reporting period, we perform quantitative and qualitative analysis of prices received from third parties to determine

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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 June 30, 2019. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during the six months ended June 30, 2019.

**Contingent Consideration**

We recorded contingent consideration related to our June 2013 license agreement for MuGard (the “MuGard License Agreement”) with Abeona Therapeutics, Inc., 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 estimates under the fair value hierarchy as these items 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 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 16%. As of June 30, 2019, we estimated that the undiscounted royalty amounts we could pay under the MuGard License Agreement, based on current projections, may range from approximately \$0.3 million to \$0.6 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 value of contingent consideration obligations is 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 are classified as Level 2 inputs. As of June 30, 2019, the estimated fair value of our 2022 Convertible Notes (as defined below) was \$256.3 million, which differed from its carrying value. See Note R, “Debt” for additional information on our debt obligations.

**G. INVENTORIES**

Our major classes of inventories were as follows as of June 30, 2019 and December 31, 2018 (in thousands):

	June 30, 2019	December 31, 2018
Raw materials	\$ 9,410	\$ 9,388
Work in process	6,816	5,932
Finished goods	8,953	11,371
Total inventories	\$ 25,179	\$ 26,691

**H. PROPERTY AND EQUIPMENT, NET**

Property and equipment, net consisted of the following as of June 30, 2019 and December 31, 2018 (in thousands):

	June 30, 2019	December 31, 2018
Computer equipment and software	\$ 1,637	\$ 1,637
Furniture and fixtures	1,681	1,737
Leasehold improvements	4,859	2,938
Laboratory and production equipment	6,397	6,000
Construction in progress	64	420
	14,638	12,732
Less: accumulated depreciation	(6,414)	(5,211)
Property and equipment, net	\$ 8,224	\$ 7,521

**I. GOODWILL AND INTANGIBLE ASSETS, NET**

**Goodwill**

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

During the first and second quarters of 2019, as a result of a number of business factors, including our market capitalization being below our carrying value, we performed a qualitative interim impairment assessment of our goodwill balance as of March 31, 2019 and again as of June 30, 2019. We determined that it was not more likely than not that the fair value of our reporting unit was less than its carrying value and therefore, did not perform a further quantitative interim impairment test for either period. Our qualitative assessments were based on management’s estimates and assumptions, a number of which are dependent on external factors. To the extent actual results differ materially from these estimates and we experience negative developments in the areas discussed above in subsequent periods, an interim impairment assessment could be triggered, which could result in an impairment of goodwill.

**Intangible Assets**

As of June 30, 2019 and December 31, 2018, our identifiable intangible assets consisted of the following (in thousands):

	June 30, 2019				December 31, 2018			
	Cost	Accumulated Amortization	Cumulative Impairments	Net	Cost	Accumulated Amortization	Cumulative Impairments	Net
Finite-lived intangible assets:								
Makena base technology	\$ 797,100	\$ 400,496	\$ 396,604	\$ —	\$ 797,100	\$ 400,495	\$ 319,246	\$ 77,359
Makena auto-injector developed technology	79,100	11,461	—	67,639	79,100	6,952	—	72,148
Intrarosa developed technology	77,655	13,505	—	64,150	77,655	10,129	—	67,526
Vyleesi developed technology	60,000	—	—	60,000	—	—	—	—
Total intangible assets	\$ 1,013,855	\$ 425,462	\$ 396,604	\$ 191,789	\$ 953,855	\$ 417,576	\$ 319,246	\$ 217,033

During the second quarter of 2019, Vyleesi received FDA approval, which triggered a \$60.0 million milestone payment, which was capitalized as developed technology. We made the \$60.0 million payment to Palatin in July 2019.

Late in the second quarter of 2019, we were notified that an additional manufacturing site for the Makena intramuscular (“IM”) products, which relate to the Makena base technology intangible asset, received FDA approval. However, the approval was received later than expected and the extended period of the stock-out caused our authorized generic partner to lose additional customers and market share, resulting in no shipments of IM to our authorized generic partner during the quarter. As a result of this loss of market share, we deemed it probable as of the end of the second quarter of 2019 that we would terminate the Distribution and Supply Agreement with our authorized generic partner. We do not expect to generate any future revenues from shipments of the IM products. Accordingly, we eliminated the Makena IM products from our long-term revenue forecast during the second quarter of 2019. These business factors were considered indicators of potential impairment for the Makena base technology intangible asset during the second quarter of 2019. We determined that the fair value of the Makena base technology intangible asset was zero at June 30, 2019, and as a result, we recorded an impairment charge for the full remaining value of the asset of \$77.4 million, which was recorded within a separate operating expense line item on our condensed consolidated statements of operations. The Distribution and Supply Agreement with our authorized generic partner was subsequently terminated in August 2019, as discussed in further detail in Note V, “Subsequent Events.”

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As of June 30, 2019, the weighted average remaining amortization period for our finite-lived intangible assets was approximately 8.8 years. Total amortization expense for the six months ended June 30, 2019 and 2018 was \$7.9 million and \$113.8 million, respectively. Amortization expense is recorded in cost of product sales on our condensed consolidated statements of operations. We expect amortization expense related to our finite-lived intangible assets to be as follows (in thousands):

Period	Estimated Amortization Expense
Remainder of Year Ending December 31, 2019	\$ 9,507
Year Ending December 31, 2020	22,258
Year Ending December 31, 2021	22,258
Year Ending December 31, 2022	22,258
Year Ending December 31, 2023	22,258
Thereafter	93,250
Total	<u>\$ 191,789</u>

**J. CURRENT LIABILITIES**

Accrued expenses consisted of the following as of June 30, 2019 and December 31, 2018 (in thousands):

	June 30, 2019	December 31, 2018
Commercial rebates, fees and returns	\$ 107,919	\$ 80,520
Milestone payment for FDA approval of Vyleesi	60,000	—
Professional, license, and other fees and expenses	23,663	23,242
Salaries, bonuses, and other compensation	16,674	22,482
Research and development expense	3,311	2,226
Interest expense	867	1,067
Restructuring expense	1,777	—
Total accrued expenses	<u>\$ 214,211</u>	<u>\$ 129,537</u>

**K. INCOME TAXES**

The following table summarizes our effective tax rate and income tax (benefit) expense from continuing operations for the three and six months ended June 30, 2019 and 2018 (in thousands except for percentages):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Effective tax rate	—%	197%	—%	(113)%
Income tax (benefit) expense	\$ (120)	\$ 52,556	\$ (257)	\$ 44,556

For the three and six months ended June 30, 2019, we recognized an income tax benefit of \$0.1 million and \$0.3 million, respectively, representing an effective tax rate of 0% for both periods. The income tax benefit for the three and six months ended June 30, 2019 primarily related to the offset of the recognition of the income tax expense recorded in other comprehensive loss associated with the increase in the value of available-for-sale securities that we carried at fair market value during the period. The difference between the statutory federal tax rate of 21% and the effective tax rate for the three and six months ended June 30, 2019, was primarily attributable to the valuation allowance established against our current period losses generated and the non-deductible IPR&D expense related to the Perosphere acquisition. We have established a valuation allowance on our deferred tax assets other than refundable alternative minimum tax (“AMT”) credits to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets.

For the three and six months ended June 30, 2018, we recognized an income tax expense of \$52.6 million and \$44.6 million, respectively, representing an effective tax rate of 197% and (113)%, respectively. The difference between the statutory federal tax rate of 21% and the effective tax rates for the three and six months ended June 30, 2018 was primarily attributable to

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the establishment of a valuation allowance on net deferred tax assets other than refundable AMT credits, the impact of non-deductible stock compensation and other non-deductible expenses, partially offset by a benefit from contingent consideration, state income taxes and orphan drug credits.

The primary driver of the decrease in tax expense for the three and six months ended June 30, 2019 as compared to the three and six months ended June 30, 2018 is the decrease in the valuation allowance established.

**L. ACCUMULATED OTHER COMPREHENSIVE LOSS**

The following table summarizes the changes in the accumulated balances of other comprehensive loss during the three and six months ended June 30, 2019 and 2018 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Beginning balance	\$ (3,376)	\$ (4,362)	\$ (3,985)	\$ (3,908)
Holding gains (losses) arising during period, net of tax	344	67	953	(387)
Ending balance	\$ (3,032)	\$ (4,295)	\$ (3,032)	\$ (4,295)

**M. EARNINGS PER SHARE**

The components of basic and diluted earnings per share for the three and six months ended June 30, 2019 and 2018 were as follows (in thousands, except per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net loss from continuing operations	\$ (120,827)	\$ (25,817)	\$ (242,911)	\$ (83,916)
Net income from discontinued operations	—	5,736	—	9,592
Net loss	\$ (120,827)	\$ (20,081)	\$ (242,911)	\$ (74,324)
Weighted average common shares outstanding	33,807	34,358	34,136	34,261
Basic and diluted net (loss) income per share:				
Loss from continuing operations	\$ (3.57)	\$ (0.75)	\$ (7.12)	\$ (2.45)
Income from discontinued operations	—	0.17	—	0.28
Basic and diluted net loss per share	\$ (3.57)	\$ (0.58)	\$ (7.12)	\$ (2.17)

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

	Six Months Ended June 30,	
	2019	2018
Options to purchase shares of common stock	3,926	3,893
Shares of common stock issuable upon the vesting of RSUs	1,621	1,415
Warrants	—	1,008
2022 Convertible Notes	11,695	11,695
2019 Convertible Notes	—	790
Total	17,242	18,801

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 were terminated in February 2019 in connection with the maturity of the 2019 Convertible Notes.

**N. EQUITY-BASED COMPENSATION**

We currently maintain three equity compensation plans; our 2019 Equity Incentive Plan (the “2019 Plan”), which was approved by our stockholders at our 2019 annual meeting and replaced our Fourth Amended and Restated 2007 Equity Incentive Plan (the “2007 Plan”), the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan (the “Lumara Health 2013 Plan”) and our 2015 Employee Stock Purchase Plan (“2015 ESPP”). All outstanding stock options granted under each of our equity compensation plans other than our 2015 ESPP have an exercise price equal to the closing price of a share of our common stock on the grant date.

**Stock Options**

The following table summarizes stock option activity for the six months ended June 30, 2019:

	2019 Equity Plan	2007 Equity Plan	2013 Lumara Equity Plan	Inducement Grants	Total
Outstanding at December 31, 2018	—	2,781,786	124,450	810,343	3,716,579
Granted	145,408	465,009	34,700	49,166	694,283
Exercised	—	(2,025)	—	—	(2,025)
Expired or terminated	—	(482,768)	(26,275)	(68,250)	(577,293)
Outstanding at June 30, 2019	145,408	2,762,002	132,875	791,259	3,831,544

**Restricted Stock Units**

The following table summarizes RSU activity for the six months ended June 30, 2019:

	2019 Equity Plan	2007 Equity Plan	2013 Lumara Equity Plan	Inducement Grants	Total
Outstanding at December 31, 2018	—	1,041,141	2,101	85,293	1,128,535
Granted	64,928	1,023,847	1,100	13,385	1,103,260
Vested	—	(348,845)	(533)	(29,076)	(378,454)
Expired or terminated	—	(231,855)	—	—	(231,855)
Outstanding at June 30, 2019	64,928	1,484,288	2,668	69,602	1,621,486

In February 2019, we granted RSUs under our 2007 Plan to certain members of our senior management covering a maximum of 365,591 shares of common stock. These performance-based RSUs will vest, if at all, on February 24, 2022, based on our total shareholder return performance measured against the median total shareholder return of a defined group of companies over a three-year period. As of June 30, 2019, the maximum shares of common stock that may be issued under these awards is 347,591. The maximum aggregate total fair value of these RSUs is \$4.5 million, which is being recognized as expense over a period of three years from the date of grant, net of any actual forfeitures.

