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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2018

or

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

For the transition period from to

Commission file number 001-10865

AMAG Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Its Charter)

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

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

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

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

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

As of October 29, 2018, there were 34,535,659 shares of the registrant's Common Stock, par value $0.01 per share, outstanding.

Table of Contents

AMAG PHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2018
TABLE OF CONTENTS

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)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 287,166	$ 162,855
Marketable securities	140,368	136,593
Accounts receivable, net	85,091	91,460
Inventories	27,953	34,443
Prepaid and other current assets	13,182	11,009
Assets held for sale	—	45,508
Total current assets	553,760	481,868
Property and equipment, net	7,047	7,904
Goodwill	422,513	422,513
Intangible assets, net	230,747	375,479
Deferred tax assets	1,185	47,120
Restricted cash	495	495
Other long-term assets	69	266
Assets held for sale, net of current portion	—	564,711
Total assets	$ 1,215,816	$ 1,900,356
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 30,331	$ 7,717
Accrued expenses	141,753	166,732
Current portion of convertible notes, net	20,999	—
Current portion of acquisition-related contingent consideration	208	49,399
Liabilities held for sale	—	53,870
Total current liabilities	193,291	277,718
Long-term liabilities:		
Long-term debt, net	—	466,291
Convertible notes, net	258,376	268,392
Acquisition-related contingent consideration	615	686
Other long-term liabilities	1,288	1,204
Liabilities held for sale, net of current portion	—	95,821
Total liabilities	453,570	1,110,112
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value $0.01 per share, 2,000,000 shares authorized; none issued	—	—
Common stock, par value $0.01 per share, 117,500,000 shares authorized; 34,522,957 and 34,083,112 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	345	341
Additional paid-in capital	1,286,227	1,271,628
Accumulated other comprehensive loss	(4,161)	(3,908)
Accumulated deficit	(520,165)	(477,817)
Total stockholders' equity	762,246	790,244
Total liabilities and stockholders' equity	$ 1,215,816	$ 1,900,356

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Product sales, net	$ 122,238	$ 124,331	$ 385,806	$ 367,190
Other revenues	—	—	75	53
Total revenues	122,238	124,331	385,881	367,243
Costs and expenses:				
Cost of product sales	46,489	31,085	187,176	90,761
Research and development expenses	10,133	16,274	32,635	63,021
Acquired in-process research and development	12,500	—	32,500	65,845
Selling, general and administrative expenses	72,451	11,962	161,780	119,482
Impairment charges of intangible assets	—	319,246	—	319,246
Total costs and expenses	141,573	378,567	414,091	658,355
Operating loss	(19,335)	(254,236)	(28,210)	(291,112)
Other income (expense):				
Interest expense	(13,366)	(16,847)	(45,400)	(52,403)
Loss on debt extinguishment	(35,922)	(314)	(35,922)	(9,830)
Interest and dividend income	1,612	487	3,207	2,181
Other expense	(19)	—	(63)	(43)
Total other expense, net	(47,695)	(16,674)	(78,178)	(60,095)
Loss from continuing operations before income taxes	(67,030)	(270,910)	(106,388)	(351,207)
Income tax (benefit) expense	(2,352)	(115,197)	42,204	(145,317)
Net loss from continuing operations	$ (64,678)	$ (155,713)	$ (148,592)	$ (205,890)
Discontinued operations:				
Income from discontinued operations	5,838	4,506	18,873	4,998
Gain on sale of CBR business	89,581	—	89,581	—
Income tax (benefit) expense	(98)	854	3,346	1,796
Net income from discontinued operations	$ 95,517	$ 3,652	$ 105,108	$ 3,202
Net income (loss)	$ 30,839	$ (152,061)	$ (43,484)	$ (202,688)
Basic and diluted net income (loss) per share:				
Loss from continuing operations	$ (1.88)	$ (4.41)	$ (4.33)	$ (5.89)
Income from discontinued operations	2.77	0.10	3.06	0.09
Basic and diluted net income (loss) per share:	$ 0.89	$ (4.31)	$ (1.27)	$ (5.80)
Weighted average shares outstanding used to compute net income (loss) per share (basic and diluted)	34,492	35,311	34,339	34,948

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net income (loss)	$ 30,839	$ (152,061)	$ (43,484)	$ (202,688)
Other comprehensive (loss) income:				
Holding gains (losses) arising during period, net of tax	134	(4)	(253)	201
Total comprehensive income (loss)	$ 30,973	$ (152,065)	$ (43,737)	$ (202,487)

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

Table of Contents

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

	Nine Months Ended September 30,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (43,484)	$ (202,688)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	158,002	88,941
Impairment of intangible assets	—	319,246
Provision for bad debt expense	754	3,503
Amortization of premium/discount on purchased securities	96	218
Gain on disposal of fixed assets	(99)	—
Non-cash equity-based compensation expense	14,599	18,058
Non-cash IPR&D expense	—	945
Loss on debt extinguishment	35,922	9,830
Amortization of debt discount and debt issuance costs	11,824	10,600
Gains on marketable securities, net	(1)	(255)
Change in fair value of contingent consideration	(49,175)	(47,142)
Deferred income taxes	43,747	(146,682)
Gain on sale of the CBR business	(89,581)	—
Transaction costs	(14,111)	—
Changes in operating assets and liabilities:		
Accounts receivable, net	7,175	(8,889)
Inventories	3,587	(600)
Prepaid and other current assets	1,101	(1,409)
Accounts payable and accrued expenses	(4,280)	29,977
Deferred revenues	8,658	14,134
Other assets and liabilities	159	(1,139)
Net cash provided by operating activities	84,893	86,648
Cash flows from investing activities:		
Proceeds from sales or maturities of marketable securities	60,146	279,526
Purchase of marketable securities	(64,400)	(110,894)
Acquisition of Intrarosa intangible asset	—	(55,800)
Proceeds from the sale of the CBR business	519,303	—
Capital expenditures	(1,913)	(6,573)
Net cash provided by investing activities	513,136	106,259
Cash flows from financing activities:		
Long-term debt principal payments	(475,000)	(328,125)
Proceeds from 2022 Convertible Notes	—	320,000
Payment to repurchase 2019 Convertible Notes	—	(191,480)
Payment of premium on debt extinguishment	(28,054)	—
Proceeds to settle warrants	—	323
Payment of convertible debt issuance costs	—	(9,553)
Payments of contingent consideration	(87)	(165)
Proceeds from the exercise of common stock options	2,635	2,350
Payments of employee tax withholding related to equity-based compensation	(2,632)	(2,588)
Net cash used in financing activities	(503,138)	(209,238)
Net increase (decrease) in cash, cash equivalents, and restricted cash	94,891	(16,331)
Cash, cash equivalents, and restricted cash related to discontinued operations	—	(50,017)
Cash, cash equivalents, and restricted cash at beginning of the period	192,770	276,898
Cash, cash equivalents, and restricted cash at end of the period	$ 287,661	$ 210,550
Supplemental data for cash flow information:		
Cash paid for taxes	$ 5,041	$ 3,565
Cash paid for interest	$ 43,546	$ 50,892
Non-cash investing and financing activities:		
Fair value of common stock issued in connection with the acquisition of the Intrarosa intangible asset	$ —	$ 12,555

Contingent consideration accrued for the acquisition of the Intrarosa intangible asset	$	—	$	9,300

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

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. We do this by leveraging our development and commercial expertise to invest in and grow our pharmaceutical products across a range of therapeutic areas, including women's health. Our currently marketed products support the health of patients in the areas of maternal and women's health, anemia management and cancer supportive care, including Makena® (hydroxyprogesterone caproate injection), Intrarosa® (prasterone) vaginal inserts, Feraheme® (ferumoxytol injection) for intravenous ("IV") use, and MuGard® Mucoadhesive Oral Wound Rinse. In addition to our marketed products, our portfolio includes two product candidates, Vyleesi™ (bremelanotide), which is being developed for the treatment of hypoactive sexual desire disorder ("HSDD") in pre-menopausal women and digoxin immune Fab (ovine) (now referred to as AMAG-423), which is being studied for the treatment of severe preeclampsia.

Since August 2015, we had provided services related to the preservation of umbilical cord blood stem cell and cord tissue units operated through Cord Blood Registry® ("CBR"). On August 6, 2018, we completed the sale of our wholly-owned subsidiary, CBR Acquisition Holdings Corp, and the CBR business to GI Chill Acquisition LLC, an affiliate of GI Partners, a private equity investment firm (together "GI") pursuant to the June 14, 2018 Stock Purchase Agreement (the "CBR Purchase Agreement") between us and GI. We received $519.3 million in cash at closing and recognized a gain of $89.6 million on the sale during the three and nine months ended September 30, 2018. For additional information, see Note C "*Discontinued Operations and Held for Sale*".

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

B. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

In accordance with GAAP for interim financial reports and the instructions for Form 10-Q and the rules of the Securities and Exchange Commission, certain information and footnote disclosures normally included in annual financial statements have been condensed or omitted. Our accounting policies are described in the Notes to the Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2017 (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.

As of June 30, 2018, our CBR business met all of the conditions to be classified as held for sale and represented a discontinued operation, as we considered the disposal of the CBR business to be a strategic shift that would have a major effect on our operations and financial results. All assets and liabilities associated with CBR were therefore classified as assets and liabilities held for sale in our condensed consolidated balance sheets for the historical period presented. Further, all historical operating results for CBR are reflected within discontinued operations in the condensed consolidated statements of operations for all periods presented. For additional information, see Note C, "*Discontinued Operations and Held for Sale.*"

Principles of Consolidation

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

Use of Estimates and Assumptions

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. The most significant estimates and assumptions are used to determine amounts and values of, but are not limited to: revenue recognition related to product sales 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 September 30, 2018 and December 31, 2017. 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 September 30, 2018, we did not have a material concentration in any single investment.

Our operations are located entirely within the U.S. We focus primarily on developing, manufacturing, and commercializing our products and product candidates. We perform ongoing credit evaluations of our customers and generally do not require collateral. The following table sets forth customers who represented 10% or more of our total revenues for the three and nine months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
AmerisourceBergen Drug Corporation	24%	28%	26%	26%
McKesson Corporation	25%	26%	26%	23%

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 September 30, 2018 and December 31, 2017, four and two customers accounted for 10% or more of our accounts receivable balance, respectively, representing approximately 74% and 57% 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 Makena drug substance, which is used for each of our intramuscular and auto-injector products, and primarily use one of two suppliers of finished drug product for our Makena vial product and 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

Effective January 1, 2018, we adopted Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers ("ASC 606"), using the modified retrospective transition method. We recognized the cumulative effect of applying the new revenue standard to all contracts with customers that were not completed as of January 1, 2018 as an adjustment to the opening balance of stockholders' equity at the beginning of 2018. The adjustment recorded was for incremental contract acquisition costs related to the CBR business. The comparative information has not been restated and continues to be reported under the accounting standards in effect for the periods presented. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. ASC 606 also impacts certain other areas, such as the accounting for costs to obtain or fulfill a contract. The standard also requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The adoption of ASC 606 did not have an impact on the amount of reported revenues with respect to our product revenue.

Reclassifications

Certain amounts in prior periods have been reclassified to reflect the impact of the held for sale and discontinued operations treatment of the CBR business in order to conform to the current period presentation.

C. DISCONTINUED OPERATIONS AND HELD FOR SALE

On August 6, 2018, we completed the sale of our CBR business to GI Partners pursuant to the CBR Purchase Agreement. We received $519.3 million in cash at closing and recognized a gain of $89.6 million on the sale during the three and nine months ended September 30, 2018. Although we are providing limited transitional services related to GI for certain agreed-upon sales and marketing, technology, human resources and finance functions for several months post-closing, we do not expect to have any (and have not had any) significant involvement in the operations of the CBR business following the close of the sale.

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 statements of operations for all periods presented. Further, all assets and liabilities associated with CBR were classified as assets and liabilities held for sale in our condensed consolidated balance sheets for the historical period presented.

Assets and liabilities held for sale were reflected separately in our condensed consolidated balance sheets and were comprised of the following as of September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash	$ —	$ 29,259
Accounts receivable, net	—	12,042
Inventories (raw materials)	—	2,913
Prepaid and other current assets	—	1,294
Total current assets held for sale	$ —	$ 45,508
Property, plant and equipment, net	$ —	$ 18,092
Intangible assets, net	—	328,991
Goodwill	—	216,971
Other long-term assets	—	496
Restricted cash	—	161
Total long-term assets held for sale	$ —	$ 564,711
Liabilities		
Current liabilities:		
Accounts payable	$ —	$ 2,618
Accrued expenses	—	8,758
Deferred revenues, short term	—	42,494
Total current liabilities held for sale	$ —	$ 53,870
Deferred revenues, long-term	—	24,387
Deferred tax liabilities	—	71,046
Other long-term liabilities	—	388
Total long-term liabilities held for sale	$ —	$ 95,821

The results of operations of the CBR business were classified as discontinued operations for all periods presented in our condensed consolidated financial statements. The following is a summary of net income from discontinued operations for the

three and nine months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Service revenues, net	$ 12,163	$ 29,410	$ 71,217	$ 84,365
Costs and expenses:				
Cost of services	1,576	5,559	12,559	16,130
Selling, general and administrative expenses	4,749	19,345	39,899	63,237
Total costs and expenses	6,325	24,904	52,458	79,367
Operating income	5,838	4,506	18,759	4,998
Other income	—	—	114	—
Income from discontinued operations	5,838	4,506	18,873	4,998
Gain on sale of CBR business	89,581	—	89,581	—
Income tax (benefit) expense	(98)	854	3,346	1,796
Net income from discontinued operations	$ 95,517	$ 3,652	$ 105,108	$ 3,202

The cash flows related to discontinued operations have not been segregated and are included in the Consolidated Statements of Cash Flows. For the nine months ended September 30, 2018 and 2017, capital expenditures related to the CBR business were $1.6 million and $3.0 million, respectively. Depreciation and amortization expense related to the CBR business for the same periods was $8.4 million and $17.1 million, respectively. Excluding the gain of $89.6 million recognized on the sale of the CBR business and the related transaction expenses of $14.1 million presented in the Consolidated Statements of Cash Flows for the nine months ended September 30, 2018, there were no other significant operating or investing non-cash items related to the CBR business for either period presented.

D. REVENUE RECOGNITION

On January 1, 2018, we adopted ASC 606 applying the modified retrospective transition method to all contracts that were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for prior periods. There was no impact to revenue for the three and nine months ended September 30, 2018 as a result of adoption.

Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps:

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

Our major sources of revenue during the reporting periods were product revenues from Makena (including both our branded and unbranded products), Feraheme and Intrarosa. The adoption of ASC 606 did not have an impact on our product revenue.

Revenue and Allowances

The following table provides information about disaggregated revenue by products for the three and nine months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Product sales, net				
Makena	$ 80,221	$ 97,635	$ 275,377	$ 286,771
Feraheme	36,963	26,095	99,796	79,492
Intrarosa	4,925	360	10,331	360
MuGard	129	241	302	567
Total	$ 122,238	$ 124,331	$ 385,806	$ 367,190

Total gross product sales were offset by product sales allowances and accruals for the three and nine months ended September 30, 2018 and 2017 as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Gross product sales	$ 238,856	$ 235,299	$ 776,458	$ 676,377
Provision for product sales allowances and accruals:				
Contractual adjustments	93,213	80,110	290,896	225,622
Governmental rebates	23,405	30,858	99,756	83,565
Total	116,618	110,968	390,652	309,187
Product sales, net	$ 122,238	$ 124,331	$ 385,806	$ 367,190

The following table summarizes the product revenue allowance and accrual activity for the three and nine months ended September 30, 2018 (in thousands):

	Contractual Adjustments	Governmental Rebates	Total
Balance at December 31, 2017	$ 62,164	$ 50,598	$ 112,762
Provisions related to current period sales	199,716	71,514	271,230
Adjustments related to prior period sales	(2,034)	4,837	2,803
Payments/returns relating to current period sales	(132,618)	(2,453)	(135,071)
Payments/returns relating to prior period sales	(55,973)	(51,142)	(107,115)
Balance at June 30, 2018	71,255	73,354	144,609
Provisions related to current period sales	93,824	20,719	114,543
Adjustments related to prior period sales	(614)	2,710	2,096
Payments/returns relating to current period sales	(102,627)	(52,040)	(154,667)
Payments/returns relating to prior period sales	(2,207)	(7,002)	(9,209)
Balance at September 30, 2018	$ 59,631	$ 37,741	$ 97,372

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

Performance Obligations and Product Revenue

At contract inception, we assess the goods promised in our contracts with customers and identify a performance obligation for each promise to transfer to the customer a good (or bundle of goods) that is distinct. To identify the performance obligations, we consider all of the goods promised in the contract regardless of whether they are explicitly stated or are implied by customary business practices. We determined that the following distinct goods represent separate performance obligations:

- Supply of Makena (branded and unbranded) product
- Supply of Feraheme product
- Supply of Intrarosa product

We principally sell our products to wholesalers, specialty distributors, specialty pharmacies and other customers, including our authorized generic partner (collectively, "Customers"), who purchase products directly from us. Our Customers subsequently resell the products to healthcare providers and patients. In addition to distribution agreements with Customers, we enter into arrangements with healthcare providers and payers that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of our products.

For the majority of our Customers, we transfer control at the point in time when the goods are delivered. In instances when we perform shipping and handling activities, these are considered fulfillment activities, and accordingly, the costs are accrued when the related revenue is recognized. Taxes collected from Customers and remitted to governmental authorities are excluded from revenues.

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, co-pay 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. Variable consideration must be determined using either an "expected value" or a "most likely amount" method.

We record product revenues net of certain allowances and accruals in our condensed consolidated statements of operations. Product sales allowances and accruals are primarily comprised of both direct and indirect fees, discounts and rebates and provisions for estimated product returns. Direct fees, discounts and rebates are contractual fees and price adjustments payable to Customers that purchase products directly from us. Indirect fees, discounts and rebates are contractual price adjustments payable to healthcare providers and organizations, such as certain physicians, clinics, hospitals, group purchasing organizations ("GPOs"), and dialysis organizations that typically do not purchase products directly from us but rather from wholesalers and specialty distributors. Consideration payable to a Customer, or other parties that purchase goods from a Customer, are considered to be a reduction of the transaction price, and therefore, of revenue.

