

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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)

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**

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

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

As of May 3, 2019, there were 33,766,939 shares of the registrant's Common Stock, par value \$0.01 per share, outstanding.

AMAG PHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED MARCH 31, 2019
TABLE OF CONTENTS

<u>PART I.</u>	<u>FINANCIAL INFORMATION (Unaudited)</u>	<u>3</u>
<u>Item 1.</u>	<u>Financial Statements</u>	<u>3</u>
	<u>Condensed Consolidated Balance Sheets as of March 31, 2019 and December 31, 2018</u>	<u>4</u>
	<u>Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2019 and 2018</u>	<u>5</u>
	<u>Condensed Consolidated Statements of Comprehensive Loss for the Three Months Ended March 31, 2019 and 2018</u>	<u>6</u>
	<u>Condensed Consolidated Statements of Stockholders' Equity for the three months ended March 31, 2019 and 2018</u>	<u>7</u>
	<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2019 and 2018</u>	<u>8</u>
	<u>Notes to Condensed Consolidated Financial Statements</u>	<u>9</u>
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>32</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>42</u>
<u>Item 4.</u>	<u>Controls and Procedures</u>	<u>43</u>
<u>PART II.</u>	<u>OTHER INFORMATION</u>	<u>43</u>
<u>Item 1.</u>	<u>Legal Proceedings</u>	<u>43</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>43</u>
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>44</u>
<u>Item 6.</u>	<u>Exhibits</u>	<u>45</u>
<u>Signatures</u>		<u>46</u>

[Table of Contents](#)

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements:

AMAG PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)
(Unaudited)

	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 137,917	\$ 253,256
Marketable securities	128,593	140,915
Accounts receivable, net	83,334	75,347
Inventories	29,664	26,691
Prepaid and other current assets	40,567	18,961
Note receivable	—	10,000
Total current assets	420,075	525,170
Property and equipment, net	8,995	7,521
Goodwill	422,513	422,513
Intangible assets, net	213,090	217,033
Operating lease right-of-use asset	7,024	—
Deferred tax assets	630	1,260
Restricted cash	495	495
Other long-term assets	29	1,467
Total assets	\$ 1,072,851	\$ 1,175,459
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 21,535	\$ 14,487
Accrued expenses	155,687	129,537
Current portion of convertible notes, net	—	21,276
Current portion of operating lease liability	3,529	—
Current portion of deferred revenue	2,112	—
Current portion of acquisition-related contingent consideration	118	144
Total current liabilities	182,981	165,444
Long-term liabilities:		
Convertible notes, net	265,576	261,933
Long-term operating lease liability	4,328	—
Long-term deferred revenue	4,288	—
Long-term acquisition-related contingent consideration	218	215
Other long-term liabilities	741	1,212
Total liabilities	458,132	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; 33,746,828 and 34,606,760 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	337	346
Additional paid-in capital	1,282,284	1,292,736
Accumulated other comprehensive loss	(3,376)	(3,985)
Accumulated deficit	(664,526)	(542,442)
Total stockholders' equity	614,719	746,655
Total liabilities and stockholders' equity	\$ 1,072,851	\$ 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 March 31,	
	2019	2018
Revenues:		
Product sales, net	\$ 75,729	\$ 117,348
Other revenues	75	39
Total revenues	<u>75,804</u>	<u>117,387</u>
Costs and expenses:		
Cost of product sales	18,477	63,912
Research and development expenses	18,066	10,809
Acquired in-process research and development	74,856	20,000
Selling, general and administrative expenses	74,682	73,431
Restructuring expenses	7,420	—
Total costs and expenses	<u>193,501</u>	<u>168,152</u>
Operating loss	<u>(117,697)</u>	<u>(50,765)</u>
Other income (expense):		
Interest expense	(6,450)	(15,977)
Interest and dividend income	1,586	643
Other income	340	—
Total other expense, net	<u>(4,524)</u>	<u>(15,334)</u>
Loss from continuing operations before income taxes	<u>(122,221)</u>	<u>(66,099)</u>
Income tax benefit	<u>(137)</u>	<u>(8,000)</u>
Net loss from continuing operations	<u>\$ (122,084)</u>	<u>\$ (58,099)</u>
Discontinued operations:		
Income from discontinued operations	\$ —	\$ 5,878
Income tax expense	—	2,021
Net income from discontinued operations	<u>\$ —</u>	<u>\$ 3,857</u>
Net loss	<u><u>\$ (122,084)</u></u>	<u><u>\$ (54,242)</u></u>
Basic and diluted net income (loss) per share:		
Loss from continuing operations	\$ (3.54)	\$ (1.70)
Income from discontinued operations	—	0.11
Basic and diluted net loss per share	<u>\$ (3.54)</u>	<u>\$ (1.59)</u>
Weighted average shares outstanding used to compute net income (loss) per share (basic and diluted)	34,469	34,162

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)

	<u>Three Months Ended March 31,</u>	
	<u>2019</u>	<u>2018</u>
Net loss	\$ (122,084)	\$ (54,242)
Other comprehensive loss:		
Holding gains (losses) arising during period, net of tax	609	(454)
Total comprehensive loss	<u>\$ (121,475)</u>	<u>\$ (54,696)</u>

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)

	<u>Common Stock</u>		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	214,868	2	(1,606)	—	—	(1,604)
Repurchase of common stock pursuant to the share repurchase program	(1,074,800)	(11)	(13,719)	—	—	(13,730)
Non-cash equity based compensation	—	—	4,873	—	—	4,873
Unrealized losses on securities, net of tax	—	—	—	609	—	609
Net loss	—	—	—	—	(122,084)	(122,084)
Balance at March 31, 2019	<u>33,746,828</u>	<u>\$ 337</u>	<u>\$ 1,282,284</u>	<u>\$ (3,376)</u>	<u>\$ (664,526)</u>	<u>\$ 614,719</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	239,081	2	(2,226)	—	—	(2,224)
Non-cash equity based compensation	—	—	5,533	—	—	5,533
Unrealized losses on securities, net of tax	—	—	—	(454)	—	(454)
Net loss	—	—	—	—	(54,242)	(54,242)
Balance at March 31, 2018	<u>34,322,193</u>	<u>\$ 343</u>	<u>\$ 1,274,935</u>	<u>\$ (4,362)</u>	<u>\$ (530,921)</u>	<u>\$ 739,995</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)

	Three Months Ended March 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (122,084)	\$ (54,242)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	4,375	59,485
Provision for bad debt expense	(16)	463
Amortization of premium/discount on purchased securities	(27)	67
Non-cash equity-based compensation expense	4,873	5,533
Non-cash IPR&D expense	18,029	—
Amortization of debt discount and debt issuance costs	3,783	3,880
Change in fair value of contingent consideration	(6)	626
Deferred income taxes	458	(6,643)
Changes in operating assets and liabilities:		
Accounts receivable, net	(7,971)	3,093
Inventories	(2,973)	3,534
Prepaid and other current assets	(21,580)	(3,720)
Accounts payable and accrued expenses	31,432	30,374
Deferred revenues	—	3,027
Other assets and liabilities	1,799	215
Net cash (used in) provided by operating activities	<u>(89,908)</u>	<u>45,692</u>
Cash flows from investing activities:		
Proceeds from sales or maturities of marketable securities	27,945	18,225
Purchase of marketable securities	(14,815)	(21,102)
Capital expenditures	(1,794)	(923)
Net cash provided by (used in) investing activities	<u>11,336</u>	<u>(3,800)</u>
Cash flows from financing activities:		
Payments to settle convertible notes	(21,417)	—
Payments of contingent consideration	(17)	(44)
Payments for repurchases of common stock	(13,730)	—
Proceeds from the exercise of common stock options	33	123
Payments of employee tax withholding related to equity-based compensation	(1,636)	(2,348)
Net cash used in financing activities	<u>(36,767)</u>	<u>(2,269)</u>
Net (decrease) increase in cash, cash equivalents, and restricted cash	(115,339)	39,623
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>\$ 138,412</u>	<u>\$ 232,393</u>
Supplemental data for cash flow information:		
Cash paid for taxes	\$ 78	\$ 136
Cash paid for interest	\$ 267	\$ 18,971
Non-cash investing and financing activities:		
Settlement of note receivable in connection with Perosphere acquisition	\$ 10,000	\$ —

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® (ferumoxylol injection) for intravenous use, Makena® (hydroxyprogesterone caproate injection), Intrarosa® (prasterone) vaginal inserts and MuGard® Mucoadhesive Oral Wound Rinse. In addition to our marketed products, our portfolio includes three product candidates, Vyleesi™ (bremelanotide), which is under review with the U.S. Food and Drug Administration (the "FDA") for the treatment of hypoactive sexual desire disorder ("HSDD") in pre-menopausal women, 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 months ended March 31, 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 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 March 31, 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 March 31, 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 months ended March 31, 2019 and 2018:

	Three Months Ended March 31,	
	2019	2018
McKesson Corporation	37%	27%
AmerisourceBergen Drug Corporation	27%	27%
Cardinal Health	13%	<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 March 31, 2019 and December 31, 2018, three customers accounted for 10% or more of our accounts receivable balances, representing approximately 80% 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 for drug substance and final packaging services for Intrarosa. In addition, we currently have a single supplier for our 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:

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

[Table of Contents](#)

- 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 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, *Revenue from Contracts with Customers*. 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 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 in 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 three months ended March 31, 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 in 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 months ended March 31, 2018.

The following is a summary of net income from discontinued operations for the three months ended March 31, 2018:

	Three Months Ended March 31, 2018
Service revenues, net	\$ 28,969
Costs and expenses:	
Cost of services	5,474
Selling, general and administrative expenses	17,619
Total costs and expenses	23,093
Operating income	5,876
Other income	2
Income from discontinued operations	5,878
Income tax expense	2,021
Net income from discontinued operations	<u>\$ 3,857</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 three months ended March 31, 2018. For the three months ended March 31, 2018, capital expenditures related to the CBR business were \$0.9 million. Depreciation and amortization expense related to the CBR business for the same period was \$4.6 million. There were no other significant operating or investing non-cash items related to the CBR business for the three months ended March 31, 2018.

D. REVENUE RECOGNITION

Our major sources of revenue during the reporting periods were product revenues from Makena (including both our branded and unbranded products), Feraheme and Intrarosa.

Product Revenue and Allowances and Accruals

The following table provides information about disaggregated revenue by products for the three months ended March 31, 2019 and 2018 (in thousands):

	Three Months Ended March 31,	
	2019	2018
Product sales, net		
Makena	\$ 31,257	\$ 89,983
Feraheme	40,015	25,135
Intrarosa	4,414	2,165
MuGard	43	65
Total product revenues	<u>\$ 75,729</u>	<u>\$ 117,348</u>

[Table of Contents](#)

Total gross product sales were offset by product sales allowances and accruals for the three months ended March 31, 2019 and 2018 as follows (in thousands):

	Three Months Ended March 31,	
	2019	2018
Gross product sales	\$ 211,718	\$ 239,870
Provision for product sales allowances and accruals:		
Contractual adjustments	108,884	86,144
Governmental rebates	27,105	36,378
Total	135,989	122,522
Product sales, net	\$ 75,729	\$ 117,348

The following table summarizes the product revenue allowance and accrual activity for the three months ended March 31, 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

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

During the three months ended March 31, 2019, we recorded an adjustment of \$8.6 million related to Medicaid rebates received during the quarter that related to prior period sales. We concluded that this adjustment represented a change in estimate during the first quarter of 2019 due to higher Medicaid utilization than anticipated.

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 March 31, 2019.

Collaboration Revenue

During the three months ended March 31, 2019, in conjunction with the Perosphere transaction, we assumed responsibility for a clinical trial collaboration agreement with a global 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.

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 global pharmaceutical company meets the definition of a customer, as they do not share in any potential reward from the research and development activities. As a result, this agreement is 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,

[Table of Contents](#)

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 March 31, 2019, the transaction price at acquisition 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 its 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 2.3 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.

We did not recognize revenue under this agreement during the three months ended March 31, 2019. Deferred revenue related to the agreement amounted to \$6.4 million, of which \$2.1 million is included in current liabilities. No milestone payments were received during the three months ended March 31, 2019.

E. MARKETABLE SECURITIES

As of March 31, 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 March 31, 2019 and December 31, 2018 (in thousands):

	March 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term marketable securities:*				
Corporate debt securities	\$ 39,368	\$ 17	\$ (90)	\$ 39,295
Certificates of deposit	10,000	—	—	10,000
U.S. treasury and government agency securities	6,391	—	(34)	6,357
Commercial paper	1,500	—	—	1,500
Total short-term marketable securities	<u>\$ 57,259</u>	<u>\$ 17</u>	<u>\$ (124)</u>	<u>\$ 57,152</u>
Long-term marketable securities:**				
Corporate debt securities	\$ 69,734	\$ 362	\$ (155)	\$ 69,941
Certificates of deposit	1,500	—	—	1,500
Total long-term marketable securities	<u>71,234</u>	<u>362</u>	<u>(155)</u>	<u>71,441</u>
Total marketable securities	<u><u>\$ 128,493</u></u>	<u><u>\$ 379</u></u>	<u><u>\$ (279)</u></u>	<u><u>\$ 128,593</u></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.

	December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term marketable securities:*				
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>
Long-term marketable securities:**				
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 in our condensed consolidated statements of operations related to our marketable securities during the three months ended March 31, 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 March 31, 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 March 31, 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 March 31, 2019 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	\$ 15,930	\$ 15,930	\$ —	\$ —
Corporate debt securities	109,236	—	109,236	—
U.S. treasury and government agency securities	6,357	—	6,357	—
Certificates of deposit	11,500	—	11,500	—
Commercial paper	1,500	—	1,500	—
Total assets	<u>\$ 144,523</u>	<u>\$ 15,930</u>	<u>\$ 128,593</u>	<u>\$ —</u>
Liabilities:				
Contingent consideration - MuGard	\$ 336	\$ —	\$ —	\$ 336
Total liabilities	<u>\$ 336</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 336</u>

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)
Assets:				
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	<u>\$ 212,483</u>	<u>\$ 71,568</u>	<u>\$ 140,915</u>	<u>\$ —</u>
Liabilities:				
Contingent consideration - MuGard	359	—	—	359
Total liabilities	<u>\$ 359</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 359</u>

Marketable Securities

Our cash equivalents, are classified as Level 1 assets under the fair value hierarchy as these assets have been valued using quoted market prices in active markets and do not have any restrictions on redemption. Our marketable securities are classified as Level 2 assets under the fair value hierarchy as 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 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 March 31, 2019. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during the three months ended March 31, 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 assets under the fair value hierarchy as these assets have been valued using unobservable inputs. These inputs include: (a) the estimated amount and timing of projected cash flows; (b) the probability of the achievement of the factors on which the contingency is based; and (c) the risk-adjusted discount rate used to present value the probability-weighted cash flows. Significant increases or decreases in any of those inputs in isolation could result in a significantly lower or higher fair value measurement.