**Equity-Based Compensation Expense**

Equity-based compensation expense for the three and six months ended June 30, 2019 and 2018 consisted of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Cost of product sales	\$ 198	\$ 107	\$ 401	\$ 307
Research and development	680	608	1,360	1,328
Selling, general and administrative	3,656	4,077	6,981	7,948
Total equity-based compensation expense	4,534	4,792	8,742	9,583
Income tax effect	—	835	—	—
After-tax effect of equity-based compensation expense	\$ 4,534	\$ 5,627	\$ 8,742	\$ 9,583

In addition to the equity-based compensation expense presented in the table above, we incurred \$0.7 million of equity-based compensation expense related to the restructuring activities during the first quarter of 2019, which is classified within restructuring expense on our condensed consolidated statement of operations for the six months ended June 30, 2019.

**O. STOCKHOLDERS' EQUITY**

As of January 1, 2019, we had \$20.5 million available under our previously approved share repurchase program to repurchase up to \$60.0 million in shares of our common stock. In March 2019, our Board authorized additional repurchases of shares in an amount up to \$20.0 million under this program. During the six months ended June 30, 2019, we repurchased and retired 1,074,800 shares of common stock for \$13.7 million. As of June 30, 2019, \$26.8 million remains available for future repurchases under this program.

**P. COMMITMENTS AND CONTINGENCIES**

**Commitments**

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

*Operating Lease Obligations*

As of January 1, 2019, we had operating leases for our corporate headquarters and vehicles utilized by sales employees. Accordingly, we recorded operating lease liabilities of \$8.5 million and related ROU assets of \$7.6 million as of January 1, 2019 in connection with our adoption of ASC 842. During the first quarter of 2019, we acquired a lease for office space in conjunction with the Perosphere transaction, entered into a new lease for office equipment and terminated certain vehicle leases in conjunction with our restructuring activities. There was no material gain or loss recognized on the early termination of the vehicle leases. As of June 30, 2019, we had operating lease liabilities of \$7.4 million and related ROU assets of \$6.6 million. As of June 30, 2019, our leases have remaining terms of one to four years. The weighted average remaining lease term and discount rate for our operating leases was 2.1 years and 4.63% at June 30, 2019, respectively.

Lease costs for our operating leases were \$1.4 million and \$2.5 million for the three and six months ended June 30, 2019, respectively. Operating cash outflows for operating leases were \$2.7 million for six months ended June 30, 2019 and ROU assets obtained in exchange for lease obligations were \$1.0 million during the six months ended June 30, 2019.

Future minimum payments under our non-cancelable operating leases as of June 30, 2019 are as follows (in thousands):

Period	Future Minimum Lease Payments
Remainder of Year Ending December 31, 2019	\$ 2,111
Year Ending December 31, 2020	3,790
Year Ending December 31, 2021	1,456
Year Ending December 31, 2022	323
Year Ending December 31, 2023	53
Thereafter	—
<b>Total</b>	<b>\$ 7,733</b>
Less: Interest	340
<b>Operating lease liability</b>	<b>\$ 7,393</b>

Under the prior lease guidance, future minimum payments under our non-cancellable leases as of December 31, 2018 were as follows (in thousands):

Period	Future Minimum Lease Payments
Year Ending December 31, 2019	\$ 5,119
Year Ending December 31, 2020	4,075
Year Ending December 31, 2021	1,034
Year Ending December 31, 2022	—
Year Ending December 31, 2023	—
<b>Total</b>	<b>\$ 10,228</b>

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### *Purchase Obligations*

Purchase obligations primarily represent minimum purchase commitments for inventory. As of June 30, 2019, our minimum purchase commitments totaled \$50.8 million.

### *Contingent Consideration Related to Business Combinations*

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

### *Contingent Regulatory and Commercial Milestone Payments*

In January 2019, we acquired Perosphere, a privately-held biopharmaceutical company focused on developing ciraparantag, a small molecule anticoagulant reversal agent. Under and subject to the terms and conditions set forth in the Perosphere Agreement (described below), we are obligated to pay future contingent consideration of up to an aggregate of \$365.0 million (the "Milestone Payments"), including (a) up to an aggregate of \$140.0 million that becomes payable upon the achievement of specified regulatory milestones for ciraparantag (the "Regulatory Milestone Payments"), including a \$40.0 million milestone payment upon approval of ciraparantag by the European Medicines Agency and (b) up to an aggregate of \$225.0 million that becomes payable conditioned upon the achievement of specified sales milestones (the "Sales Milestone Payments"). If the final label approved for ciraparantag in the U.S. includes a boxed warning, the Regulatory Milestone Payments shall no longer be payable, and any previously paid Regulatory Milestone Payments shall be credited against 50% of any future Milestone Payments that otherwise becomes payable. The first Sales Milestone Payment of \$20.0 million will be payable upon annual net sales of ciraparantag of at least \$100.0 million. For more information on the Perosphere acquisition, see Note Q, "Acquisitions, Collaboration, License and Other Strategic Agreements."

In September 2018, we exercised our option to acquire the global rights to AMAG-423 pursuant to an option agreement entered into in July 2015 with Velo Bio, LLC, a privately-held life-sciences company ("Velo"), the terms of which were amended at the time of exercise. In connection with the exercise of the option and consummation of the acquisition, we are responsible for completing the Phase 2b/3a clinical study that Velo initiated in the second quarter of 2017 and will incur all of the clinical, regulatory and other costs required to pursue FDA approval. We are obligated to pay Velo a \$30.0 million milestone payment upon FDA approval of AMAG-423. In addition, we are obligated to pay sales milestone payments of up to \$240.0 million in the aggregate, triggered at various annual net sales thresholds between \$300.0 million and \$900.0 million and low-single digit royalties based on net sales. Further, we have assumed additional obligations under a previous agreement entered into by Velo with a third-party, including a \$5.0 million milestone payment upon regulatory approval and \$10.0 million following the first commercial sale of AMAG-423, payable in quarterly installments as a percentage of quarterly gross commercial sales until the obligation is met. We are also obligated to pay the third-party low-single digit royalties based on net sales.

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

In connection with a license agreement we entered into with Palatin Technologies, Inc. ("Palatin") in January 2017 (the "Palatin License Agreement"), we were required to pay Palatin \$60.0 million upon FDA approval of Vyleesi, which payment was triggered in June 2019 and paid in July 2019. Accordingly, we accrued for the \$60.0 million milestone payment, and recorded an intangible asset for the Vyleesi developed technology, as of June 30, 2019. We are also required to pay up to



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\$300.0 million of aggregate sales milestone payments upon the achievement of certain annual net sales milestones over the course of the license. The first sales milestone payment of \$25.0 million will be triggered when Vyleesi annual net sales exceed \$250.0 million. We are also obligated to pay tiered royalties on annual net sales in North America of the Vyleesi Products, on a product-by-product basis, in the Palatin Territory ranging from the high-single digits to the low double-digits. The royalties will expire on a product-by-product and country-by-country basis upon the latest to occur of (a) the earliest date on which there are no valid claims of Palatin patent rights covering such Vyleesi Product in such country, (b) the expiration of the regulatory exclusivity period for such Vyleesi Product in such country and (c) 10 years following the first commercial sale of such Vyleesi Product in such country. These royalties are subject to reduction in the event that: (x) we must license additional third-party intellectual property in order to develop, manufacture or commercialize a Vyleesi Product or (y) generic competition occurs with respect to a Vyleesi Product in a given country, subject to an aggregate cap on such deductions of royalties otherwise payable to Palatin. After the expiration of the applicable royalties for any Vyleesi Product in a given country, the license for such Vyleesi Product in such country would become a fully paid-up, royalty-free, perpetual and irrevocable license. For more information on the Palatin License Agreement, see Note Q, *“Acquisitions, Collaboration, License and Other Strategic Agreements.”*

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

## **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.

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 refile and on October 6, 2016, all claims against the Subsidiaries were dismissed without prejudice. We are in discussions with Plaintiff’s counsel to similarly dismiss all claims in the Delaware Valley case. Because we have not been served with process in the Delaware Valley case, we are currently unable to predict the outcome or reasonably estimate the range of potential loss associated with this matter, if any.

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. As previously disclosed, we provided the FTC with a response in August 2015. We

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believe we have fully cooperated with the FTC and we have had no further interactions with the FTC on this matter since our response in August 2015. For further information on this matter, see Note P, “*Commitments and Contingencies*” to our Annual Report.

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 June 30, 2019.

## Q. ACQUISITIONS, 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 development assets as well as forming alliances with other companies to facilitate the sale and distribution of our products. As of June 30, 2019, we were a party to the following agreements:

### Perosphere

On January 16, 2019, we acquired Perosphere pursuant to the Agreement and Plan of Merger (the “Perosphere Agreement”), dated as of December 12, 2018 between AMAG and Perosphere. Pursuant to the Perosphere Agreement, in January 2019, we paid approximately \$50.0 million (the “Upfront Merger Consideration”), subject to adjustments for working capital, cash, transaction expenses and specified indebtedness. Of the Upfront Merger Consideration, approximately \$40.0 million was funded from our available cash and approximately \$10.0 million was deemed paid in connection with the cancellation of a convertible note in the principal amount of \$10.0 million issued to us by Perosphere in October 2018. The purchase price was subject to customary post-closing adjustments under the Perosphere Agreement. In addition to the Upfront Merger Consideration, we used available cash to repay \$12.0 million of Perosphere’s term loan indebtedness and approximately \$6.2 million of Perosphere’s other liabilities. We are also required to pay regulatory and sales milestone payments to Perosphere as described in more detail above in Note P, “*Commitments and Contingencies*.” Further, provided certain clinical milestones are met, the Phase 3 program for ciraparantag will be partially funded under an existing clinical trial collaboration agreement, as amended, with a pharmaceutical company, under which we may receive certain payments anticipated in 2019 and 2020 related to ciraparantag for use as an anticoagulant reversal agent to reverse the effects of Savaysa®(edoxaban) and low molecular weight heparin. Subsequent to June 30, 2019, we were informed by the pharmaceutical company of its intention to terminate the clinical trial collaboration agreement. See Note V, “*Subsequent Events*.”

Substantially all of the fair value of the assets acquired in conjunction with the Perosphere transaction was concentrated in the IPR&D asset. As a result, we accounted for this transaction as an asset acquisition under ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* (“ASU 2017-01”). The acquired IPR&D was charged to expense at acquisition, as it relates to a development stage compound with no alternative future use. A summary of the assets and liabilities acquired in exchange for cash consideration of \$60.8 million and \$10.0 million that was deemed paid in connection with the cancellation of the convertible note, described above, is presented in the following table (in millions):

Assets:		
Cash	\$	2.6
Operating lease right-of-use asset		0.8
Property and equipment		1.4
IPR&D		74.9
	\$	79.7
Liabilities:		
Accrued severance liabilities	\$	(1.7)
Deferred revenue		(6.4)
Operating lease liability		(0.8)
	\$	(8.9)

The fair values of certain of the assets and liabilities acquired are classified as Level 3 estimates under the fair value hierarchy as they 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 key development and regulatory objectives; 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 fair values of the assets and

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liabilities acquired were determined based on various market factors, including an analysis of estimated sales using a discount rate of approximately 34%.