Product sales allowances and accruals are based on definitive contractual agreements or legal requirements (such as Medicaid laws and regulations) related to the purchase and/or utilization of the product by these entities and are recorded in the same period that the related revenue is recognized. We use the expected value method for estimating variable consideration. We estimate product sales allowances and accruals using either historical, actual and/or other data, including estimated patient usage, applicable contractual rebate rates, contract performance by the benefit providers, other current contractual and statutory requirements, historical market data based upon experience of our products and other products similar to them, specific known market events and trends such as competitive pricing and new product introductions, current and forecasted Customer buying patterns and inventory levels, and the shelf life of our products. As part of this evaluation, we also review changes to federal and other legislation, changes to rebate contracts, changes in the level of discounts, and changes in product sales trends. Although allowances and accruals are recorded at the time of product sale, rebates are typically paid out in arrears, one to three months after the sale.

The estimate of variable consideration, which is included in the transaction price, may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved in a future period. Estimating variable consideration and the related constraint requires the use of significant management judgment and actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known. No amounts were constrained as of September 30, 2018.

Discounts

We typically offer a 2% prompt payment discount to certain customers as an incentive to remit payment in accordance with the stated terms of the invoice, generally 30 days. Because we anticipate that those customers who are offered this discount will take advantage of the discount, 100% of the prompt payment discount at the time of sale is accrued, based on the gross amount of each invoice. We adjust the accrual quarterly to reflect actual experience.

Chargebacks

Chargeback reserves represent the estimated obligations resulting from the difference between the prices at which we sell our products to wholesalers and the sales price ultimately paid to wholesalers under fixed price contracts by third-party payers, including governmental agencies. The chargeback estimates are determined based on actual product sales data and forecasted customer buying patterns. Actual chargeback amounts are determined at the time of resale to the qualified healthcare provider, and we generally issue credits for such amounts within several weeks of receiving notification from the wholesaler. Estimated chargeback amounts are recorded at the time of sale and adjusted quarterly to reflect actual experience.

Distributor/Wholesaler and Group Purchasing Organization Fees

Fees under arrangements with distributors and wholesalers are usually based upon units of product purchased during the prior month or quarter and are usually paid by us within several weeks of the receipt of an invoice from the wholesaler or distributor, as the case may be. Fees under the arrangements with GPOs are usually based upon member purchases during the prior quarter and are generally billed by the GPO within 30 days after period end. In accordance with ASC 606, since the consideration given to the Customer is not for a distinct good or service, the consideration is a reduction of the transaction price of the vendor's products or services. We have included these fees in contractual adjustments in the table above. We generally pay such amounts within several weeks of the receipt of an invoice from the distributor, wholesaler or GPO. Accordingly, we accrue the estimated fee due at the time of sale, based on the contracted price invoiced to the Customer. We adjust the accrual quarterly to reflect actual experience.

Product Returns

Consistent with industry practice, we generally offer wholesalers, specialty distributors and other customers a limited right to return our products based on the product's expiration date. Currently the expiration periods for our products have a range of three to five years. Product returns are estimated based on the historical return patterns and known or expected changes in the marketplace. We track actual returns by individual production lots. Returns on lots eligible for credits under our returned goods policy are monitored and compared with historical return trends and rates. We expect that wholesalers and healthcare providers will not stock significant inventory due to the cost of the product, the expense to store our products, and/or that our products are readily available for distribution. We record an estimate of returns at the time of sale. If necessary, our estimated rate of returns may be adjusted for actual return experience as it becomes available and for known or expected changes in the marketplace. We did not significantly adjust our reserve for product returns during the three and nine months ended September 30, 2018. To date, our product returns have been relatively limited; however, returns experience may change over time. We may be required to make future adjustments to our product returns estimate, which would result in a corresponding change to our net product sales in the period of adjustment and could be significant.

Sales Rebates

We contract with various private payer organizations, primarily pharmacy benefit managers, for the payment of rebates with respect to utilization of our products. We determine our estimates for rebates, if applicable, based on actual product sales data and our historical product claims experience. Rebate amounts generally are invoiced quarterly and are paid in arrears, and we expect to pay such amounts within several weeks of notification by the provider. We regularly assess our reserve balance and the rate at which we accrue for claims against product sales. If we determine in future periods that our actual rebate experience is not indicative of expected claims, if actual claims experience changes, or if other factors affect estimated claims rates, we may be required to adjust our current accumulated reserve estimate, which would affect net product sales in the period of the adjustment and could be significant.

Governmental Rebates

Governmental rebate reserves relate to our reimbursement arrangements with state Medicaid programs. We determine our estimates for Medicaid rebates, if applicable, based on actual product sales data and our historical product claims experience. In estimating these reserves, we provide for a Medicaid rebate associated with both those expected instances where Medicaid will act as the primary insurer as well as in those instances where we expect Medicaid will act as the secondary insurer. Rebate amounts generally are invoiced quarterly and are paid in arrears, and we expect to pay such amounts within several weeks of notification by the Medicaid or provider entity. We regularly assess our Medicaid reserve balance and the rate at which we accrue for claims against product sales. If we determine in future periods that our actual rebate experience is not indicative of expected claims, if actual claims experience changes, or if other factors affect estimated claims rates, we may be required to adjust our current Medicaid accumulated reserve estimate, which would affect net product sales in the period of the adjustment and could be significant.

Other Discounts

Other discounts which we offer include voluntary patient assistance programs, such as co-pay assistance programs, which are intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payers. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue.

E. MARKETABLE SECURITIES

As of September 30, 2018 and December 31, 2017, 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 September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term marketable securities:*				
Corporate debt securities	$ 53,862	$ 1	$ (174)	$ 53,689
Certificates of deposit	13,000	—	—	13,000
U.S. treasury and government agency securities	6,149	—	(29)	6,120
Commercial paper	5,462	—	—	5,462
Total short-term marketable securities	$ 78,473	$ 1	$ (203)	$ 78,271
Long-term marketable securities:**				
Corporate debt securities	$ 55,017	$ 2	$ (580)	$ 54,439
U.S. treasury and government agency securities	6,236	—	(78)	6,158
Certificates of deposit	1,500	—	—	1,500
Total long-term marketable securities	62,753	2	(658)	62,097
Total marketable securities	$ 141,226	$ 3	$ (861)	$ 140,368

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

	December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term marketable securities:*				
Corporate debt securities	$ 57,257	$ —	$ (68)	$ 57,189
Certificates of deposit	9,151	—	—	9,151
U.S. treasury and government agency securities	1,999	—	(13)	1,986
Commercial paper	1,999	—	—	1,999
Total short-term marketable securities	$ 70,406	$ —	$ (81)	$ 70,325
Long-term marketable securities:**				
Corporate debt securities	$ 59,282	$ 1	$ (320)	$ 58,963
U.S. treasury and government agency securities	7,381	—	(76)	7,305
Total long-term marketable securities	66,663	1	(396)	66,268
Total marketable securities	$ 137,069	$ 1	$ (477)	$ 136,593

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

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 and nine months ended September 30, 2018 and 2017. 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 September 30, 2018, 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 September 30, 2018 and December 31, 2017, for those assets and liabilities that we measure at fair value on a recurring basis (in thousands):

	Fair Value Measurements at September 30, 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	$ 120,778	$ 120,778	$ —	$ —
Corporate debt securities	108,128	—	108,128	—
U.S. treasury and government agency securities	12,278	—	12,278	—
Certificates of deposit	14,500	—	14,500	—
Commercial paper	5,462	—	5,462	—
Total assets	$ 261,146	$ 120,778	$ 140,368	$ —
Liabilities:				
Contingent consideration - MuGard	$ 823	$ —	$ —	$ 823
Total liabilities	$ 823	$ —	$ —	$ 823

	Fair Value Measurements at December 31, 2017 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 4,591	$ 4,591	$ —	$ —
Corporate debt securities	116,152	—	116,152	—
U.S. treasury and government agency securities	9,291	—	9,291	—
Certificates of deposit	9,151	—	9,151	—
Commercial paper	1,999	—	1,999	—
Total assets	$ 141,184	$ 4,591	$ 136,593	$ —
Liabilities:				
Contingent consideration - Lumara Health	$ 49,187	$ —	$ —	$ 49,187
Contingent consideration - MuGard	898	—	—	898
Total liabilities	$ 50,085	$ —	$ —	$ 50,085

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 September 30, 2018. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during the nine months ended September 30, 2018.

Contingent Consideration

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

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

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

Balance as of December 31, 2017	$ 50,085
Payments made	(87)
Adjustments to fair value of contingent consideration	(49,175)
Balance as of September 30, 2018	$ 823

During the nine months ended September 30, 2018, we reduced the fair value of our contingent consideration liability by approximately $49.2 million based primarily on actual Makena net sales to date and our expectations for future performance, which indicated that achievement of future milestones is not probable. This adjustment was based on our estimates, which are reliant on a number of external factors as well as the exercise of judgment.

The fair value of the contingent milestone payments payable by us to the former stockholders of Lumara Health has been determined based on our probability-adjusted discounted cash flows estimated to be realized from the net sales of Makena from December 1, 2014 through December 31, 2019.

The 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 13%. As of September 30, 2018, we estimated that the undiscounted royalty amounts we could pay under the MuGard License Agreement, based on current projections, may range from approximately $2.0 million to $6.0 million over the remainder of the ten year period, which commenced on June 6, 2013, the acquisition date, which is our best estimate of the period over which we expect the majority of the asset's cash flows to be derived.

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

Debt

We estimate the fair value of our debt obligations by using quoted market prices obtained from third-party pricing services, which is classified as a Level 2 input. As of September 30, 2018, the estimated fair value of our 2022 Convertible Notes and 2019 Convertible Notes (each as defined below) was $335.2 million and $21.4 million, respectively, which differed from their carrying values. See Note R, "*Debt*" for additional information on our debt obligations.

G. INVENTORIES

Our major classes of inventories were as follows as of September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018	December 31, 2017
Raw materials	$ 11,318	$ 9,505
Work in process	1,866	4,146
Finished goods	14,769	20,792
Total inventories	$ 27,953	$ 34,443

H. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following as of September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018	December 31, 2017
Computer equipment and software	$ 1,438	$ 1,401
Furniture and fixtures	1,442	1,442
Leasehold improvements	2,938	2,938
Laboratory and production equipment	6,000	654
Construction in progress	59	5,068
	11,877	11,503
Less: accumulated depreciation	(4,830)	(3,599)
Property and equipment, net	$ 7,047	$ 7,904

I. GOODWILL AND INTANGIBLE ASSETS, NET

Goodwill

Our $422.5 million goodwill balance represents goodwill of the continuing business following the goodwill allocation required by the CBR transaction discussed in Note C "*Discontinued Operations and Held for Sale.*" We determined that CBR met the definition of a business and as a result, in accordance with ASC 350 - *Intangibles - Goodwill and Other*, allocated goodwill on a relative fair value basis between CBR and the continuing business for the purposes of determining the carrying value of CBR. Further, we performed a qualitative goodwill impairment test for our continuing business at June 30, 2018 to assess whether there were indicators that its fair value was less than its carrying value. As a result of this evaluation, we determined that there was no impairment of the goodwill of our continuing business at June 30, 2018.

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.

Intangible Assets

As of September 30, 2018 and December 31, 2017, our identifiable intangible assets consisted of the following (in thousands):

	September 30, 2018				December 31, 2017			
	Cost	Accumulated Amortization	Cumulative Impairments	Net	Cost	Accumulated Amortization	Cumulative Impairments	Net
Finite-lived intangible assets:								
Makena base technology	$ 797,100	$ 390,724	$ 319,246	$ 87,130	$ 797,100	$ 255,754	$ 319,246	$ 222,100
Makena auto-injector developed technology	79,100	4,697	—	74,403	—	—	—	—
Intrarosa developed technology	77,655	8,441	—	69,214	77,655	3,376	—	74,279
	953,855	403,862	319,246	230,747	874,755	259,130	319,246	296,379
Indefinite-lived intangible assets:								
Makena IPR&D	—	—	—	—	79,100	—	—	79,100
Total intangible assets	$ 953,855	$ 403,862	$ 319,246	$ 230,747	$ 953,855	$ 259,130	$ 319,246	$ 375,479

During the first quarter of 2018, following the U.S. Food and Drug Administration (the "FDA") approval of Makena for administration via a pre-filled subcutaneous auto-injector (the "Makena auto-injector"), we reclassified the Makena IPR&D as the Makena auto-injector developed technology and placed it into service. Amortization of the Makena auto-injector developed technology is being recognized on a straight-line basis over 8.8 years.

As of September 30, 2018, the weighted average remaining amortization period for our finite-lived intangible assets was approximately 7.7 years. Total amortization expense for the nine months ended September 30, 2018 and 2017 was $144.7 million and $69.6 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, 2018	$ 28,860
Year Ending December 31, 2019	35,010
Year Ending December 31, 2020	26,636
Year Ending December 31, 2021	26,488
Year Ending December 31, 2022	26,469
Thereafter	87,284
Total	$ 230,747

J. CURRENT AND LONG-TERM LIABILITIES

Accrued expenses consisted of the following as of September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018	December 31, 2017
Commercial rebates, fees and returns	$ 89,157	$ 101,852
Professional, license, and other fees and expenses	21,442	23,657
Salaries, bonuses, and other compensation	23,623	15,882
Interest expense	3,533	13,525
Intrarosa-related license fees	—	10,000
Research and development expense	3,998	1,816
Total accrued expenses	$ 141,753	$ 166,732

K. INCOME TAXES

The following table summarizes our effective tax rate and income tax (benefit) expense from continuing operations for the three and nine months ended September 30, 2018 and 2017 (in thousands except for percentages):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Effective tax rate	4%	43%	(40)%	41%
Income tax (benefit) expense	$ (2,352)	$ (115,197)	$ 42,204	$ (145,317)

For the three and nine months ended September 30, 2018, we recognized an income tax benefit of $2.4 million and income tax expense of $42.2 million, respectively, representing an effective tax rate of 4% and (40)%, respectively. The difference between the 2018 statutory federal tax rate of 21% and the effective tax rates for the three and nine months ended September 30, 2018, was primarily attributable to the establishment of a valuation allowance on net deferred tax assets other than refundable alternative minimum tax ("AMT") credits, the impact of non-deductible stock compensation and other non-deductible expenses, partially offset by a benefit from contingent consideration, state income taxes and orphan drug credits. We have established a valuation allowance on our deferred tax assets other than refundable 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. Our valuation allowance on our deferred tax assets, other than refundable AMT credits, increased during the three and nine months ended September 30, 2018 primarily because the deferred tax liabilities associated with the CBR business, which was reclassified to discontinued operations for the three and nine months ended September 30, 2018, are no longer available as a source of income to realize the benefits of the net deferred tax assets.

In December 2017, the Tax Cuts and Jobs Act (the "2017 Tax Act") was enacted. The 2017 Tax Act included significant changes to the U.S. corporate income tax system, including a reduction of the federal corporate income tax rate from 35% to 21%, effective January 1, 2018. Deferred tax assets and liabilities are measured using enacted rates in effect for

the year in which those temporary differences are expected to be recovered or settled. As a result of the reduction in the federal tax rate from 35% to 21%, we revalued our ending net deferred tax liabilities at December 31, 2017 and recognized a provisional $17.6 million tax benefit. We are still assessing the implications of the 2017 Tax Act on both a federal and state level. Any additional impacts will be recorded as they are identified during the measurement period as provided for in accordance with Staff Accounting Bulletin No. 118, which addresses the application of GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the 2017 Tax Act.

For the three and nine months ended September 30, 2017, we recognized an income tax benefit of $115.2 million and $145.3 million, respectively, representing an effective tax rate of 43% and 41%, respectively. The difference between the expected 2017 statutory federal tax rate of 35% and the effective tax rates for the three and nine months ended September 30, 2017 was primarily attributable to the impact of state income taxes and the federal research and development tax credit, partially offset by non-deductible stock compensation.

The primary drivers of the increase in tax expense for the three and nine months ended September 30, 2018 as compared to the three and nine months ended September 30, 2017 is primarily attributable to an increase in valuation allowance on net deferred tax assets other than refundable AMT credits and a decrease in the federal tax benefit attributable to the decrease in the statutory federal rate from 35% to 21%, as well as an increase in nondeductible expenses, partially offset by contingent consideration.

L. ACCUMULATED OTHER COMPREHENSIVE LOSS

The following table summarizes the changes in the accumulated balances of other comprehensive loss during the three and nine months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Beginning balance	$ (4,295)	$ (3,633)	$ (3,908)	$ (3,838)
Holding gains (losses) arising during period, net of tax	134	(4)	(253)	201
Ending balance	$ (4,161)	$ (3,637)	$ (4,161)	$ (3,637)

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

We compute basic net income (loss) per share by dividing net income (loss) by the weighted average number of common shares outstanding during the relevant period. Diluted net income (loss) per common share has been computed by dividing net income (loss) by the diluted number of common shares outstanding during the period. Except where the result would be antidilutive to net income, diluted net income per common share is computed assuming the impact of the conversion of the 2.5% convertible senior notes due 2019 (the “2019 Convertible Notes”) and the 3.25% convertible senior notes due 2022 (the “2022 Convertible Notes”), the exercise of outstanding stock options, the vesting of restricted stock units (“RSUs”), and the exercise of warrants.

We have a choice to settle the conversion obligation of our 2022 Convertible Notes and the 2019 Convertible Notes (together, the “Convertible Notes”) in cash, shares, or any combination of the two. Our current policy is to settle the principal balance of the Convertible Notes in cash. As such, we apply the treasury stock method to these securities and the dilution related to the conversion premium, if any, of the Convertible Notes is included in the calculation of diluted weighted-average shares outstanding to the extent each issuance is dilutive based on the average stock price during each reporting period being greater than the conversion price of the respective Convertible Notes. The dilutive effect of the warrants, stock options and RSUs has been calculated using the treasury stock method.