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

Balance as of December 31, 2018	\$ 359
Payments made	(17)
Adjustments to fair value of contingent consideration	(6)
Balance as of March 31, 2019	<u>\$ 336</u>

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 15%. As of March 31, 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.

[Table of Contents](#)

We believe the estimated fair value of the MuGard Rights are based on reasonable assumptions; however, our actual results may vary significantly from the estimated results.

Debt

We estimate the fair value of our debt obligations by using quoted market prices obtained from third-party pricing services, which are classified as Level 2 inputs. As of March 31, 2019, the estimated fair value of our 2022 Convertible Notes (as defined below) was \$275.3 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 March 31, 2019 and December 31, 2018 (in thousands):

	March 31, 2019	December 31, 2018
Raw materials	\$ 9,978	\$ 9,388
Work in process	6,412	5,932
Finished goods	13,274	11,371
Total inventories	\$ 29,664	\$ 26,691

H. PROPERTY AND EQUIPMENT, NET

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

	March 31, 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	65	420
	14,639	12,732
Less: accumulated depreciation	(5,644)	(5,211)
Property and equipment, net	\$ 8,995	\$ 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 quarter 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 at March 31, 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. Our qualitative assessment is 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.

[Table of Contents](#)

Intangible Assets

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

	March 31, 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	\$ 319,246	\$ 77,358	\$ 797,100	\$ 400,495	\$ 319,246	\$ 77,359
Makena auto-injector developed technology	79,100	9,206	—	69,894	79,100	6,952	—	72,148
Intrarosa developed technology	77,655	11,817	—	65,838	77,655	10,129	—	67,526
Total intangible assets	<u>\$ 953,855</u>	<u>\$ 421,519</u>	<u>\$ 319,246</u>	<u>\$ 213,090</u>	<u>\$ 953,855</u>	<u>\$ 417,576</u>	<u>\$ 319,246</u>	<u>\$ 217,033</u>

As of March 31, 2019, the weighted average remaining amortization period for our finite-lived intangible assets was approximately 7.3 years. Total amortization expense for the three months ended March 31, 2019 and 2018 was \$3.9 million and \$52.4 million, respectively. Amortization expense is recorded in cost of product sales in our condensed consolidated statements of operations. We expect amortization expense related to our finite-lived intangible assets to be as follows (in thousands):

Period	Estimated Amortization Expense
Remainder of Year Ending December 31, 2019	\$ 41,329
Year Ending December 31, 2020	35,714
Year Ending December 31, 2021	30,016
Year Ending December 31, 2022	27,167
Year Ending December 31, 2023	18,046
Thereafter	60,818
Total	<u>\$ 213,090</u>

As of March 31, 2019, we determined that the ongoing supply issue with the Makena intramuscular (“IM”) products, which relates to the Makena base technology intangible asset was an indicator of potential impairment for that asset. As a result, we compared the projected undiscounted future cash flows for the Makena IM products and found that they exceeded the asset’s carrying value as of March 31, 2019. The evaluation of projected cash flows is dependent on management’s annual and ongoing forecasting, budgeting and planning processes and represents our best estimate of the future results of the Makena IM products as of a point in time. These estimates are subject to a number of assumptions. Actual results could differ materially from our assumptions in future periods and to the extent forecasted cash flows are lower in the future, an impairment charge could result.

J. CURRENT LIABILITIES

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

	March 31, 2019	December 31, 2018
Commercial rebates, fees and returns	\$ 104,521	\$ 80,520
Professional, license, and other fees and expenses	24,210	23,242
Salaries, bonuses, and other compensation	13,797	22,482
Interest expense	3,467	1,067
Research and development expense	4,634	2,226
Restructuring expense	5,058	—
Total accrued expenses	<u>\$ 155,687</u>	<u>\$ 129,537</u>

[Table of Contents](#)**K. INCOME TAXES**

The following table summarizes our effective tax rate and income tax benefit from continuing operations for the three months ended March 31, 2019 and 2018 (in thousands except for percentages):

	Three Months Ended March 31,	
	2019	2018
Effective tax rate	—%	12%
Income tax benefit	\$ (137)	\$ (8,000)

For the three months ended March 31, 2019, we recognized an income tax benefit of \$0.1 million, representing an effective tax rate of 0%. The income tax benefit for the three months ended March 31, 2019 primarily related to state taxes and 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 months ended March 31, 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 months ended March 31, 2018, we recognized an income tax benefit of \$8.0 million, representing an effective tax rate of 12%. The difference between the statutory federal tax rate of 21% and the effective tax rate for the three months ended March 31, 2018 was primarily attributable to the impact of the establishment of a valuation allowance related to certain deferred tax assets, the impact of non-deductible stock compensation, and other non-deductible expenses, partially offset by state income taxes and orphan drug tax credits.

The primary driver of the decrease in tax benefit for the three months ended March 31, 2019 as compared to the three months ended March 31, 2018 is the increase in valuation allowance on our current period losses generated.

L. ACCUMULATED OTHER COMPREHENSIVE LOSS

The following table summarizes the changes in the accumulated balances of other comprehensive loss during the three months ended March 31, 2019 and 2018 (in thousands):

	Three Months Ended March 31,	
	2019	2018
Beginning balance	\$ (3,985)	\$ (3,908)
Holding gains (losses) arising during period, net of tax	609	(454)
Ending balance	\$ (3,376)	\$ (4,362)

[Table of Contents](#)**M. EARNINGS PER SHARE**

The components of basic and diluted earnings per share for the three months ended March 31, 2019 and 2018 were as follows (in thousands, except per share data):

	Three Months Ended March 31,	
	2019	2018
Net loss from continuing operations	\$ (122,084)	\$ (58,099)
Net income from discontinued operations	—	3,857
Net loss	\$ (122,084)	\$ (54,242)
Weighted average common shares outstanding	34,469	34,162
Basic and diluted net income (loss) per share:		
Loss from continuing operations	\$ (3.54)	\$ (1.70)
Income from discontinued operations	—	0.11
Basic and diluted net loss per share	\$ (3.54)	\$ (1.59)

The following table sets forth the potential common shares issuable upon the exercise of outstanding options, the vesting of 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):

	Three Months Ended March 31,	
	2019	2018
Options to purchase shares of common stock	3,946	3,771
Shares of common stock issuable upon the vesting of RSUs	1,720	1,401
Warrants	—	1,008
2022 Convertible Notes	11,695	11,695
2019 Convertible Notes	—	790
Total	17,361	18,665

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 Fourth Amended and Restated 2007 Equity Incentive Plan, as amended (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 three months ended March 31, 2019:

	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	358,683	26,400	16,500	401,583
Exercised	(2,025)	—	—	(2,025)
Expired or terminated	(214,881)	(10,613)	(2,250)	(227,744)
Outstanding at March 31, 2019	2,923,563	140,237	824,593	3,888,393

Restricted Stock Units

The following table summarizes RSU activity for the three months ended March 31, 2019:

	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	1,007,719	1,100	2,100	1,010,919
Vested	(309,877)	—	(10,669)	(320,546)
Expired or terminated	(99,163)	—	—	(99,163)
Outstanding at March 31, 2019	1,639,820	3,201	76,724	1,719,745

In March 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 March 31, 2019, the maximum shares of common stock that may be issued under these awards is 365,591. The maximum aggregate total fair value of these RSUs is \$4.7 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 months ended March 31, 2019 and 2018 consisted of the following (in thousands):

	Three Months Ended March 31,	
	2019	2018
Cost of product sales	\$ 202	\$ 200
Research and development	680	720
Selling, general and administrative	3,325	3,870
Total equity-based compensation expense	4,207	4,790
Income tax effect	—	(835)
After-tax effect of equity-based compensation expense	\$ 4,207	\$ 3,955

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 three months ended March 31, 2019, which is classified within restructuring expense on our condensed consolidated statement of operations for the three months ended March 31, 2019.

We reduce the compensation expense being recognized to account for estimated forfeitures, which we estimate based primarily on historical experience, adjusted for unusual events such as corporate restructurings, which may result in higher than expected turnover and forfeitures. Under current accounting guidance, forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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 quarter ended March 31, 2019, we repurchased and retired 1,074,800 shares of common stock for \$13.7 million. As of March 31, 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 March 31, 2019, we had operating lease liabilities of \$7.9 million and related ROU assets of \$7.0 million. As of March 31, 2019, our leases have remaining lease terms of one to four years. The weighted average remaining lease term and discount rate for our operating leases was 2.17 years and 4.63% at March 31, 2019, respectively.

Lease costs for our operating leases were \$1.1 million for the three months ended March 31, 2019. Operating cash outflows for operating leases were \$1.2 million for three months ended March 31, 2019 and ROU assets obtained in exchange for lease obligations were \$1.0 million during the three months ended March 31, 2019.

Future minimum payments under our non-cancelable operating leases as of March 31, 2019 are as follows (in thousands):

Period	Future Minimum Lease Payments
Remainder of Year Ending December 31, 2019	\$ 3,092
Year Ending December 31, 2020	3,622
Year Ending December 31, 2021	1,239
Year Ending December 31, 2022	214
Year Ending December 31, 2023	53
Thereafter	—
Total	\$ 8,220
Less: Interest	363
Operating lease liability	\$ 7,857

[Table of Contents](#)

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	—
Total	<u>\$ 10,228</u>

Purchase Obligations

Purchase obligations primarily represent minimum purchase commitments for inventory. As of March 31, 2019, our minimum purchase commitments totaled \$42.7 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 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 to Velo 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

[Table of Contents](#)

a second milestone payment of \$30.0 million, which would be triggered when annual net U.S. sales of Intrarosa exceed \$300.0 million. If annual net U.S. sales of Intrarosa exceed \$500.0 million, there are additional sales milestone payments totaling up to \$850.0 million, which would be triggered at various sales thresholds. We are also obligated to pay tiered royalties to Endoceutics equal to a percentage of net 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 are required to pay Palatin (a) \$60.0 million upon FDA approval of Vyleesi, and (b) up to \$300.0 million of aggregate sales milestone payments upon the achievement of certain annual net sales milestones over the course of the license. The first sales milestone payment of \$25.0 million will be triggered when Vyleesi annual net sales exceed \$250.0 million. We are also obligated to pay Palatin 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

[Table of Contents](#)

“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 the Delaware Valley case is in the earliest stages and we have not been served with process in this case, we are currently unable to predict the outcome or reasonably estimate the range of potential loss associated with this matter, if any.

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 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 March 31, 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 March 31, 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 global 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.

[Table of Contents](#)

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 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 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 Makena in the U.S. (the “Makena authorized generic”). In July 2018, Prasco launched the Makena authorized generic of both the single-dose and multi-dose intramuscular injections. Under the Prasco Agreement, we are responsible for the manufacture and supply of the Makena authorized generic to be sold to Prasco at a predetermined supply price. Prasco is also required to pay us a certain percentage of the net distributable profits from the sale of the Makena authorized generic. We account 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 three months ended March 31, 2019, we incurred \$3.6 million of failure to supply penalties. The Prasco Agreement expires on July 2, 2022, which term will be automatically extended thereafter for additional one-year periods, unless canceled by us or Prasco within an agreed upon notice period. The Prasco Agreement is subject to early termination by us for convenience after a certain period of time or if Prasco is subject to a change of control or by either party for, among other things, uncured breach by or bankruptcy of the other party, lack of commercial viability or FDA notice, or by mutual agreement.

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 required to

[Table of Contents](#)

pay royalties to Antares on net sales of the Makena auto-injector for 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. In addition, we are required to pay Antares sales milestone payments upon the achievement of certain annual net sales. 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.*”

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.

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 and to identify, validate and transfer manufacturing intellectual property to the second source supplier by April 2019. 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, an investigational product designed to be a treatment for HSDD in pre-menopausal women, (b) a worldwide non-exclusive license, with the right to grant sub-licenses, to manufacture the 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 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 March 31, 2019 and December 31, 2018 consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
2022 Convertible Notes	\$ 265,576	\$ 261,933
2019 Convertible Notes	—	21,276
Total long-term debt	265,576	283,209
Less: current maturities	—	21,276
Long-term debt, net of current maturities	\$ 265,576	\$ 261,933

Convertible Notes

The outstanding balances of our Convertible Notes as of March 31, 2019 consisted of the following (in thousands):

	2022 Convertible Notes
Liability component:	
Principal	\$ 320,000
Less: debt discount and issuance costs, net	54,424
Net carrying amount	\$ 265,576
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.

[Table of Contents](#)

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 in our condensed consolidated balance sheets. The portion allocated to the liability component is amortized to interest expense using the effective interest method over five years.

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

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

- 1) during any calendar quarter (and only during such calendar quarter), 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 March 31, 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 March 31, 2019. As of March 31, 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.

[Table of Contents](#)*Convertible Notes Interest Expense*

The following table sets forth total interest expense recognized related to the Convertible Notes during the three months ended March 31, 2019 and 2018 (in thousands):

	Three Months Ended March 31,	
	2019	2018
Contractual interest expense	\$ 2,667	\$ 2,734
Amortization of debt issuance costs	354	339
Amortization of debt discount	3,429	3,237
Total interest expense	\$ 6,450	\$ 6,310

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 March 31, 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	—
Total	\$ 320,000

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 both Intrarosa and Makena. 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 in our condensed consolidated statement of operations for the three months ended March 31, 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.

[Table of Contents](#)

The following table displays charges taken related to restructuring activities during the three months ended March 31, 2019 and a rollforward of the changes to the accrued balances as of March 31, 2019 (in thousands):

2019 Restructuring charges:		
Workforce reduction	\$	7,034
Contract termination costs		229
Other		157
Total 2019 restructuring charges	\$	7,420
Rollforward of accrued restructuring:		
Balance at December 31, 2018	\$	—
Total 2019 restructuring charges		7,420
Workforce reduction payments		(2,159)
Contract termination cost payments		(59)
Other payments		(144)
Balance at March 31, 2019	\$	5,058

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 entities to recognize on its balance sheet assets and liabilities associated with the rights and obligations created by leases with terms greater than twelve months. 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 in 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 three months ended March 31, 2019. The adoption of ASU 2018-18 did not have a material impact on our financial

position or results of operations.

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;*
- *beliefs regarding our commercial strategies and efforts, including the timing of the commercial launch of Vyleesi, the impact of our efforts to convert current Makena IM prescribers to the Makena auto-injector, the impact of the Makena IM stock-out on Makena revenues and expected timing for remediation, including the ability of our contract manufacturers to gain and maintain FDA approval and to manufacture adequate supply;*
- *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 (which may be conducted by third parties), if approved, including plans to raise awareness and education of dyspareunia, VVA and HSDD and the results of such efforts;*
- *the timing and amounts of milestone and royalty payments;*
- *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 recent 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.

[Table of Contents](#)

AMAG Pharmaceuticals® and Feraheme® and the logo and designs 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® (ferumoxytol injection) for intravenous use, Makena® (hydroxyprogesterone caproate injection), Intrarosa® (prasterone) vaginal inserts and MuGard® Mucoadhesive Oral Wound Rinse. In addition to our marketed products, our portfolio includes three product candidates, Vyleesi™ (bremelanotide), which is under review with the U.S. Food and Drug Administration (the "FDA") for the treatment of hypoactive sexual desire disorder ("HSDD") in pre-menopausal women, 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 ciraparantag with our acquisition of Perosphere Pharmaceuticals Inc. ("Perosphere"), a privately-held biopharmaceutical company. Ciraparantag is an anticoagulant reversal agent in development for patients treated with novel oral anticoagulants ("NOACs") or 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. For additional information on the Perosphere acquisition, 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.