### **Velo**

In September 2018, we exercised our option to acquire the global rights to the AMAG-423 program, which we accounted for as an asset acquisition under ASU No. 2017-01. For more information on the AMAG-423 acquisition, see Note P, “*Commitments and Contingencies*.”

### **Prasco**

In December 2017, we entered into a Distribution and Supply Agreement (the “Prasco Agreement”) with Prasco, LLC (“Prasco”), under which Prasco was granted an exclusive, non-sublicensable, nontransferable license to purchase, distribute and sell a generic version of the Makena IM product in the U.S. (the “Makena authorized generic”). The Prasco Agreement was subsequently terminated in August 2019, as discussed in further detail in Note V, “*Subsequent Events*.” In July 2018, Prasco launched the Makena authorized generic of both the single-dose and multi-dose IM injections. Under the Prasco Agreement, we were responsible for the manufacture and supply of the Makena authorized generic to be sold to Prasco at a predetermined supply price. Prasco was also required to pay us a certain percentage of the net distributable profits from the sale of the Makena authorized generic. We accounted for revenue recognized under the Prasco Agreement in accordance with ASC 606. Pursuant to the terms of the Prasco Agreement, in certain circumstances we have reimbursed and may be required to reimburse Prasco for additional penalties incurred by Prasco as a result of our failure to supply a certain percentage of product ordered by Prasco in a prespecified timeframe. During the six months ended June 30, 2019, we incurred \$3.5 million of failure to supply penalties, the majority of which were incurred in the first quarter of 2019.

### **Antares**

We are party to the Antares License Agreement, which grants us an exclusive, worldwide, royalty-bearing license, with the right to sublicense, to certain intellectual property rights, including know-how, patents and trademarks, to develop, use, sell, offer for sale and import and export the Makena auto-injector. Under the terms of the Antares License Agreement, as amended in March 2018, 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 also required to pay royalties to Antares as described in more detail above in Note P, “*Commitments and Contingencies*.” The Antares License Agreement terminates at the end of the Antares Royalty Term, but is subject to early termination by us for convenience and by either party upon an uncured breach by or bankruptcy of the other party. In March 2018, the Antares License Agreement was amended to, among other things, transfer the agreement to AMAG from our subsidiary, amend certain confidentiality provisions, and to provide for co-termination with the Antares Manufacturing Agreement (described below).

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

### **Endoceutics**

In February 2017, we entered into the Endoceutics License Agreement. Pursuant to the Endoceutics License Agreement, Endoceutics granted us the right to develop and commercialize pharmaceutical products containing dehydroepiandrosterone (“DHEA”), including Intrarosa, at dosage strengths of 13 mg or less per dose and formulated for intravaginal delivery, excluding any combinations with other active pharmaceutical ingredients, in the U.S. for the treatment of VVA and FSD. We accounted for the Endoceutics License Agreement as an asset acquisition under ASU 2017-01.

Upon the closing of the Endoceutics License Agreement, we made an upfront payment of \$50.0 million and issued 600,000 shares of unregistered common stock to Endoceutics, which had a value of \$13.5 million, as measured on April 3, 2017, the date of closing. In addition, we paid Endoceutics \$10.0 million in 2017 upon the delivery by Endoceutics of Intrarosa launch quantities and \$10.0 million in 2018 following the first anniversary of the closing. In 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 are required to pay royalties and sales milestone payments to Endoceutics as described in more detail above in Note P, “*Commitments and Contingencies*.”

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In the third quarter of 2017, Endoceutics initiated a clinical study with Intrarosa for the treatment of HSDD in post-menopausal women, which is now fully enrolled. Upon review of the full data set, it will be determined whether to continue to pursue an additional clinical trial to support an eventual filing with the FDA for an HSDD indication. We have agreed to share the direct costs related to such studies based upon a negotiated allocation with us funding up to \$20.0 million, of which we have paid approximately \$6.0 million, which was recorded as research and development expense as incurred.

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

In April 2017, we entered into an exclusive commercial supply agreement with Endoceutics pursuant to which Endoceutics, itself or through affiliates or contract manufacturers, agreed to manufacture and supply Intrarosa to us (the "Endoceutics Supply Agreement") and is our exclusive supplier of Intrarosa in the U.S., subject to certain rights for us to manufacture and supply Intrarosa in the event of a cessation notice or supply failure (as such terms are defined in the Endoceutics Supply Agreement). Under the Endoceutics Supply Agreement, Endoceutics has agreed to maintain at all times a second source supplier for the manufacture of DHEA and the drug product. The Endoceutics Supply Agreement will generally remain in effect until the termination of the Endoceutics License Agreement.

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

### **Palatin**

In January 2017, we entered into the Palatin License Agreement under which we acquired (a) an exclusive license in all countries of North America (the "Palatin Territory"), with the right to grant sub-licenses, to research, develop and commercialize the Vyleesi products, a product for the treatment of acquired, generalized HSDD in pre-menopausal women, (b) a worldwide non-exclusive license, with the right to grant sub-licenses, to manufacture the Vyleesi Products, and (c) a non-exclusive license in all countries outside the Palatin Territory, with the right to grant sub-licenses, to research and develop (but not commercialize) the Vyleesi Products. The transaction closed in February 2017 and was accounted for as an asset acquisition under ASU 2017-01.

Under the terms of the Palatin License Agreement, in February 2017 we paid Palatin \$60.0 million as a one-time upfront payment and subject to agreed-upon deductions reimbursed Palatin approximately \$25.0 million for reasonable, documented, out-of-pocket expenses incurred by Palatin in connection with the development and regulatory activities necessary to submit an NDA in the U.S. for Vyleesi for the treatment of HSDD in pre-menopausal women. During 2017, we fulfilled these payment obligations to Palatin. The \$60.0 million upfront payment made in February 2017 to Palatin was recorded as IPR&D expense as the product candidate had not received regulatory approval. In June 2018, our NDA submission to the FDA for Vyleesi was accepted, which triggered a \$20.0 million milestone payment, which we paid in the second quarter of 2018 and recorded as an IPR&D expense in the first quarter of 2018 when acceptance was deemed probable. In June 2019, the FDA approval of Vyleesi triggered a \$60.0 million milestone payment to Palatin, which we accrued in the second quarter of 2019 and recorded as a developed technology intangible asset. In addition, we are required to pay royalties and regulatory and sales milestone payments to Palatin as described in more detail above in Note P, "*Commitments and Contingencies*."

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

**R. DEBT**

Our outstanding debt obligations as of June 30, 2019 and December 31, 2018 consisted of the following (in thousands):

	June 30, 2019	December 31, 2018
2022 Convertible Notes	\$ 269,305	\$ 261,933
2019 Convertible Notes	—	21,276
Total long-term debt	269,305	283,209
Less: current maturities	—	21,276
Long-term debt, net of current maturities	\$ 269,305	\$ 261,933

**Convertible Notes**

The outstanding balance of our 2022 Convertible Notes as of June 30, 2019 consisted of the following (in thousands):

	2022 Convertible Notes
Liability component:	
Principal	\$ 320,000
Less: debt discount and issuance costs, net	50,695
Net carrying amount	\$ 269,305
Gross equity component	\$ 72,576

In accordance with accounting guidance for debt with conversion and other options, we separately account for the liability and equity components of our 2022 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 2022 Convertible Notes in cash, common stock or a combination of cash and common stock, at our option. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected our non-convertible debt borrowing rate for similar debt. The Equity Component of the 2022 Convertible Notes was recognized as a debt discount and represents the difference between the proceeds from the issuance of the 2022 Convertible Notes and the fair value of the liability of the 2022 Convertible Notes on the date of issuance. The excess of the principal amount of the liability component over its carrying amount is amortized to interest expense using the effective interest method over five years. The Equity Component is not remeasured as long as it continues to meet the conditions for equity classification.

*2022 Convertible Notes*

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

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

The conversion rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the issuance of stock dividends and payment of cash dividends. At any time prior to the close of business on the

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business day immediately preceding March 1, 2022, holders may convert their 2022 Convertible Notes at their option only under the following circumstances:

- 1) during any calendar quarter (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;
- 2) during the five business day period after any five consecutive trading day period (the “measurement period”) in which the trading price per \$1,000 principal amount of the 2022 Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; or
- 3) upon the occurrence of specified corporate events.

On or after March 1, 2022, until the close of business on the business day immediately preceding the maturity date, holders may convert all or any portion of their 2022 Convertible Notes, in multiples of \$1,000 principal amount, at the option of the holder regardless of the foregoing circumstances. The 2022 Convertible Notes were not convertible as of June 30, 2019.

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 June 30, 2019. As of June 30, 2019, 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. During 2017, we entered into privately negotiated transactions with certain investors to repurchase approximately \$178.5 million aggregate principal amount of the 2019 Convertible Notes for an aggregate repurchase price of approximately \$192.7 million, including accrued interest. The remaining \$21.4 million of 2019 Convertible Notes matured on February 15, 2019 and were settled with cash.

#### Convertible Notes Interest Expense

The following table sets forth total interest expense recognized related to the Convertible Notes during the three and six months ended June 30, 2019 and 2018 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Contractual interest expense	\$ 2,600	\$ 2,734	\$ 5,267	\$ 5,468
Amortization of debt issuance costs	345	347	699	685
Amortization of debt discount	3,385	3,313	6,814	6,550
Total interest expense	<u>\$ 6,330</u>	<u>\$ 6,394</u>	<u>\$ 12,780</u>	<u>\$ 12,703</u>

#### Convertible Bond Hedge and Warrant Transactions

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 certain financial institutions (the “call spread counterparties”). In connection with the 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. In February 2019, the 2019 Convertible Notes matured and were settled with cash and the remaining bond hedge and warrant transactions expired.

**Future Payments**

Future annual principal payments on our long-term debt as of June 30, 2019 were as follows (in thousands):

Period	Future Annual Principal Payments
Remainder of Year Ending December 31, 2019	\$ —
Year Ending December 31, 2020	—
Year Ending December 31, 2021	—
Year Ending December 31, 2022	320,000
Year Ending December 31, 2023	—
Thereafter	—
<b>Total</b>	<b>\$ 320,000</b>

**S. RESTRUCTURING EXPENSES**

In February 2019, we completed a restructuring to combine our women’s health and maternal health sales forces into one integrated sales team, which will promote Intrarosa, Makena and Vyleesi. Approximately 110 employees were displaced through this workforce reduction. We recorded one-time restructuring charges of \$7.4 million primarily related to severance and related benefits on our condensed consolidated statement of operations for the six months ended June 30, 2019. We expect the restructuring charges incurred to date under this program to be substantially paid in cash by the end of the first quarter of 2020.