The components of basic and diluted net income (loss) per share for the three and nine months ended September 30, 2018 and 2017 were as follows (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss from continuing operations	$ (64,678)	$ (155,713)	$ (148,592)	$ (205,890)
Net income from discontinued operations	95,517	3,652	105,108	3,202
Net income (loss)	$ 30,839	$ (152,061)	$ (43,484)	$ (202,688)
Weighted average common shares outstanding	34,492	35,311	34,339	34,948
Basic and diluted net income (loss) per share:				
Loss from continuing operations	$ (1.88)	$ (4.41)	$ (4.33)	$ (5.89)
Income from discontinued operations	2.77	0.10	3.06	0.09
Basic and diluted net income (loss) per share:	$ 0.89	$ (4.31)	$ (1.27)	$ (5.80)

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

	Nine Months Ended September 30,	
	2018	2017
Options to purchase shares of common stock	3,700	3,389
Shares of common stock issuable upon the vesting of RSUs	1,135	1,140
Warrants	1,008	1,008
2022 Convertible Notes	11,695	11,695
2019 Convertible Notes	790	790
Total	18,328	18,022

In connection with the issuance of the 2019 Convertible Notes, in February 2014, we entered into convertible bond hedges. The convertible bond hedges are not included for purposes of calculating the number of diluted shares outstanding, as their effect would be anti-dilutive. The convertible bond hedges are generally expected, but not guaranteed, to reduce the potential dilution and/or offset the cash payments we are required to make upon conversion of the remaining 2019 Convertible Notes. During the three and nine months ended September 30, 2018 and 2017, our average common stock price was below the exercise price of the warrants.

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"). In June 2018 at our annual meeting of stockholders, our stockholders approved (a) an amendment to our 2007 Plan to, among other things, increase the number of shares of our common stock available for issuance thereunder by 1,043,000 shares and (b) an amendment to our 2015 ESPP to increase the maximum number of shares of our common stock that will be made available for sale thereunder by 500,000 shares. 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 nine months ended September 30, 2018:

	2007 Equity Plan	2013 Lumara Equity Plan	Inducement Grants	Total
Outstanding at December 31, 2017	2,590,373	125,536	815,450	3,531,359
Granted	836,846	35,400	102,393	974,639
Exercised	(133,547)	(2,812)	—	(136,359)
Expired or terminated	(549,156)	(30,675)	(90,000)	(669,831)
Outstanding at September 30, 2018	2,744,516	127,449	827,843	3,699,808

Restricted Stock Units

The following table summarizes RSU activity for the nine months ended September 30, 2018:

	2007 Equity Plan	2013 Lumara Equity Plan	Inducement Grants	Total
Outstanding at December 31, 2017	966,623	11,611	91,541	1,069,775
Granted	752,797	1,600	48,418	802,815
Vested	(370,388)	(10,650)	(47,764)	(428,802)
Expired or terminated	(306,234)	(460)	(2,502)	(309,196)
Outstanding at September 30, 2018	1,042,798	2,101	89,693	1,134,592

In March 2018, we granted RSUs under our 2007 Plan to certain members of our senior management covering a maximum of 206,250 shares of common stock. These performance-based RSUs will vest, if at all, on March 1, 2021, 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 September 30, 2018, the maximum shares of common stock that may be issued under these awards is 188,250. The maximum aggregate total fair value of these RSUs is $3.5 million, which is being recognized as expense over a period of three years from the date of grant, net of any actual forfeitures.

Equity-Based Compensation Expense

Equity-based compensation expense for the three and nine months ended September 30, 2018 and 2017 consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of product sales	$ 281	$ 432	$ 588	$ 690
Research and development	568	799	1,896	2,651
Selling, general and administrative	4,202	4,410	12,149	12,037
Total equity-based compensation expense	5,051	5,641	14,633	15,378
Income tax effect	—	(1,674)	—	(4,569)
After-tax effect of equity-based compensation expense	$ 5,051	$ 3,967	$ 14,633	$ 10,809

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. We adopted ASU No. 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* during the first quarter of 2017. We will continue to use the current method of estimated forfeitures each period rather than accounting for forfeitures as they occur.

O. STOCKHOLDERS' EQUITY

Change in Stockholders' Equity

Total stockholders' equity decreased by $28.0 million during the nine months ended September 30, 2018. This decrease was primarily driven by the following:

- $43.5 million due to our net loss for the nine months ended September 30, 2018;
- $14.6 million increase related to equity-based compensation expense;
- $1.1 million increase related to the cumulative effect adjustment to our accumulated deficit from the adoption of ASC 606, net of tax;
- $2.6 million decrease due to the payment of employee tax withholdings related to equity-based compensation; and
- $2.6 million increase from net shares issued related to the exercise of stock options.

Share Repurchase Program

In January 2016, we announced that our Board authorized a program to repurchase up to $60.0 million in shares of our common stock. The repurchase program does not have an expiration date and may be suspended for periods or discontinued at any time. Under the program, we may purchase our stock from time to time at the discretion of management in the open market or in privately negotiated transactions. The number of shares repurchased and the timing of the purchases will depend on a number of factors, including share price, trading volume and general market conditions, along with working capital requirements, general business conditions and other factors. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate purchases of our shares under this program. As of September 30, 2018, we repurchased and retired a cumulative total of 2,198,010 shares of common stock under this repurchase program for $39.5 million at an average purchase price of $17.97 per share. As of September 30, 2018, $20.5 million remains available for the repurchase of shares under the program. We did not repurchase any of our common stock during the first nine months of 2018.

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 leases, purchases of inventory, debt obligations, and other purchase obligations.

Purchase Obligations

Purchase obligations primarily represent minimum purchase commitments for inventory. As of September 30, 2018, our minimum purchase commitments totaled $66.4 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. During the nine months ended September 30, 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 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. AMAG-423 is a polyclonal antibody currently in clinical development for the treatment of severe preeclampsia in pregnant women and has been granted both orphan drug and fast-track review designations by the FDA. In connection with the exercise of the option and consummation of the acquisition, we have assumed responsibility to complete

the Phase 2b/3a clinical study that Velo initiated in the second quarter of 2017 and will incur the necessary clinical, regulatory and other costs required to pursue FDA approval. As part of the acquisition, in September 2018 we paid Velo an upfront option exercise fee of $12.5 million, which was recorded as IPR&D expense as the product candidate is in development and has no alternative future use. We will also be obligated to pay Velo a $30.0 million milestone payment upon FDA approval of the product. In addition, if we are successful with the commercial launch of the product, we will be 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 upon first commercial sale, payable in quarterly installments as a percentage of quarterly gross sales. We will also be obligated to pay the third-party low-single digit royalties based on net sales.

In connection with a license agreement we entered into with Endoceutics, Inc. ("Endoceutics") in February 2017 (the "Endoceutics License Agreement"), we are required to pay Endoceutics certain sales milestone payments, including a first sales milestone payment of $15.0 million, which would be triggered when Intrarosa annual net U.S. sales exceed $150.0 million, and a second milestone payment of $30.0 million, which would be triggered when annual net U.S. sales of Intrarosa exceed $300.0 million. If annual net U.S. sales of Intrarosa exceed $500.0 million, there are additional sales milestone payments totaling up to $850.0 million, which would be triggered at various sales thresholds. We are also obligated to pay tiered royalties to Endoceutics equal to a percentage of net sales of Intrarosa in the U.S. ranging from mid-teens for calendar year net sales up to $150.0 million to mid twenty percent for any calendar year net sales that exceed $1.0 billion for the commercial life of Intrarosa, with deductions (a) after the later of (i) the expiration date of the last to expire of a licensed patent containing a valid patent claim or (ii) ten years after the first commercial sale of Intrarosa for the treatment of 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.

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 up to $380.0 million in regulatory and commercial milestone payments, of which $20.0 million was paid in the second quarter of 2018 following the acceptance by the FDA of our New Drug Application ("NDA") for Vyleesi. As of September 30, 2018, the remaining potential milestone payments include $60.0 million upon FDA approval of Vyleesi and up to $300.0 million of aggregate sales milestone payments upon the achievement of certain annual net sales milestones over the course of the license. We are also obligated to pay Palatin tiered royalties on annual net sales of Vyleesi and any other products containing Vyleesi (collectively, the "Vyleesi Products"), on a product-by-product basis, in the Palatin Territory ranging from the high-single digits to the low double-digits.

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.

Contingencies

Legal Proceedings

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

Sandoz Patent Infringement Lawsuit

In March 2016, we initiated a patent infringement suit regarding an Abbreviated New Drug Application submitted to the FDA by Sandoz Inc. ("Sandoz") requesting approval to engage in commercial manufacture, use and sale of a generic version of ferumoxytol. On March 23, 2018, we and Sandoz entered a stipulation of dismissal in the United States District Court for the District of New Jersey pursuant to a settlement agreement that dismissed and resolved this action. According to the terms of the settlement, if Sandoz receives FDA approval by a certain date, Sandoz may launch its generic version of Feraheme on July 15, 2021, or earlier under certain circumstances customary for settlement agreements of this nature. Sandoz will pay a royalty on the sales of its generic version of Feraheme to us until the expiration of the last Feraheme patent listed in the Orange Book. If Sandoz is unable to secure approval by such date, Sandoz will launch an authorized generic version of Feraheme on July 15, 2022 for up to twelve months. Sandoz's right to distribute, and our obligation to supply, the authorized generic product shall be in accordance with standard commercial terms and profit splits.

Other

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

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

We may periodically become subject to other legal proceedings and claims arising in connection with ongoing business activities, including claims or disputes related to patents that have been issued or that are pending in the field of research on which we are focused. Other than the above actions, we are not aware of any material claims against us as of September 30, 2018.

Q. COLLABORATION, LICENSE AND OTHER STRATEGIC AGREEMENTS

Our commercial strategy includes expanding our portfolio through the in-license or acquisition of additional pharmaceutical products or companies, including revenue-generating commercial products and late-state development assets as well as forming alliances with other companies to facilitate the sale and distribution of our products. As of September 30, 2018, we were a party to the following collaborations and license agreements:

Velo

As described above in Note P, "*Commitments and Contingencies,*" in September 2018, we exercised our option to acquire the global rights to the AMAG-423 program, which we account for as an asset acquisition under ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* ("ASU 2017-01").

Prasco

In anticipation of the entry of generic competition to our branded Makena intramuscular product following the February 2018 expiration of Makena's orphan drug exclusivity, we entered into a Distribution and Supply Agreement (the "Prasco Agreement") with Prasco, LLC ("Prasco"). The Prasco Agreement grants Prasco an exclusive, non-sublicensable, nontranferable license to purchase, distribute and sell a generic version of Makena in the U.S. In July 2018, following the approval by the FDA of a generic version of the Makena single-dose intramuscular injection in late June 2018, in order to participate in the generic market, we authorized Prasco to launch the authorized generic of both the single-dose and multi-dose intramuscular injection of Makena. Under the Prasco Agreement, we are responsible for the manufacture and supply of the generic Makena product to be sold to Prasco at a predetermined supply price and Prasco is also required to pay us a certain percentage of the net distributable profits from the sale of the generic Makena product. 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 may be required to pay penalties if we fail to supply a certain percentage of product ordered by Prasco. The Prasco Agreement will continue for a set period of time, including mutually agreed to additional renewals, but 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 or for lack of commercial viability, FDA notice, or by mutual agreement.

Antares

Through our acquisition of Lumara Health, 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 Antares License Agreement, we are responsible for the clinical development and preparation, submission and maintenance of all regulatory applications in each country where we desire to market and sell the Makena auto-injector, including the U.S. We are required to pay royalties to Antares on net sales of the Makena auto-injector for the 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 with Endoceutics. Pursuant to the Endoceutics License Agreement, Endoceutics granted us the right to develop and commercialize pharmaceutical products containing dehydroepiandrosterone ("DHEA"), including Intrarosa, at dosage strengths of 13 mg or less per dose and formulated for intravaginal delivery, excluding any combinations with other active pharmaceutical ingredients, in the U.S. for the treatment of VVA and FSD. The transactions contemplated by the Endoceutics License Agreement closed on April 3, 2017. We accounted for the Endoceutics License Agreement as an asset acquisition under 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 the third quarter of 2017 upon the delivery by Endoceutics of Intrarosa launch quantities and $10.0 million in the second quarter of 2018 following the first anniversary of the closing. In the second quarter of 2017, we recorded a total of $83.5 million of consideration, of which $77.7 million was allocated to the Intrarosa developed technology intangible asset and $5.8 million was recorded as IPR&D expense based on their relative fair values.

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

In the third quarter of 2017, Endoceutics initiated a clinical study to support an application for U.S. regulatory approval for Intrarosa for the treatment of HSDD in post-menopausal women. We and Endoceutics have agreed to share the direct costs related to such studies based upon a negotiated allocation with us funding up to $20.0 million. We may, with Endoceutics' consent (not to be unreasonably withheld, conditioned or delayed), conduct any other studies of Intrarosa for the treatment of VVA and FSD anywhere in the world for the purpose of obtaining or maintaining regulatory approval of or commercializing Intrarosa for the treatment of VVA or FSD in the U.S. All data generated in connection with the above described studies would be owned by Endoceutics and licensed to us pursuant to the Endoceutics License Agreement.

We 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, including having final decision making authority with respect to commercial strategy, pricing and reimbursement and other commercialization matters. We have agreed to use commercially reasonable efforts to market, promote and otherwise commercialize Intrarosa for the treatment of VVA and, 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 will be our exclusive supplier of Intrarosa in the U.S., subject to certain rights for us to manufacture and supply Intrarosa in the event of a cessation notice or supply failure (as such terms are defined in the 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 remain in effect until the termination of the Endoceutics License Agreement, unless terminated earlier by either party for an uncured material breach or insolvency of the other party, or by us if we exercise our rights to manufacture and supply Intrarosa following a cessation notice or supply failure.

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

Palatin

In January 2017, we entered into the Palatin License Agreement with Palatin under which we acquired (a) an exclusive license in all countries of North America (the "Palatin Territory"), with the right to grant sub-licenses, to research, develop and commercialize 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 the payment of a $20.0 million milestone obligation, 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, the Palatin License Agreement requires us to make contingent payments of (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: (a) we must license additional third-party intellectual property in order to develop, manufacture or commercialize a Vyleesi Product or (b) 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. 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 September 30, 2018 and December 31, 2017 consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
2023 Senior Notes	$ —	$ 466,291
2022 Convertible Notes	258,376	248,194
2019 Convertible Notes	20,999	20,198
Total long-term debt	279,375	734,683
Less: current maturities	(20,999)	—
Long-term debt, net of current maturities	$ 258,376	$ 734,683

2023 Senior Notes

In August 2015, in connection with the CBR acquisition, we completed a private placement of $500.0 million aggregate principal amount of 7.875% Senior Notes due 2023 (the "2023 Senior Notes"). The 2023 Senior Notes were issued pursuant to an Indenture, dated as of August 17, 2015 (the "Indenture"), by and among us, certain of our subsidiaries acting as guarantors of the 2023 Senior Notes and Wilmington Trust, National Association, as trustee. In October 2017, we repurchased $25.0 million of the 2023 Senior Notes in a privately negotiated transaction, resulting in a loss on extinguishment of debt of $1.1 million. In September 2018, we repurchased the remaining $475.0 million of the 2023 Senior Notes at a premium of $28.1 million using the proceeds from the CBR sale, which resulted in a loss on extinguishment of debt of $35.9 million, inclusive of the premium paid.

Convertible Notes

The outstanding balances of our Convertible Notes as of September 30, 2018 consisted of the following (in thousands):

	2022 Convertible Notes	2019 Convertible Notes	Total
Liability component:			
Principal	$ 320,000	$ 21,417	$ 341,417
Less: debt discount and issuance costs, net	61,624	418	62,042
Net carrying amount	$ 258,376	$ 20,999	$ 279,375
Equity Component	$ 72,576	$ 9,905	$ 82,481

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

2022 Convertible Notes

In the second quarter of 2017, we issued $320.0 million aggregate principal amount of convertible senior notes due in 2022 (the "2022 Convertible Notes") and received net proceeds of $310.4 million from the sale of the 2022 Convertible Notes, after deducting fees and expenses of $9.6 million. The approximate $9.6 million of debt issuance costs primarily consisted of underwriting, legal and other professional fees, and we allocated these costs to the liability and equity components based on the allocation of the proceeds. Of the total $9.6 million of debt issuance costs, $2.2 million was allocated to the Equity Component and recorded as a reduction to additional paid-in capital and $7.4 million was allocated to the liability component and is now recorded as a reduction of the 2022 Convertible Notes 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 September 30, 2018.

We determined the expected life of the debt was equal to the five-year term on the 2022 Convertible Notes. The effective interest rate on the liability component was 9.49% for the period from the date of issuance through September 30, 2018. As of September 30, 2018, the "if-converted value" did not exceed the remaining principal amount of the 2022 Convertible Notes.

2019 Convertible Notes

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

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

The conversion rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the issuance of stock dividends and payment of cash dividends. Beginning on or after May 15, 2018 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert all or any portion of their 2019 Convertible Notes, in multiples of $1,000 principal amount, at the option of the holder. The 2019 Convertible Notes were convertible as of September 30, 2018.

We determined the expected life of the debt was equal to the five-year term of the 2019 Convertible Notes. The effective interest rate on the liability component was 7.79% for the period from the date of issuance through September 30, 2018. As of September 30, 2018, the “if-converted value” did not exceed the remaining principal amount of the 2019 Convertible Notes.

Convertible Notes Interest Expense

The following table sets forth total interest expense recognized related to the Convertible Notes during the three and nine months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Contractual interest expense	$ 2,734	$ 2,840	$ 8,202	$ 6,033
Amortization of debt issuance costs	355	348	1,040	944
Amortization of debt discount	3,391	3,264	9,942	7,909
Total interest expense	$ 6,480	$ 6,452	$ 19,184	$ 14,886

Convertible Bond Hedge and Warrant Transactions

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

As of September 30, 2018, the remaining bond hedge transactions covered approximately 0.8 million shares of our common stock underlying the remaining $21.4 million principal amount of the 2019 Convertible Notes. The convertible bond

hedges have an exercise price of approximately $27.09 per share, subject to adjustment upon certain events, and are exercisable when and if the 2019 Convertible Notes are converted. If upon conversion of the 2019 Convertible Notes, the price of our common stock is above the exercise price of the convertible bond hedges, the call spread counterparties will deliver shares of our common stock and/or cash with an aggregate value equal to the approximate difference between the price of our common stock at the conversion date and the exercise price, multiplied by the number of shares of our common stock underlying the convertible bond hedges being exercised. The convertible bond hedges were separate transactions entered into by us and were not part of the terms of the 2019 Convertible Notes or the warrants, discussed below. Holders of the 2019 Convertible Notes will not have any rights with respect to the convertible bond hedges.