On February 7, 2019, we announced that we combined our women's and maternal health sales forces into one integrated sales team. This combined sales force promotes both Intrarosa and Makena and provides healthcare professionals with one commercial point of contact for our women's health sales force to seek to maximize efficiency and effectiveness for the promotion of our commercial products. As a result, we reduced our overall headcount by approximately 110 employees, approximately 100 of whom were part of our field-based commercial organization with the remainder coming from our general and administrative functions. We recorded a one-time restructuring charge of approximately \$7.4 million, primarily related to severance and related benefits, in the first quarter of 2019.

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 from sales of Makena, 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 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 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

[Table of Contents](#)

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 (0.9% of patients) compared to those receiving Injectafer® (50.8% 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”). The Makena auto-injector offers an alternative administration option for patients and providers and was designed with features, such as a shorter, thinner, non-visible needle compared to the Makena IM product, to help address some of the known barriers to treatment of recurrent preterm birth, including the lack of patient acceptance and adherence. Our commercial strategy for Makena currently focuses on driving awareness of the availability and attributes of the Makena auto-injector and converting current IM prescribers to the Makena auto-injector.

In July 2018, simultaneously with the launch of the first generic competitor to Makena, 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 a result of this partnership, we are able to provide patients and healthcare providers with access to therapeutically equivalent versions of the branded Makena IM injection. Currently, there are two generic competitors in the market in addition to the Makena authorized generic product, and we expect additional generic entrants could enter the market in 2019, including two generic competitors recently approved by the FDA, which we expect will compete against the 1ml and/or 5ml presentations.

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, with different demographics compared to the participants in the Meis trial, which served as the basis for the FDA’s approval of Makena. We are preparing for initial discussions to take place at an upcoming meeting with the FDA. In addition, we are working closely with our publications committee to further assess the data and 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

[Table of Contents](#)

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, 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. 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

In January 2017, we entered into a license agreement (the “Palatin License Agreement”) with Palatin Technologies, Inc. (“Palatin”) pursuant to which we acquired Vyleesi, an investigational product designed to treat acquired generalized HSDD in pre-menopausal women. In June 2018, the FDA accepted the Vyleesi NDA. The Prescription Drug User Fee Act (“PDUFA”) date for completion of FDA review of the Vyleesi NDA is June 23, 2019, and if approved on that date, we expect to launch Vyleesi in the third quarter 2019. If approved, we will also be obligated to make a \$60.0 million milestone payment to Palatin. In November 2018, as part of our discussions with the FDA regarding its review of the NDA submission for Vyleesi, the FDA requested additional data assessing 24-hour ambulatory blood pressure with short-term daily use of Vyleesi. This Phase 1 study, which was conducted in premenopausal healthy volunteers, has been completed and submitted to the FDA.

Vyleesi, a melanocortin 4 receptor agonist is designed to be an on demand 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. Two identically-designed Phase 3 studies evaluating the safety and efficacy of Vyleesi compared to placebo were conducted by Palatin for the treatment of HSDD in pre-menopausal women. 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 an ongoing open-label safety extension phase of the study for an additional 52 weeks, which gathered additional data on the safety of long-term and repeated use of Vyleesi. Nearly 80% of patients who completed the randomized portion of the study elected to remain in the open-label portion of the study. All of the patients in the extension study 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. For women taking Vyleesi compared to placebo, the change from baseline in low sexual desire, as measured by the FSFI-D, showed statistically significant improvement with Vyleesi in both median and mean measures of desire in both Phase 3 studies. The median change from baseline was 0.60 vs. 0.00 for both studies, and the mean change from baseline was 0.54 vs. 0.24 ($p=0.0002$) for one study and 0.63 vs. 0.21 ($p<0.0001$) for the other study. Likewise, for women taking Vyleesi compared to placebo, the change from baseline in related distress, as measured by the FSDS-DAO Question 13, also demonstrated statistically significant improvement with Vyleesi in both median and mean measures of desire in both Phase 3 studies. The median change from baseline was -1.0 vs. 0.0 for both studies, and the mean change from baseline was -0.7 vs. -0.4 for both studies, with pValues of <0.0001 for one study and 0.0053 for the other study. The change in the number of satisfying sexual events, a key secondary endpoint, was not significantly different from placebo in either clinical trial.

In the Phase 3 clinical trials, the most frequent adverse events were nausea, flushing, injection site reactions and headache, which were generally mild-to-moderate in severity and were transient. Approximately 18% of patients discontinued participation in the Vyleesi arm due to adverse events in both studies versus 2% in placebo. The adverse events in the extension portion of the study were consistent with that of the controlled studies described above.

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 have re-initiated the study as the sponsor, and have begun reactivating the current sites, seeking new sites and, as of January 2019, enrolling new patients. 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

In January 2019, we acquired Perosphere, a privately-held biopharmaceutical company focused on developing ciraparantag, a small molecule anticoagulant reversal agent in development as a single dose solution that is delivered intravenously to reverse the effects of certain NOACs (Xarelto®(rivaroxaban), Eliquis®(apixaban), and Savaysa®(edoxaban), as well as Lovenox® (enoxaparin sodium injection), a 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 and we intend to seek orphan drug designation and Breakthrough Therapy designation in 2019. 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 1/2 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 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 to confirm the design of our Phase 3b/4 trials in healthy volunteers, designed to determine the lowest effective dose of ciraparantag. We intend to initiate the Phase 3a trials in the second half of 2019.

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 three months ended March 31, 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 March 31, 2019 and 2018**Revenues**

Total product revenues for the three months ended March 31, 2019 and 2018 consisted of the following (in thousands except for percentages):

	Three Months Ended March 31,		2019 to 2018	
	2019	2018	\$ Change	% Change
Product sales, net				
Makena	\$ 31,257	\$ 89,983	\$ (58,726)	(65)%
Feraheme	40,015	25,135	14,880	59 %
Intrarosa	4,414	2,165	2,249	>100 %
MuGard	43	65	(22)	(34)%
Total product revenues	75,729	117,348	(41,619)	(35)%

Our total product revenues for the three months ended March 31, 2019 decreased by \$41.6 million as compared to the same period in 2018, due primarily to a \$58.7 million decrease in Makena net sales. The decrease in Makena revenue reflected the significant decline in sales of the Makena IM product due substantially to the entry of generic competition beginning in mid-2018, as well as manufacturing issues at our primary third-party Makena IM manufacturer, which resulted in supply disruptions of our IM products during the first quarter of 2019. Total Makena revenues for the first quarter of 2019 were further impacted by certain gross-to-net charges, including \$3.6 million due to Prasco for charges they incurred due to their inability to meet their contractual obligations as a result of our IM supply disruptions, an estimated \$5.0 million of increased Medicaid rebates due to the impact of the IM supply constraints on government reported pricing and \$6.0 million due to changes in estimate adjustments related to prior period Medicaid rebates received during the quarter. Partially offsetting these declines was a significant increase in Makena auto-injector sales, which was launched at the end of the first quarter of 2018, and a 59% increase in Feraheme sales driven almost exclusively by volume gains.

We expect that sales of Feraheme, the Makena auto-injector, and Intrarosa will continue to increase for the remainder of 2019. In addition, we expect to provide Prasco with new supply of Makena IM product in the second quarter of 2019 and that revenues from the Makena IM product, particularly the authorized generic presentation, will increase for the remainder of 2019 as compared to the first quarter of 2019. The continued impact of generic competition to our Makena sales is dependent on the timing, number and behavior of current and future generic competitors.

In 2019, we expect to recognize collaboration revenue under the terms of a clinical trial collaboration agreement with a global pharmaceutical company, provided certain clinical obligations are met in connection with our ciraparantag program.

[Table of Contents](#)

Total gross product sales were offset by product sales allowances and accruals for the three months ended March 31, 2019 and 2018 as follows (in thousands, except for percentages):

	Three Months Ended March 31,				2019 to 2018	
	2019	Percent of gross product sales	2018	Percent of gross product sales	\$ Change	% Change
Gross product sales	\$ 211,718		\$ 239,870		\$ (28,152)	(12)%
Provision for product sales allowances and accruals:						
Contractual adjustments	108,884	51%	86,144	36%	22,740	26 %
Governmental rebates	27,105	13%	36,378	15%	(9,273)	(25)%
Total	135,989	64%	122,522	51%	13,467	11 %
Product sales, net	\$ 75,729		\$ 117,348		\$ (41,619)	(35)%

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. The decrease in governmental rebates as a percentage of gross product sales primarily related to a shift in the mix of business.

Product Sales Allowances and Accruals

We record product revenue net of certain allowances and accruals in 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 March 31, 2019 and 2018 were as follows (in thousands except for percentages):

	Three Months Ended March 31,		2019 to 2018	
	2019	2018	\$ Change	% Change
Direct cost of product sales	\$ 14,535	\$ 11,548	\$ 2,987	26 %
Amortization of intangible assets	\$ 3,942	\$ 52,364	\$ (48,422)	(92)%
	\$ 18,477	\$ 63,912	\$ (45,435)	(71)%
Direct cost of product sales as a % of net product sales	19%	10%		

Direct cost of product sales was \$14.5 million and \$11.5 million for the three months ended March 31, 2019 and 2018, respectively. Direct cost of product sales as a percentage of net product sales increased from 10% to 19% during the first quarter of 2019 driven by higher gross-to-net adjustments and therefore lower net price during the first quarter of 2019. We expect that a substantial portion of these gross-to-net adjustments are non-recurring in nature and we therefore anticipate net price to increase from these levels in future quarters of 2019. As net price normalizes, we expect that direct cost of product sales will decrease as a percentage of revenue, compared to the first quarter of 2019.

Amortization of intangible assets decreased by \$48.4 million from March 31, 2018 to March 31, 2019 primarily due to a decrease in amortization related to the Makena base technology intangible asset which relates to our Makena IM products and is recognized based on an economic consumption model. We expect amortization of intangible assets to increase in future quarters of 2019 as Makena IM supply becomes available and revenues from the Makena IM products increase.

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

Research and development expenses for the three months ended March 31, 2019 and 2018 consisted of the following (in thousands except for percentages):

	Three Months Ended March 31,		2019 to 2018	
	2019	2018	\$ Change	% Change
External research and development expenses	\$ 12,499	\$ 6,754	\$ 5,745	85%
Internal research and development expenses	5,567	4,055	1,512	37%
Total research and development expenses	\$ 18,066	\$ 10,809	\$ 7,257	67%

Total research and development expenses incurred in the three months ended March 31, 2019 increased by \$7.3 million, or approximately 67%, as compared to the same period in 2018. The \$7.3 million increase was primarily related to our development programs for our recently acquired products, AMAG-423 and ciraparantag and for Vyleesi-related costs, primarily related to the Phase 1 study to assess 24-hour ambulatory blood pressure with short-term daily use of Vyleesi recently conducted as part of our NDA submission.

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. In addition, we expect our internal research and development expenses to increase substantially for the remainder of 2019 as we expand our internal infrastructure and continue to establish more robust development capabilities. 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.

Acquired In-Process Research and Development

During the three months ended March 31, 2019, we recorded \$74.9 million for acquired in-process research and development (“IPR&D”) related to the acquisition of Perosphere.

During the three months ended March 31, 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 three months ended March 31, 2019 and 2018 consisted of the following (in thousands except for percentages):

	Three Months Ended March 31,		2019 to 2018	
	2019	2018	\$ Change	% Change
Compensation, payroll taxes and benefits	\$ 30,350	\$ 30,235	\$ 115	—%
Professional, consulting and other outside services	41,013	38,700	2,313	6%
Fair value of contingent consideration liability	(6)	626	(632)	>(100)%
Equity-based compensation expense	3,325	3,870	(545)	(14)%
Total selling, general and administrative expenses	\$ 74,682	\$ 73,431	\$ 1,251	2%

We expect that total selling, general and administrative expenses for the remainder of 2019 will approximate the level of expense incurred in the first quarter. As a result of the consolidation of the women’s health and maternal health sales forces that we completed during the first quarter of 2019, we expect employee-related spend to decrease for the remainder of 2019. These decreases will be offset by planned increases in external spending as we prepare for the potential launch of Vyleesi, assuming FDA approval, and as we continue to invest in the growth of our commercial products.

[Table of Contents](#)

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 currently promotes both Intrarosa and Makena and will ultimately promote Vyleesi, assuming FDA approval. 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 three months ended March 31, 2019 and expect restructuring charges incurred to date under this program to be substantially paid in cash by the end of the first quarter of 2020. As a result of the restructuring, we expect a reduction in selling, general and administrative expense, specifically related to compensation, payroll taxes and benefits beginning in the second quarter of 2019. We estimate total savings from the restructuring to be approximately \$15.2 million for the remaining nine months of 2019, offset by planned increases in external spending as we prepare for the potential launch of Vyleesi, assuming FDA approval, 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 three months ended March 31, 2019 decreased by \$10.8 million compared to the same period in 2018, primarily due to a \$9.5 million reduction in interest expense in the three months ended March 31, 2019 as a result of the early redemption of our 7.875% Senior Notes due 2023 in 2018.

Income Tax Benefit

The following table summarizes our effective tax rate and income tax benefit for the three months ended March 31, 2019 and 2018 (in thousands except for percentages):

	Three Months Ended March 31,	
	2019	2018
Effective tax rate	—%	12%
Income tax benefit	\$ (137)	\$ (8,000)

For the three months ended March 31, 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 March 31, 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 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 March 31, 2019 primarily related to state taxes and 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 March 31, 2018, we recognized an income tax benefit of \$8.0 million, representing an effective tax rate of 12%. The difference between the statutory federal tax rate of 21% and the 12% effective tax rate for the three months ended March 31, 2018, was primarily attributable to the impact of the establishment of a valuation allowance related to certain deferred tax assets, the impact of non-deductible stock compensation, and other non-deductible expenses, partially offset by state income taxes and orphan drug tax credits.

The primary driver of the decrease in tax benefit for the three months ended March 31, 2019 as compared to the three months ended March 31, 2018 was the increase in valuation allowance on our current period losses generated.

Net Income from Discontinued Operations

Net income from discontinued operations was \$3.9 million for the three months ended March 31, 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 March 31, 2019

[Table of Contents](#)

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

	March 31, 2019	December 31, 2018	\$ Change	% Change
Cash and cash equivalents	\$ 137,917	\$ 253,256	\$ (115,339)	(46)%
Marketable securities	128,593	140,915	(12,322)	(9)%
Total	\$ 266,510	\$ 394,171	\$ (127,661)	(32)%
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 three months ended March 31, 2019 and 2018 (in thousands):

	March 31, 2019	March 31, 2018	\$ Change
Net cash (used in) provided by operating activities	\$ (89,908)	\$ 45,692	\$ (135,600)
Net cash provided by (used in) investing activities	11,336	(3,800)	15,136
Net cash used in financing activities	(36,767)	(2,269)	(34,498)
Net (decrease) increase in cash, cash equivalents, and restricted cash	\$ (115,339)	\$ 39,623	\$ (154,962)

Operating Activities

Cash flows from operating activities represent 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 incomes taxes; and
- Changes associated with the fair value of contingent payments associated with our acquisitions of businesses.