The following table displays charges taken related to restructuring activities during the six months ended June 30, 2019 and a rollforward of the changes to the accrued balances as of June 30, 2019 (in thousands):

	Workforce reduction	Contract termination	Other	Total
Balance accrued at December 31, 2018	\$ —	\$ —	\$ —	\$ —
2019 restructuring charges	7,034	229	157	7,420
Payments	(2,159)	(59)	(144)	(2,362)
Balance accrued at March 31, 2019	\$ 4,875	\$ 170	\$ 13	\$ 5,058
Payments	(3,098)	(170)	(13)	(3,281)
Balance accrued at June 30, 2019	\$ 1,777	\$ —	\$ —	\$ 1,777

**T. RECENTLY ISSUED AND PROPOSED ACCOUNTING PRONOUNCEMENTS**

From time to time, new accounting pronouncements are issued by FASB or other standard setting bodies that are adopted by us as of the specified effective date.

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

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

**U. RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS**

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* (“ASC 842”). This standard requires an entity to recognize on its balance sheet assets and liabilities associated with the rights and obligations created by leases with terms greater than twelve months. We adopted the standard effective January 1, 2019. We chose to apply the provisions of ASC 842

as of the effective date with no restatement of prior periods or cumulative adjustment to retained earnings. Upon adoption, we elected to utilize the package of transition practical expedients, which allowed us to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. We also made accounting policy elections to not separate lease and non-lease components for our real estate lease and to not recognize leases with an initial term of twelve months or less within our condensed consolidated balance sheets and to recognize those lease payments on a straight-line basis on our condensed consolidated statements of income over the lease term.

In preparation for adoption of the standard, we implemented internal controls to enable the preparation of financial information. The adoption of this standard resulted in the recognition of operating lease liabilities of \$8.5 million and related ROU assets of \$7.6 million on our condensed consolidated balance sheets as of January 1, 2019, but did not have an impact on our condensed consolidated statements of operations.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* (“ASU 2018-18”). This standard clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, ASU 2018-18 precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. We adopted ASU 2018-18 during the first quarter of 2019 and applied the provisions of this update retrospectively to all contracts that were not completed as of the date of our initial adoption of ASC 606. The adoption of ASU 2018-18 did not have a material impact on our financial position or results of operations.

## V. SUBSEQUENT EVENTS

On August 2, 2019, we were informed by the pharmaceutical company, who is a party to a clinical trial collaboration agreement acquired through the Perosphere transaction, of its intention to terminate the agreement. Although we do not believe this company has grounds for termination, the potential termination of the collaboration agreement does not change our overall clinical development plan or timing for ciraparantag. See the Perosphere section of Note Q, “*Acquisitions, Collaboration, License and Other Strategic Agreements*” for additional detail on this agreement.

Based on mutual agreement, on August 6, 2019, we and Prasco terminated the Prasco Agreement based on our determination that it was not commercially viable to continue the relationship and, therefore, we do not expect to ship any further authorized generic product to Prasco. See Note Q, “*Acquisitions, Collaboration, License and Other Strategic Agreements*.” for additional detail on the Prasco Agreement.

### 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, 2018 (our “Annual Report”). Except for the historical information contained herein, the matters discussed in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In this Quarterly Report on Form 10-Q terminology such as “may,” “will,” “could,” “should,” “would,” “expect,” “anticipate,” “continue,” “believe,” “plan,” “estimate,” “intend” or other similar words and expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.*

*Examples of forward-looking statements contained in this report include, without limitation, statements regarding the following:*

- our plans regarding the growth potential of our portfolio and our ability to identify additional product candidates;*
- beliefs regarding the expenses, challenges and timing of our preclinical studies and clinical trials, including expectations regarding the clinical trial results for ciraparantag and AMAG-423;*
- beliefs regarding our commercial strategies and efforts, including the timing of the commercial launch of Vyleesi, the impact of our efforts to promote prescriptions of the Makena auto-injector and the impact of the Makena IM stock-out and terminated generic partnership on Makena revenues;*
- our estimates and beliefs regarding the market opportunities for each of our products and product candidates;*
- beliefs about and expectations for our commercialization, marketing and manufacturing of our products and product candidates, if approved, (which may be conducted by third parties), including plans to raise awareness and education of dyspareunia, VVA and HSDD and the results of such efforts;*
- expectations related to the planned Advisory Committee meeting for Makena and potential FDA regulatory actions;*
- the timing and amounts of milestone and royalty payments;*



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- expectations related to development milestone payments from a development partner in light of such partners notice of intent to terminate the related agreement;
- expectations and plans as to recent and upcoming regulatory and commercial developments and activities, including requirements, initiatives and timelines for clinical trials and post-approval commitments for our products and product candidates, and their impact on our business and competition;
- expectations for our intellectual property rights covering our product candidates and technology and the impact of generics and other competition could have on each of our products and our business generally, including the timing and number of generic entrants;
- developments relating to our competitors and our industry, including the impact of government regulation;
- expectations regarding third-party reimbursement and the behaviors of payers, healthcare providers, patients and other industry participants, including with respect to product price increases and volume-based and other rebates and incentives;
- expectations regarding the contribution of revenues from our products to the funding of our on-going operations and costs to be incurred in connection with revenue sources to fund our future operations;
- expectations regarding customer returns and other revenue-related reserves and accruals;
- expectations as to the manufacture of drug substances, drug and biological products and key materials for our products and product candidates;
- the expected impact of tax reform legislation and estimates regarding our effective tax rate and our ability to realize our net operating loss carryforwards and other tax attributes;
- the impact of accounting pronouncements;
- expectations regarding our financial performance and our ability to implement our strategic plans for our business;
- estimates and beliefs related to our 2022 Convertible Notes and the manner in which we intend or are required to settle the 2022 Convertible Notes;
- estimates, beliefs and judgments related to the valuation of certain intangible assets, goodwill, contingent consideration, debt and other assets and liabilities, including our impairment analysis and our methodology and assumptions regarding fair value measurements; and
- beliefs regarding the impact of our recent restructuring initiative, including the impact of the combination of our women's and maternal health sales forces and the related reduction in head count.

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.

AMAG Pharmaceuticals®, the logo and designs and Feraheme® are registered trademarks of AMAG Pharmaceuticals, Inc. Vyleesi™ is a trademark of AMAG Pharmaceuticals, Inc. Makena® is a registered trademark of AMAG Pharma USA, Inc. Intrarosa® is a registered trademark of Endoceutics, Inc. Other trademarks referenced in this report are the property of their respective owners.

## **Overview**

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a pharmaceutical company focused on bringing innovative products to patients with unmet medical needs by leveraging our development and commercial expertise to invest in and grow our pharmaceutical products across a range of therapeutic areas. 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 Feraheme® (ferumoxitol injection) for intravenous use, Makena® (hydroxyprogesterone caproate injection), Intrarosa® (prasterone) vaginal inserts and MuGard® Mucoadhesive Oral Wound Rinse. On June 21, 2019, Vyleesi™ (bremelanotide injection) was approved by the U.S. Food and Drug Administration (the "FDA") for the treatment of acquired, generalized hypoactive sexual desire disorder ("HSDD") in premenopausal women and is expected to be commercially available in September 2019. In addition to our approved products, our portfolio includes two product candidates, AMAG-423 (digoxin immune fab (ovine)), which is being studied for the treatment of severe preeclampsia, and ciraparantag, which is being studied as an anticoagulant reversal agent.

We intend to continue to expand the impact of our current and future products for patients by delivering on our growth strategy, which includes collaborating on and acquiring promising therapies at various stages of development, and advancing them through the clinical and regulatory process to deliver new treatment options to patients. Our primary sources of revenue are currently from sales of the Makena auto-injector, Feraheme and Intrarosa. Except as otherwise stated below, the following discussions of our results of operations reflect the results of our continuing operations, excluding the results related to the CBR

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business, which we sold in August 2018. The historical results of our CBR business has been separated from continuing operations and reflected as a discontinued operation. See Note C, “*Discontinued Operations*,” to our condensed consolidated financial statements included in this Quarterly Report on Form-10-Q.

### ***AMAG’s Portfolio of Products and Product Candidates***

#### *Feraheme*

Feraheme received approval from the FDA in June 2009 for the treatment of iron deficiency anemia (“IDA”) in adult patients with chronic kidney disease (“CKD”). In February 2018, the FDA approved the supplemental New Drug Application (“NDA”) to expand the Feraheme label to include all eligible adult IDA patients who have intolerance to oral iron or have had unsatisfactory response to oral iron in addition to patients who have CKD. IDA is prevalent in many different patient populations, such as patients with CKD, gastrointestinal diseases or disorders, inflammatory diseases, chemotherapy-induced anemia and abnormal uterine bleeding. For many of these patients, treatment with oral iron is unsatisfactory or is not tolerated. It is estimated that approximately five million people in the U.S. have IDA and we estimate that a small fraction of the patients who are diagnosed with IDA regardless of the underlying cause are currently being treated with IV iron.

The expanded Feraheme label was supported by two positive pivotal Phase 3 trials, which evaluated Feraheme versus iron sucrose or placebo in a broad population of patients with IDA and positive results from a third Phase 3 randomized, double-blind non-inferiority trial that evaluated the incidence of moderate-to-severe hypersensitivity reactions (including anaphylaxis) and moderate-to-severe hypotension with Feraheme compared to Injectafer® (ferric carboxymaltose injection) (the “Feraheme comparator trial”). The Feraheme comparator trial demonstrated comparability to Injectafer® based on the primary composite endpoint of the incidence of moderate-to-severe hypersensitivity reactions (including anaphylaxis) and moderate-to-severe hypotension (Feraheme incidence 0.6%; Injectafer® incidence 0.7%). Adverse event rates were similar across both treatment groups; however, the incidence of severe hypophosphatemia (defined by blood phosphorous of <0.2 mg/dl at week 2) was less in the patients receiving Feraheme (0.4% of patients) compared to those receiving Injectafer® (38.7% of patients).

#### *Makena*

Makena is indicated to reduce the risk of preterm birth in women pregnant with a single baby who have a history of singleton spontaneous preterm birth. We acquired the rights to Makena in connection with our acquisition of Lumara Health Inc. (“Lumara Health”) in November 2014.

Makena was approved by the FDA in February 2011 as an intramuscular (“IM”) injection (the “Makena IM product”) packaged in a multi-dose vial and in February 2016 as a single-dose preservative-free vial. In February 2018, the Makena auto-injector was approved by the FDA for administration via a pre-filled subcutaneous auto-injector, a drug-device combination product (the “Makena auto-injector”). In mid-2018, as the first generic competitors to the Makena IM product entered the market, we launched our own authorized generic of both the single- and multi-dose vials through our generic partner, Prasco, LLC (the “Makena authorized generic”). As previously disclosed, we have experienced supply issues with our primary third-party manufacturer, which led to supply disruptions and ultimately an out-of-stock situation of our Makena IM products. As a result, Prasco had been unable to meet demand and had consequently lost significant market share. Despite the recent FDA approval of a new facility to manufacture Makena IM drug product, we and Prasco determined it was not commercially viable to continue the relationship. As such, on August 6, 2019, we and Prasco mutually terminated our distribution and supply agreement and we do not expect to ship any further Makena authorized generic product to Prasco. Further, as a result of the loss of substantial market share continuing through the second quarter of 2019, we revised our long-term Makena IM products forecast resulting in the recording of a \$77.4 million impairment charge and a \$4.8 million inventory write-down on the Makena IM products during the second quarter of 2019, as discussed in Note I, “*Goodwill and Intangible Assets, Net*” to the condensed consolidated financial statements included in this quarterly report on Form 10-Q.