As of September 30, 2018, the remaining warrant transactions covered approximately 1.0 million shares of our common stock underlying the remaining $21.4 million principal amount of the 2019 Convertible Notes. The initial exercise price of the warrants is $34.12 per share, subject to adjustment upon certain events, which was 70% above the last reported sale price of our common stock of $20.07 on February 11, 2014. The warrants would separately have a dilutive effect to the extent that the market value per share of our common stock, as measured under the terms of the warrants, exceeds the applicable exercise price of the warrants. The warrants were issued to the call spread counterparties pursuant to the exemption from registration set forth in Section 4(a)(2) of the Securities Act of 1933, as amended.

Future Payments

Future annual principal payments on our long-term debt as of September 30, 2018 were as follows (in thousands):

Period	Future Annual Principal Payments
Remainder of Year Ending December 31, 2018	$ —
Year Ending December 31, 2019	21,417
Year Ending December 31, 2020	—
Year Ending December 31, 2021	—
Year Ending December 31, 2022	320,000
Thereafter	—
Total	$ 341,417

S. RECENTLY ISSUED AND PROPOSED ACCOUNTING PRONOUNCEMENTS

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that are adopted by us as of the specified effective date.

In 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.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). 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. This statement is effective for annual reporting periods beginning after December 15, 2018 and interim periods within those annual periods and early adoption is permitted. As of September 30, 2018 we have completed our identification of the population of leases. Our next phase of implementation will include calculation of the financial statement impact of adoption. We currently expect to recognize material operating lease liabilities and right-of-use assets related to our current operating lease commitments upon our adoption of ASU 2016-02 on January 1, 2019. In addition, we are evaluating our internal control framework and required disclosures to identify any changes that may need to be made in response to the new guidance.

T. RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* ("ASU 2016-18"), which requires amounts generally described as restricted cash and restricted cash equivalents to be included with cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. We adopted the standard on January 1, 2018 using the retrospective approach and modified the presentation of our condensed consolidated statements of cash flows in accordance with the standard. The adoption of ASU 2016-18 did not have a material impact on our condensed consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). This standard clarifies certain aspects of the statement of cash flows, including the classification of debt prepayment or debt extinguishment costs or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate owned life insurance policies, distributions received from equity method investees and beneficial interests in securitization transactions. This new standard also clarifies that an entity should determine each separately identifiable source or use within the cash receipts and payments on the basis of the nature of the underlying cash flows. In situations in which cash receipts and payments have aspects of more than one class of cash flows and cannot be separated by source or use, the appropriate classification should depend on the activity that is likely to be the predominant source or use of cash flows for the item. We adopted the standard on January 1, 2018 using the retrospective approach. ASU 2016-15 did not have a material impact on our condensed consolidated financial statements upon adoption.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU 2016-01"). This new standard amends certain aspects of accounting and disclosure requirements of financial instruments, including the requirement that equity investments with readily determinable fair values be measured at fair value with changes in fair value recognized in our results of operations. This new standard does not apply to investments accounted for under the equity method of accounting or those that result in consolidation of the investee. Equity investments that do not have readily determinable fair values may be measured at fair value or at cost minus impairment adjusted for changes in observable prices. A financial liability that is measured at fair value in accordance with the fair value option is required to be presented separately in other comprehensive income for the portion of the total change in the fair value resulting from change in the instrument-specific credit risk. In addition, a valuation allowance should be evaluated on deferred tax assets related to available-for-sale debt securities in combination with other deferred tax assets. We adopted the standard on January 1, 2018 using the modified retrospective approach. The adoption of ASU 2016-01 did not have a material impact on our condensed consolidated financial statements.

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, 2017 (our "Annual Report").

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

Examples of forward-looking statements contained in this report include, without limitation, statements regarding the following: plans to continue to expand the impact of our current and future products for patients by delivering on our growth strategy; plans for our product candidates, including timing for data release and regulatory submissions; the timing of additional generic competition to the Makena intramuscular ("IM") product and the impact of generic competition on sales and rebates; expectations related to our filing of a supplemental New Drug Application ("NDA") for the treatment of HSDD in post-menopausal women with Intrarosa; anticipated clinical, developmental, regulatory and other undertakings and cooperation efforts by our licensing parties; the impact and benefits of the CBR disposition and transitional services; expectations regarding our intellectual property, including patent protection and related litigation, and the impact and timing that generic and other competition could have on our business; beliefs regarding the intellectual property of our licensing and collaboration partners, and our rights to such property; the market opportunities for each of our products; plans regarding our sales and marketing initiatives; expectations regarding our future sales of Feraheme, Intrarosa and Makena; the impact of our

license and collaboration agreements on our results of operations; our expectation of costs to be incurred in connection with, and revenue sources to fund, our future operations; our expectations regarding the contribution of revenues from our products to the funding of our ongoing operations; expectations regarding the manufacture of all drug substance, drug products and key materials at our third-party manufacturers or suppliers; our expectations regarding customer returns and other revenue-related reserves and accruals; estimates regarding our effective tax rate and our ability to realize our net operating loss carryforwards and other tax attributes; the impact of accounting pronouncements; expectations regarding our financial results, including revenues, product sales allowances and accruals, cost of product sales, research and development expenses, selling, general and administrative expenses, amortization and other income (expense); our investing activities and the impact of our operations on our cash, cash equivalents and marketable securities balances; our belief that our cash, cash equivalents and marketable securities as of September 30, 2018, and the cash we currently expect to receive, will be sufficient to satisfy our cash flow needs for the foreseeable future (including the remainder of 2018); our expectation that our anticipated spending as we enter 2019 may exceed our expected revenues; expectations related to the timing and amounts of milestone payments to former Lumara Health security holders, Palatin, Endoceutics and Velo; estimates and beliefs related to our debt; the valuation of certain intangible assets, goodwill, contingent consideration, debt and other assets and liabilities, including our methodology and assumptions regarding fair value measurements; the manner in which we intend or are required to settle the conversion of our 2022 Convertible Notes and 2019 Convertible Notes; the timing and amounts (if any) of share repurchases; and our expectations for our cash, revenue, cash equivalents, marketable securities balances, capital needs and information with respect to any other plans and strategies for our business. Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements.

Any forward-looking statement should be considered in light of the factors discussed in Part II, Item 1A below under "Risk Factors" in this Quarterly Report on Form 10-Q and in Part I, Item 1A in our Annual Report. We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the U.S. Securities and Exchange Commission, to publicly update or revise any such statements to reflect any change in company expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a pharmaceutical company focused on bringing innovative products to patients with unmet medical needs. We do this by leveraging our development and commercial expertise to invest in and grow our pharmaceutical products across a range of therapeutic areas, including women's health. Our currently marketed products support the health of patients in the areas of maternal and women's health, anemia management and cancer supportive care, including Makena® (hydroxyprogesterone caproate injection), Intrarosa® (prasterone) vaginal inserts, Feraheme® (ferumoxytol injection) for intravenous ("IV") use, and MuGard® Mucoadhesive Oral Wound Rinse. In addition to our marketed products, our portfolio includes two product candidates, Vyleesi™ (bremelanotide), which is being developed for the treatment of hypoactive sexual desire disorder ("HSDD") in pre-menopausal women and digoxin immune Fab (ovine) (now referred to as AMAG-423), which is being studied for the treatment of severe preeclampsia.

Since August 2015, we had provided services related to the preservation of umbilical cord blood stem cell and cord tissue units operated through Cord Blood Registry® ("CBR"). On August 6, 2018, we completed the sale of our wholly-owned subsidiary, CBR Acquisition Holdings Corp, and the CBR business to GI Chill Acquisition LLC, an affiliate of GI Partners, a private equity investment firm (together "GI") pursuant to the June 14, 2018 Stock Purchase Agreement between us and GI. We received $519.3 million in cash at closing and recognized a gain of $89.6 million on the sale during the three and nine months ended September 30, 2018. For additional information, see Note C "*Discontinued Operations and Held for Sale*" to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

We intend 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 product 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. The CBR business has been separated from continuing operations and reflected as a discontinued operation. See Note C, "*Discontinued Operations and Held for Sale*" to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

AMAG's Portfolio of Products and Product Candidates

AMAG-423

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. AMAG-423 is a polyclonal antibody currently in clinical development for the treatment of severe preeclampsia in pregnant women and has been granted both orphan drug and fast-track review designations by the U.S. Food and Drug Administration (the "FDA"). In connection with the exercise of the option and the consummation of the acquisition, we paid Velo an upfront option exercise fee of $12.5 million in September 2018, which was recorded in acquired in-process research and development ("IPR&D") expense. See Note P, "*Commitments and Contingencies*," to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for more information on the AMAG-423 acquisition.

Preeclampsia is a multi-system disorder that occurs only during pregnancy and the postpartum period and affects both the mother and baby. Preeclampsia is the leading cause of maternal morbidity and mortality and typically develops in women after 20 weeks of pregnancy and is characterized by elevated blood pressure, as well as vascular abnormalities, that can lead to end organ damage, intrauterine growth restriction and premature delivery. Premature delivery can lead to a number of serious health consequences for the infant, including intraventricular hemorrhage (bleeding in the brain) or necrotizing enterocolitis (severe inflammation of the infant bowels). Approximately 140,000 pregnant women in the U.S. are affected by preeclampsia, with approximately 50,000 impacted by severe preeclampsia, a more serious form of the condition that can be life threatening to both the mother and the baby. There are currently no effective treatments that address the underlying condition, rather treatments include medications to address the symptoms, such as antihypertensives and early delivery of the baby.

We have assumed responsibility to complete the Phase 2b/3a clinical study that Velo initiated in the second quarter of 2017 and will incur the necessary 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, including the 26 patients who were enrolled prior to the transfer of the study to us. No additional patients will be enrolled during the study transition, and we expect to re-initiate new patient enrollment in early 2019. Participants in the study will receive AMAG-423 or placebo intravenously four times a day over four days. The study's primary endpoint is to demonstrate a reduction in the percentage of babies who develop severe intraventricular hemorrhage, necrotizing enterocolitis or death by 36 weeks corrected gestational age between the AMAG-423 and placebo arms. Secondary endpoints include the maternal incidence of pulmonary edema during treatment and the period of time between treatment and delivery.

Vyleesi

In January 2017, we entered into a license agreement with Palatin Technologies, Inc. ("Palatin") pursuant to which Palatin granted us the North American rights to research, develop and commercialize Vyleesi (previously referred to as bremelanotide), which is being developed for the treatment of HSDD in pre-menopausal women. Vyleesi is designed to be an on demand therapy used in anticipation of sexual activity and self-administered by the patient in the thigh or abdomen via a single-use subcutaneous auto-injector. Two Phase 3 studies conducted by Palatin for the treatment of HSDD in pre-menopausal women met the pre-specified co-primary efficacy endpoints of improvement in desire and decrease in distress associated with low sexual desire as measured using validated patient-reported outcome instruments. Each trial consisted of over 600 patients randomized in a 1:1 ratio to either the treatment arm or placebo arm, each with a 24 week evaluation period. The most frequent adverse events were nausea, flushing and headache, which were generally mild-to-moderate in severity and were transient. Approximately 17% of patients discontinued participation in the Vyleesi arm due to adverse events in both studies versus 2% in placebo. Women in the trials had the option, after completion of the randomized trial, to continue in an ongoing open-label safety extension study for an additional 52 weeks, which 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, which was completed in 2017, received Vyleesi.

In June 2018, the FDA accepted the New Drug Application ("NDA") for Vyleesi for the treatment of HSDD in pre-menopausal women. The Prescription Drug User Fee Act ("PDUFA") date for completion of FDA review of the Vyleesi NDA is March 23, 2019 and we expect an Advisory Committee meeting for Vyleesi to be held in January 2019. Additional details regarding the license with Palatin (the "Palatin License Agreement") can be found in Note Q, "*Collaboration, License and Other Strategic Agreements*," to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

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. 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. The orphan drug exclusivity period that was granted to the Makena IM product in 2011 expired in February 2018. In July 2018, we launched our own authorized generic of both the single- and multi-dose vials through our generic partner, Prasco, LLC. 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.

In February 2018, Makena was approved by the FDA for administration via a pre-filled subcutaneous auto-injector (the "Makena auto-injector"), a drug-device combination product. 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 benefits of the Makena auto-injector and converting current IM prescribers to the Makena auto-injector.

Feraheme

Feraheme was approved for marketing by the FDA in June 2009 for the treatment of iron deficiency anemia ("IDA") in adult patients with chronic kidney disease ("CKD") only and was launched commercially shortly thereafter. In February 2018, we received FDA approval to expand the Feraheme label to treat 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 widely prevalent in many different patient populations, such as patients with gastrointestinal disease, cancer and chemotherapy-induced anemia or abnormal uterine bleeding. For many of these patients, treatment with oral iron is unsatisfactory or is not tolerated. It is estimated that more than 4.5 million people in the U.S. have IDA (CKD and non-CKD) 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 recently expanded Feraheme label is supported by two positive pivotal Phase 3 trials which evaluated Feraheme versus iron sucrose or placebo in a broad population of patients with IDA. It was also supported by positive results from a third Phase 3 randomized, double-blind non-inferiority trial that evaluated the incidence of moderate-to-severe hypersensitivity reactions (including anaphylaxis) and moderate-to-severe hypotension with Feraheme compared to Injectafer® (ferric carboxymaltose injection) (the "Feraheme comparator trial"). This Feraheme comparator trial demonstrated non-inferiority to Injectafer® based on the primary 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 <0.6 mmol/L at week 2) was less in the patients receiving Feraheme (0.4% of patients) compared to those receiving Injectafer® (38.7% of patients).

Intrarosa

In February 2017, we entered into a license agreement (the "Endoceutics License Agreement") with Endoceutics, Inc. ("Endoceutics") pursuant to which Endoceutics granted us 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, vaginally administered, daily steroid, which is prescribed for the treatment of moderate to severe dyspareunia, a symptom of VVA, due to menopause. The effectiveness of Intrarosa on moderate to severe dyspareunia in post-menopausal women was examined in two primary 12-week placebo-controlled efficacy trials. All women in both studies were assessed for improvement from baseline to week 12 for four co-primary efficacy endpoints: (a) most bothersome symptom (moderate to severe dyspareunia), (b) the percentage of vaginal superficial cells, (c) the percentage of parabasal cells, and (d) vaginal pH. All primary endpoints were statistically significant. Women taking Intrarosa 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.

Endoceutics initiated a clinical study in the third quarter of 2017 to support an application for U.S. regulatory approval of Intrarosa for the treatment of hypoactive sexual desire disorder ("HSDD") in post-menopausal women. We and Endoceutics have agreed to share the direct costs related to two Phase 3 clinical studies based upon a negotiated allocation with us funding up to $20.0 million, including the HSDD trial. If the studies are successful, we will file a supplemental New Drug Application

with the FDA for the treatment of HSDD in post-menopausal women. Furthermore, each party's commercialization activities and budget are described in a commercialization plan, which is updated annually. Additional details regarding the Endoceutics License Agreement can be found in Note Q, "*Collaboration, License and Other Strategic Agreements*," to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Critical Accounting Policies

Except as described in Note B, "*Basis of Presentation and Summary of Significant Accounting Policies*," and Note D, "*Revenue Recognition*," to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, with respect to changes in our revenue recognition policy related to our adoption of the requirements of Accounting Standards Codification Topic 606, Revenue from Contracts with Customers, there have been no significant changes to our critical accounting policies and estimates during the nine months ended September 30, 2018, compared to the critical accounting policies and estimates disclosed in Part II, Item 7, of our Annual Report.

Results of Operations - Three Months Ended September 30, 2018 and 2017

Revenues

Total revenues for the three months ended September 30, 2018 and 2017 consisted of the following (in thousands except for percentages):

	Three Months Ended September 30,		2018 to 2017	
	2018	2017	$ Change	% Change
Product sales, net				
Makena	$ 80,221	$ 97,635	$ (17,414)	(18)%
Feraheme	36,963	26,095	10,868	42 %
Intrarosa	4,925	360	4,565	>100 %
MuGard	129	241	(112)	(46)%
Total revenues	$ 122,238	$ 124,331	$ (2,093)	(2)%

Net product sales decreased by $2.1 million, or approximately 2%, during the three months ended September 30, 2018 as compared to the same period in 2017. The $17.4 million decrease in Makena net sales was primarily impacted by a supply disruption of our IM products, as discussed further below, and the entry of generic competition. The decrease of total revenues was partially offset by a $10.9 million increase in Feraheme net sales following the approval of its expanded label in February 2018 and a $4.6 million increase in Intrarosa net sales, which was launched commercially in July 2017.

Product Sales

Total gross product sales were offset by product sales allowances and accruals for the three months ended September 30, 2018 and 2017 as follows (in thousands, except for percentages):

	Three Months Ended September 30,				2018 to 2017	
	2018	Percent of gross product sales	2017	Percent of gross product sales	$ Change	% Change
Gross product sales	$ 238,856		$ 235,299		$ 3,557	2 %
Provision for product sales allowances and accruals:						
Contractual adjustments	93,213	39%	80,110	34%	13,103	16 %
Governmental rebates	23,405	10%	30,858	13%	(7,453)	(24)%
Total	116,618	49%	110,968	47%	5,650	5 %
Product sales, net	$ 122,238		$ 124,331		$ (2,093)	(2)%

We expect that sales of Feraheme, Intrarosa and the Makena auto-injector will increase for the remainder of 2018 and throughout 2019. In addition, we expect overall Makena net sales to continue to decline due to (i) volume and pricing pressure as a result of current generic competition to Makena, (ii) the expectation of additional generic competitors in the market and (iii) continued manufacturing-related issues. As previously disclosed, we continue to experience delays at our third-party manufacturer, which has resulted in our single-dose vial being out of stock and we expect will result in an out of stock situation

for our multi-dose vial in the near future. We are attempting to mitigate this supply issue by manufacturing at our secondary supplier; however, we anticipate that revenues for the IM products will continue to decrease. We expect that such decline will be partially offset by Makena auto-injector sales. The continued impact of generic competition to our Makena sales is dependent on the timing, number and behavior of current and future generic competitors.