For the period ended March 31, 2019 compared to March 31, 2018, net cash flows provided by operating activities decreased by \$135.6 million, driven primarily by a decrease in net income as adjusted for non-cash charges of \$99.8 million and a \$35.8 million decrease due to changes in operating assets and liabilities. Included within net loss 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 quarter ended March 31, 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 \$11.3 million for the three months ended March 31, 2019 due to net proceeds from the sale of marketable securities of \$13.1 million offset by capital expenditures of \$1.8 million. Cash used in investing activities for the three months ended March 31, 2018 was \$3.8 million due to net purchases of marketable securities of \$2.9 million and capital expenditures of \$0.9 million.

Financing Activities

Cash used in financing activities was \$36.8 million for the three months ended March 31, 2019 due to the repayment of the \$21.4 million balance of our 2019 Convertible Note, \$13.7 million for the repurchase of common stock and \$1.6 million for payments of employee tax withholdings related to equity based compensation. Cash used in financing activities for the three months ended March 31, 2018 was \$2.3 million driven by the payment of employee tax withholdings related to equity based compensation.

Future Liquidity Considerations

We believe that our cash, cash equivalents and marketable securities as of March 31, 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 \$266.5 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, since March 31, 2019, our expected utilization of cash includes, but is not limited to, the following:

- Approximately \$7.8 million of cash interest in connection with our 2022 Convertible Notes;
- A \$60.0 million milestone obligation to Palatin conditioned and payable upon FDA approval of Vyleesi.

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 March 31, 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 quarter ended March 31, 2019, we repurchased and retired 1,074,800 shares of common stock for \$13.7 million. As of March 31, 2019, \$26.8 million remains available for future repurchases under this program.

Off-Balance Sheet Arrangements

As of March 31, 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 March 31, 2019 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting. We implemented internal controls to ensure management properly assessed the impact of the new lease accounting standards on our condensed consolidated financial statements to facilitate adoption of the new leasing standard effective January 1, 2019. There were no significant changes to our internal control over financial reporting due to the adoption of the new standard.

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.

Our revenues for the Makena franchise may continue to be negatively impacted by recent and future generic entries into the market and the supply disruptions of certain of our Makena products.

Our ability to continue to successfully commercialize Makena is dependent upon a number of factors, including our ability to differentiate Makena from other treatment options, especially now that four independent generic competitors have been approved by the FDA. Although our partner, Prasco, LLC (“Prasco”) markets a generic version of Makena in the U.S. (“the Makena authorized generic”) to mitigate the decrease in Makena revenue as generic entrants gain market share, our Makena products will 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.

The long-term success of the Makena franchise is highly dependent on our ability to successfully commercialize the pre-filled subcutaneous auto-injector (the “Makena auto-injector”), which provides us with an alternative treatment method to the intramuscular (“IM”) formulation of Makena (the “Makena IM product”). Although there is no direct competition with the Makena auto-injector, the auto-injector competes for the same patients as generic versions of the Makena IM product, including Makena authorized generic. Although we have experienced an increase in auto-injector starts, we may not 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. Even if we are successful in such efforts, Makena revenues could continue to be negatively impacted as a result of the Makena IM supply outage. Further, increased demand of the auto-injector product could result in issues for that product as well.

[Table of Contents](#)

In addition, we have lost and could lose additional market share if we continue to be unable to deliver sufficient quantities of Makena IM inventory to meet demand. Due to continued manufacturing issues at our primary third-party manufacturer, we are currently experiencing a supply disruption of our Makena IM products, which has resulted in both our single-dose and multi-dose branded Makena vials being out-of-stock and has caused periodic disruptions, including, at times, supply outages, of our authorized generic supply. We are attempting to mitigate and remediate this supply issue by manufacturing at our secondary supplier and anticipate a decision from the FDA on an additional manufacturing site in the second quarter of 2019. However, if the approval of the additional site is delayed, we will be unable to meet demand for the Makena branded and generic IM products, which will impact our and Prasco's continued ability to sell the Makena IM products. We can make no guarantees that additional supply will be available in a timely manner, or at all, which will continue to negatively impact Makena sales, including our ability to gain or even retain market share in the generic market, much of which has already been lost to our competition. We are currently exploring all of our rights and remedies under the supply agreement with our third-party manufacturer of the Makena IM product and are also working with the FDA, healthcare providers, distribution partners and our manufacturers to minimize the impact of the current supply disruption of the IM products, including by encouraging healthcare providers to support new patient starts on the auto-injector. These supply issues have caused and will continue to cause a disruption in our ability to meet commercial demand of Makena more generally, which has and could continue to negatively impact revenues.

Further, we rely on Prasco for our successful commercialization of the Makena authorized generic. We have limited experience working with a generic vendor and selling products under terms customary in the generic marketplace. We are responsible for supplying product to Prasco, and due to the problems with our supply chain, revenues with respect to the Makena authorized generic have been and could continue to be adversely affected and we have been and could continue to be subject to certain charges, which could be substantial. 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.

If we and Prasco are not able to capture or maintain sufficient market share, if generics are sold at a significant discount to Makena's price, if we continue to experience supply disruptions related to our Makena IM branded and generic products or if we become unable to meet commercial demand for our Makena auto-injector or Makena authorized generic, our Makena revenues could continue to be materially and adversely affected and, ultimately, could negatively impact our stock price and results of operations.

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

The following table provides certain information with respect to our purchases of shares of our stock during the three months ended March 31, 2019.

Period	Total Number of Shares Purchased ⁽¹⁾	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs ⁽²⁾	Maximum Number of Shares (or approximate dollar value) That May Yet Be Purchased Under the Plans or Programs ⁽²⁾
January 1, 2019 through January 31, 2019	3,808	\$ 16.14	—	1,252,685
February 1, 2019 through February 28, 2019	50,909	15.56	—	1,377,196
March 1, 2019 through March 31, 2019	52,986	14.72	1,074,800	2,077,241
Total	107,703	\$ 15.17	1,074,800	

(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 March 31, 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 remains authorized for repurchase as of March 31, 2019. The repurchase program does not have an expiration date and may be suspended for periods or discontinued at any time.

[Table of Contents](#)

Item 6. Exhibits:

Exhibit Number	Description
10.1+*	Product Supply Agreement, dated as of June 1, 2017, by and between AMAG Pharmaceuticals, Inc. and Pfizer, Inc.
10.2+	AMAG Pharmaceuticals, Inc. Non-Employee Directors' Compensation Policy
10.3+	AMAG Pharmaceuticals, Inc. Non-Employee Directors' Deferred Compensation Program
10.4+	Form of Restricted Stock Unit Agreement (Deferred) for Non-Employee Directors under AMAG Pharmaceuticals, Inc.'s Fourth Amended and Restated 2007 Equity Incentive Plan
31.1+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS+	XBRL Instance Document
101.SCH+	XBRL Taxonomy Extension Schema Document
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+	XBRL Taxonomy Extension Label Linkbase Document
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document

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

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

* Certain information in this exhibit was omitted by means of redacting a portion of the text and replacing it with “[***]”. AMAG Pharmaceuticals, Inc. has determined that the omitted information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

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

AMAG PHARMACEUTICALS, INC.

By: /s/ William K. Heiden

William K. Heiden

*President and Chief Executive Officer
(Principal Executive Officer)*

Date: May 8, 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: May 8, 2019

*Portions of this Exhibit have been redacted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed. Information that was omitted has been noted in this document with a placeholder identified by the mark “[***]”.*

EXHIBIT 10.1

PRODUCT SUPPLY AGREEMENT

by and between

PFIZER INC.

and

AMAG PHARMACEUTICALS, INC.

dated as of June 1, 2017

Signature Version *Confidential*

This SUPPLY AGREEMENT (the “Agreement”), dated as of April 1, 2017 (the “Effective Date”), is by and between Pfizer Inc., a corporation with offices at 235 East 42nd St., New York, NY 10017 (“Pfizer”), and AMAG Pharmaceuticals, Inc. a corporation with offices at 1100 Winter St., Waltham, MA 02451, (“Customer”). Pfizer and Customer may be referred to herein individually as a “Party” or collectively as the “Parties.”

WHEREAS, Customer desires to purchase from Pfizer, and Pfizer agrees to supply, Product under the terms and conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the mutual covenants and agreements of the Parties contained in this Agreement, intending to be legally bound hereby, the Parties agree as follows:

ARTICLE 1 DEFINITIONS

1.1 Definitions. For purposes of this Agreement:

“Affiliate” means, with respect to any Party, any Person which directly or indirectly controls or is controlled by or is under common control with such Party. For purposes of this definition, “control” (including, with correlative meaning, the terms “controlled by” and “under common control with”) shall be presumed to exist if one of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors of such entity or any direct or indirect parent of such entity, and (b) in the case of non-corporate entities, the direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management or policies of such non-corporate entities.

“Batch” means an initiation and completion of a discrete batch of Product that is intended to be of uniform character and quality, within specified limits, and is produced during the same cycle of Manufacture as defined by the applicable Batch Records.

“Batch Records” means, with respect to a Batch, documents prepared in accordance with cGMP that record the relevant Manufacturing or packaging of the Product, including the controls, quality specifications and regulatory and other requirements, under which such Batch of Product was Manufactured or packaged.

“Business Day” means any day other than Saturday, Sunday, or any day on which banks located in the United States are authorized or obligated to be closed.

“Certificate of Analysis” means a document signed by an authorized representative of Pfizer, describing Specifications for, and results of testing applied by Pfizer to Product.

“Current Good Manufacturing Practices” or “cGMP” means the then current requirements under all applicable Laws relating to manufacturing practices for products (including ingredients, testing, storage, handling, intermediates, and bulk products) including as set forth in ICHQ7 “cGMP for Active Pharmaceutical Ingredients” and as otherwise required by any Regulatory Authority having jurisdiction over the Facility (as such term is defined below), as the same may be updated, supplemented or amended from time to time.

“Claim or Proceeding” means any claim, action, suit, proceeding or arbitration, including any Governmental Entity action, notification, investigation or audit.

“Confidential Information” means all information relating to (i) a disclosing Party’s business or business plans, including, but not limited to, suppliers, customers, prospective customers, contractors, clinical data, the content and format of various clinical and medical databases, utilization data, cost and pricing data, disease management data, software products, programming techniques, data warehouse and methodologies, all proprietary information, know-how, trade secrets, technical and non-technical materials, products, specifications, processes, sales and marketing plans or strategies, designs, and any such information developed by the disclosing Party or its personnel for or on behalf of the disclosing Party, (ii) information of any Third Parties, and (iii) any discussions and proceedings relating to any of the foregoing information, whether disclosed in oral, electronic, visual, written or any other form. Confidential Information includes the terms and conditions of this Agreement. Confidential Information shall also include information of the disclosing Party that a reasonable Person would consider confidential or proprietary under the circumstances. The fact that the disclosing Party may have marked or identified as confidential or proprietary any specific information shall be indicative that the disclosing Party believes such information to be confidential or proprietary, but the failure to so mark information shall not conclusively determine that such information is or is not considered Confidential Information by the disclosing Party.

“Contract Quarter” means each successive three (3) calendar month period beginning on the Effective Date.

“Contract Year” means any four (4) Contract Quarter periods beginning on the Effective Date and ending on each successive anniversary of that date.

“Exempt Information” means any information which the receiving Party can demonstrate (i) was lawfully in its possession and reduced in writing prior to the time of disclosure by or on behalf of the disclosing Party and which is not subject to another obligation of confidentiality; (ii) is or becomes generally available to the public through no breach of this Agreement by the receiving Party or its personnel; (iii) is obtained from a Third Party lawfully entitled to possession of such Confidential Information and under no obligation of confidentiality to the disclosing Party or its Affiliates; or (iv) was independently developed by or for the recipient without reference to, aid from or reliance upon the Confidential Information of the disclosing Party. In clarification of the foregoing, a general disclosure in the public domain will not cause more specific (but related) information to be deemed Exempt Information under one of the above exceptions; similarly, a combination of several pieces of information, where each piece of information individually is deemed Exempt Information, will not operate to exempt the combination as Exempt Information unless the combination itself is in the public domain, independently developed by the receiving Party, or otherwise lawfully in the receiving Party’s possession.

“Facility” means Pfizer’s manufacturing facility located at [***] and such other facilities used by Pfizer in the Manufacture, packaging and storage of Product.

“Global Trade Control Laws” means the U.S. Export Administration Regulations; the U.S. International Traffic in Arms Regulations; the economic sanctions rules and regulations implemented under statutory authority and/or President’s Executive Orders and administered by the U.S. Department of the Treasury Office of Foreign Assets Control; European Union (E.U.) Council Regulations on export controls, including Nos. 428/2009, 267/2012; other E.U. Council sanctions regulations as implemented in E.U. Member States; United Nations sanctions policies; all relevant regulations and legislative instruments made under any of the above; other relevant economic sanctions, export and import control laws, regulations, legislation, orders and requirements imposed by a relevant Governmental Entity.

“Governmental Entity” means any court, tribunal or arbitral body with competent jurisdiction; any military, quasi-military or law enforcement agency; or any other entity, agency, department, authority or other instrumentality of any supra-national, federal, national, state, county, local, municipal, other political subdivision, administrative authority, agency, commission, instrumentality, or other governmental regulatory body.

“Intellectual Property” means (a) any processes, trade secrets, inventions, industrial models, designs, methodologies, drawings, formulae, procedures, techniques, clinical data or technical or other information or data, manufacturing, engineering and technical drawings necessary or useful in the registration, packaging, Manufacture, use or sale of the Product, (b) registered trademarks, trademark applications, unregistered marks, trade dress, and copyrights, (c) know-how, and (d) patents, patent applications, and any provisionals, divisions, continuations, continuations in part, extensions, substitutions, renewals, registrations, revalidations, reissues or additions, including supplementary certificates of protection, of or to any of the aforesaid patents and patent applications, and all foreign counterparts of any, or to any, of the aforesaid patents and patent applications, or any future patents or patent applications covering such Product or any components thereof or improvements thereof.

“Losses” means losses, damages, fines, fees, settlements, payments, obligations, penalties, deficiencies, costs and expenses (including interest, court costs, reasonable fees of attorneys, accountants and other experts, and other reasonable expenses of litigation or other proceedings or of any claim, default or assessment) arising out of Third Party Claims or Proceedings.

“Manufacture” and “Manufacturing” means any steps, processes and activities necessary to produce Product including, without limitation, the manufacturing, processing, packaging, quality control testing, and release, of Product.

“Manufacturing Process” means any processes and activities (or any step in any process or activity) used, as evidenced in the Batch Records or master Batch Records, or planned to be used by Pfizer or its approved subcontractor to Manufacture Product.