In March 2019, we announced topline results from the Progestin’s Role in Optimizing Neonatal Gestation (“PROLONG”) trial, a randomized, double-blinded, placebo-controlled clinical trial evaluating Makena in patients with a history of a prior spontaneous singleton preterm delivery. The PROLONG trial was conducted as part of an approval commitment under the FDA’s “Subpart H” accelerated approval process. The PROLONG trial did not demonstrate a statistically significant difference between the treatment and placebo arms for the co-primary endpoints: the incidence of preterm delivery at less than 35 weeks (Makena treated group 11.0% vs. placebo 11.5%,  $p=.72$ ) and the percentage of patients who met criteria for the pre-specified neonatal morbidity and mortality composite index (Makena treated group 5.4% vs 5.2%,  $p=.84$ ). The adverse event profile between the two arms was comparable. Adverse events of special interest, including miscarriage and stillbirth, were infrequent and similar between the treatment and placebo groups. The PROLONG trial enrolled approximately 1,700 pregnant women, over 75% of whom were enrolled outside the U.S., predominantly from Eastern European countries and Russia, with different

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demographics compared to the participants in the Meis trial, which served as the basis for the FDA’s approval of Makena. The FDA recently informed us that it plans to hold an Advisory Committee meeting in the fourth quarter of 2019 to facilitate transparent discussions of the PROLONG study and allow the FDA to obtain input from the committee members and important stakeholders to inform its regulatory decision making for Makena. In addition, we continue to work closely with our publications committee to prepare the data for peer reviewed publication.

### *Intrarosa*

In February 2017, we entered into a license agreement (the “Endoceutics License Agreement”) with Endoceutics, Inc. (“Endoceutics”) pursuant to which Endoceutics granted us the U.S. rights to Intrarosa, an FDA-approved product for the treatment of moderate to severe dyspareunia (pain during sexual intercourse), a symptom of vulvar and vaginal atrophy (“VVA”), due to menopause. Intrarosa was approved by the FDA in November 2016 and was launched commercially in July 2017.

Intrarosa is the only FDA-approved vaginal non-estrogen treatment indicated for the treatment of moderate to severe dyspareunia, a symptom of VVA, due to menopause. Intrarosa contains prasterone, a synthetic form of dehydroepiandrosterone, which is an inactive endogenous (i.e. occurring in the body) sex steroid. Prasterone is converted by enzymes in the body into androgens and estrogens to help restore the vaginal tissue as indicated by improvements in the percentage of superficial cells, parabasal cells, and pH. The mechanism of action of Intrarosa is not fully established. The effectiveness of Intrarosa on moderate to severe dyspareunia in post-menopausal women was examined in two primary 12-week placebo-controlled efficacy trials. Women who used Intrarosa in these trials experienced a significant reduction in moderate to severe dyspareunia, as well as statistically significant improvements in the percentage of vaginal superficial cells, parabasal cells and vaginal pH. In these trials, vaginal discharge and atypical pap smears were the most common adverse reactions. Intrarosa is contraindicated in women with undiagnosed abnormal genital bleeding. The label for Intrarosa contains a precaution that it has not been studied in women with a history of breast cancer.

In the third quarter of 2017, Endoceutics initiated a clinical study with Intrarosa for the treatment of HSDD in post-menopausal women. Upon review of the full data set by Endoceutics, which we believe will be completed by the end of the third quarter of 2019, it will be determined whether to continue to pursue an additional clinical trial to support an eventual filing with the FDA for an HSDD indication. We have agreed to share the direct costs related to such studies based upon a negotiated allocation with us funding up to \$20.0 million, of which we have paid approximately \$6.0 million. Additional details regarding the Endoceutics License Agreement can be found in Note Q, “Acquisitions, Collaboration, License and Other Strategic Agreements,” to our condensed consolidated financial statements included in this Quarterly Report on Form-10-Q.

### *Vyleesi*

On June 21, 2019, the FDA approved Vyleesi for the treatment of acquired, generalized HSDD in premenopausal women, and which is expected to be commercially available in September 2019 through select specialty pharmacies. In January 2017, we entered into a license agreement (the “Palatin License Agreement”) with Palatin Technologies, Inc. (“Palatin”) pursuant to which we acquired Vyleesi. Based on the June 2019 approval, we were obligated to make a \$60.0 million milestone payment to Palatin, which we paid in July 2019 and accrued for and capitalized as developed technology during the second quarter of 2019.

Vyleesi, a melanocortin 4 receptor agonist is an as needed therapy used in anticipation of sexual activity and self-administered by premenopausal women with HSDD in the thigh or abdomen via a single-use subcutaneous auto-injector. The FDA approval of Vyleesi was supported by data from approximately 1,200 women in two pivotal, identically-designed Phase 3 studies conducted by Palatin, which evaluated the safety and efficacy of Vyleesi for the treatment of HSDD in premenopausal women as compared to placebo. Both trials consisted of a 24-week double-blind, placebo-controlled, randomized parallel group core study phase, comparing a subcutaneous dose of 1.75 mg Vyleesi versus placebo, self-administered via an auto-injector, on demand, and patients were equally randomized (1:1 ratio) to either Vyleesi or placebo. The co-primary endpoints for these trials were evaluated using patient self-reported scores from Question One and Two of the Female Sexual Function Index: Desire Domain (“FSFI-D”) and Question 13 from the Female Sexual Distress Scale-Desires/Arousal/Orgasm (“FSDS-DAO”). Women who completed the randomized control core study phase of either study had the option to continue in a voluntary open-label safety extension phase of the study for an additional 12 months, which gathered additional data on the safety of long-term and repeated use of Vyleesi. Nearly 80% of patients who completed the Phase 3 trials elected to remain in the open-label portion of the study, in which all of the patients received Vyleesi.

Both studies met the pre-specified co-primary efficacy endpoints of improvement in low sexual desire and decrease in related distress as measured using validated patient-reported outcome instruments and demonstrated statistically significant improvement with Vyleesi in both median and mean measures of desire. The change in the number of satisfying sexual events,

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a key secondary endpoint, was not significantly different from placebo in either clinical trial.

In the Phase 3 clinical trials and the extension study, the most frequent adverse events were nausea, flushing, injection site reactions, and headache. Approximately 18% of patients discontinued participation in the Vyleesi arm due to adverse events in both studies versus 2% in placebo. In addition, in the clinical trials, Vyleesi caused small, transient increases in blood pressure, and is contraindicated in women with uncontrolled high blood pressure or known cardiovascular disease.

### *AMAG-423*

In September 2018, we acquired the global rights to AMAG-423 pursuant to an option agreement entered into in July 2015 with Velo Bio, LLC, a privately-held life sciences company (“Velo”). AMAG-423 is a polyvalent antibody currently in development for the treatment of severe preeclampsia in pregnant women and has been granted both orphan drug and Fast Track designations by the FDA. AMAG-423 is intended to bind to endogenous digitalis-like factors (“EDLFs”) and remove them from the circulation. EDLFs appear to be elevated in preeclampsia and may play an important role in the pathogenesis of preeclampsia. By decreasing EDLFs, AMAG-423 is believed to improve vascular endothelial function and lead to better post-delivery outcomes in affected mothers and their babies.

We have assumed responsibility to complete the Phase 2b/3a clinical study that Velo initiated in the second quarter of 2017 and will incur all of the future clinical, regulatory and other costs required to pursue FDA approval. Approximately 200 antepartum women with severe preeclampsia between 23 and 32 weeks gestation will be enrolled in the multi-center, randomized, double-blind, placebo-controlled, parallel-group Phase 2b/3a study. We re-initiated the study as the sponsor, and, as of January 2019, began enrolling new patients and continue to initiate new sites. Participants in the study receive either AMAG-423 or placebo intravenously four times a day over a maximum of four days. The study’s primary endpoint is to demonstrate a reduction in the percentage of babies who develop severe intraventricular hemorrhage (bleeding in the brain), necrotizing enterocolitis (severe inflammation of the infant bowels) or death by 36 weeks corrected gestational age between the AMAG-423 and placebo arms. Secondary endpoints include the change from baseline in maternal creatinine clearance, maternal incidence of pulmonary edema during treatment and the period of time between treatment and delivery. As with previous clinical trials conducted for treatments of preeclampsia, enrollment is challenging and while we continue to implement strategies to enhance enrollment, the nature of the patient population makes it difficult to predict the timing of enrollment completion.

### *Ciraparantag*

On January 16, 2019, we acquired ciraparantag with our acquisition of Perosphere Pharmaceuticals Inc. (“Perosphere”), a privately-held biopharmaceutical company. Ciraparantag is an anticoagulant reversal agent in development as a single dose solution that is delivered intravenously to reverse the effects of certain novel oral anticoagulants (“NOACs”) (Xarelto®(rivaroxaban), Eliquis®(apixaban), and Savaysa®(edoxaban) as well as Lovenox® (enoxaparin sodium injection), a low molecular weight heparin (“LMWH”) when reversal of the anticoagulant effect of these products is needed for emergency surgery, urgent procedures or due to life-threatening or uncontrolled bleeding. Ciraparantag has been granted Fast Track designation by the FDA. We have recently filed for Orphan Drug designation and expect a decision from the FDA in the second half of 2019; however, based on recent discussions with the FDA, we have decided not to further pursue Breakthrough Therapy designation. For additional information on our acquisition of Perosphere, see Note Q, “Acquisitions, Collaboration, License and Other Strategic Agreements” to our condensed consolidated financial statements included in this Quarterly Report on Form-10-Q.

Ciraparantag has been evaluated in more than 250 healthy volunteers across seven clinical trials. A first in human Phase 1 study evaluated the safety, tolerability, pharmacokinetic, and pharmacodynamic effects of ciraparantag alone and following a single dose of Savaysa®, and another Phase 1 study evaluated the overall metabolism of the drug. Two Phase 2A studies evaluated the safety, tolerability, pharmacokinetic, and pharmacodynamic effects related to the reversal of unfractionated heparin and Lovenox® and three Phase 2b randomized, single-blind, placebo-controlled dose-ranging studies evaluated the reversal of Savaysa®, Eliquis®, and Xarelto® to assess the safety and efficacy of ciraparantag, each of which included 12 subjects dosed with ciraparantag. The Phase 2b studies to reverse Xarelto® and Eliquis® are currently ongoing; however, both studies are nearly complete, with the low dose cohort expected to finish during 2019. In these Phase 2b clinical trials, ciraparantag or placebo was administered to healthy volunteers in a blinded fashion after achieving steady blood concentrations of the respective anticoagulant. Pharmacodynamic assessments of whole blood clotting time (“WBCT”), an important laboratory measure of clotting capacity, were sampled frequently for the first hour post study drug dose, and then periodically thereafter out to 24 hours post administration of study drug. Key endpoints in the Phase 2 trials included mean change from baseline in WBCT and the proportion of subjects that returned to within 10% of their baseline WBCT. Subjects in these studies experienced a rapid and statistically significant ( $p < 0.001$ ) reduction in WBCT compared to placebo as early as 15 minutes after

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the administration of ciraparantag in each of the four studies and the effect was sustained for 24 hours. Moreover, in both the Eliquis® and Xarelto® studies, 100% of subjects in the highest dose cohorts (180 mg of ciraparantag) were responders, as defined by a return to within 10% of baseline WBCT within 30 minutes and sustained for at least six hours. Ciraparantag has been well tolerated in clinical trials, with the most common related adverse events to date being mild sensations of coolness, warmth or tingling, skin flushing, and alterations in taste. There have been no drug-related serious adverse events to date. Following the completion of the Phase 2b studies, we plan to conduct an End of Phase 2 meeting with the FDA primarily to confirm the design of our Phase 3b trials, designed to determine the lowest effective dose of ciraparantag. We and Perosphere Technologies Inc. (“Perosphere Technologies”), an independent company, recently met with the FDA and Perosphere Technologies is preparing to submit an investigational device exemption to enable the use of the automated coagulometer in a Phase 3a clinical study, which we expect to begin in the fourth quarter of 2019.