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. The increases in contractual adjustments as a percentage of gross product sales for the three months ended September 30, 2018 as compared to the same period in 2017 primarily related to a higher mix of business through commercial reimbursement channels and additional discounts offered to commercial entities. The decreases in governmental rebates as a percentage of gross product sales for the three months ended September 30, 2018 as compared to the same period in 2017 are primarily related to a shift in the mix of business.

We did not materially adjust our product sales allowances and accruals during the three months ended September 30, 2018 or 2017. 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 September 30, 2018 and 2017 were as follows (in thousands except for percentages):

	Three Months Ended September 30,		2018 to 2017	
	2018	2017	$ Change	% Change
Cost of product sales	$ 46,489	$ 31,085	$ 15,404	50%
Percentage of net product sales	38%	25%		

Amortization of intangible assets related to Makena and Intrarosa comprised $30.9 million and $23.7 million, respectively of the $46.5 million and $31.1 million cost of product sales for the three months ended September 30, 2018 and 2017, respectively. The non-amortization related increase in cost of product sales of $8.2 million was due to a larger portion of product sales from higher cost products as well as royalty obligations related to the Makena auto-injector and Intrarosa products.

We expect our cost of product sales, excluding amortization expense, to increase as a percentage of net product sales for the remainder of 2018 and throughout 2019, due to a shift in our product mix toward products with higher royalty obligations, such as the Makena auto-injector and Intrarosa.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2018 and 2017 consisted of the following (in thousands except for percentages):

	Three Months Ended September 30,		2018 to 2017	
	2018	2017	$ Change	% Change
External research and development expenses				
Feraheme-related costs	$ 1,611	$ (370)	$ 1,981	<(100 %)
Makena-related costs	721	3,616	(2,895)	(80)%
Vyleesi-related costs	1,582	6,516	(4,934)	(76)%
Intrarosa-related costs	1,623	336	1,287	>100 %
Other external costs	101	824	(723)	(88)%
Total	5,638	10,922	(5,284)	(48)%
Internal research and development expenses	4,495	5,352	(857)	(16)%
Total research and development expenses	$ 10,133	$ 16,274	$ (6,141)	(38)%

Total research and development expenses incurred in the three months ended September 30, 2018 decreased by $6.1 million as compared to the same period in 2017. The $4.9 million decrease of Vyleesi-related costs reflects the completion of certain agreed-upon Palatin reimbursement costs incurred in 2017 in preparation for the March 2018 NDA submission, partially offset by increased costs associated with manufacturing process development and the manufacture of drug product for Vyleesi in preparation for potential approval in 2019. Makena-related costs reflect a $2.9 million decline due to the completion of the Makena auto-injector development program in 2017 partially offset by costs incurred in the Makena sub-part H trials. The decreased spend for Vyleesi and Makena was partially offset by a $2.0 million increase in Feraheme-related costs related to an ongoing pediatric study and a $1.3 million increase of costs for the Intrarosa HSDD study in post-menopausal women.

We expect our research and development expenses to increase during the remainder of 2018 and throughout 2019, as we increase our investment to accelerate enrollment in the AMAG-423 clinical trial. We also expect to incur additional costs as we prepare for the Advisory Committee meeting for Vyleesi and continue to invest in Intrarosa development, including the HSDD study. 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 September 30, 2018, we recorded $12.5 million for acquired IPR&D related to the upfront option exercise fee paid to Velo in September 2018 in connection with our acquisition of AMAG-423.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended September 30, 2018 and 2017 consisted of the following (in thousands except for percentages):

	Three Months Ended September 30,		2018 to 2017	
	2018	2017	$ Change	% Change
Compensation, payroll taxes and benefits	$ 34,538	$ 28,177	$ 6,361	23 %
Professional, consulting and other outside services	33,702	29,304	4,398	15 %
Fair value of contingent consideration liability	9	(49,929)	49,938	>(100%)
Equity-based compensation expense	4,202	4,410	(208)	(5)%
Total selling, general and administrative expenses	$ 72,451	$ 11,962	$ 60,489	>100 %

Total selling, general and administrative expenses, excluding the $49.9 million contingent consideration liability expense reversal in the third quarter of 2017, increased by $10.6 million, or approximately 17%, in the three months ended September 30, 2018 as compared to the same period in 2017. This increase included a $6.4 million increase in compensation, payroll taxes and benefits primarily driven by the establishment of our women's health sales force in mid-2017 and related organizational growth, as well as a significant increase in external costs related to the commercialization of Intrarosa.

We expect that total selling, general and administrative expenses will increase for the remainder of 2018 and throughout 2019 as we prepare for the potential launch of Vyleesi, assuming FDA approval in March 2019, and as we continue to invest in Intrarosa.

Impairment of Intangible Assets

There were no impairments of intangible assets for the three months ended September 30, 2018. During the three months ended September 30, 2017, we determined that a revised long-term forecast, resulting from certain information we received in the third quarter of 2017, constituted a triggering event with respect to our Makena base technology intangible asset, which relates solely to the Makena IM product. We determined that as of September 30, 2017, the fair value of the Makena base technology intangible asset was less than the carrying value and accordingly, we recorded an impairment charge of $319.2 million in the third quarter of 2017.

Other Expense, Net

Other expense, net for the three months ended September 30, 2018 increased by $31.0 million compared to the same period in 2017, primarily due to a $35.9 million loss on extinguishment of debt (including a $28.1 million redemption premium) incurred as a result of the early redemption of the 7.875% Senior Notes due 2023 (the "2023 Senior Notes"). The $31.0 million increase was partially offset by a $3.5 million reduction in interest expense in the three months ended September 30, 2018 due primarily to this redemption.

Income Tax Benefit

The following table summarizes our effective tax rate and income tax benefit for the three months ended September 30, 2018 and 2017 (in thousands except for percentages):

	Three Months Ended September 30,	
	2018	2017
Effective tax rate	4%	43%
Income tax benefit	$ (2,352)	$ (115,197)

For the three months ended September 30, 2018, we recognized an income tax benefit of $2.4 million, representing an effective tax rate of 4%. The difference between the 2018 statutory federal tax rate of 21% and the 4% effective tax rate for the three months ended September 30, 2018 was primarily attributable to the valuation allowance established against our current period losses generated, the impact of non-deductible stock compensation and other non-deductible expenses, partially offset by a benefit from contingent consideration, state income taxes and orphan drug credits. We established a valuation allowance on our deferred tax assets other than refundable 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 deferred tax liabilities associated with the CBR business, which was sold during the three months ended September 30, 2018, are no longer expected to be available as a source of income to realize the benefits of our net deferred tax assets.

For the three months ended September 30, 2017, we recognized an income tax benefit of $115.2 million, representing an effective tax rate of 43%. The difference between the expected 2017 statutory federal tax rate of 35% and the 43% effective tax rate for the three months ended September 30, 2017 was primarily attributable to the impact of state income taxes, federal research and development and orphan drug tax credits, and contingent consideration associated with Lumara Health, partially offset by the establishment of a valuation allowance related to certain deferred tax assets. During the three months ended September 30, 2017, we entered into a three-year cumulative loss position and established a valuation allowance on certain deferred tax assets to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets.

The primary drivers of the increase in tax expense for the three months ended September 30, 2018 as compared to the three months ended September 30, 2017 is primarily attributable to an increase in valuation allowance on our current period losses generated and a decrease in the federal tax benefit attributable to the decrease in the statutory federal rate from 35% to 21%, as well as an increase in non-deductible expenses, partially offset by contingent consideration.

Net Income from Discontinued Operations

Net income from discontinued operations was $95.5 million during the third quarter of 2018 as compared to $3.7 million in the same period in 2017. Of the $95.5 million net income from discontinued operations, $89.6 million represented a gain on the sale of the CBR business, which closed on August 6, 2018. For additional information, see Note C, "*Discontinued*

Operations and Held for Sale" to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Results of Operations - Nine Months Ended September 30, 2018 and 2017

Revenues

Total revenues for the nine months ended September 30, 2018 and 2017 consisted of the following (in thousands except for percentages):

	Nine Months Ended September 30,		2018 to 2017	
	2018	2017	$ Change	% Change
Product sales, net				
Makena	$ 275,377	$ 286,771	$ (11,394)	(4)%
Feraheme	99,796	79,492	20,304	26 %
Intrarosa	10,331	360	9,971	>100 %
MuGard	302	567	(265)	(47)%
Total	385,806	367,190	18,616	5 %
Other revenues	75	53	22	42 %
Total revenues	$ 385,881	$ 367,243	$ 18,638	5 %

Net product sales increased by $18.6 million, or approximately 5%, during the nine months ended September 30, 2018 as compared to the same period in 2017, primarily due to a $20.3 million increase in Feraheme net sales following the approval of its expanded label in February 2018 and $10.0 million in Intrarosa net sales, which was launched commercially in July 2017. The increase of total revenues was partially offset by a $11.4 million decrease in Makena net sales, which were impacted by a supply disruption of our IM products and the entry of generic competition.

Product Sales

Total gross product sales were offset by product sales allowances and accruals for the nine months ended September 30, 2018 and 2017 as follows (in thousands, except for percentages):

	Nine Months Ended September 30,				2018 to 2017	
	2018	Percent of gross product sales	2017	Percent of gross product sales	$ Change	% Change
Gross product sales	$ 776,458		$ 676,377		$ 100,081	15%
Provision for product sales allowances and accruals:						
Contractual adjustments	290,896	37%	225,622	33%	65,274	29%
Governmental rebates	99,756	13%	83,565	12%	16,191	19%
Total	390,652	50%	309,187	45%	81,465	26%
Product sales, net	$ 385,806		$ 367,190		$ 18,616	5%

We did not materially adjust our product sales allowances and accruals during the nine months ended September 30, 2018 or 2017.

Costs and Expenses

Cost of Product Sales

Cost of product sales for the nine months ended September 30, 2018 and 2017 were as follows (in thousands except for percentages):

	Nine Months Ended September 30,		2018 to 2017	
	2018	2017	$ Change	% Change
Cost of product sales	$ 187,176	$ 90,761	$ 96,415	>100 %
Percentage of net product sales	49%	25%		

Amortization of intangible assets related to Makena and Intrarosa comprised $144.7 million and $69.6 million, respectively, of the $187.2 million and $90.8 million cost of product sales for the nine months ended September 30, 2018 and 2017, respectively. The non-amortization related increase of $21.3 million in cost of product sales was due to a larger portion of product sales from higher cost products and royalty obligations related to the Makena auto-injector and Intrarosa products.

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2018 and 2017 consisted of the following (in thousands except for percentages):

	Nine Months Ended September 30,		2018 to 2017	
	2018	2017	$ Change	% Change
External research and development expenses				
Feraheme-related costs	$ 3,033	$ 7,046	$ (4,013)	(57)%
Makena-related costs	4,118	10,736	(6,618)	(62)%
Vyleesi-related costs	7,716	26,521	(18,805)	(71)%
Intrarosa-related costs	4,885	498	4,387	>100 %
Other external costs	286	3,516	(3,230)	(92)%
Total	20,038	48,317	(28,279)	(59)%
Internal research and development expenses	12,597	14,704	(2,107)	(14)%
Total research and development expenses	$ 32,635	$ 63,021	$ (30,386)	(48)%

Total research and development expenses incurred in the nine months ended September 30, 2018 decreased by $30.4 million, as compared to the same period in 2017. The $18.8 million decrease in Vyleesi-related costs reflects the completion of certain agreed-upon Palatin reimbursement costs incurred in 2017 in preparation for the March 2018 NDA submission, partially offset by increased costs associated with manufacturing process development and the manufacture of drug product for Vyleesi in preparation for potential approval in 2019. Makena-related costs reflect a $6.6 million decline due to the completion of the Makena auto-injector development program in 2017, partially offset by costs incurred in the Makena sub-part H trials. Feraheme-related costs decreased by $4.0 million due to the completion of the IDA study in 2017, partially offset by costs related to an ongoing pediatric study. The decreased spend for Feraheme, Makena, and Vyleesi was partially offset by an increase of $4.4 million for the Intrarosa HSDD study in post-menopausal women.

Acquired In-Process Research and Development

During the nine months ended September 30, 2018, we recorded $32.5 million for acquired IPR&D related to AMAG-423 and Vyleesi as the respective product candidates had not received regulatory approval. Of the $32.5 million, $12.5 million was paid to Velo in September 2018 as an upfront option exercise fee in connection with our acquisition of AMAG-423 and $20.0 million was paid to Palatin in the second quarter of 2018 related to the milestone obligation associated with the FDA acceptance of the Vyleesi NDA.

During the nine months ended September 30, 2017, we recorded IPR&D expense of $65.8 million primarily related to (a) a $60.0 million one-time upfront payment under the terms of the Palatin License Agreement, which we entered into in February 2017, and which we characterized as acquired IPR&D as the product candidate had not received regulatory approval and (b) $5.8 million, which represented a portion of the $83.5 million of consideration recorded to date under the terms of the Endoceutics License Agreement, based on our determination that the this portion of the total consideration did not have an alternative future use.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the nine months ended September 30, 2018 and 2017 consisted of the following (in thousands except for percentages):

	Nine Months Ended September 30,		2018 to 2017	
	2018	2017	$ Change	% Change
Compensation, payroll taxes and benefits	$ 98,213	$ 72,852	$ 25,361	35%
Professional, consulting and other outside services	100,593	81,736	18,857	23%
Fair value of contingent consideration liability	(49,175)	(47,143)	(2,032)	4%
Equity-based compensation expense	12,149	12,037	112	1%
Total selling, general and administrative expenses	$ 161,780	$ 119,482	$ 42,298	35%

Total selling, general and administrative expenses increased $42.3 million, or approximately 35%, in the nine months ended September 30, 2018 as compared to the same period in 2017 as a result of:

- $25.4 million increase in compensation, payroll taxes and benefits primarily driven by the establishment of our women's health sales force in mid-2017 and related organizational growth; and
- $18.9 million increase in external spending related to Intrarosa and Vyleesi marketing activities and the launches of the expanded Feraheme label and the Makena auto-injector.

In addition, total selling, general and administrative expenses for each of the nine months ended September 30, 2018 and 2017 included a $49.2 million and $47.1 million reversal, respectively, to the fair value of contingent consideration liability primarily due to changes in our estimated Makena revenues and associated milestone payments.

Impairment of Intangible Assets

There were no impairments of intangible assets for the nine months ended September 30, 2018. During the nine months ended September 30, 2017, we determined that a revised long-term forecast, resulting from certain information we received in the third quarter of 2017, constituted a triggering event with respect to our Makena base technology intangible asset, which relates solely to the Makena IM product. We determined that as of September 30, 2017, the fair value of the Makena base technology intangible asset was less than the carrying value and, accordingly, we recorded an impairment charge of $319.2 million in the third quarter of 2017.

Other Expense, Net

Other expense, net for the nine months ended September 30, 2018 increased by $18.1 million compared to the same period in 2017. This increase was primarily driven by a $35.9 million loss on extinguishment of debt (including a $28.1 million redemption premium), incurred during the nine months ended September 30, 2018 as a result of the early redemption of the 2023 Senior Notes, partially offset by a $9.8 million loss on extinguishment of debt in 2017 and a $7.0 million reduction in interest expense in the nine months ended September 30, 2018 due primarily to these redemptions.

Income Tax Expense (Benefit)

The following table summarizes our effective tax rate and income tax expense (benefit) for the nine months ended September 30, 2018 and 2017 (in thousands except for percentages):

	Nine Months Ended September 30,	
	2018	2017
Effective tax rate	(40)%	41%
Income tax expense (benefit)	$ 42,204	$ (145,317)

For the nine months ended September 30, 2018, we recognized an income tax expense of $42.2 million, representing an effective tax rate of (40)%. The difference between the expected 2018 statutory federal tax rate of 21% and the (40)% effective tax rate for the nine months ended September 30, 2018 was primarily attributable to the establishment of a valuation allowance on net deferred tax assets other than refundable AMT credits, the impact of non-deductible stock compensation and other non-deductible expenses, partially offset by a benefit from contingent consideration, state income taxes and orphan drug credits. We have established a valuation allowance on our deferred tax assets other than refundable 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.

Our valuation allowance on our deferred tax assets, other than refundable AMT credits, increased during the nine months ended September 30, 2018 primarily because the deferred tax liabilities associated with the CBR business, which was reclassified to discontinued operations for the nine months ended September 30, 2018, are no longer available as a source of income to realize the benefits of the net deferred tax assets.

For the nine months ended September 30, 2017 we recognized an income tax expense of $145.3 million, representing an effective tax rate of 41%. The difference between the expected 2017 statutory federal tax rate of 35% and the 41% effective tax rate for the nine months ended September 30, 2017 was primarily attributable to the impact of state income taxes, federal research and development and orphan drug tax credits, and contingent consideration associated with Lumara Health, partially offset by the establishment of a valuation allowance related to certain deferred tax assets. During the nine months ended September 30, 2017, we entered into a three-year cumulative loss position and established a valuation allowance on certain deferred tax assets to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets.

The primary drivers of the increase in tax expense for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017 is primarily attributable to an increase in valuation allowance on net deferred tax assets other than refundable AMT credits and a decrease in the federal tax benefit attributable to the decrease in the statutory federal rate from 35% to 21%, as well as an increase in nondeductible expenses, partially offset by contingent consideration.