“Person” means any natural person, entity, corporation, general partnership, limited partnership, other business organization, trust, union, association or any Governmental Entity, including any Regulatory Authority.

“Product” means “17-Hydroxy Progesterone Caproate” as described in Schedule 1 attached and incorporated herein.

“Quality Agreement” means an agreement between the Parties that describes the Parties’ quality control, technical, quality assurance and regulatory responsibilities relating to the Manufacture and release of Product Manufactured under this Agreement, as the same may be modified from time to time by mutual written agreement of the parties.

“Restricted Market” means, as applicable under Global Trade Control Laws, the Crimean Peninsula, Cuba, the Donbass Region, Iran, North Korea, Sudan and Syria.

“Restricted Party” means any individual or entity on any of the Restricted Party Lists.

“Restricted Party List” means the list of sanctioned entities maintained by the United Nations; the Specially Designated Nationals List and the Sectoral Sanctions Identifications List, as administered by the U.S. Department of the Treasury Office of Foreign Assets Control; the U.S. Denied Persons List, the U.S.

Entity List, and the U.S. Unverified List, all administered by the U.S. Department of Commerce; the entities subject to restrictive measures and the Consolidated List of Persons, Groups and Entities Subject to E.U. Financial Sanctions, as implemented by the E.U. Common Foreign & Security Policy; the List of Excluded Individuals / Entities, as published by the U.S. Health and Human Services – Office of Inspector General; any lists of prohibited or debarred parties established under the U.S. Federal Food Drug and Cosmetic Act; the list of persons and entities suspended or debarred from contracting with the U.S. government; and similar lists of restricted parties maintained by the Governmental Entities of the countries that have jurisdiction over the activities conducted under or covered by this Agreement.

“Restricted Party Screening” means the comparison of any Person directly or indirectly involved in activities conducted under or covered by this Agreement, against the Restricted Party Lists.

“Regulatory Authorities” means any duly authorized Governmental Entity, court, tribunal, arbitrator, agency, commission, official or other instrumentality of any federal, state, province, county, city, or other political subdivision, domestic or foreign. Regulatory Authorities may include USFDA or the Pharmaceutical and Medical Devices Agency.

“Reprocess” or “Reprocessing” means introducing Product back into the Manufacturing Process and repeating appropriate manipulation steps that are part of the established Manufacturing Process. Continuation of a process step after an in-process control test showing the process to be incomplete is not considered reprocessing.

“Rework” or “Reworking” means subjecting Product to one or more processing steps that are different from the established Manufacturing Process.

“SOPs” means the standard operating procedures that each Party uses in its manufacturing and quality operations.

“Specifications” means the specifications of Product as set forth in Schedule 1 hereto and incorporated herein.

“Territory” means [***].

“Third Party” means any Person other than a Party or any of its Affiliates.

“USFDA” means the United States Food and Drug Administration or any successor agency.

1.2 Other Terms. The following terms have the meanings set forth in the Sections set forth below:

<u>Term</u>	<u>Section</u>
“Customer Indemnified Party”	6.1
“Customer Property”	7.2(a)
“Developments”	7.1(b)
“Extension Term”	9.1
“Force Majeure Event”	11.6
“Improvements”	7.1(b)
“Indemnified Party”	6.3
“Indemnifying Party”	6.3
“Initial Supply Forecast”	2.2(a)
“Initial Term”	9.1
“Pfizer Indemnified Party”	6.2
“Pfizer Property”	7.1(a)
“Purchase Order”	2.3
“Records”	5.1
“Rolling Supply Forecast”	2.2(b)

**ARTICLE 2
SUPPLY OF PRODUCTS**

2.1 Supply. Subject to and in accordance with the terms and conditions of this Agreement:

(a) Minimum Supply. [***].

(b) Supply. Pfizer or its designated Affiliate shall use commercially reasonable efforts to Manufacture Customer’s requirements of Product, as such requirements are set forth in this Article 2. During the term of the Agreement, Pfizer will [***].

(c) Quality Agreement. Representatives of the Parties’ quality assurance departments shall meet to develop and approve a Quality Agreement. In the event of conflict between terms of the Quality Agreement and this Agreement, the terms of the Quality Agreement shall prevail for all quality and regulatory compliance matters and the terms of this Agreement shall prevail for all other matters. The Quality Agreement may be modified from time to time by mutual written agreement. Once executed by both Parties, the Quality Agreement shall be incorporated into and made part of this Agreement by this reference.

(d) Performance of Manufacturing Services. Pfizer will: (a) Manufacture Product at the Facility, (b) provide all staff necessary to Manufacture Product in accordance with the terms of this Agreement, and (c) hold at such Facility all equipment and other items necessary to Manufacture Product. The Parties agree that in the event Pfizer chooses not to perform any steps of the Manufacture itself, it will notify Customer of its intent to use a subcontractor for such steps and obtain Customer’s written consent to the use of such subcontractor, which shall not be unreasonably withheld, prior to engaging such subcontractor, provided that Pfizer shall be responsible for the performance of any such subcontractor as if Pfizer itself had provided such performance.

2.2 Forecasts for Supply.

(a) Initial Supply Forecast. Upon execution of this Agreement, Customer will provide Pfizer with a good faith estimate of Customer's projected requirements for supply of Product during the first [***] of the Term (such estimate, the "Initial Supply Forecast"). The first [***] of the Initial Supply Forecast will be binding. The following [***] of such Initial Supply Forecast will be binding with a tolerance of [***]. The last [***] of the Initial Supply Forecast constitutes a non-binding estimate provided that Customer may not order quantities for such period exceeding (in aggregate) [***] of the forecasted requirements for such period.

(b) Rolling Supply Forecasts. After [***] the Initial Supply Forecast, Customer will provide Pfizer with a good faith estimate of Customer's projected requirements for supply of Product for delivery during each of the [***] following the [***] covered by the Initial Supply Forecast (each such [***], a "Rolling Supply Forecast"). Customer shall provide Pfizer with its Rolling Supply Forecast by the [***] of each [***]. The first Rolling Supply Forecast shall be for Customer's projected requirements of Product during the [***] subsequent to the end of the [***] of the Initial Supply Forecast. The first [***] of each such Rolling Supply Forecast will be binding. The subsequent [***] of each such Rolling Supply Forecast will be binding with a tolerance of [***]. The last [***] of the Initial Supply Forecast constitutes a non-binding estimate. Such non-binding estimates may be decreased or increased in subsequent Rolling Supply Forecasts; provided, however, that Customer's forecasted needs for Product in any [***] covered by a Rolling Supply Forecast may not exceed [***] of the amount forecasted for such [***] in the immediately preceding Rolling Supply Forecast and in any [***] may not exceed [***] of the amount supplied in the immediately preceding [***], unless mutually agreed upon in writing.

2.3 Purchase Orders.

(a) All Product purchased under this Agreement shall be pursuant to Customer's issuance of individual written purchase orders to Pfizer for specific quantities of Product (each, a "Purchase Order"). Each Purchase Order will set forth the quantities of Product desired, the shipping location and delivery date(s), provided that such delivery date(s) shall be no earlier than [***] after the date such Purchase Order is issued. In addition, Customer shall ensure that the total quantities of Product in Purchase Orders issued during any binding [***] period of a Rolling Supply Forecast satisfy Customer's binding purchase obligations under the applicable Rolling Supply Forecast. Pfizer shall acknowledge such Purchase Order within [***] of issuance, failing which the Purchase Order will be deemed accepted at the expiration of such [***] period; provided that any Purchase Order that is inconsistent with this Agreement shall not be deemed accepted.

(b) Each Purchase Order issued by Customer and confirmed by Pfizer as provided in this Section constitutes the binding obligation of Pfizer to Manufacture, sell and deliver to Customer whole Batch quantities or quantities in increments of prepackaged stock of Product by the delivery date specified in such Purchase Order, and the binding obligation of Customer to purchase the quantity of Product specified therein.

(c) In the event of any conflict between the provisions of this Agreement and any Purchase Order, acknowledgement, invoice, bill of lading, acceptance or other preprinted form provided by either Party, the provisions of this Agreement shall govern.

(d) All Product ordered by Customer pursuant to a Purchase Order or binding forecast pursuant to Section 2.2 shall be consistent with Pfizer's then-current minimum Batch sizes, or multiples

thereof. Any change to such minimum Batch sizes will not affect any binding forecasts previously submitted by Customer.

(e) The Parties shall use commercially reasonable efforts to correspond and/or meet periodically, at mutually convenient times and places, to discuss each Party's requirements under this Section and the mechanisms that can be established to assure that those requirements are met on a timely basis.

2.4 Shipments.

(a) Pfizer shall deliver Product to Customer [***]. Customer shall be responsible for obtaining all applicable licenses, regulatory approvals or clearances to and for any further export, import, or use of the Product. Pfizer shall include the following with each shipment of Product: (i) Pfizer lot and Batch numbers, (ii) the quantity of Product included in such shipment, (iii) a Certificate of Analysis, and (iv) a bill of lading.

(b) Title to Product and risk of loss or damage shall pass to Customer when [***].

(c) Customer will promptly notify Pfizer in writing of loss, damage, defect or non-delivery of all or any part of a shipment of Product to Customer or its designee, and if any loss, damage, defect or partial non-delivery is present but is not evident to Customer at the time of delivery, Customer shall provide such notification to Pfizer no later than [***] after receipt by Customer; provided, however, that Customer shall notify Pfizer within [***] after its receipt of such shipment if Customer is rejecting such shipment due to obvious external physical damage or quantity discrepancies that are, or would be, evident upon reasonable visual inspection of such packaged Product as shipped by Pfizer.

2.5 Product Acceptance.

(a) Customer shall notify Pfizer in writing of any deficiencies or objections to the Product(s) within [***] after the delivery date. Any notice of rejection by Customer shall be accompanied by a reasonably detailed statement of its reasons for rejection. Pfizer shall notify Customer in writing as promptly as practicable, but in any event [***] after receipt of such notice of rejection, whether Pfizer accepts or rejects Customer's assertions of non-conformity or non-compliance. If Customer fails to notify Pfizer of any objections to the Product(s) within the above-noted [***] period, the Products shall be conclusively presumed satisfactory and deemed accepted.

(b) If the Parties disagree as to whether Product conforms to the applicable Specifications, the Parties' quality assurance representatives shall attempt in good faith to resolve any such disagreement and Customer and Pfizer will follow their respective SOPs to determine the conformity of the Product to the Specifications. If the foregoing discussions do not resolve the disagreement within a reasonable time [***], the Parties will submit a representative sample of the Product to an independent testing laboratory mutually agreed upon by the Parties for a final determination of whether the Product conforms to the Specifications. The laboratory must meet cGMP and be of recognized standing in the industry and, provided that the laboratory meets such requirements, neither Party shall unreasonably withhold, condition or delay its consent to the appointment of such laboratory. Such laboratory will use the test methods contained in the Specifications. The determination of conformance by such laboratory with respect to all or part of such Product will be final and binding on the Parties. The fees and expenses incurred by the laboratory in making such determination will be paid [***].

(c) If Pfizer accepts Customer's assertion that a Batch of Product fails to conform to the Specifications, or if such Batch of Product is found under this Section not to conform to the Specifications,

then the parties will discuss and mutually agree, [***] of Pfizer's notice of non-conformance to Customer, which of the following options Pfizer shall move forward with: (i) [***] (ii) [***] or (iii) [***].

(d) If Pfizer requests that Customer return or dispose of any nonconforming or noncomplying Product, Pfizer will reimburse Customer for [***] incurred by Customer for such return shipment or lawful disposal of such nonconforming or noncomplying Product. Pfizer shall give Customer written instructions as to how Customer should lawfully dispose of such nonconforming or noncomplying Product, and Customer shall provide Pfizer with written certification of such destruction. Pfizer shall reimburse Customer for [***] for such lawful disposal of such nonconforming or noncomplying Product.

2.6 Change in Specifications.

(a) If at any time any Regulatory Authority or applicable law requires Pfizer to change the Specifications, configuration, packaging and/or Manufacturing Process for Product to be supplied to Customer hereunder, then: (i) Pfizer will provide Customer with [***] of such change; and (ii) Pfizer shall [***] associated with such change; provided however, that [***] will be responsible for, and will [***] it must take with Regulatory Authority as a result of such change.

(b) If at any time Pfizer wishes to change the, configuration, packaging and/or Manufacturing Process for Product to be supplied to Customer and such change is not required by Regulatory Authorities or a change in applicable law, then: (i) Pfizer will provide Customer with at least [***] prior written notice of such change; and (ii) Pfizer shall [***] associated with such change; provided however, that [***] will [***], any filings or other actions it must take as a result of such change.

(c) If at any time Customer wishes to change the Specifications, configuration, packaging and/or Manufacturing Process for Product to be supplied to Customer, then: (i) Customer will request such change in writing; (ii) the Parties shall meet promptly to discuss the feasibility of the requested change, [***]; and (iii) if Pfizer agrees to implement the requested change, Customer shall [***] associated with such change; including but not limited to [***].

ARTICLE 3 REPRESENTATIONS, WARRANTIES AND COVENANTS

3.1 Representations, Warranties and Covenants. The Parties represent and warrant as follows:

(a) Representations of Authority. Pfizer and Customer each represents and warrants to the other Party that, as of the Effective Date, it has full right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement.

(b) No Conflict. Pfizer and Customer each represents and warrants to the other Party that the execution and delivery of this Agreement by such Party and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of applicable law existing as of the Effective Date and (ii) do not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date.

(c) Enforceability. Pfizer and Customer each represents and warrants to the other Party that, as of the Effective Date, this Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms.

(d) Anti-Bribery and Anti-Corruption. Each Party represents and warrants that it shall neither take nor refrain from taking any action that could result in liability for the other Party under any anti-corruption or anti-bribery laws including, without limitation, the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act of 2010, plus any other anti-bribery or anti-corruption law or treaty applicable to either Party or, if applicable, its Affiliates. Each Party has and shall maintain in place throughout the Term policies and procedures to confirm compliance with applicable Laws relating to anti-bribery and anti-corruption. Each Party shall promptly report to the other Party any request received by such Party for any undue financial or other advantage of any kind in connection with the performance of this Agreement. Neither Party shall accept, offer or make any payment or provide anything else of value, or take or fail to take any other action which is either prohibited or required by applicable Laws in connection with this Agreement.

3.2 Additional Representations, Warranties and Covenants of Pfizer. Pfizer further represents, warrants and covenants that, at the time of delivery to Customer, the Product Manufactured under this Agreement will have been Manufactured in accordance with cGMP and all other applicable law, the Quality Agreement, and Specifications.

3.3 Additional Representations Warranties and Covenants of Customer.

(a) Compliance with Laws. Customer further represents, warrants and covenants to Pfizer that Customer shall comply with all applicable laws relating to the handling, storage, use, disposal, sale, advertising and marketing of all Product and product containing the Product while such Product or product is in Customer's possession and/or control.

(i) Trade Control Laws.