On August 2, 2019, we were informed by the pharmaceutical company, who is a party to a clinical trial collaboration agreement acquired through the Perosphere transaction, of its intention to terminate the agreement. Although we do not believe this company has grounds for termination, the potential termination of the collaboration agreement does not change our overall clinical development plan or timing for ciraparantag, as described above. See the Perosphere section of Note Q, “Acquisitions, Collaboration, License and Other Strategic Agreements” to our condensed consolidated financial statements included in this Quarterly Report on Form-10-Q for additional detail on this agreement.

### Critical Accounting Policies

Except as described in Note B, “Basis of Presentation and Summary of Significant Accounting Policies,” and Note P, “Commitments and Contingencies,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, with respect to changes in our accounting policy related to our adoption of the requirements of Accounting Standards Codification (“ASC”) Topic 842, *Leases* and our consideration of collaboration type agreements that could fall under ASC 808, *Collaborative Arrangements* or ASC 606, *Revenue from Contracts with Customers*, there have been no significant changes to our critical accounting policies and estimates during the six months ended June 30, 2019, compared to the critical accounting policies and estimates disclosed in Part II, Item 7, of our Annual Report.

### Results of Operations - Three Months Ended June 30, 2019 and 2018

#### Revenues

Total net product sales for the three months ended June 30, 2019 and 2018 consisted of the following (in thousands except for percentages):

	Three Months Ended June 30,		2019 to 2018	
	2019	2018	\$ Change	% Change
Product sales, net				
Makena	\$ 30,935	\$ 105,172	\$ (74,237)	(71)%
Feraheme	42,074	37,699	4,375	12 %
Intrarosa	4,877	3,241	1,636	50 %
MuGard	90	107	(17)	(16)%
Total product sales, net	\$ 77,976	\$ 146,219	\$ (68,243)	(47)%

Our total net product sales for the three months ended June 30, 2019 decreased by \$68.2 million as compared to the same period in 2018, due primarily to a \$74.2 million decrease in Makena net sales. The decrease in Makena net sales was attributable to the significant decline in sales of the Makena IM product due substantially to manufacturing issues at our primary third-party Makena IM manufacturer, which resulted in supply disruptions and a stock-out of our IM products, which continued in the first half of 2019 and from the entry of generic competition beginning in mid-2018. Partially offsetting these declines was an increase in Makena auto-injector net sales from \$13.5 million in the second quarter of 2018 to \$41.0 million in the second quarter of 2019, an increase of 204%. Additionally, net sales for the three months ended June 30, 2019 were negatively impacted by a change in estimate of \$9.2 million primarily related to prior period liabilities for Medicaid and commercial rebates for Makena. Partially offsetting these declines was a 12% increase in Feraheme net sales in the second quarter of 2019, as compared to the same period in 2018.

We expect that net sales of Feraheme, the Makena auto-injector, and Intrarosa will continue to increase for the remainder of 2019. Due to the August 6, 2019 termination of our relationship with Prasco we do not expect any future sales of the Makena authorized generic. Any remaining impact of generic competition to our Makena franchise sales is dependent on the timing,

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number and behavior of current and future generic competitors and our ability to continue to differentiate Makena auto-injector from generic IM products.

**Product Sales Allowances and Accruals**

Total gross product sales were offset by product sales allowances and accruals for the three months ended June 30, 2019 and 2018 as follows (in thousands, except for percentages):

	Three Months Ended June 30,				2019 to 2018	
	2019	Percent of gross product sales	2018	Percent of gross product sales	\$ Change	% Change
Gross product sales	\$ 239,185		\$ 297,732		\$ (58,547)	(20)%
Provision for product sales allowances and accruals:						
Contractual adjustments	128,641	54%	111,539	37%	17,102	15 %
Governmental rebates	32,568	14%	39,974	13%	(7,406)	(19)%
Total	161,209	67%	151,513	51%	9,696	6 %
Product sales, net	\$ 77,976		\$ 146,219		\$ (68,243)	(47)%

The increase in contractual adjustments as a percentage of gross product sales primarily related to a higher mix of business through commercial reimbursement channels and additional discounts offered to commercial entities.

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

We may refine our estimated revenue reserves as we continue to obtain additional experience or as our customer mix changes. If we determine in future periods that our actual experience is not indicative of our expectations, if our actual experience changes, or if other factors affect our estimates, we may be required to adjust our allowances and accruals estimates, which would affect our net product sales in the period of the adjustment and could be significant.

**Costs and Expenses**

**Cost of Product Sales**

Cost of product sales for the three months ended June 30, 2019 and 2018 were as follows (in thousands except for percentages):

	Three Months Ended June 30,		2019 to 2018	
	2019	2018	\$ Change	% Change
Direct cost of product sales	\$ 20,347	\$ 15,353	\$ 4,994	33 %
Amortization of intangible assets	3,943	61,423	(57,480)	(94)%
	\$ 24,290	\$ 76,776	\$ (52,486)	(68)%
Direct cost of product sales as a percentage of net product sales	26%	11%		

Direct cost of product sales as a percentage of net product sales increased from 11% during the three months ended June 30, 2018 to 26% during the three months ended June 30, 2019 primarily driven by a \$4.8 million one-time inventory write-down related to the Makena IM products. Consistent with our expectations, excluding this one-time charge, direct cost of product sales was higher as a percentage of net product sales due to higher costs associated with the Makena auto-injector, which we expect to continue for the remainder of 2019.

Amortization of intangible assets decreased by \$57.5 million from June 30, 2018 to June 30, 2019 primarily due to a decrease in amortization related to the Makena base technology intangible asset which relates to our Makena IM products and had been amortized utilizing an economic consumption model. We recorded an impairment charge of the full remaining carrying value of the Makena base technology intangible asset during the second quarter of 2019, which is excluded from cost of product sales and discussed separately below.

[Table of Contents](#)**Research and Development Expenses**

Research and development expenses for the three months ended June 30, 2019 and 2018 consisted of the following (in thousands except for percentages):

	Three Months Ended June 30,		2019 to 2018	
	2019	2018	\$ Change	% Change
External research and development expenses	\$ 8,810	\$ 7,646	\$ 1,164	15%
Internal research and development expenses	6,170	4,047	2,123	52%
Total research and development expenses	\$ 14,980	\$ 11,693	\$ 3,287	28%

The \$3.3 million increase in research and development expenses incurred in the three months ended June 30, 2019, as compared to the three months ended June 30, 2018, was primarily related to our development program for AMAG-423.

We have a number of ongoing research and development programs that we are conducting independently or in collaboration with third parties. We expect our external research and development expenses to increase, primarily driven by our investments in AMAG-423 and ciraparantag, including costs related to our contract research organization services and drug supply needed to support our clinical trials. We cannot determine with certainty the duration and completion costs of our current or future clinical trials of our products or product candidates as the duration, costs and timing of clinical trials depends on a variety of factors including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rates and significant and changing government regulation.

**Selling, General and Administrative Expenses**

Selling, general and administrative expenses for the three months ended June 30, 2019 and 2018 consisted of the following (in thousands except for percentages):

	Three Months Ended June 30,		2019 to 2018	
	2019	2018	\$ Change	% Change
Compensation, payroll taxes and benefits	\$ 29,032	\$ 33,440	\$ (4,408)	(13)%
Professional, consulting and other outside services	44,650	28,191	16,459	58 %
Fair value of contingent consideration liability	(14)	(49,810)	49,796	(100)%
Equity-based compensation expense	3,656	4,077	(421)	(10)%
Total selling, general and administrative expenses	\$ 77,324	\$ 15,898	\$ 61,426	>100 %

Total selling, general and administrative expenses for the three months ended June 30, 2018 included a \$49.8 million decrease to the fair value of contingent consideration liability expense based on actual Makena net sales and our expectations for future performance at June 30, 2018. Excluding this decrease, selling, general and administrative expenses increased by \$11.6 million in the three months ended June 30, 2019 as compared to the same period in 2018 primarily due to an increase in marketing expenses associated with the upcoming launch of Vyleesi.

We expect that total selling, general and administrative expenses for the remaining quarters of 2019 will approximate the level of spend incurred in the second quarter of 2019.

**Impairment of Intangible Assets**

As more fully described in Note I, "Goodwill and Intangible Assets, Net" to the condensed consolidated financial statements included in this quarterly report on Form 10-Q, we recorded a \$77.4 million impairment charge during the second quarter of 2019 related to the Makena base technology intangible asset, which relates to the Makena IM products.

There were no impairments of intangible assets for the three months ended June 30, 2018.

**Other Expense, Net**

Other expense, net for the three months ended June 30, 2019 decreased by \$10.0 million compared to the same period in 2018, primarily due to a \$9.7 million reduction in interest expense in the three months ended June 30, 2019 as a result of the early redemption of our 7.875% Senior Notes due 2023 in 2018.

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**Income Tax (Benefit) Expense**

The following table summarizes our effective tax rate and income tax (benefit) expense for the three months ended June 30, 2019 and 2018 (in thousands except for percentages):

	Three Months Ended June 30,	
	2019	2018
Effective tax rate	—%	197%
Income tax (benefit) expense	\$ (120)	\$ 52,556

For the three months ended June 30, 2019, we recognized an income tax benefit of \$0.1 million, representing an effective tax rate of 0%. The difference between the statutory federal tax rate of 21% and the 0% effective tax rate for the three months ended June 30, 2019 was primarily attributable to the valuation allowance established against our current period losses generated and the non-deductible in-process research and development (“IPR&D”) expense related to the Perosphere acquisition. We have established a valuation allowance on our deferred tax assets other than refundable alternative minimum tax (“AMT”) credits to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets. The income tax benefit for the three months ended June 30, 2019 primarily related to the offset of the recognition of the income tax expense recorded in other comprehensive loss associated with the increase in the value of available-for-sale securities that we carried at fair market value during the period.

For the three months ended June 30, 2018, we recognized an income tax expense of \$52.6 million, representing an effective tax rate of 197%. The difference between the statutory federal tax rate of 21% and the 197% effective tax rate for the three months ended June 30, 2018, was primarily attributable to the establishment of a valuation allowance on net deferred tax assets other than refundable AMT credits, the impact of non-deductible stock compensation and other non-deductible expenses, partially offset by a benefit from contingent consideration, state income taxes and orphan drug credits.

The primary driver of the decrease in tax expense for the three months ended June 30, 2019 as compared to the three months ended June 30, 2018 was the decrease in the valuation allowance established.