Net Income from Discontinued Operations

Net income from discontinued operations was $105.1 million for the nine months ended September 30, 2018 as compared to $3.2 million in the same period in 2017. Of the $105.1 million net income from discontinued operations, $89.6 million represented a gain on the sale of the CBR business, which closed on August 6, 2018. For additional information, see Note C, "*Discontinued Operations and Held for Sale*" 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 products. Cash, cash equivalents, marketable securities and certain financial obligations as of September 30, 2018 and December 31, 2017 consisted of the following (in thousands except for percentages):

	September 30, 2018	December 31, 2017	$ Change	% Change
Cash and cash equivalents	$ 287,166	$ 162,855	$ 124,311	76 %
Marketable securities	140,368	136,593	3,775	3 %
Total	$ 427,534	$ 299,448	$ 128,086	43 %
Outstanding principal on 2023 Senior Notes	$ —	$ 475,000	$ (475,000)	(100)%
Outstanding principal on 2022 Convertible Notes	320,000	320,000	—	— %
Outstanding principal on 2019 Convertible Notes	21,417	21,417	—	— %
Total	$ 341,417	$ 816,417	$ (475,000)	(58)%

Cash Flows

The following table presents a summary of our primary sources and uses of cash for the nine months ended September 30, 2018 and 2017 (in thousands):

	September 30, 2018	September 30, 2017	$ Change
Net cash provided by operating activities	$ 84,893	$ 86,648	$ (1,755)
Net cash provided by investing activities	513,136	106,259	406,877
Net cash used in financing activities	(503,138)	(209,238)	(293,900)
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 94,891	$ (16,331)	$ 111,222

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 ending September 30, 2018 compared to September 30, 2017, net cash flows provided by operating activities decreased by $1.8 million, driven primarily by an increase in net income as adjusted for non-cash charges of $13.9 million and an $15.7 million decrease due to changes in operating assets and liabilities. The aforementioned cash flows from operating activities include cash flows from the operating activities of the CBR business, which is 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 and Held for Sale*," of the notes 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 used in investing activities was $513.1 million for the nine months ended September 30, 2018 due to $519.3 million in proceeds from the sale of CBR offset by net purchases of marketable securities of $4.3 million and capital expenditures of $1.9 million. Cash provided by investing activities for the nine months ended September 30, 2017 was $106.3 million due to net proceeds from the sale of marketable securities of $168.6 million, offset by $55.8 million of cash used to purchase the Intrarosa asset and fund capital expenditures of $6.6 million.

Financing Activities

Cash used in financing activities was $503.1 million for the nine months ended September 30, 2018 due to the repayment of the $475.0 million balance of our 2023 Senior Notes and a related redemption premium of $28.1 million. Cash used in financing activities for the nine months ended September 30, 2017 was $209.2 million driven by $328.1 million of principal payments made during 2017 and the full repayment of the remaining balance of our 2015 Term Loan Facility and $191.5 million used for the repurchase of a portion of our 2019 Convertible Notes, partially offset by $310.4 million net proceeds related to the issuance of our 2022 Convertible Notes.

Future Liquidity Considerations

We believe that our cash, cash equivalents and marketable securities as of September 30, 2018, and the cash we expect to receive from sales of our products and earnings on our investments, will be sufficient to satisfy our cash flow needs for the foreseeable future. As we enter 2019 and look to our significant portfolio investment opportunities, we intend to spend more than our expected revenues and will therefore utilize a portion of our $427.5 million of cash and investments. 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. Our expected utilization of cash includes, but is not limited to, the following:

- Costs associated with manufacturing process development and the manufacture of drug product for Vyleesi to support its mid-2019 commercialization, if approved;
- Launch-related commercialization costs for Vyleesi we expect to incur in preparation for the launch and thereafter, if approved;
- A $60.0 million milestone obligation to Palatin conditioned and payable upon FDA approval of Vyleesi;
- Clinical trial costs for AMAG-423;
- Repayment of the $21.4 million outstanding principal balance on our 2019 Convertible Notes in cash in February 2019; and
- Potential business development opportunities.

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 August 2015, in connection with the CBR acquisition, we completed a private placement of $500.0 million aggregate principal amount of 7.875% Senior Notes due 2023 (the "2023 Senior Notes"). In October 2017, we repurchased $25.0 million principal of the 2023 Senior Notes in a privately negotiated transaction with cash on hand. In September 2018, we repurchased the remaining $475.0 million of the 2023 Senior Notes using the proceeds from the CBR sale. For additional information, see Note R, "*Debt,*" to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

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 Q, "*Debt,*" to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. We 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 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 September 30, 2018.

In February 2014, we issued $200.0 million aggregate principal amount of 2.5% convertible senior notes due February 15, 2019 (the "2019 Convertible Notes"). In May 2017 and September 2017, we entered into privately negotiated transactions with certain investors to repurchase approximately $158.9 million and $19.6 million, respectively, aggregate principal amount of the 2019 Convertible Notes for an aggregate repurchase price of approximately $171.3 million and $21.4 million, respectively, including accrued interest, as discussed in more detail in Note R, "*Debt,*" to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. The remaining 2019 Convertible Notes are senior unsecured obligations and bear interest at a rate of 2.5% per year, payable semi-annually in arrears on February 15 and August 15 of each year. The 2019 Convertible Notes will mature on February 15, 2019, unless repurchased or converted earlier. The 2019 Convertible Notes will be convertible into cash, shares of our common stock, or a combination thereof, at our election, at a conversion rate of 36.9079 shares of common stock per $1,000 principal amount of the 2019 Convertible Notes, which corresponds to a conversion price of approximately $27.09 per share of our common stock. The conversion rate is subject to adjustment from time to time. The 2019 Convertible Notes were convertible as of September 30, 2018.

Share Repurchase Program

In January 2016, we announced that our Board authorized a program to repurchase up to $60.0 million in shares of our common stock. The repurchase program does not have an expiration date and may be suspended for periods or discontinued at any time. Under the program, we may purchase our stock from time to time at the discretion of management in the open market

or in privately negotiated transactions. The number of shares repurchased and the timing of the purchases will depend on a number of factors, including share price, trading volume and general market conditions, along with working capital requirements, general business conditions and other factors. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate purchases of our shares under this program. As of September 30, 2018, we repurchased and retired a cumulative total of 2,198,010 shares of common stock under this repurchase program for $39.5 million at an average purchase price of $17.97 per share. As of September 30, 2018, $20.5 million remains available for the repurchase of shares under the program. We did not repurchase any of our common stock during the first three quarters of 2018.

Off-Balance Sheet Arrangements

As of September 30, 2018, 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 S, "*Recently Issued and Proposed Accounting Pronouncements*," and Note T, "*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 September 30, 2018 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings:

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

Item 1A. Risk Factors:

With the exception of the risk factors 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 a supply disruption 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 a generic competitor has entered the market. Although we recently launched our own authorized generic presentation of Makena to mitigate the anticipated 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 Makena auto-injector, which was approved for commercialization in February 2018, and which is intended to provide us with an alternative treatment method to 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 our own authorized generic of the Makena IM product. We may not be able 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 lack of improvement in 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. If we do not convert a sufficient number of patients to the auto-injector product, we could lose a significant amount of our Makena revenue and market share to generic competitors.

In addition, we have lost and could lose additional market share if we are unable to deliver sufficient quantities of Makena 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 our single-dose vial being out of stock and we expect will result in an out of stock situation for our multi-dose vial in the near future. Although we are attempting to mitigate this supply issue by manufacturing at our secondary supplier, we can make no guarantees that additional supply will be available in a timely manner and we anticipate that our revenues for the IM products could continue to be adversely impacted. We are currently working with healthcare providers, distribution partners and our manufacturers to minimize the impact of the current supply disruption of the IM products by encouraging new patient starts on the auto-injector. However, due to increased demand of the auto-injector product we could face supply issues for that product as well. Further, although we recently secured approval for a supplier for Makena API, we continue to work to secure a secondary source API supplier, which has experienced and may continue to experience approval delays. 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, LLC ("Prasco") for our successful commercialization of our own generic formulation. We have limited experience working with a generic vendor and Prasco may not be able to continue to enter into contracts with retail and specialty pharmacies or distributors on favorable terms, or at all. In addition, we are responsible for supplying product to Prasco, and if we continue to experience problems with our supply chain, revenues with respect to our authorized generic formulation of Makena IM product could be adversely affected and we could be subject to certain penalties, which could be substantial.

If we and Prasco are not able to capture 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 products or if we become unable to meet commercial demand for our Makena auto-injector or authorized generic, our Makena revenues could be materially and adversely affected and, ultimately, could negatively impact our stock price and results of operations.

We have limited experience with development stage products and cannot ensure that we will be successful in gaining approval of our product candidates, including Vyleesi and AMAG-423, on a timely basis, or at all, or that such approvals, if obtained, will not contain restrictions that the FDA may impose on the use or distribution of such product candidates or that we will be successful in commercializing our product candidates.

Our long-term success and revenue growth depends upon our ability to continue to successfully develop new products. Drug development is inherently risky and the U.S. Food and Drug Administration (the "FDA") imposes substantial requirements on the development of such candidates to become eligible for marketing approval. The FDA has substantial discretion in the approval process and may decide that our data is insufficient for approval. Clinical data is often susceptible to varying interpretations, and many companies in the pharmaceutical and biotechnology industries that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products. The FDA could also determine that our manufacturing processes are not properly designed, are not conducted in accordance with federal laws or otherwise not properly managed. If we do not obtain FDA approval for our product candidates, including Vyleesi or AMAG-423, as discussed below, or if we experience significant delays or setbacks in obtaining approval, our ability to grow our business and leverage our product portfolio and the future prospects of our business could be materially adversely affected.

In January 2017, we acquired an exclusive license from Palatin to research, develop and commercialize Vyleesi in North America. During 2016, Palatin completed two Phase 3 clinical trials to treat HSDD in pre-menopausal women. The trials consisted of double-blind placebo-controlled, randomized parallel group studies comparing a subcutaneous dose of 1.75 mg Vyleesi versus placebo, in each case, delivered via an auto-injector. In both clinical trials, Vyleesi met the pre-specified co-primary efficacy endpoints of median improvement in desire and decrease in distress associated with low sexual desire as measured using validated patient-reported outcome instruments; however, the change in the number of satisfying sexual events, the key secondary endpoint, was not significantly different from placebo in either clinical trial. The most frequent adverse events were nausea, flushing and headache, which were generally mild-to-moderate in severity. Approximately 18% of patients discontinued participation in the Vyleesi arm due to adverse events in both studies. In June 2018, the FDA accepted our NDA for Vyleesi, which has a PDUFA date of March 23, 2019 and we expect an Advisory Committee meeting for Vyleesi to be held in January 2019. Advisory Committee decisions are not binding, but an adverse decision at the advisory committee may have a negative impact on the outcome of the regulatory review of Vyleesi. In addition, if the Advisory Committee reports a negative recommendation in its briefing package to the FDA, which is publicly available, our stock could be adversely impacted.

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

- The FDA may determine that Vyleesi does not demonstrate safety and efficacy in accordance with regulatory agency standards based on the results of the Phase 3 trials, including the co-primary and secondary endpoints and safety results;
- The FDA may determine that the magnitude of efficacy demonstrated in the Vyleesi studies does not amount to a clinically meaningful benefit to pre-menopausal women with HSDD and thus that the product cannot be approved despite statistically significant efficacy results;
- The FDA could analyze and/or interpret data from preclinical testing and clinical trials in different ways than we or Palatin interpret them;
- The auto-injector device that we plan to use to administer Vyleesi may not be adequate or may not be considered adequate by the FDA;
- We may be unable to establish, and obtain FDA approval for, a commercially viable manufacturing process for Vyleesi in a timely manner, or at all;
- Adverse medical events reported during the trials, including increases in blood pressure noted in prior clinical trials and a serious adverse event of hepatitis of unknown etiology;
- The failure of clinical investigational sites and the records kept at such sites, including the clinical trial data, to be in compliance with the FDA's current good clinical practices regulations ("cGCP"), including the failure to pass FDA inspections of clinical trial sites; and
- The FDA may change their approval policies or adopt new regulations.

Additionally, in September 2018, we exercised our option to acquire the global rights to develop and market digoxin immune Fab (ovine), a polyclonal antibody in development for the treatment of severe preeclampsia in pregnant women, pursuant to an option agreement entered into in July 2015 agreement 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 acquisition, we have taken over a 200 patient multi-center, randomized, double-blind, placebo-controlled, parallel-group Phase 2b/3a trial, which was initiated by Velo in July 2017. The approval of AMAG-423 for commercial sale in the U.S. could be delayed, limited or denied or we may be required to conduct additional studies for a number of reasons, including:

- The Phase 2b/3a trial may produce negative or inconclusive results or may not demonstrate to the FDA's satisfaction that AMAG-423 is safe and effective, particularly in light of the limited amount of data to date demonstrating that AMAG-423 effectively treats severe preeclampsia in this patient population;
- Slower than expected rate of patient enrollment, particularly since only 26 patients have been enrolled to date, which could continue as a result of any number of factors, including failure of our third-party vendors, including our CROs, to effectively perform their obligations to us in a timely manner, a lack of patients who meet the enrollment

criteria, our inability to establish sufficient trial sites, including outside of the U.S., in a timely manner, or our inability to secure sufficient supply of drug product to meet the accelerated clinical timeline;

- There is no FDA approved treatment for severe preeclampsia and there is not an established regulatory pathway, which may increase the uncertainty and risk of approval;
- The size of the patient population required to establish efficacy to the satisfaction of the FDA may be larger than we anticipated;
- Adverse medical events reported during the trials;
- The supply or quality of AMAG-423 for our clinical trial needs may be insufficient, inadequate or delayed; and
- FDA may not deem our third party manufacturers' processes or facilities adequate for approval.

Furthermore, the degree of protection afforded by any intellectual property related to AMAG-423 may not enable us to protect or commercially exploit AMAG-423, providing us with little or no competitive advantage. For example, digoxin immune FAB (ovine) has been approved and marketed in the U.S. for many years and accordingly, no longer has composition of matter patent protection. We do have four issued U.S. patents covering methods of using AMAG-423 to treat women exhibiting symptoms of preeclampsia or eclampsia, each of which expires in November 2022. If possible, we plan to seek additional patent protection for AMAG-423 through additional patent applications; however, we may not be able to obtain additional patent protection that would provide us with a competitive advantage.

Further, AMAG-423 has received Orphan Drug designation from the FDA. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, defined, in part, as a patient population of fewer than 200,000. The company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. We cannot guarantee that our clinical data or other information that we generate or submit will be adequate for AMAG-423 to receive new orphan drug exclusivity. Even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, orphan drug exclusivity marketing rights may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. If we do not receive Orphan Drug designation, or if the FDA approves another drug for the same indication, we may have limited market exclusivity.

Any failure or delay in obtaining regulatory approval for Vyleesi or AMAG-423 could adversely affect our ability to successfully commercialize such products. In addition, share prices have declined significantly in certain instances where companies have failed to obtain FDA approval of a product or where the timing of FDA approval is delayed. If we are required to conduct additional studies, our share price could decline significantly. Further, the market for products that address unmet medical needs is highly speculative and if we have over-estimated the market opportunity for any of our products or product candidates, or if we are unsuccessful in gaining market share, then our business and results of operations could be materially and adversely affected.

Even if regulatory approval to market Vyleesi or AMAG-423 is granted by the FDA, the approvals may impose limitations on the indicated use for which the drug product may be marketed and additional post-approval requirements with which we and, in the case of Vyleesi, Palatin would need to comply in order to maintain approval of Vyleesi or AMAG-423. Our business could be seriously harmed if we and/or Palatin do not complete any post-approval requirements and the FDA, as a result, requires us to change sections of the labeling.

The manufacture of AMAG-423 involves a complicated and time-consuming process with limited manufacturers.

AMAG-423 is a polyclonal antibody that is produced through a time intensive, complex process in which immunogens consisting of an analog of digoxin medication are produced in a laboratory and used to immunize sheep, which then produce certain antibodies. These antibodies are collected, separated, purified, and formulated into digoxin immune Fab (ovine). There is currently only one third-party that can manufacture AMAG-423, which utilizes its own flock of sheep located solely in Australia for the production of the antibodies used to produce AMAG-423. We currently do not have commercial supply agreements to manufacture AMAG-423 and may not be able to enter into such agreements on acceptable terms, if at all. In addition, even if we enter into such agreements, since there would only be one source of supply, if there are any disruptions to

any part of the supply chain process, including the ability to obtain certain raw materials or any issues with the sheep used to produce the antibodies, such as diseases or natural disasters, our ability to complete the Phase 2b/3a trial or commercialize AMAG-423, if approved, would be adversely affected.

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

The following table provides certain information with respect to our purchases of shares of our stock during the three months ended September 30, 2018.

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]
July 1, 2018 through July 31, 2018	6,791	$ 19.93	—	929,998
August 1, 2018 through August 31, 2018	2,742	24.72	—	840,428
September 1, 2018 through September 30, 2018	2,951	22.33	—	1,025,322
Total	12,484	$ 21.55	—	

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

(2) We did not repurchase any of our common stock during the third quarter of 2018. We have repurchased and retired $39.5 million of our common stock under our share repurchase program through September 30, 2018. These shares were purchased pursuant to a repurchase program authorized by our Board that was announced in January 2016 to repurchase up to $60.0 million of our common stock, of which $20.5 million remains authorized for repurchase as of September 30, 2018. 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+	Contract Manufacturing Agreement, dated September 1, 2018, by and between AMAG Pharmaceuticals, Inc. and Fresenius Kabi Austria GmbH (Certain confidential information contained in this exhibit was omitted by means of redacting a portion of the text and replacing it with [***]. This exhibit has been filed separately with the SEC without any redactions pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended)
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.

SIGNATURES

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

AMAG PHARMACEUTICALS, INC.

By: /s/ William K. Heiden

William K. Heiden

President and Chief Executive Officer
(Principal Executive Officer)

Date: November 2, 2018

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: November 2, 2018

Execution Version

CONTRACT MANUFACTURING AGREEMENT

This Contract Manufacturing Agreement is made by and between (1) Fresenius Kabi Austria GmbH, having its registered office at Hafnerstrasse 36, A-8055 Graz, Austria ("**FRESENIUS**") and (2) AMAG Pharmaceuticals, Inc., a Delaware corporation having an office at 1100 Winter Street, Waltham, MA 02451, U.S.A. ("**COMPANY**"), effective as of September 1, 2018 (the "**Effective Date**").

Recitals

(A) WHEREAS, COMPANY holds or is seeking the marketing authorisation of the Product (as defined herein).

(B) WHEREAS, COMPANY desires to engage FRESENIUS for the manufacture and supply of the Product which is intended for commercial use.

(C) WHEREAS, FRESENIUS desires to manufacture such Product and supply it to COMPANY.

(D) WHEREAS, the Parties have agreed to enter into this Agreement to set forth the terms and conditions on which the manufacture and supply of any particular Product under a Product Schedule (as defined herein) will be carried out.

NOW, THEREFORE, the Parties hereto agree as follows:

1. Definitions

1.1 "**Affiliate**" shall mean any company, corporation, partnership, joint venture and/or firm which, directly or indirectly, controls or is controlled by or is under common control with a Party. As used in the definition of "Affiliate", "control" means (a) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote for the election of directors (or such lesser percentage that is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction), and (b) in the case of non-corporate entities, the direct or indirect power to manage, direct or cause the direction of the management and policies of the non-corporate entity or the power to elect more than fifty percent (50%) of the members of the governing body of such non-corporate entity.