(A) Compliance with Global Trade Control Laws. Activities covered by, and Product supplied under, this Agreement may be subject to Global Trade Control Laws. Customer represents and warrants that it will perform all activities covered by this Agreement in full compliance with all applicable Global Trade Control Laws.

(B) Restricted Markets. Customer represents and warrants that activities under this Agreement will not (i) be in a Restricted Market; (ii) involve individuals ordinarily resident in a Restricted Market, or (iii) include companies, organizations or Government Entities from or located in a Restricted Market. Customer agrees that Product will not be supplied to Restricted Markets without all required licenses or other authorizations from the U.S. or other relevant Governmental Entities.

(C) Restricted Parties. Customer represents and warrants that neither it, nor its respective owners, directors and officers, are a Restricted Party or are owned or controlled by a Restricted Party. Customer confirms that any of its Affiliates, agents, employees or subcontractors directly or indirectly involved with any of the activities covered by this Agreement are not Restricted Parties and that no such Restricted Parties will be engaged in or delegated any activities covered by this Agreement. In the event that any of the Persons noted above, or any Third Party directly or indirectly engaged by such Person, becomes designated as a Restricted Party during the Term of this Agreement, Customer will immediately inform Pfizer and suspend all activities covered by this Agreement until the Parties agree otherwise. Notwithstanding all cure periods or dispute resolution periods set forth herein, Customer acknowledges and agrees that its designation as, or association with, a Restricted Party shall be grounds for immediate termination of this Agreement for cause, with no applicable cure period.

(D) Restricted Party Screening. Customer shall conduct a Restricted Party Screening of the names and addresses of all individuals, agents, employees, subcontractors, carriers (including vessel names), and any other relevant Person that is involved, directly or indirectly, with the supply of Product under this Agreement or any activities covered by this Agreement.

(E) Termination and Blocked Payment. If this Agreement is terminated due to inclusion of a Restricted Party, Restricted Market, or Restricted Market national in activities covered by this Agreement without a license or other authorization required by Global Trade Control Laws or any other violation of Global Trade Control Laws, Pfizer shall not be responsible for any payments due to Customer, or for further supply of any Product. Customer shall be responsible for reimbursing Pfizer for any payments due to Pfizer under this Agreement that may be blocked due to inclusion of a Restricted Party, Restricted Market, or Restricted Market national in any activities covered under this Agreement without a license or other authorization required by Global Trade Control Laws, or due to any other violation of Global Trade Control Laws.

3.4 Limited Applicability. The representations and warranties of a Party set forth in this Agreement are intended for the sole and exclusive benefit of the Parties hereto, and may not be relied upon by any Third Party, other than permitted successors or assigns.

3.5 Limitation. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, PFIZER MAKES NO REPRESENTATION NOR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO CUSTOMER, AND PFIZER HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT WITH RESPECT TO THE PRODUCT SUPPLIED HEREUNDER. PFIZER HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION OF ANY PRODUCT USING THE PRODUCT WILL BE SUCCESSFUL OR THAT THE PRODUCT WILL BE ACCEPTABLE TO, OR SUITABLE FOR USE IN PRODUCING A PRODUCT ACCEPTABLE TO, USFDA FOR SUBMISSION APPROVAL PURPOSES.

3.6 Insurance. Each Party shall maintain [***] full and sufficient Third Party, public and product liability, and product recall insurance, which may be by means of self-insurance, to cover its actual and potential liabilities hereunder and shall provide to the other a certificate of such insurance (or equivalent) upon request.

ARTICLE 4 PURCHASE PRICE FOR PRODUCTS; PAYMENTS

4.1 Price. The purchase price of Product sold to Customer under this Agreement is [***].

4.2 Payment and Payment Terms.

(a) Customer shall make all payments required under this Agreement by wire transfer in United States dollars to a bank account designated by Pfizer [***].

(b) Pfizer shall submit invoices for Product, [***]. The invoices shall reflect the price [***] of Product provided in Section 4.1. Customer shall pay Pfizer in full for Products delivered by Pfizer within [***] of its receipt of the invoice. For avoidance of doubt, if one or more invoices contains amounts

that are subject to a bona fide dispute, Customer will pay any amounts that are not subject to such dispute within such [***] period.

4.3 Currency. All dollar (\$) amounts specified in this Agreement are United States dollar amounts.

ARTICLE 5 OTHER OBLIGATIONS

5.1 Records. Pfizer will keep complete and accurate records (including reports, accounts, data, and records of all information and results obtained from performance of services) of all work done by it under this Agreement, in form and substance as specified in the Quality Agreement and this Agreement (collectively, the “Records”). While in the possession or control of Pfizer, Records will be available at reasonable times for inspection, examination and copying by USFDA. Pfizer will ensure that all Records of the Manufacture of Product under this Agreement will be retained and archived in accordance with cGMP and applicable law, but in no case for less than a period of [***] following completion of the applicable Manufacturing Process for the Product.

ARTICLE 6 INDEMNIFICATION

6.1 Indemnification of Customer. Pfizer shall defend, indemnify and hold harmless Customer, its Affiliates and its and their respective directors, officers, employees, agents and representatives (each, a “Customer Indemnified Party”), from and against any Losses arising out of or relating to any and all Claims or Proceedings of Third Parties to the extent based upon: (i) any breach by Pfizer of this Agreement or any representation or warranty contained in Section 3.1 or 3.2 of this Agreement; or (ii) the gross negligence, recklessness, or willful misconduct of Pfizer, its Affiliates and its and their respective directors, officer, employees and agents; Notwithstanding the foregoing, Pfizer shall not be liable for Losses to the extent such Losses are caused by the negligence, recklessness, or misconduct of Customer or breach of any of the terms of this Agreement by Customer.

6.2 Indemnification of Pfizer. Customer shall defend, indemnify and hold harmless Pfizer, its Affiliates and its and their respective directors, officers, employees and agents (each, a “Pfizer Indemnified Party”), from and against any Losses arising out of or relating to any Claims or Proceedings by Third Parties to the extent based upon: (i) Customer’s breach of this Agreement or of any representation or warranty made by Customer in this Agreement; or (ii) the gross negligence, recklessness, or willful misconduct of Customer, its Affiliates and its and their respective directors, officers, employees and agents; (iii) any sales to Third Parties of the Product or any product incorporating the Product; or (iv) any claims that any Intellectual Property owned by Customer and provided to Pfizer by Customer pursuant to this Agreement infringes any intellectual property right of any Third Party. Notwithstanding the foregoing, Customer shall not be liable for Losses to the extent such Losses are caused by the negligence, recklessness, or misconduct of Pfizer or breach of any of the terms of this Agreement by Pfizer.

6.3 Indemnification Procedures. A Party (an “Indemnified Party”) which intends to claim indemnification under this Article shall notify the other Party (an “Indemnifying Party”) within a reasonable time in writing [***] of any Third Party Claim or Proceeding in respect of which the Indemnified Party believes it is entitled to claim indemnification, provided that the failure to give timely notice to the Indemnifying Party shall not release the Indemnifying Party from any liability to the Indemnified Party to the extent the Indemnifying Party is not prejudiced thereby. The Indemnifying Party shall have the right, by notice to the Indemnified Party, to assume the defense of any such action or claim within [***] after the

Indemnifying Party's receipt of notice of any Third Party action or claim with counsel of the Indemnifying Party's choice [***]. If the Indemnifying Party does not so assume the defense of such Third Party claim, the Indemnified Party may assume such defense with counsel of its choice [***]. If the Indemnifying Party so assumes such defense, the Indemnified Party may participate therein through counsel of its choice, [***]. The Party not assuming the defense of any such claim shall render all reasonable assistance to the Party assuming such defense, [***]. No such claim shall be settled other than by the Party defending the same, and then only with the consent of the other Party which shall not be unreasonably withheld, provided that the Indemnified Party shall have no obligation to consent to any settlement of any such action or claim which imposes on the Indemnified Party any liability or obligation which cannot be assumed and performed in full by the Indemnifying Party, and the Indemnified Party shall have no right to withhold its consent to any settlement of any such action or claim if the settlement involves only the payment of money by the Indemnifying Party or its insurer.

6.4 Limitation on Liability.

(a) Notwithstanding anything in this Agreement to the contrary, Pfizer's aggregate liability to Customer under this Agreement shall in no event exceed, on a cumulative basis, the lesser of (i) [***] under this Agreement during [***] period [***] or (ii) [***] dollars, whichever amount is less. Pfizer's indemnification obligations under this Article 6 shall terminate on the date that is [***] from the termination or expiration of this Agreement.

(b) NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR [***].

ARTICLE 7 INTELLECTUAL PROPERTY

7.1 Pfizer Property.

(a) All Intellectual Property provided or otherwise made available to Customer by or on behalf of Pfizer, or which is used by Pfizer or Customer with respect to the performance of its respective obligations hereunder, and which was owned or Controlled by Pfizer prior to being provided or made available to Customer, shall remain the property of Pfizer (the "Pfizer Property"). Without limiting the foregoing, Pfizer shall retain all rights, title and interest in and to such Pfizer Property, including all Intellectual Property and proprietary rights embodied in or appurtenant to such Pfizer Property. Customer shall not acquire any right, title or interest in or to the Pfizer Property as a result of its or Pfizer's performance hereunder. For purposes of this Article 7, "Controlled" means, with respect to any materials, information or Intellectual Property right, the possession, whether by ownership or license, of the right to grant a license, sublicense or other right without violating the contractual or Intellectual Property rights of any Third Party.

7.2 Customer Property. All Intellectual Property provided to Pfizer by or on behalf of Customer, or which is used by Customer or Pfizer with respect to the performance of its respective obligations hereunder, and which was owned or Controlled by Customer prior to being provided to Pfizer, shall remain the property of Customer (the "Customer Property"). For avoidance of doubt, Customer Property excludes any Pfizer Property. Pfizer shall acquire no right, title or interest in Customer Property as a result of Customer's or Pfizer's performance hereunder.

7.3 Improvements.

(a) [***]

(b) [***]

(c) [***]

ARTICLE 8 CONFIDENTIALITY AND PUBLICITY

8.1 Confidential Information. During the Term and for a period of [***] after expiration or termination of this Agreement, each Party agrees to keep in confidence and not to disclose to any Third Party, or use for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, any Confidential Information of the other Party. The restrictions on the disclosure and use of Confidential Information set forth in the first sentence of this Section shall not apply to Exempt Information. In addition, if either Party is required to disclose Confidential Information of the other Party by regulation, law or legal process, the disclosing Party shall provide prior notice of such intended disclosure to the other Party if possible under the circumstances and shall disclose only such Confidential Information of the other Party as is required to be disclosed.

8.2 Employee, Consultant and Advisor Obligations. Each Party agrees that it and its Affiliates shall provide or permit access to Confidential Information received from the other Party and such other Party's Affiliates and representatives only to the receiving Party's, and its Affiliates', employees, consultants and advisors who, in such Party's reasonable judgment have a need to know such Confidential Information to assist the receiving Party with the activities contemplated by this Agreement and who are subject to obligations of confidentiality and non-use with respect to such Confidential Information similar to the obligations of confidentiality and non-use of the receiving Party under this Agreement; provided however, that each of Pfizer and Customer shall remain responsible for any failure by its Affiliates, and its and its Affiliates' respective employees, consultants and advisors, to treat such Confidential Information as required under Section 8.1 as if such Affiliates, employees, consultants and advisors were Parties directly bound by the requirements of Section 8.1.

8.3 Publicity. Neither Party shall issue a press release or other public announcement relating to this Agreement or its subject matter without the prior written approval of the other Party.

ARTICLE 9 TERM AND TERMINATION AND SUPPLY FAILURE

9.1 Term. This Agreement shall become effective as of the Effective Date and, unless sooner terminated as provided in this Article 9 or unless extended pursuant to agreement of the Parties, shall continue until the end of three (3) Contract Years (the "Initial Term"). At the end of the Initial Term, the Parties may upon mutual agreement extend the Agreement for an additional one (1) Contract Year period not to exceed three extensions (each an "Extension Term") unless notice of termination is given by a Party, as provided below. After the Initial Term, each Party may terminate the Agreement by giving notice to the other Party of at least [***] before the end of the then current Term.

9.2 Termination.

(a) Termination by Pfizer. Pfizer may terminate this Agreement upon written notice to Customer if Customer breaches any material obligation hereunder, including failing to pay any amount due hereunder which is not subject to a bona fide dispute pursuant to Subsection 4.2(b) within [***], and Customer: (a) fails to cure such payment default within [***] after Customer's receipt of written notice thereof; and (b) fails to cure any other default [***] after receipt of written notice thereof.

(b) Termination by Customer; Supply Failure. If Pfizer breaches any of its material obligations hereunder then (i) if such breach is not curable, Customer may terminate this Agreement upon written notice to Pfizer, and (ii) if such breach is curable and is not cured within [***] after Pfizer's receipt of written notice specifying such breach, Customer may terminate this Agreement upon written notice to Pfizer; provided, however, that (1) if Pfizer reasonably believes that such curable breach cannot be reasonably cured within such a [***] period and so notifies Customer within [***] after Pfizer's receipt of Customer's notice, and (2) Pfizer has commenced commercially reasonable efforts to cure such breach during such [***] period, the Parties shall meet and confer in good faith for a period not to go beyond the [***] following Pfizer's receipt of Customer's notice to determine a reasonable resolution of such breach and if, despite good faith attempts, the Parties fail to reach a reasonable resolution, then Customer may terminate this Agreement upon expiration of such [***] period. If, however, after meeting and conferring in good faith, the Parties reach a mutually acceptable resolution to cure the breach, [***].

(c) Termination in Event of Insolvency. In the event that either Party (the "Insolvent Party"): (i) becomes insolvent, or institutes or has instituted against it a petition for bankruptcy or is adjudicated bankrupt; or (ii) executes a bill of sale, deed of trust, or a general assignment for the benefit of creditors; or (iii) is dissolved or transfers a substantial portion of its assets to a Third Party; or (iv) a receiver is appointed for the benefit of its creditors, or a receiver is appointed on account of insolvency; then the Insolvent Party shall immediately notify the other Party of such event and such other Party shall be entitled to: (a) terminate this Agreement for cause immediately upon written notice to the Insolvent Party; or (b) request that the Insolvent Party or its successor provide adequate assurances of continued and future performance in form and substance acceptable to such other Party, which shall be provided by the Insolvent Party within [***] of such request, and the other Party may terminate this Agreement for cause immediately upon written notice to the Insolvent Party in the event that the Insolvent Party fails to provide such assurances acceptable to the other Party within such [***] period.

(d) Termination. In the event that Pfizer undergoes a business transaction with a Third Party and Pfizer is required by or informed by any government competition authority that it must terminate this Agreement in order to obtain antitrust clearance for such transaction, Pfizer may, upon [***] prior written notice to Customer, terminate this Agreement without cause. Such notice period may be extended if permitted by the relevant competition authority.

(e) Other Remedies. Subject to Article 6, Any termination of this Agreement as provided herein shall not be an exclusive remedy but shall be in addition to any remedies that may otherwise be available to either Party.