**Net Income from Discontinued Operations**

Net income from discontinued operations was \$5.7 million for the three months ended June 30, 2018. For additional information on discontinued operations, see Note C, “Discontinued Operations” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

**Results of Operations - Six Months Ended June 30, 2019 and 2018**

**Revenues**

Total net product sales for the six months ended June 30, 2019 and 2018 consisted of the following (in thousands except for percentages):

	Six Months Ended June 30, 2019		2019 to 2018	
	2019	2018	\$ Change	% Change
Product sales, net				
Makena	\$ 62,192	\$ 195,156	\$ (132,964)	(68)%
Feraheme	82,089	62,833	19,256	31 %
Intrarosa	9,291	5,406	3,885	72 %
MuGard	133	172	(39)	(23)%
Total product sales, net	\$ 153,705	\$ 263,567	\$ (109,862)	(42)%

Our total net product sales for the six months ended June 30, 2019 decreased by \$109.9 million as compared to the same period in 2018, due primarily to a \$133.0 million decrease in Makena net sales. The decrease in Makena net sales was attributable to the significant decline in sales of the Makena IM product due substantially to manufacturing issues at our primary third-party Makena IM manufacturer, which resulted in supply disruptions and a stock-out of our IM products, which continued in the first half of 2019 as well as from the entry of generic competition beginning in mid-2018. Partially offsetting these declines was an increase in Makena auto-injector net sales from \$14.8 million in the first half of 2018 to \$78.8 million in the first half of 2019. Additionally, net sales in the first half of 2019 were negatively impacted by approximately \$15.1 million and \$4.2 million due to changes in estimates related to prior period liabilities for governmental rebates and contractual



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adjustments, respectively, and \$8.5 million due to non-recurring items during the first quarter, which is comprised of \$3.5 million due to Prasco for charges they incurred resulting from their inability to meet their contractual obligations due to our IM supply disruptions and an estimated \$5.0 million of increased Medicaid rebates due to the impact of the IM supply constraints on government reported pricing. Partially offsetting these declines was a 31% increase in Feraheme net sales.

Total gross product sales were offset by product sales allowances and accruals for the six months ended June 30, 2019 and 2018 as follows (in thousands, except for percentages):

	Six Months Ended June 30,				2019 to 2018	
	2019	Percent of gross product sales	2018	Percent of gross product sales	\$ Change	% Change
Gross product sales	\$ 450,904		\$ 537,602		\$ (86,698)	(16)%
Provision for product sales allowances and accruals:						
Contractual adjustments	237,526	53%	197,683	37%	39,843	20 %
Governmental rebates	59,673	13%	76,352	14%	(16,679)	(22)%
Total	297,199	66%	274,035	51%	23,164	8 %
Product sales, net	\$ 153,705		\$ 263,567		\$ (109,862)	(42)%

The increase in contractual adjustments as a percentage of gross product sales primarily related to a higher mix of business through commercial reimbursement channels and additional discounts offered to commercial entities.

**Costs and Expenses**

**Cost of Product Sales**

Cost of product sales for the six months ended June 30, 2019 and 2018 were as follows (in thousands except for percentages):

	Six Months Ended June 30,		2019 to 2018	
	2019	2018	\$ Change	% Change
Direct cost of product sales	\$ 34,881	\$ 26,902	\$ 7,979	30 %
Amortization of intangible assets	7,886	113,786	(105,900)	(93)%
	\$ 42,767	\$ 140,688	\$ (97,921)	
Direct cost of product sales as a percentage of net product sales	23%	10%		

Direct cost of product sales as a percentage of net product sales increased from 10% to 23% during the first half of 2019 driven primarily by a \$4.8 million one-time inventory write-down related to the Makena IM product as well as a lower net price during the first half of 2019 as compared to the first half of 2018.

Amortization of intangible assets decreased by \$105.9 million from June 30, 2018 to June 30, 2019 primarily due to a decrease in amortization related to the Makena base technology intangible asset, which relates to our Makena IM products and was amortized using an economic consumption model. We recorded an impairment charge for the full remaining carrying value of the Makena base technology intangible asset during the second quarter of 2019, which is excluded from cost of product sales and discussed separately below.

[Table of Contents](#)**Research and Development Expenses**

Research and development expenses for the six months ended June 30, 2019 and 2018 consisted of the following (in thousands except for percentages):

	Six Months Ended June 30,		2019 to 2018	
	2019	2018	\$ Change	% Change
External research and development expenses	\$ 21,309	\$ 14,400	\$ 6,909	48%
Internal research and development expenses	11,737	8,102	3,635	45%
Total research and development expenses	\$ 33,046	\$ 22,502	\$ 10,544	47%

The \$10.5 million increase in research and development expenses incurred in the six months ended June 30, 2019 as compared to the same period in 2018 was primarily related to our development program for AMAG-423.

**Acquired In-Process Research and Development**

During the six months ended June 30, 2019, we recorded \$74.9 million for acquired IPR&D related to the acquisition of Perosphere.

During the six months ended June 30, 2018, we recorded \$20.0 million for acquired IPR&D related to a milestone obligation to Palatin associated with the FDA acceptance of the Vyleesi NDA.

**Selling, General and Administrative Expenses**

Selling, general and administrative expenses for the six months ended June 30, 2019 and 2018 consisted of the following (in thousands except for percentages):

	Six Months Ended June 30, 2019		2019 to 2018	
	2019	2018	\$ Change	% Change
Compensation, payroll taxes and benefits	\$ 59,383	\$ 63,675	\$ (4,292)	(7)%
Professional, consulting and other outside services	85,663	66,890	18,773	28 %
Fair value of contingent consideration liability	(21)	(49,184)	49,163	(100)%
Equity-based compensation expense	6,981	7,948	(967)	(12)%
Total selling, general and administrative expenses	\$ 152,006	\$ 89,329	\$ 62,677	70 %

Total selling, general and administrative expenses for the six months ended June 30, 2018 included a \$49.2 million decrease to the fair value of contingent consideration liability expense based on actual Makena net sales and our expectations for future performance at June 30, 2018. Excluding this decrease, selling, general and administrative expenses increased by \$13.5 million in the six months ended June 30, 2019 as compared to the same period in 2018 primarily due to an increase in advertising costs.

**Impairment of Intangible Assets**

As more fully described in Note I, "Goodwill and Intangible Assets, Net" to the condensed consolidated financial statements included in this quarterly report on Form 10-Q, we recorded a \$77.4 million impairment charge during the second quarter of 2019 related to the Makena base technology intangible asset, which relates to the Makena IM products.

There were no impairments of intangible assets for the six months ended June 30, 2018.

**Restructuring Expense**

In February 2019, we completed a restructuring to combine our women's health and maternal health sales forces into one integrated sales team, which promotes Intrarosa, Makena and now Vyleesi. Approximately 110 employees were displaced through this workforce reduction. We recorded a one-time restructuring charge of \$7.4 million primarily related to severance and related benefits in the first quarter of 2019. We estimate total savings from the restructuring in 2019 to be approximately \$15.2 million, partially offset by planned increases in external spending associated with the launch of Vyleesi and as we continue to invest in the growth of our commercial products. For additional information on restructuring expenses, see Note S, "Restructuring Expenses" to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

**Other Expense, Net**

Other expense, net for the six months ended June 30, 2019 decreased by \$20.9 million compared to the same period in 2018, primarily due to a \$19.3 million reduction in interest expense in the six months ended June 30, 2019 as a result of the early redemption of our 7.875% Senior Notes due 2023 in 2018.

**Income Tax (Benefit) Expense**

The following table summarizes our effective tax rate and income tax (benefit) expense for the six months ended June 30, 2019 and 2018 (in thousands except for percentages):

	Six Months Ended June 30,	
	2019	2018
Effective tax rate	—%	(113)%
Income tax (benefit) expense	\$ (257)	\$ 44,556

For the six months ended June 30, 2019, we recognized an income tax benefit of \$0.3 million, representing an effective tax rate of 0%. The difference between the statutory federal tax rate of 21% and the 0% effective tax rate for the six months ended June 30, 2019 was primarily attributable to the valuation allowance established against our current period losses generated and the non-deductible IPR&D expense related to the Perosphere acquisition. We have established a valuation allowance on our deferred tax assets other than refundable AMT credits to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets. The income tax benefit for the six months ended June 30, 2019 primarily related to the offset of the recognition of the income tax expense recorded in other comprehensive loss associated with the increase in the value of available-for-sale securities that we carried at fair market value during the period.

For the six months ended June 30, 2018, we recognized an income tax expense of \$44.6 million, representing an effective tax rate of (113)%. The difference between the statutory federal tax rate of 21% and the (113)% effective tax rate for the six months ended June 30, 2018, was primarily attributable to the establishment of a valuation allowance on net deferred tax assets other than refundable AMT credits, the impact of non-deductible stock compensation and other non-deductible expenses, partially offset by a benefit from contingent consideration, state income taxes and orphan drug credits.

The primary driver of the decrease in tax expense for the six months ended June 30, 2019 as compared to the six months ended June 30, 2018 was the decrease in the valuation allowance established.

**Net Income from Discontinued Operations**

Net income from discontinued operations was \$9.6 million for the six months ended June 30, 2018. For additional information on discontinued operations, see Note C, "Discontinued Operations" to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

**Liquidity and Capital Resources****General**

We currently finance our operations primarily from cash generated from our operating activities, including sales of our commercialized products. Cash, cash equivalents, marketable securities and certain financial obligations as of June 30, 2019

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and December 31, 2018 consisted of the following (in thousands except for percentages):

	June 30, 2019	December 31, 2018	\$ Change	% Change
Cash and cash equivalents	\$ 150,461	\$ 253,256	\$ (102,795)	(41)%
Marketable securities	110,583	140,915	(30,332)	(22)%
Total	\$ 261,044	\$ 394,171	\$ (133,127)	(34)%
Outstanding principal on 2022 Convertible Notes	320,000	320,000	—	—%
Outstanding principal on 2019 Convertible Notes	—	21,417	(21,417)	(100)%
Total	\$ 320,000	\$ 341,417	\$ (21,417)	(6)%

### Cash Flows

The following table presents a summary of the primary sources and uses of cash for the six months ended June 30, 2019 and 2018 (in thousands):

	June 30, 2019	June 30, 2018	\$ Change
Net cash (used in) provided by operating activities	\$ (96,452)	\$ 85,128	\$ (181,580)
Net cash provided by (used in) investing activities	29,698	(4,241)	33,939
Net cash used in financing activities	(36,041)	(949)	(35,092)
Net (decrease) increase in cash, cash equivalents, and restricted cash	\$ (102,795)	\$ 79,938	\$ (182,733)

### Operating Activities

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

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

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

For the period ended June 30, 2019 compared to June 30, 2018, net cash flows provided by operating activities decreased by \$181.6 million, driven primarily by a decrease in net income as adjusted for non-cash charges of \$177.4 million and a \$4.2 million decrease due to changes in operating assets and liabilities. Included within net loss for the six months ended June 30, 2019 was \$74.9 million of acquired IPR&D expense related to the Perosphere asset acquisition, of which \$60.8 million was paid in cash during the first quarter of 2019. The cash flows from operating activities for the six months ended June 30, 2018 include cash flows from the operating activities of the CBR business, which are included in discontinued operations. Subsequent to the closing of the CBR transaction on August 6, 2018, we no longer generated cash flows from that business. See Note C, “Discontinued Operations,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for further detail regarding our discontinued operations.

### Investing Activities

Cash flows provided by investing activities was \$29.7 million for the six months ended June 30, 2019 due primarily to net proceeds from the sale of marketable securities of \$31.6 million, partially offset by capital expenditures of \$1.9 million. Cash used in investing activities for the six months ended June 30, 2018 was \$4.2 million due to net purchases of marketable securities of \$2.7 million and capital expenditures of \$1.6 million.