1.2 "**Agreement**" means this Contract Manufacturing Agreement, together with all Appendices attached hereto, as amended from time to time by the Parties in accordance with Section 26.1, and all fully signed Product Schedules.

1.3 [***].

1.4 "**Applicable Laws**" means the applicable laws, statutes, rules, codes, regulations, orders, judgments and/or ordinances of any Authority related to granting approvals for, or the performance of Services under this Agreement, and/or registration, approval, and/or use of Product in Austria, the European Union, and the United States, as may be in effect from time to time or as any of the same may be amended from time to time, including GMP.

1.5 "**Authority**" means any government regulatory authority responsible for granting approvals for the performance of Services under this Agreement or for issuing regulations pertaining to the Manufacture and/or use of Product in the intended country of use, including the FDA.

1.6 "**Average Yield**" has the meaning set forth in Part C.7 of the applicable Product Schedule.

1.7 "**Background Intellectual Property**" means any and all Intellectual Property of a Party, which, as demonstrated by admissible evidence, (i) already existed as of the Effective Date of this Agreement or (ii) was developed or obtained by or on behalf of such Party independent of this Agreement, and without reliance upon the Confidential Information of the other Party.

1.8 "**Batch**" means a specific quantity of Product that is produced during one instance of Manufacture in accordance with the instructions in the applicable MBR, and which Batch of Product is intended to satisfy Specifications.

1.9 "**Batch Documentation**" has the meaning set forth in Section 16.2.

1.10 "Business Day" means a day other than Saturday or Sunday or a day that is not a public holiday in the jurisdiction in which COMPANY and/or FRESENIUS are located or a day that is not in the shutdown times at FRESENIUS which COMPANY has been notified of at least [***] in advance of such shutdown.

1.11 "**Certificate of Analysis**" means a document signed by an authorized representative of FRESENIUS, describing Specifications for the Product, and the results of testing of the Batch.

1.12 "**Certificate of Conformity**" means a document signed by an authorized representative of FRESENIUS, certifying that a particular Batch was Manufactured in accordance with GMP, this Agreement, and all other requirements of the applicable Quality Agreement.

1.13 "**Change Of Control**" means any transaction or series of related transactions involving: (i) the sale, lease, or transfer of all or substantially all of the assets of the COMPANY to any third party; (ii) any merger or consolidation of the COMPANY into or with another person or entity that is a third party (other than a merger or consolidation effected exclusively to change the COMPANY's domicile or solely for internal restructuring purposes), or any other corporate reorganization, in each case following which the COMPANY is not the surviving or successor entity and the stockholders of the COMPANY in their capacity as such immediately prior to such merger, consolidation or reorganization, own less than a majority of the surviving or successor entity's outstanding voting power; or (iii) any sale or other transfer by the stockholders of the COMPANY of shares representing at least a majority of the COMPANY's then-total outstanding combined voting power. As used in this definition of "Change Of Control", "third party" means an entity other than an Affiliate of COMPANY.

1.14 "**Change Order**" has the meaning in Section 8.

1.15 "**Confidential Information**" means any and all non-public information (a) furnished or disclosed by or on behalf of one Party ("**Disclosing Party**") to the other Party ("**Receiving Party**") or (b) developed by a Party via the use of Confidential Information under this Agreement or generated in the performance of this Agreement, in either case whether marked "confidential" or not, whether in oral, visual, electronic, written or any other form

including, but not limited to, financial data, trade secrets, know-how, forecasts, marketing plans, strategies, inventions, ideas, formulas, processes, test data, procedures, formulations and specifications, and all of those portions of notes, compilations, summaries, memoranda or other documents prepared by the Receiving Party which contain, reflect or are otherwise derived from the before mentioned information as well as any copies thereof and of the before mentioned information.

1.16 "**Effective Date**" has the meaning set forth above.

1.17 "**Facility**" means the facility(ies) of FRESENIUS identified in the applicable Product Schedule and any additional facilities to be used for Manufacture of Product as identified in the applicable Quality Agreement.

1.18 "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

1.19 [***].

1.20 "**Fixed Price Term**" means the term for which the Price specified in the relevant Product Schedule will remain fixed, as specified in Part C.3 of the relevant Product Schedule.

1.21 "**Force Majeure**" has the meaning in Section 25.

1.22 "**Forecast**" has the meaning set forth in Section 5.1.

1.23 "**GMP**" means current good manufacturing practices, rules, regulations and guidelines specified in applicable European Union and Pharmaceutical Inspection Convention and Co-Operating Scheme (PIC/S) directives (and the corresponding national laws and regulations), in the United States Code of Federal Regulations, and in any other applicable laws, rules and regulations and guidelines.

1.24 "**Intellectual Property**" means all know-how, copyrights, trademarks, patents, trade secrets, designs, information, documentation, drawings, methods, techniques, data, regulatory submissions, specifications, and other intellectual property of any kind (whether or not protected under patent, trademark, copyright or similar jaws).

1.25 "**Invoice Currency**" means the currency in which each Product will be invoiced and paid, as specified in Part C.2 of the relevant Product Schedule.

1.26 "**Loss(es)**" shall mean any and all liabilities, costs, damages and expenses, including [***].

1.27 "**Manufacturing Activities**", "**Manufacture**", "**Manufactured**", or "**Manufacturing**" means any steps, processes and activities necessary for production by FRESENIUS of Product including the manufacturing, processing, packaging, labelling, quality control testing, stability testing, release, storage or supply of Product as required by the applicable Product Schedule, this Agreement, the MBR, and the applicable Quality Agreement.

1.28 "**Manufacturing Process**" means any and all procedures and activities (or any step in any procedure or activity) (a) planned to be used by FRESENIUS to Manufacture Product, as

evidenced in the MBR or (b) actually used by FRESENIUS, as evidenced in the Batch Documentation the particular Batch.

1.29 "**MBR**" means the version-controlled complete detailed instructions agreed to in writing by the Parties for the Manufacturing Process to be used to Manufacture a Batch of the applicable Product, which may be modified or changed only in accordance with the applicable Quality Agreement.

1.30 "**Minimum Order Quantities**" means the minimum quantity of primary packaging materials that a Designated Supplier (as defined in Section 14.1) will sell per order.

1.31 "**Parties**" means FRESENIUS and COMPANY. "Party" shall mean either FRESENIUS or COMPANY as the context indicates.

1.32 "**Price**" means, with respect to the Product, the amount payable for such Product as specified in Part C.1 of the relevant Product Schedule, subject to adjustment as set forth in such Product Schedule.

1.33 "**Product(s)**" means, with respect to a Product Schedule, the final form of the product including if applicable Supplied Materials, to be supplied pursuant to and as detailed in Part A of such Product Schedule.

1.34 "**Product Schedule**" means a schedule for supply of Product that is executed and delivered by the Parties in accordance with Section 4.

1.35 "**Product Schedule Effective Date**" means, with respect to each Product Schedule, the date on which such Product Schedule becomes effective, as set forth in such Product Schedule.

1.36 "**Purchase Order**" means a binding order issued by COMPANY pursuant to this Agreement substantially in the form identified in Exhibit 2 for such quantities of a Product as COMPANY desires to purchase from FRESENIUS in accordance with the terms of this Agreement stating, amongst others, purchase order number, COMPANY product code, COMPANY product name, quantities, Prices, desired delivery date and address.

1.37 "**Quality Agreement**" means a quality agreement(s) entered into by the Parties, as it may be amended from time to time by the Parties in accordance with its terms, containing quality assurance responsibilities for Product.

1.38 "**Records**" have the meaning set forth in Section 9.1.

1.39 "**Services**" means the services to be performed by FRESENIUS under this Agreement.

1.40 "**Specification(s)**" means (a) with respect to each Product Schedule, the specifications for such Product, as specified in Part A of such Product Schedule and/or the applicable Quality Agreement as the same may be updated from time to time in accordance with this Agreement and the respective Quality Agreement.

1.41 "**Supplied Materials**" has the meaning set forth in Section 15.1.

1.42 "**Territory**" means all countries or regions in which a commercial sale of the applicable Product is intended to take place as listed in Part A.3 of the relevant Product Schedule.

2. General.

2.1 Performance of Services. FRESENIUS will perform Services in accordance with this Agreement, the applicable Quality Agreement, the applicable Product Schedule and all Applicable Laws, including GMP. FRESENIUS will perform all Services at the Facility, provide all staff and equipment necessary to perform the Services in accordance with this Agreement, and hold at such Facility all equipment, Supplied Materials and other items used in the Services. FRESENIUS will supply, in accordance with the relevant approved raw material specifications as identified in the applicable Quality Agreement, all materials to be used by FRESENIUS in the performance of Services other than the Supplied Materials.

2.2 Facility Requirements. FRESENIUS will not change the location of such Facility or use any additional facility for the performance of Services under this Agreement without prior written notice to, and prior written consent from, COMPANY. FRESENIUS will maintain, at its own expense, the Facility and all equipment required for the Manufacture of Product in a state of repair and operating efficiency consistent with the requirements of GMP and all Applicable Laws, and FRESENIUS Standard Operating Procedures ("**SOPs**"). FRESENIUS will notify COMPANY of any proposed changes to the Facility, its utilities, layout or other matters that may impact the Product in accordance with the requirements of the applicable Quality Agreement.

2.3 Validation. FRESENIUS will be responsible for performing all validation of the Facility, equipment and cleaning and maintenance processes employed in the Manufacturing Process as set forth in the Quality Agreement and if not identified therein in accordance with GMP, FRESENIUS' SOPs, and Applicable Laws.

2.4 Changes to Laws. If there are any material changes in GMP or Applicable Laws enacted after the execution of a Product Schedule that impact the Manufacture of such Product, and such changes are specific to the Product and not of general requirement for contract manufacturing services and [***], then FRESENIUS will promptly provide written notice to COMPANY documenting such change and [***], and the Parties shall in good faith discuss and negotiate ways to continue the Manufacture of Product overcoming [***] and the possibility of a Change Order. In the event the Parties are unable to reach a mutually agreeable arrangement within [***], FRESENIUS may terminate this Agreement by providing COMPANY with written notice of its intent to terminate, with a notice period of [***], beginning with the date such notice is delivered to COMPANY.

2.5 Subcontracting. FRESENIUS may not subcontract with any third party or any Affiliate of FRESENIUS, to perform any of its obligations under this Agreement without the prior written consent of COMPANY. Such consent shall be deemed given for such third party performing certain Services if such subcontractor is specified in the applicable Quality Agreement as providing such Services. FRESENIUS will be solely responsible for the performance of any permitted subcontractor, and liability arising out of such performance as if such performance had been provided by FRESENIUS itself under this Agreement. FRESENIUS will cause any such permitted subcontractor to be bound by, and to comply with, the terms of this

Agreement, as applicable, including all confidentiality, quality assurance, regulatory and other obligations and requirements of, FRESENIUS set forth in this Agreement.

2.6 Duty to Notify. FRESENIUS will promptly notify COMPANY if, at any time during the term of this Agreement, FRESENIUS has reason to believe that it will be unable to perform or complete the Services in a timely manner. Compliance by FRESENIUS with this Section will not relieve FRESENIUS of any other obligation or liability under this Agreement.

2.7 Ownership of Materials. COMPANY will at all times retain title to and ownership of the Supplied Materials, Product, any intermediates and components of Supplied Materials or Product, and any work in process at each and every stage of the Manufacturing Process, with the exception of packaging material and other materials which are procured by FRESENIUS. Title to and ownership of the FRESENIUS procured materials will be transferred to COMPANY upon delivery of Product to COMPANY. FRESENIUS will provide within the Facility an area or areas where such materials and any work in process are segregated and stored in accordance with the Specifications and GMP, and in such a way as to be able at all times to clearly distinguish such materials from products and materials belonging to FRESENIUS, or held by it for any other party's account. FRESENIUS will ensure that Supplied Materials, Product, any intermediates and components of any Supplied Materials or Product, and any work in process are free and clear of any liens or encumbrances. FRESENIUS will protect such materials from loss, damage and theft at all stages of the Manufacturing Process, and immediately notifies COMPANY if at any time it believes any such materials have been damaged, lost or stolen.

3. Engagement of FRESENIUS.

3.1 Manufacture of Product. FRESENIUS will Manufacture and sell Product to COMPANY in accordance with the terms of this Agreement and upon terms consistent with any confirmed Purchase Order pursuant to Section 6.2.

4. Product Schedules.

4.1 The Parties shall enter into a Product Schedule (substantially in the form of Exhibit 1) for each Product that is or may be the subject of a marketing authorization of an Authority that is to be manufactured and supplied subject to the terms and conditions of this Agreement.

4.2 Any number of Product Schedules may be executed pursuant to this Agreement. Each Product Schedule will govern the supply of the Product set forth therein.

4.3 Each Product Schedule will operate for the term specified in that Product Schedule unless earlier terminated in accordance with Section 23 of this Agreement.

5. Forecasting; Minimum purchase quantity; Delivery.

5.1 For every Product Schedule, [***] when such Product Schedule remains in effect, COMPANY shall submit to FRESENIUS a rolling forecast covering each product code set forth in such Product Schedule for COMPANY's good faith estimate of the quantity of the relevant Product it expects to order from FRESENIUS pursuant to such Product Schedule for the time period of the following [***], broken down on a [***] basis, (each such estimate, a "**Forecast**"). The first [***] of each Forecast shall be binding to COMPANY (the "**Binding**

Forecast"). The Binding Forecasts can only be changed with FRESENIUS written consent. The following [***] after the Binding Forecast period shall be semi-binding on COMPANY, meaning COMPANY may order [***] of the forecasted quantity of Product in such portion of the Forecast (the "**Semi-Binding Forecast**") without FRESENIUS' prior written consent. The subsequent [***] of each Forecast are estimations and shall be used by FRESENIUS for planning purposes only.

5.2 In addition, COMPANY shall submit to FRESENIUS [***] for every Product Schedule in effect a non-binding to [***] Forecast for planning purposes only.

5.3 Primary packaging materials (as described in the applicable Quality Agreement) used to manufacture the Products can be purchased by FRESENIUS based on [***] rolling forecast figures pursuant to Section 5.1. [***] shall bear all costs of such materials if they expire, including reasonable scrapping costs of the materials if primary packaging materials in stock expire during the term of this Agreement due to [***]. For the avoidance of doubt, any Minimum Order Quantities shall be specified in the applicable Product Schedule. FRESENIUS is responsible for maintaining a sufficient inventory of materials in order to meet its obligations under this Agreement, including the Forecasts, and such materials will be used in a first-expiry, first out (FEFO) basis.

5.4 Concerning Product under the Semi-Binding Forecast and Binding Forecasts: if the quantity of Product ordered by COMPANY pursuant to Purchase Orders submitted to FRESENIUS is (a) less than the quantity forecasted in the Binding Forecast for such period, or (b) less than [***] of the quantity forecasted in the Semi-Binding Forecast for such period, then COMPANY shall pay FRESENIUS the compensation specified in Part C.6 of the relevant Product Schedule for such shortfall. For avoidance of doubt, if (x) as set forth in Section 5.1, FRESENIUS provides its written consent to a change in the Binding Forecast, or (y) FRESENIUS is unable to supply the quantity of Product under any Purchase Order that is consistent with the Binding Forecast, FRESENIUS shall not be entitled to such compensation, unless agreed to by COMPANY in a signed writing.

5.5 Subject to Section 2.6, based on the analysis of Forecasts it receives from COMPANY, FRESENIUS undertakes to inform COMPANY within [***] of receipt of the Forecast of any significant unavailability of capacity it might face in fulfilling COMPANY's needs.

5.6 COMPANY guarantees to purchase and pay a minimum purchase quantity of Product as stated in the relevant Product Schedule under Part B.5. If COMPANY does not purchase the minimum purchase quantity, FRESENIUS is entitled to compensation as defined in Part B.5 to the relevant Product Schedule.

5.7 The delivery terms for Product are specified in Part B.1 of the relevant Product Schedule.

5.8 The packaging and labelling requirements are specified in Part B.3 of the relevant Product Schedule.

5.9 Notwithstanding any terms and conditions in a Product Schedule or this Agreement that obligate COMPANY to purchase a minimum quantity of Product, and pay compensation to FRESENIUS for a failure to purchase such quantities, such purchase obligations and compensation that would otherwise be due from COMPANY will be reduced [***] for Product

quantities affected by the events set forth in Sections 5.9(a)-(e) below, if COMPANY cannot fulfil its minimum purchase quantity obligations [***] due to:

(a)[***];

(b)[***];

(c)[***];

(d)[***];

(e)[***].

6. Orders.

6.1 COMPANY shall submit to FRESENIUS Purchase Orders for its planned requirements of Product under each Product Schedule not less than [***] prior to the required delivery date of the Product. Each Purchase Order shall detail COMPANY's purchase order number, FRESENIUS' product codes, and FRESENIUS product names for the Product, as specified in the applicable Product Schedule, as well as the delivery date and required quantities per delivery date. Each Purchase Order shall also include the shipping and invoice address of COMPANY.

6.2 All Purchase Orders shall be in writing and be transmitted by facsimile or by email. Each Purchase Order submitted to FRESENIUS by COMPANY that conforms to the requirements of this Agreement, the applicable Product Schedule, and the applicable Forecast shall be confirmed [***] in writing by FRESENIUS at the latest [***] after receipt of each such Purchase Order; provided, that, (i) Purchase Orders are for Product within the Binding Forecast and (ii) FRESENIUS [***] shall act in good faith and use [***] to accept and fulfil any other Purchase Order that is consistent with the Forecast except if FRESENIUS has notified COMPANY of (a) its inability to supply the quantity of Product under Purchase Orders consistent with the Binding Forecast in accordance with Section 5.5 or 25, or (b) an uncured material breach by COMPANY. Each Purchase Order issued by COMPANY pursuant to this Agreement will be subject to the terms of this Agreement and will be incorporated herein and form part of this Agreement.

6.3 Confirmed Purchase Orders can only be changed by a mutual written agreement of both Parties. Unless otherwise agreed by the Parties, each Purchase Order shall specify one delivery date for all Batches ordered thereunder. Notwithstanding the foregoing, delivered quantities of Product [***] consistent with the Average Yield set forth in Part C.7 of the applicable Product Schedule. In this event, [***] only the quantities of Product delivered by FRESENIUS to COMPANY are payable by COMPANY.