9.3 Effect of Termination of this Agreement. Upon any termination of this Agreement, Customer will promptly: (i) return to Pfizer all relevant Records, materials or Pfizer Confidential Information relating to the Product in its (or any of its Affiliates' or contractors') possession or control; and (ii) return, at Customer's expense, any inventory of Product then on hand at Customer's facilities or those of its designee(s) for which Customer has failed to pay.

9.4 Accrued Rights; Surviving Obligations. Upon termination of this Agreement, the Parties will have no further obligations to each other, except that termination or expiration of this Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either Party prior to such termination or expiration. Further, such termination or expiration shall not relieve either Party from obligations which are expressly indicated to survive termination or expiration of this Agreement. In addition, all of the Parties' rights and obligations under Articles 3, 4, 5, 6, 7 and 8, Section 9.3 and Section 9.4 shall survive termination.

ARTICLE 10
NOTICES

10.1 Any notice required to be given hereunder shall be in writing and shall be deemed to have been sufficiently given: (i) when delivered in person, (ii) on the fifth Business Day after mailing by registered or certified mail, postage prepaid, return receipt requested, or (iii) on the next Business Day after mailing by overnight courier service, to the addresses specified below. Each notice shall specify the name and date of and Parties to this Agreement:

If to Pfizer:

Pfizer
[***]
Attention: Vice President, Pfizer CentreOne
Facsimile Number: [***]

with copy to (which shall not constitute notice):

Pfizer Inc.
[***]
Attn: General Counsel

If to Customer:

AMAG Pharmaceuticals, Inc.
1100 Winter Street
Waltham, MA 02451
Attn: SVP Technical Operations

with a copy to (which shall not constitute notice):

AMAG Pharmaceuticals, Inc.
1100 Winter Street
Waltham, MA 02451
Attn: General Counsel

Either Party may, by notice to the other Party, change the addresses and names given above.

ARTICLE 11
MISCELLANEOUS

11.1 Negotiations of Dispute. Prior to commencing any litigation with respect to any controversy, claim, counterclaim, dispute, difference or misunderstanding arising out of or relating to the interpretation or application of any term or provisions of this Agreement, a Party shall provide written notice to the other Party of the existence of such dispute. The Parties shall for a period of [***] following such notice enter into good faith discussions and negotiations in an attempt to resolve such dispute, unless acts or circumstances such as bankruptcy, insolvency, refusal to negotiate in good faith, or repudiation frustrate or make impossible such good faith discussions and negotiations. If, by the end of such [***] period, unless such period is extended by mutual agreement of the Parties, the Parties have been unable to resolve such dispute, either Party may initiate litigation. The procedures specified in this Section are a precondition to the initiation of litigation by a Party, in connection with disputes between the Parties arising from or related to this Agreement; provided, however, that a Party may: (i) seek a preliminary injunction or other preliminary judicial relief,

without attempting to resolve such dispute as provided in this Section, if in its judgment such action is necessary to avoid irreparable harm; or (ii) institute formal proceedings to avoid the expiration of any applicable limitations period. Further, the requirement to attempt to resolve a dispute in accordance with this Section does not affect a Party's right to terminate this Agreement as provided in Article 9 hereof, and neither Party shall be required to follow these procedures prior to terminating the Agreement.

11.2 Publicity. Neither Party shall issue any press release or other publicity materials, or make any presentation with respect to the existence of this Agreement or the terms and conditions hereof without the prior written consent of the other Party in each instance. This restriction shall not, however, apply to the extent that any such disclosures are required by applicable laws, including as may be required in connection with any filings required to be made with the United States Securities and Exchange Commission or by the disclosure policies of a major stock exchange. Customer agrees not to use or refer to, without Pfizer's written permission, which permission may not be unreasonably withheld, the name of Pfizer or any of Pfizer's Affiliates in any public statement, whether oral or written, including, but not limited to, shareholder reports, communications with stock market analysts, press releases or other communications with the media, or prospectuses.

11.3 Governing Law; Venue; Limitations Period.

(a) The validity, interpretation and performance of this Agreement shall be governed by and construed in accordance with the laws of the State of New York without reference to the principles of conflicts of laws. THE PARTIES EXPRESSLY AGREE THAT THE APPLICATION OF THE UNITED NATION CONVENTION ON CONTRACTS FOR THE INTERNATIONAL SALE OF GOODS (1980) IS SPECIFICALLY EXCLUDED AND SHALL NOT APPLY TO THIS AGREEMENT.

(b) All Claims and Proceedings under this Agreement shall be brought exclusively in the state or federal courts of competent subject matter jurisdiction in the City of New York City in the State of New York. The Parties hereby waive: (i) any objection which it may have at any time to the venue of the proceedings in any such court, (ii) any claim that such proceedings have been brought in an inconvenient forum, and (iii) the right to object, with respect to such proceedings, that such court does not have any jurisdiction over such Party. IN ANY CONTROVERSY OR CLAIM, WHETHER BASED IN CONTRACT, TORT OR OTHER LEGAL THEORY, ARISING OUT OF OR RELATING TO THIS AGREEMENT, ITS NEGOTIATION, ENFORCEABILITY OR VALIDITY, OR THE PERFORMANCE OR BREACH HEREOF OR THE RELATIONSHIPS ESTABLISHED HEREUNDER, ALL PARTIES EXPRESSLY WAIVE THEIR RIGHT TO TRIAL BY JURY.

(c) Notwithstanding subsection (a) above, any action and proceeding under this Agreement shall be commenced within [***] of the expiration or termination of this Agreement.

11.4 Relationship of the Parties. The relationship hereby established between Customer and Pfizer is solely that of independent contractors. This Agreement is not intended to create, and shall not be construed as creating, between Pfizer and Customer, the relationship of principal and agent, joint ventures, co-partners, or any other such relationship, the existence of which is expressly denied.

11.5 Assignment; Binding Effect. Neither Party will assign this Agreement nor any part thereof without the prior written consent of the other Party; provided, however, that either Party may, without such consent, assign the rights and obligations of this Agreement (a) to one of its Affiliates, subsidiaries or parent corporation, and/or (b) in connection with the transfer, sale or divestiture of substantially all of its business to which this Agreement pertains or in the event of its spin-off, merger or consolidation with another company. Any permitted assignee will assume all obligations of its assignor under this Agreement. No assignment will

relieve either Party of responsibility for the performance of any accrued obligation which such Party then has hereunder. This Agreement shall apply to, inure to the benefit of, and be binding upon the Parties hereto and their respective successors and permitted assigns. The Parties agree that this Agreement is not intended by any Party to give any benefits, rights, privileges, actions or remedies to any person or entity, partnership, firm or corporation as a Third Party beneficiary or otherwise under any theory of law.

11.6 Force Majeure. No Party shall be liable for any failure to perform or any delays in performance, and no Party shall be deemed to be in breach or default of its obligations set forth in this Agreement, if, to the extent and for so long as, such failure or delay is due to any causes that are beyond its reasonable control and not to its acts or omissions, including such causes as acts of God, natural disasters, fire, flood, severe storm, earthquake, civil disturbance, lockout, riot, unavailability of any materials, including, but not limited to Product materials (including a Force Majeure event at a Product material or other supplier's facility) order of any court or administrative body, embargo, acts of government, war (whether or not declared), acts of terrorism, or other similar causes (each, a "Force Majeure Event"). In the event of a Force Majeure Event, the Party prevented from or delayed in performing shall promptly give notice to the other Party and shall use commercially reasonable efforts to avoid or minimize the delay. In the event that the delay continues for a period of at least [***], the Party affected by the other Party's delay may elect to: (a) suspend performance and extend the time for performance for the duration of the Force Majeure Event, or (b) cancel all or any part of the unperformed part of this Agreement and/or any Purchase Orders.

11.7 Severability. If and solely to the extent that any court or tribunal of competent jurisdiction holds any provision of this Agreement to be unenforceable in a final non-appealable order, such unenforceable provision shall be stricken and the remainder of this Agreement shall not be affected thereby. In such event, the Parties shall in good faith attempt to replace such unenforceable provision with a provision that is enforceable and that comes as close as possible to expressing the intention of the original provision

11.8 Non-Waiver; Remedies. A waiver by any Party of any term or condition of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach thereof. All remedies specified in this Agreement shall be cumulative and in addition to any other remedies provided at law or in equity.

11.9 Headings. Headings of sections or other parts of this Agreement are included herein for convenience of reference only and shall not constitute a part of this Agreement or change the meaning of this Agreement.

11.10 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall constitute an original and all of which together shall constitute one and the same agreement, in effect as of the Effective Date, and may be delivered to the other Party in accordance with the means set forth in Article 10 or by reliable electronic means (with receipt electronically confirmed).

11.11 Electronic Delivery and Storage. This Agreement may be stored by electronic means and either an original or an electronically stored copy of this Agreement can be used for all purposes, including in any proceeding to enforce the rights and/or obligations of the Parties to this Agreement.

11.12 Entire Agreement; Amendments. This Agreement, together with any exhibits, attachments and amendments, constitutes the entire agreement of the Parties with respect to its subject matter and merges and supersedes all prior discussions and writings with respect to thereto. No modification or alteration of this Agreement shall be binding upon the Parties unless contained in a writing signed by a duly authorized agent for each respective Party and specifically referring hereto or thereto.

11.13 Rule of Construction. The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement.

[Signature Page Follows]

Signature Version *Confidential*

IN WITNESS WHEREOF, each of the Parties has caused this Agreement to be executed by its duly authorized representative.

PFIZER, INC.

By: /s/ [***]

Name: /s/ [***]

Title: Vice President, Pfizer CentreOne

Signed on the 28th day of June 2017

Signature Version *Confidential*

AMAG PHARMACEUTICALS, INC.

By: /s/ William H. Heiden

Name: /s/ William H. Heiden

Title: Chief Executive Officer

Signed on the 29th day of June 2017

Schedule 1

[***]

Signature Version *Confidential*

AMAG PHARMACEUTICALS, INC.
Amended and Restated Non-Employee Director Compensation Policy

(Effective January 1, 2015, as amended April 4, 2018 and April 10, 2019)

The Board of Directors (the “Board”) of AMAG Pharmaceuticals, Inc. (the “Company” or “AMAG”) has approved this Amended and Restated Non-Employee Director Compensation Policy (the “Policy”) to establish compensation to be paid to non-employee directors of the Company or any Affiliate, effective as of January 1, 2015, which policy supersedes in its entirety the policy previously amended and restated effective January 1, 2012, to provide an inducement to obtain and retain the services of qualified persons to serve as members of the Company’s Board. Each such Director will receive as compensation for his or her services equity grants and cash compensation, all as further set forth herein.

1. Applicable Persons

This Policy shall apply to each member of the Board of the Company who is not an employee of the Company or an Affiliate (each, an “Outside Director”). Affiliate shall mean a corporation which is a direct or indirect parent or subsidiary of the Company, as determined pursuant to Section 424 of the Internal Revenue Code of 1986, as amended.

2. Equity Grants

A. Equity Grant Upon Initial Appointment or Election as a Director

Each new Outside Director, on the date of his or her initial appointment or election to the Board, will receive an equity grant comprised of two components: (i) an inducement grant and (ii) an annual grant.

As an inducement to joining the Board, each new Outside Director will be granted a non-qualified stock option to purchase **6,000** shares of the Company’s common stock pursuant to the Company’s Third Amended and Restated 2007 Equity Incentive Plan, as it may be amended from time to time (the “Stock Plan”), subject to automatic adjustment in the event of any stock split or other recapitalization affecting the Company’s common stock. Such option shall vest in equal monthly installments over a period of two (2) years from the date of his or her election to the Board, provided such Outside Director continues to serve as a member of the Board.

Upon joining the Board, each new Outside Director who joins the Board subsequent to the date of the Annual Meeting of Stockholders will also receive an annual equity grant of non-qualified stock options and restricted stock units (“RSUs”) on the date of his or her appointment or election as described below under the heading “Annual Equity Grant;” provided, that the amount of options and RSUs granted to such new Outside Director will be pro-rated based on the

number of expected whole months of service before the next Annual Meeting of Stockholders; provided further, that such options and RSUs will vest in equal monthly installments beginning on the first day of the first full month following appointment or election and continuing on the first day of each month thereafter through the first day of the month in which the next Annual Meeting of Stockholders is to be held, so long as the newly-appointed Outside Director continues to serve as a member of the Board.

As an example, assume the Company's Annual Meeting of Stockholders is expected to be held in May, and the annual equity grant for each Outside Director (as calculated based on the target value as indicated below at the time such new Outside Director joins the Board) would otherwise include (i) a non-qualified option to purchase 4,000 shares of the Company's common stock, and (ii) an RSU covering 2,000 shares of the Company's common stock. If the new Outside Director were hired in September with eight full months of service expected before the next Annual Meeting of Stockholders, the new Outside Director's option would be pro-rated to 2,667 shares (calculated as $8/12 \times 4,000$), and the new Outside Director's RSUs would be pro-rated to 1,334 shares (calculated as $8/12 \times 2,000$). If the new Outside Director were hired in January with four full months of service expected before the next Annual Meeting of Stockholders, the new Outside Director's option would be prorated to 1,334 shares (calculated as $4/12 \times 4,000$), and the new Outside Director's RSUs would be pro-rated to 667 shares (calculated as $4/12 \times 2,000$).

B. Annual Equity Grant

At the first meeting of the Board following the Annual Meeting of Stockholders, each Outside Director will be provided an equity grant with a target value of **\$175,000**, with 50% of such value to be delivered in the form of a non-qualified stock option to purchase shares of the Company's common stock, and 50% of such value to be delivered in the form of RSUs covering shares of the Company's common stock, in each case pursuant to the Stock Plan. The number of shares underlying the non-qualified stock option portion of the equity grant shall be based on the Black-Scholes valuation of such options, and the number of shares underlying the RSU portion of the equity grant shall be based on the actual value of the shares on the date of grant, and in each case shall be subject to automatic adjustment in the event of any stock split or other recapitalization affecting the Company's common stock. The foregoing equity grants are intended to provide each Outside Director with an equity grant comparable in value to annual grants provided to non-employee directors of companies in AMAG's then current peer group as established by the Compensation Committee of the Board (the "Compensation Committee").

The foregoing options and RSUs will vest in twelve equal monthly installments beginning on the first day of the first full month following the Annual Meeting of Stockholders and continuing on the first day of each of the following eleven months thereafter, so long as the Outside Director continues to serve as a member of the Board; provided, that delivery of any vested shares of common stock underlying the foregoing RSUs shall be deferred until the earlier of (i) the first anniversary of the date of grant or (ii) the date the Outside Director's service to the Company terminates; provided, that such termination constitutes a "separation from service" as such term is defined in Treasury Regulation Section 1.409A-1(h).

C. Exercise Price and Term of Options

Each option granted to an Outside Director shall have an exercise price per share equal to the fair market value of the common stock of the Company on the date of grant of the option (as determined by the Board in accordance with the Stock Plan), have a term of ten years and shall be subject to the terms and conditions of the Stock Plan. Each such option grant shall be evidenced by the issuance of the Company's form non-qualified stock option agreement for Outside Director grants.