### ***Financing Activities***

Cash used in financing activities was \$36.0 million for the six months ended June 30, 2019 due to the repayment of the \$21.4 million balance of our 2019 Convertible Notes, \$13.7 million for the repurchase of common stock and \$1.7 million for payments of employee tax withholdings related to equity based compensation. Cash used in financing activities for the six months ended June 30, 2018 was \$0.9 million driven by the payment of employee tax withholdings of \$2.4 million related to equity based compensation, partially offset by proceeds from the exercise of stock options of \$1.5 million.

### ***Future Liquidity Considerations***

We believe that our cash, cash equivalents and marketable securities as of June 30, 2019, and the cash we expect to receive from sales of our products, will be sufficient to satisfy our cash flow needs for the foreseeable future. For the remainder of 2019, we intend to spend more than our expected revenues and will therefore utilize a portion of our \$261.0 million of cash and investments to fund our operations, including investment in significant development programs. This period of cash outflow is consistent with our evolving business plan to develop and launch innovative products that address unmet medical needs and can deliver long-term, durable revenue growth. Additionally, our expected utilization of cash for the remainder of 2019 includes, but is not limited to, the following:

- A \$60.0 million milestone paid to Palatin in July 2019 based upon the June 2019 FDA approval of Vyleesi, which was accrued in June; and
- Approximately \$5.2 million of cash interest in connection with our 2022 Convertible Notes.

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

### ***Borrowings and Other Liabilities***

In the second quarter of 2017, we issued \$320.0 million aggregate principal amount of convertible senior notes due 2022 (the “2022 Convertible Notes”), as discussed in more detail in Note R, “*Debt*,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. The 2022 Convertible Notes are senior unsecured obligations and bear interest at a rate of 3.25% per year, payable semi-annually in arrears on June 1 and December 1 of each year, beginning on December 1, 2017. The 2022 Convertible Notes will mature on June 1, 2022, unless earlier repurchased or converted. Upon conversion of the 2022 Convertible Notes, such 2022 Convertible Notes will be convertible into, at our election, cash, shares of our common stock, or a combination thereof, at a conversion rate of 36.5464 shares of common stock per \$1,000 principal amount of the 2022 Convertible Notes, which corresponds to an initial conversion price of approximately \$27.36 per share of our common stock. The conversion rate is subject to adjustment from time to time. The 2022 Convertible Notes were not convertible as of June 30, 2019.

### ***Share Repurchase Program***

As of January 1, 2019, we had \$20.5 million available under our previously approved share repurchase program to repurchase up to \$60.0 million in shares of our common stock. In March 2019, our Board authorized additional repurchases of shares in an amount up to \$20.0 million under this program. During the six months ended June 30, 2019, we repurchased and retired 1,074,800 shares of common stock for \$13.7 million (no repurchases were made during the three months ended June 30, 2019). As of June 30, 2019, \$26.8 million remained available for future repurchases under this program.

### ***Off-Balance Sheet Arrangements***

As of June 30, 2019, 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 T, “*Recently Issued and Proposed Accounting Pronouncements*,” and Note U, “*Recently Adopted Accounting Pronouncements*,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for information regarding new accounting pronouncements.

### ***Item 3. Quantitative and Qualitative Disclosures About Market Risk:***

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

**Item 4. Controls and Procedures:**

**Managements' Evaluation of our Disclosure Controls and Procedures**

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

**Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting (as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) that occurred during the three months ended June 30, 2019 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings:**

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

**Item 1A. Risk Factors:**

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

***The Makena franchise is currently dependent exclusively on sales from the Makena auto-injector in light of our recent termination of our partnership with Prasco, LLC (“Prasco”). The Makena franchise could also be negatively affected if the FDA takes adverse action related to the commercialization of Makena.***

The commercial success of Makena is currently exclusively dependent upon sales from the pre-filled subcutaneous auto-injector (the “Makena auto-injector”). In August 2019, we terminated our partnership with Prasco, who had been marketing a generic version of the intramuscular (“IM”) Makena product (the “Makena authorized generic”). As a result of the supply disruptions of our Makena IM products, Prasco had been unable to meet demand for the Makena authorized generic and had consequently lost significant market share. Accordingly, we and Prasco determined it was not commercially viable to continue the relationship and decided to mutually terminate our agreement and cease commercialization of the Makena authorized generic. In light of the termination of our partnership with Prasco, we do not expect to ship any further authorized generic product to Prasco.

Although there is no direct competition with the Makena auto-injector, the Makena auto-injector competes for the same patients as generic versions of the Makena IM product and we cannot guarantee that we will be able to continue to convince patients or healthcare providers to use or to switch from using the IM method of administration to the auto-injector, including if patients or healthcare providers are hesitant or apprehensive to use an auto-injector product due to perceptions regarding safety, efficacy or pain associated with the Makena auto-injector, or if the auto-injector is not priced competitively or is not provided comparable insurance coverage, or if there are concerns about our supply chain more generally in light of the Makena IM products supply disruption or if we experience a similar supply disruption for the Makena auto-injector, especially if demand increases. We expect that the Makena auto-injector may continue to experience pricing and supply chain pressure and as a result, our Makena revenues may fall below expectations, which could cause our financial condition and results of operations to be adversely impacted. If we are unsuccessful with any such efforts, Makena revenues could continue to be negatively and materially impacted, which could have a material and negative impact on our stock price and results of operations.

Further, we have incurred considerable expenses and our revenues have suffered as a result of the Makena IM supply

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disruption. For example, we were required to reimburse Prasco for certain charges it incurred in 2018 and 2019 due to our inability to supply them with sufficient product to meet their contractual obligations with customers. We expect to continue to incur expenses in connection with the termination of our relationship with Prasco. We also expect to incur expenses as we pursue our remedies under our supply agreement with our third party manufacturer of the Makena IM products, which will be costly to pursue and may not result in satisfactory, adequate or any compensation for the damages we suffered.

In addition, in March 2019, we announced topline results from the Progestin's Role in Optimizing Neonatal Gestation ("PROLONG") clinical trial, which evaluated Makena in patients with a history of a prior spontaneous singleton preterm delivery. The PROLONG trial was conducted as part of an approval commitment under the FDA's "Subpart H" accelerated approval process to confirm the efficacy of the Meis trial. The PROLONG trial results did not demonstrate a statistically significant difference between the treatment and placebo arms for the co-primary endpoints. Since the results of the PROLONG study were negative, the FDA could withdraw the approval of Makena, require us to generate or conduct additional clinical trials or update the approved labeling to include information on the PROLONG study, including the possibility of restrictions to the current indication or the insertion of new warnings or precautions. Although the FDA has indicated that the usual regulatory process for a Subpart H approved product with a failed confirmatory trial is for the FDA to issue a Notice of Opportunity for Hearing to initiate the process to withdraw accelerated approval, the FDA noted that it believed that an Advisory Committee is the preferred next step to inform regulatory decision-making for Makena. In addition, certain medical professional organizations and other societies could change their guidelines to physicians. The FDA has noted that it considered post-hoc subset analysis informative for hypothesis generation only but does not consider such data adequate to support efficacy for any subgroup. The FDA further noted that it will not opine on the safety of Makena while the FDA review is ongoing. Any of these outcomes could negatively impact or prevent our ability to commercialize Makena, and would materially and adversely impact our results of operations and could materially and adversely impact our stock price.

**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 June 30, 2019.

Period	Total Number of Shares Purchased <sup>(1)</sup>	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs <sup>(2)</sup>	Maximum Number of Shares (or approximate dollar value) That May Yet Be Purchased Under the Plans or Programs <sup>(2)</sup>
April 1, 2019 through April 30, 2019	8,365	\$ 11.79	—	2,397,390
May 1, 2019 through May 31, 2019	1,298	11.02	—	2,807,436
June 1, 2019 through June 30, 2019	194	8.56	—	2,678,165
Total	9,857	\$ 11.63	—	

(1) Includes 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 have repurchased and retired \$53.2 million of our common stock under our share repurchase program through June 30, 2019. These shares were purchased pursuant to a repurchase program authorized by our Board to repurchase up to \$80.0 million of our common stock (including increased authority to repurchase an additional \$20.0 million approved by our Board in March 2019), of which \$26.8 million remained authorized for repurchase as of June 30, 2019. 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 5. Other Information:**

On August 6, 2019, we and Prasco, LLC (“Prasco”) terminated the December 2017 Distribution and Supply Agreement (the “Prasco Agreement”) under which Prasco was granted an exclusive, non-sublicensable, nontransferable license to purchase, distribute and sell a generic version of Makena in the U.S. The Prasco Agreement was mutually terminated based on our and Prasco’s determination that it was no longer commercially viable to continue the relationship in light of the loss of significant market share resulting from the supply issues with our primary third-party manufacturer, which led to supply disruptions and ultimately an out-of-stock situation of our Makena IM products. We do not expect to ship any further authorized generic product to Prasco.

**Item 6. Exhibits:**

<b>Exhibit Number</b>	<b>Description</b>
10.1	<a href="#">AMAG Pharmaceuticals, Inc. 2019 Equity Incentive Plan (incorporated herein by reference to Appendix A to the Registrants’ Definitive Proxy Statement on Schedule 14A filed April 15, 2019, File No. 001-10865)</a>
10.2	<a href="#">AMAG Pharmaceuticals, Inc.’s Amended and Restated Non-Employee Directors’ Compensation Policy Plan (incorporated herein by reference to Exhibit 10.2 to the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, File No. 001-10865)</a>
10.3	<a href="#">AMAG Pharmaceuticals, Inc. Non-Employee Directors’ Deferred Compensation Program (incorporated herein by reference to Exhibit 10.3 to the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, File No. 001-10865)</a>
10.4	<a href="#">Form of Restricted Stock Unit Agreement (Deferred) for Non-Employee Directors under AMAG Pharmaceuticals, Inc.’s Fourth Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 to the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, File No. 001-10865)</a>
31.1+	<a href="#">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</a>
31.2+	<a href="#">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</a>
32.1++	<a href="#">Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
32.2++	<a href="#">Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
101.SCH+	Inline XBRL Taxonomy Extension Schema Document
101.CAL+	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE+	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104+	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)

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

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



**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: August 7, 2019

AMAG PHARMACEUTICALS, INC.

By: /s/ Edward Myles

Edward Myles

*Executive Vice President of Finance, Chief Financial Officer and  
Treasurer (Principal Financial and Accounting Officer)*

Date: August 7, 2019

## CERTIFICATIONS

I, William K. Heiden, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of AMAG Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 7, 2019

/s/ William K. Heiden

William K. Heiden  
President and Chief Executive Officer  
(Principal Executive Officer)

## CERTIFICATIONS

I, Edward Myles, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of AMAG Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 7, 2019

/s/ Edward Myles

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Edward Myles

Executive Vice President of Finance, Chief Financial Officer and Treasurer  
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of AMAG Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William K. Heiden, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ William K. Heiden

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William K. Heiden

*President and Chief Executive Officer*

*(Principal Executive Officer)*

August 7, 2019

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of AMAG Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Edward Myles, Executive Vice President of Finance, Chief Financial Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Edward Myles

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Edward Myles

*Executive Vice President of Finance, Chief Financial Officer and Treasurer  
(Principal Financial Officer)*

August 7, 2019

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