D. Early Termination of Options or RSUs Upon Termination of Service

If an Outside Director ceases to be a member of the Board for any reason, any then vested and unexercised options granted to such Outside Director may be exercised by the Outside Director (or, in the case of the Outside Director's death or disability, by the Outside Director's personal representative, or the Outside Director's survivors) within three years after the date the director ceases to be a member of the Board and in no event later than the expiration date of the option.

If an Outside Director's service to the Company is terminated (provided, that such termination constitutes a "separation from service" as such term is defined in Treasury Regulation Section 1.409A-1(h)), all then vested and undelivered shares underlying any RSUs held by such Outside Director shall be delivered to the Outside Director (or, in the case of the director's death or disability, by the director's personal representative, or the director's survivors) as of the date he or she ceases to be a member of the Board.

E. Deferral of Equity Retainer Awards

Outside Directors may elect to defer RSUs pursuant to the terms and conditions of the Company's Non-Employee Directors' Deferred Compensation Program (the "Plan"), and this Policy.

3. Retainer Fees

A. Annual Board Retainer

Each Outside Director, other than the Chair, will receive an aggregate annual retainer fee of **\$50,000**, payable in four equal quarterly installments. The Chair, provided that he or she is also an Outside Director, will receive an aggregate annual retainer fee of **\$95,000**, payable in four equal quarterly installments.

B. Annual Standing Committee Retainer

Each member of each of the Company's standing committees, other than the Chair, will also be paid an additional aggregate annual retainer fee in four equal quarterly installments as follows:

Audit Committee:	\$12,500
Compensation Committee:	\$10,000
Governance & Risk Committee:	\$7,500

The Chair of each of the standing committees will be paid an additional aggregate annual retainer fee in four equal quarterly installments as follows:

Audit Committee:	\$25,000
Compensation Committee:	\$20,000
Governance & Risk Committee:	\$15,000

4. Per Meeting Fees

In addition to the foregoing retainer fees, for any ad hoc committee (special committees not mentioned above, that may be formed from time to time by the full Board) each Outside Director may receive (i) a per meeting fee of \$1,000 for each meeting attended by such Outside Director (other than the Chair of such Committee), and (ii) a per meeting fee of \$2,000 for each ad hoc Committee of the Board attended by the Chair.

The Board reserves the right to institute a per meeting fee for each Board or Committee meeting which is meaningfully in excess of the regularly scheduled meetings ("Special Meeting"), including a per meeting fee of \$1,000 for each Special Meeting of the Board and a per meeting fee of \$500 for each Special Meeting of the Audit, Compensation, and Nominating and Corporate Governance Committees attended by such Outside Director. It is expected that Special Meetings of the Board and the Committees will be called when necessary to address material matters faced by the Corporation outside of the ordinary course of business.

The foregoing per meeting fees will be paid by the Company quarterly in arrears.

5. Reasonable and Documented Expenses

Upon presentation of documentation of such expenses reasonably satisfactory to the Company, each Outside Director shall be reimbursed for his or her reasonable out-of-

pocket business expenses incurred in connection with attending meetings of the Board, Committees thereof or in connection with other Board related business.

6. Maximum Annual Compensation

The aggregate amount of compensation, including both equity compensation and cash compensation, paid to any Outside Director in a calendar year period shall not exceed \$500,000 for the first year of service and \$750,000 for each year of service thereafter (or such other limit as may be set forth in the Company's Fourth Amended and Restated 2007 Equity Incentive Plan, as may be amended from time to time, or any similar provision of a successor plan). For this purpose, the "amount" of equity compensation paid in a calendar year shall be determined based on the grant date fair value thereof, as determined in accordance with ASC 718 or its successor provision, but excluding the impact of estimated forfeitures related to service-based vesting conditions.

7. Amendments

The Board shall review this Policy from time to time to assess whether any amendments in the type and amount of compensation provided herein should be adjusted in order to fulfill the objectives of this Policy.

8. Interpretation of Policy

Any interpretation of or decisions regarding the application of this Policy shall be made by the Compensation Committee of the Board.

[Remainder of this page is intentionally left blank]

AMAG PHARMACEUTICALS, INC.
NON-EMPLOYEE DIRECTORS' DEFERRED COMPENSATION PROGRAM

(THE "PROGRAM")

The following rules and conditions have been adopted by the Board of Directors of AMAG Pharmaceuticals, Inc. (the "Company") to govern the deferral of Restricted Stock Units by Non-Employee Directors pursuant to the AMAG Pharmaceuticals, Inc. 2019 Equity Incentive Plan (the "Stock Plan") and the AMAG Pharmaceuticals, Inc. Amended and Restated Non-Employee Director Compensation Policy (the "Policy"). Capitalized terms used but not defined herein shall have the meaning given such terms in the Stock Plan.

1. Election to Defer the Restricted Stock Units. A Non-Employee Director may elect in advance to defer the receipt of the initial and/or annual grant of Restricted Stock Units made to such Non-Employee Director pursuant to the Policy under the Stock Plan (such grant, the "Equity Retainer"). To make such an election, except with respect to a newly elected or appointed Non-Employee Director or with respect to the establishment of this Program, the Non-Employee Director must execute and deliver to the Company a deferral election form before the end of the calendar year preceding the calendar year in which the applicable Equity Retainer is scheduled to be earned and granted. A Non-Employee Director who is serving as a Non-Employee Director on the Effective Date shall be permitted, within 30 days of the Effective Date, to file a deferral election which shall apply to Restricted Stock Units that are earned with respect to services performed subsequent to the election. A newly elected or appointed Non-Employee Director, may, upon (but no later than 30 days after) becoming a Non-Employee Director, file a deferral election with respect to the initial Equity Retainer and/or to annual Equity Retainers that are awarded subsequent to the election. An election shall remain in effect from year to year until revoked in writing by the Non-Employee Director, but any revocation shall become effective only with respect to Equity Retainers that are granted in calendar years beginning after receipt and acceptance by the Company of a written revocation. All elections (including revocation thereof) must be made during an open window period while the Non-Employee Director is not in possession of any material non-public information relating to the Company.

2. Deferred Account. Upon the vesting of any Equity Retainer awarded to any Non-Employee Director who has elected to defer his or her Equity Retainer(s) pursuant to this Program, any shares of Stock that would otherwise have been issued to the Non-Employee Director upon such vesting shall be converted to deferred stock units on a one-to-one basis and credited to the Non-Employee Director's deferred account ("Account").

3. Dividend Equivalent Amounts. If dividends (other than dividends payable only in shares of Stock) are paid with respect to Stock, each Account shall be credited with a number of whole and fractional stock units determined by multiplying the dividend value per share by the stock unit balance of the Account on the record date and dividing the result by the Fair Market Value of a share of Stock on the dividend payment date.

4. Period of Deferral. The deferred stock units in each Account shall be deferred until, and the period of deferral shall cease upon, the earliest of (a) the date a Non-Employee Director ceases to serve as a member of the Board of Directors of the Company and incurs a “separation from service” within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder (“Section 409A”), or (b) the consummation of a Sale Event (as defined in the Stock Plan) so long as such Sale Event constitutes a “change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the assets of the Company” within the meaning of Section 409A (a “Change in Control”).

5. Designation of Beneficiary. A Non-Employee Director may designate one or more beneficiaries to receive payments from his or her Account in the event of his or her death. A designation of beneficiary may apply to a specified percentage of a Non-Employee Director’s entire interest in his or her Account. Such designation, or any change therein, must be in writing and shall be effective upon receipt by the Company. If there is no effective designation of beneficiary, or if no beneficiary survives the Non-Employee Director, the estate of the Non-Employee Director shall be deemed to be the beneficiary. All payments to a beneficiary or estate shall be made in a lump sum in shares of Stock, with any fractional share paid in cash.

6. Payment. All amounts credited to a Non-Employee Director’s Account shall be paid to the Non-Employee Director, or his or her designated beneficiary (or beneficiaries) or estate, in a single lump sum as soon as practicable (but in no event later than 75 days) after the end of the first applicable period of deferral specified in Section 4 (above) occurs. Such payment shall be made in shares of Stock, provided, however, that fractional shares shall be paid in cash.

7. Adjustments. In the event of a stock dividend, stock split or similar change in capitalization affecting the Stock, the Company shall make appropriate adjustments in the number of stock units credited to the Non-Employee Directors’ Accounts.

8. Non-transferability of Rights. During a Non-Employee Director’s lifetime, any payment under this Program shall be made only to the Non-Employee Director. No sum or other interest under this deferred compensation arrangement shall be subject in any manner to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or charge, and any attempt by a Non-Employee Director or any beneficiary under this Program to do so shall be void. No interest under this deferred compensation arrangement shall in any manner be liable for or subject to the debts, contracts, liabilities, engagements or torts of a Non-Employee Director or beneficiary entitled thereto. Notwithstanding the foregoing, the Company may make payments to an individual other than a Non-Employee Director to the extent required by a domestic relations order.

9. Company’s Obligations to Be Unfunded and Unsecured. The Accounts maintained under this Program shall at all times be entirely unfunded, and no provision shall at any time be made with respect to segregating assets of the Company (including Stock) for payment of any amounts hereunder. No Non-Employee Director or other person shall have any interest in any particular assets of the Company (including Stock) by reason of the right to receive payment under this Program, and any Non-Employee Director or other person shall have only the rights of a general unsecured creditor of the Company with respect to any rights under this Program.

10. Section 409A. This Program is intended to be a compliant deferred compensation plan under Section 409A and shall be administered in accordance with the requirements of Section 409A.

11. Incorporation of Plan. This Program shall be subject to the terms and conditions of the Stock Plan and the Policy. Capitalized terms in this document shall have the meaning specified in the Stock Plan, unless a different meaning is specified herein.

Adopted as of April 10, 2019 (the "Effective Date")

**AMAG PHARMACEUTICALS, INC.
RESTRICTED STOCK UNIT AWARD AGREEMENT (DEFERRED)
FOR NON-EMPLOYEE DIRECTORS**

Name of Grantee:

No. of Restricted Stock Units:

Grant Date:

Pursuant to the AMAG Pharmaceuticals, Inc. 2019 Equity Incentive Plan through the date hereof (the “Plan”), AMAG Pharmaceuticals, Inc. (the “Company”) hereby grants an award of the number of Restricted Stock Units listed above (an “Award”) to the Grantee named above. Each Restricted Stock Unit shall relate to one share of Common Stock, par value \$0.01 per share (the “Stock”) of the Company. Reference is also made to the AMAG Pharmaceuticals, Inc. Non-Employee Directors’ Deferred Compensation Program (the “Program”) and the Grantee’s deferral election thereunder.

1. Restrictions on Transfer of Award. This Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of by the Grantee, and any shares of Stock issuable with respect to the Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of until (i) the Restricted Stock Units have vested as provided in Section 2 of this Agreement and (ii) shares of Stock have been issued to the Grantee in accordance with the terms of the Plan and this Agreement.

2. Vesting of Restricted Stock Units. The restrictions and conditions of Section 1 of this Agreement shall lapse on the Vesting Date or Dates specified in the following schedule so long as the Grantee maintains a Business Relationship with the Company (as defined below) on such Dates. If a series of Vesting Dates is specified, then the restrictions and conditions in Section 1 of this Agreement shall lapse only with respect to the number of Restricted Stock Units specified as vested on such date.

<u>Incremental Number of Restricted Stock Units Vested</u>	<u>Vesting Date</u>
[1/12 of [Number]]	June 1, 20XX
[1/12 of [Number]]	July 1, 20XX
[1/12 of [Number]]	August 1, 20XX
[1/12 of [Number]]	September 1, 20XX
[1/12 of [Number]]	October 1, 20XX
[1/12 of [Number]]	November 1, 20XX
[1/12 of [Number]]	December 1, 20XX
[1/12 of [Number]]	January 1, 20XX
[1/12 of [Number]]	February 1, 20XX
[1/12 of [Number]]	March 1, 20XX
[1/12 of [Number]]	April 1, 20XX
[1/12 of [Number]]	May 1, 20XX

The Administrator may at any time accelerate the vesting schedule specified in this Section 2.

“Business Relationship” means service to the Company or its successor in the capacity of an employee, officer, director, consultant, or advisor.

3. Termination of Business Relationship. If the Grantee ceases to maintain a Business Relationship with the Company for any reason (including death or disability) prior to the satisfaction of the vesting conditions set forth in Section 2 above, any Restricted Stock Units that have not vested as of such date shall automatically and without notice terminate and be forfeited, and neither the Grantee nor any of his or her successors, heirs, assigns, or personal representatives will thereafter have any further rights or interests in such unvested Restricted Stock Units.

4. Issuance of Shares of Stock. The Company shall issue to the Grantee on such date as specified in the Program in accordance with the terms and conditions of the Program (the “Delivery Date”), the number of shares of Stock equal to the aggregate number of Restricted Stock Units that have vested pursuant to Section 2 of this Agreement, provided however that the Grantee acknowledges that the exact date of issuance of the shares shall be at the sole and exclusive discretion of the Company in accordance with this Section 4 and the Program. The form of such issuance (*e.g.*, a stock certificate or electronic entry evidencing such shares) shall be determined by the Company. Upon such issuance, the Grantee shall thereafter have all the rights of a stockholder of the Company with respect to such shares.

5. Incorporation of Plan and Program. Notwithstanding anything herein to the contrary, this Agreement shall be subject to and governed by all the terms and conditions of the Plan and the Program, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan and the Program, unless a different meaning is specified herein.

6. Section 409A of the Code. The parties intend that this Award will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Award is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments and provisions hereunder comply with Section 409A of the Code. Anything in this Agreement to the contrary notwithstanding, if at the time of the Grantee's separation from service within the meaning of Section 409A of the Code, the Company determines that the Grantee is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent the shares of Stock that the Grantee becomes entitled to receive under this Agreement on account of the Grantee's separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such shares of Stock shall not be issued until the date that is the earlier of (a) six months and one day after the Grantee's separation from service, or (b) the Grantee's death. The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

7. No Obligation to Continue Service. Neither the Plan nor the Program nor this Award confers upon the Grantee any rights with respect to continued service as a member of the Board or to the Company.

8. Integration. This Agreement and the Program (including any elections thereunder) constitute the entire agreement between the parties with respect to this Award and supersedes all prior agreements and discussions between the parties concerning such subject matter.

9. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Grantee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Grantee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Grantee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

10. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business to the attention of the Treasurer of the Company and shall be mailed or delivered to the Grantee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

AMAG PHARMACEUTICALS, INC.

By: _____
Name: William K. Heiden
Title: President and Chief Executive Officer

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned, and the undersigned acknowledges receipt of a copy of this entire Agreement, a copy of the Plan, a copy of the Program, and a copy of the Plan's related prospectus. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

Dated: _____

Grantee's Signature

Grantee's name and address:

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: May 8, 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: May 8, 2019

/s/ Edward Myles

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 March 31, 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

William K. Heiden

President and Chief Executive Officer

(Principal Executive Officer)

May 8, 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 March 31, 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

Edward Myles

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

May 8, 2019