6.4 Product ordered pursuant to confirmed Purchase Orders will be delivered [***] unless otherwise mutually agreed by the Parties in writing, Product shall be delivered at the latest within [***] of the delivery date specified by COMPANY in any Purchase Order that is consistent with the Forecast and Section 6.1.

7. Quality.

7.1 The Product shall satisfy the Specifications. The Parties shall comply with the provisions and requirements of the relevant Quality Agreement.

7.2 Each Party shall maintain governmental permits, licenses and approvals enabling such Party to perform its obligations under this Agreement.

7.3 FRESENIUS shall maintain, at its own expense, governmental permits and licenses for the Facility enabling it to perform its obligations under this Agreement. At COMPANY's request, FRESENIUS will provide COMPANY with copies of all such permits and licenses, COMPANY will have the right to use any and all information contained in such governmental permits and licenses, in connection with regulatory approval of Product.

7.4 Further quality relevant issues and the allocation of the responsibilities are listed in the applicable Quality Agreement. The Parties shall comply with the provisions of the applicable Quality Agreement. If there are any direct conflicts between the terms of the applicable Quality Agreement and this Agreement, the provisions in this Agreement shall govern, except that if there is a conflict between this Agreement and the applicable Quality Agreement related to quality matters, the Quality Agreement will prevail.

8 Unless and until otherwise agreed by the Parties by entering into a new or additional Quality Agreement or otherwise amending the Quality Agreement, the Quality Agreement for Product that is supplied under a Product Schedule will apply to all Products delivered by FRESENIUS to COMPANY under all Product Schedules. If changes to the Specifications or the Quality Agreement are necessary and such changes would materially increase or reduce the costs for FRESENIUS, as documented and reasonably demonstrated to COMPANY, the Parties shall negotiate in good faith a Change Order to modify the Price of the effected Product as well as the fees payable. Changes, Manufacturing Process and Specifications.

8.1 Changes. If a required modification to this Agreement, or a Product Schedule, or the Quality Agreement is identified by a Party including as a result of a change in GMP as described in Section 2.4, the identifying Party will notify the other Party in writing as soon as reasonably possible, and FRESENIUS will provide COMPANY with a change order ("**Change Order**") containing a description of the required modifications and their effect on the scope, fees, costs and timelines of this Agreement, or Product Schedule or Quality Agreement, as applicable, and will use reasonable efforts to do so within [***] of receiving or providing such notice, as the case may be. No Change Order will be effective unless and until it has been signed by authorized representatives of both Parties.

8.2 Process/Specifications Changes. No change or modification to the Manufacturing Process or Specifications for any Product will be made by FRESENIUS unless approved in advance in writing signed by COMPANY and made in accordance with the change control provisions of the applicable Quality Agreement.

9. Record and Sample Retention.

9.1 Records. FRESENIUS will keep complete and accurate records of Batch Documentation of Product and/or other documents related to the Manufacturing Process of Product as required by Applicable Laws, the applicable Quality Agreement, and this Agreement (collectively, the "**Records**"). All Records will be the property of COMPANY and, except as

required by Applicable Laws or to meet its obligations under this Agreement, will not be transferred, delivered or otherwise provided to any party other than COMPANY, without the prior written approval of COMPANY. FRESENIUS will retain Records in accordance with the FRESENIUS SOPs for records retention, the Quality Agreement, and Applicable Laws. COMPANY may require FRESENIUS to provide such Records after the retention period ends. In such case, COMPANY shall inform FRESENIUS in writing at least [***] prior to end of the respective retention period. FRESENIUS shall make the Records available to COMPANY for inspection or copying upon COMPANY's reasonable request or during audits by COMPANY. For the avoidance of doubt, nothing in this Section 9.1 is intended to alter or affect the parties' respective rights pursuant to Section 20.2(b) below.

9.2 Samples.

(a) Retained Samples. FRESENIUS will take and retain, for such period and in such quantities as required by GMP and the applicable Quality Agreement, samples of Product Manufactured under this Agreement ("**Retained Samples**").

(b) Other Samples. From time to time, COMPANY may request from FRESENIUS, and FRESENIUS shall provide to COMPANY or its designee, samples of Product (other than any Retained Samples that FRESENIUS is required to retain pursuant to GMP) in accordance with the applicable Quality Agreement, Section 16.4, or as otherwise reasonably required by COMPANY. Upon COMPANY's written request, FRESENIUS will provide such samples to COMPANY or its designee in accordance with the applicable Quality Agreement, or if such samples are for a purpose other than as contemplated under the applicable Quality Agreement (such samples, "**Other Samples**"), FRESENIUS shall provide such Other Samples to COMPANY or its designee in accordance with COMPANY's reasonable written instructions according to Prices per unit defined in the relevant Product Schedule plus additional out of pocket costs.

10. Regulatory Matters.

10.1 Regulatory Inspections.

(a) FRESENIUS will inform COMPANY of any unannounced Regulatory Authority inspections that involve the Products within [***]. FRESENIUS will inform COMPANY of any scheduled Authority inspections that involve the Products within [***] of the notification to FRESENIUS of such an inspection. FRESENIUS will permit a representative from COMPANY to be present at the Facility for a pre-approval inspection or any subsequent inspection that directly involves Product. COMPANY personnel will participate in the inspection related to COMPANY's Products if it so chooses or at the request of the regulatory agency.

(b) FRESENIUS will inform COMPANY within [***] of any Authority critical or major findings (i.e. Form 483's, warning letters or such other similar correspondence) that have an impact on the manufacture of the Product. Copies of Authority audit findings and responses will be provided to COMPANY; proprietary information may be redacted unless such information directly relates to COMPANY's products.

(c) COMPANY will maintain reports of any inspection carried out by regulatory authorities at COMPANY's facilities that are directly related to the Product with details of any major, minor, or adverse comments. For inspections that are specifically related to the manufacture of Product(s) at the Facility, COMPANY will notify FRESENIUS within [***] of the initiation of such inspection and provide updates at regular intervals during such inspection. COMPANY shall make any response to Authorities with respect to such inspections if needed within [***]. Copies of the regulatory agency findings and the site responses specifically relating to the manufacture of Product at the Facility are to be sent to FRESENIUS, redacted if applicable, or confirm absence of observations and/or responses.

10.2 Inspections/Audits by COMPANY. FRESENIUS will permit COMPANY and/or its representatives to perform audits to inspect the Facility including the Records and the holding facilities for Supplied Materials in an interval, duration, and notice period as defined in the applicable Quality Agreement to ensure compliance with the terms of this Agreement, and (b) for cause with the notice period defined in the applicable Quality Agreement, in each case [***], and as may be further defined in the applicable Quality Agreement. For all other audits by COMPANY or its representatives, such additional audit must be agreed to by the Parties including, [***].

10.3 Waste Disposal. The generation, collection, storage, handling, transportation, movement and release of hazardous materials and waste generated in connection with the Services will be the responsibility of FRESENIUS at FRESENIUS' sole cost and expense except for reasonable costs associated with such activities for hazardous materials that expire (a) due to changes in the [***] rolling Forecast provided by COMPANY provided such changes or hazardous material expiration are unrelated to FRESENIUS acts or omissions, or (b) due to COMPANY's omissions. Without limiting other applicable requirements, FRESENIUS will prepare, execute and maintain, as the generator of waste, all licenses, registrations, approvals, authorizations, notices, shipping documents and waste manifests required under Applicable Laws.

10.4 Safety Procedures. FRESENIUS will be solely responsible for implementing and maintaining health and safety procedures for the performance of Services and for the handling of any materials or hazardous waste used in or generated by the Services. FRESENIUS, in consultation with COMPANY, will develop safety and handling procedures for Product; provided, however, that COMPANY will have no responsibility for FRESENIUS' health and safety program.

11. Price.

11.1 The Price of each Product is [***]. The Price is payable in the applicable Invoice Currency. Price for Product is indicated in the respective Product Schedule. [***].

11.2 The Price for Product and the period for which it will be valid, and the conditions under which such Price will be reviewed, except as set forth below, are laid out in the relevant Product Schedule. [***].

11.3 [***].

11.4 [***]:

a) [***].

b) [***].

c) [***].

d) [***].

Index	*Internet link*
[***]	[***]

11.5 If COMPANY requests specific quality and regulatory activities [***] not defined in the applicable Quality Agreement or that are specifically identified in the applicable Product Schedule as excluded from the Price for such Product, such activities, and the fees associated with such additional activities must be expressly authorized to be performed by COMPANY in writing. [***].

12. Invoicing and Payment.

12.1 All amounts due under this Agreement will be invoiced by FRESENIUS in accordance with this Agreement and the applicable Product Schedule. FRESENIUS shall issue an invoice to COMPANY for the applicable Price for all Products delivered to COMPANY hereunder pursuant to a Product Schedule [***]. Each duly issued invoice shall contain a reference to the Purchase Order number of COMPANY and shall state FRESENIUS' registered VAT number.

12.2 COMPANY shall pay all invoices in full within [***] from the date of receipt of the relevant invoice to the payee set forth in the applicable Product Schedule, unless such invoice is the subject of a good faith dispute in which case COMPANY will promptly advise FRESENIUS of the dispute and the Parties will cooperate with each other to timely resolve such dispute.

13. Shipping and Delivery.

Delivery terms of Product are defined in the respective Product Schedule. FRESENIUS will not make Product available to COMPANY's carrier until FRESENIUS has received written instructions from COMPANY to do so. FRESENIUS will ensure that each Batch will be delivered to COMPANY or COMPANY's designee in accordance with the instructions for shipping and packaging specified by COMPANY in the applicable Product Schedule or otherwise agreed in writing.

14. Designated Suppliers.

14.1 The Parties may agree that FRESENIUS will only order certain or all raw material or packaging, which are needed to manufacture the Product, from certain suppliers pre-approved in writing by COMPANY ("**Designated Suppliers**"). If the Parties agree on Designated Suppliers, these Designated Suppliers will be listed in the relevant Annex of

the applicable Quality Agreement. For the avoidance of doubt, the term "Designated Suppliers" does not include suppliers of Supplied Materials (as defined in Section 15.1 below).

14.2 COMPANY is responsible for auditing and qualification of Designated Suppliers if expressly agreed to in writing by COMPANY. If a Designated Supplier does not deliver in the quality or time demanded by FRESENIUS or if its deliveries suffer shortfalls, damages or defects, COMPANY and FRESENIUS will negotiate further actions and shall [***] to overcome and resolve [***] such shortfalls, damages and defects. [***].

15. Supplied Materials.

15.1 The Parties may agree that COMPANY supplies certain or all raw materials or packaging, which are needed to manufacture the Product, to FRESENIUS ("**Supplied Materials**"). If the Parties agree on this, the Supplied Materials will be listed and specified in the relevant Annex of the applicable Quality Agreement and/or the applicable Product Schedule.

15.2 COMPANY will provide Supplied Materials (as specified in the applicable Product Schedule or as specified in the relevant Annex of the applicable Quality Agreement), unless otherwise mutually agreed in writing by the Parties, [***], to the FRESENIUS manufacturing site for the Product, in such quantities and quality of the Supplied Materials as are required to enable FRESENIUS to manufacture and deliver the quantities and quality of Products ordered. FRESENIUS agrees (a) to use the Supplied Materials exclusively for the manufacturing of the Products under this Agreement, (b) to account for all Supplied Materials, (c) not to provide Supplied Materials to any third party without the express prior written consent of COMPANY, and (d) [***], to destroy or return to COMPANY all unused quantities of Supplied Materials according to COMPANY's written directions.

15.3 If any Supplied Materials negatively deviate from the quality agreed to in writing by the Parties in the applicable Quality Agreement for such Supplied Materials or if the deliveries of Supplied Materials suffer shortfalls, damages, delays or defects not caused by FRESENIUS actions or inactions, FRESENIUS shall immediately notify COMPANY, and COMPANY shall promptly supply FRESENIUS with conforming Supplied Materials. Should COMPANY not be able to timely meet the requirements for Supplied Materials through no fault of FRESENIUS and therefore the Manufacturing is stopped, delayed, frustrated or otherwise blocked, the Parties will discuss in good faith the impact and how to deal with this situation and possible losses. [***].

15.4 Replacement: In the event of any loss or damage of any Supplied Materials delivered hereunder and needed for Manufacture of a Batch of Product, COMPANY shall replace and provide FRESENIUS with Supplied Materials according to the terms set forth in Section 15.2, [***]. The Supplied Material reimbursement costs will be as set forth in the applicable Product Schedule.

16. Testing and Acceptance of Product.

16.1 Testing by FRESENIUS. The Product will be Manufactured in accordance with the Manufacturing Process approved by COMPANY, and with GMP. Each Batch of Product will be sampled and tested by FRESENIUS against the Specifications, and as set forth in the applicable Quality Agreement.

16.2 Provision of Records. If, based upon such tests and documentation review for the Batch, a Batch of Product conforms to the Specifications and was Manufactured according to GMP and the Manufacturing Process, then a Certificate of Analysis and a Certificate of Conformity will be completed and approved by FRESENIUS and delivered to COMPANY, and such Certificate of Analysis and Certificate of Conformity will include any other requirements set forth in the applicable Quality Agreement. This Certificate of Conformity, a Certificate of Analysis, raw data from quality control testing and analysis as defined in the relevant Appendix of the Quality Agreement, and a complete and accurate copy of the Batch records and any other documentation specified in the applicable Quality Agreement (collectively, the "**Batch Documentation**") for each Batch of Product will be promptly delivered to COMPANY as an electronic copy. [***].

16.3 Review of Batch Documentation; Acceptance. COMPANY will review the Batch Documentation for each Batch of Product after delivery of the Batch Documentation and may test samples of the Batch of Product against the Specifications [***]. COMPANY will notify FRESENIUS in writing of its acceptance or rejection of such Batch within [***] of date of receipt (as set forth in Section 16.2) of the electronic copy of the complete Batch Documentation relating to such Batch, subject to Section 16.6. During this review period, the Parties agree to respond promptly, to any reasonable inquiry or request for a correction or change by the other Party with respect to such Batch Documentation. COMPANY has no obligation to accept a Batch if such Batch does not comply with the Specifications and/or was not Manufactured in compliance with GMP and/or the Manufacturing Process specified in the MBR for the Batch; [***]. If such notice is not given by COMPANY in the time period specified above, the Product is deemed to be delivered in the right quantities, in compliance with the Specifications, and Manufactured in accordance with GMP and the agreed Manufacturing Process subject to Section 16.6.

16.4 Disputes. In case of any disagreement as to whether Product conforms to the applicable Specifications or was Manufactured in compliance with GMP or the agreed Manufacturing Process, the quality assurance representatives of the parties will work in good faith, which shall include providing such documents and samples as may be reasonably requested by the other Party, to resolve any such disagreement and COMPANY and FRESENIUS will follow their respective SOPs to determine the conformity of the Product to the Specifications, and the Manufacturing Process and GMP. If the foregoing discussions do not resolve the disagreement in a reasonable time [***].

16.5 Product Non-Compliance and Remedies. If [***] a Batch of Product fails to conform to the Specifications subject to Section 16.7 or was not Manufactured in compliance with GMP and the Manufacturing Process [***], then FRESENIUS will, at COMPANY's sole option, promptly:

(a) Replace, [***], the Product of a failed Batch by Manufacturing a compliant Batch of Product (i.e., the replacement Batch conforms to the Specifications and was Manufactured in accordance with GMP and the agreed to Manufacturing Process. [***];

or

(b) [***].

[***].

16.6 Latent Defects. Notwithstanding anything to the contrary in Section 16.3, the provisions of Section 16.5 and the dispute mechanism in Section 16.4, will apply to any Batch of Product that is a non-conforming Batch as a result of a Latent Defect (defined below) if COMPANY advises FRESENIUS in writing of such Latent Defect within [***] of discovery of such Latent Defect. "**Latent Defect**" means [***].

16.7 Product Non-Compliance. Notwithstanding Section 16.5, if a Batch of Product fails to conform to the Specifications as a result of COMPANY-provided Supplied Materials that were defective when delivered to FRESENIUS, [***].

16.8 Disposition of Non-Conforming Product. The ultimate disposition of non-conforming Product will be the responsibility of [***].

17. Insurance. The Parties shall maintain throughout the term of this Agreement and for **[***]** after effective termination or expiry of the Agreement a commercial liability insurance covering product liability and other consumer injuries arising from the sale of the Products in an amount of at least **[***]** per occurrence and **[***]** in the aggregate. At the request of a Party, the other Party shall provide documentation sufficient to show proof of such coverage.

18. Indemnification; Limitation of Liability.

18.1 COMPANY shall defend, indemnify and hold harmless FRESENIUS and its Affiliates, and its and their respective officers, statutory representatives, directors, and employees, and agents (the "**FRESENIUS Indemnitees**") from and against any and all Losses incurred by the FRESENIUS Indemnitees for or in connection with any claims brought by third parties against the FRESENIUS Indemnitees to the extent arising or related to (i) infringement of any third party rights by FRESENIUS from its use of COMPANY Background Intellectual Property [***], in accordance with the terms of this Agreement as determined by a court of competent jurisdiction, (ii) failure of COMPANY to conform with the stipulations under this Agreement or the applicable Quality Agreement, (iii) [***], (iv) breach of this Agreement by COMPANY; or (v) negligence or wilful misconduct of COMPANY Indemnitees.

18.2 FRESENIUS shall defend, indemnify and hold harmless COMPANY and its Affiliates, and its and their respective officers, directors, and employees and agents (the "**COMPANY Indemnitees**") from and against any and all Losses incurred by the COMPANY Indemnitees for or in connection with any claims brought by third parties against the COMPANY Indemnitees to the extent arising or related to (i) infringement of any third party rights by COMPANY from its use of FRESENIUS Background Intellectual Property in accordance with the terms of this Agreement, (ii) failure of FRESENIUS to conform with the stipulations under this Agreement or the applicable Quality Agreement due to its negligence, (iii) breach of this Agreement by FRESENIUS; or (iv) negligence or wilful misconduct of FRESENIUS Indemnitees.

18.3 Each Party must notify the other Party within [***] of receipt of any claims made by a third party for which the other Party might be liable under this Section 18. Subject to Section 18.4, the indemnifying Party will have the sole right to defend, negotiate, and settle such third-party claims. The indemnified Party will be entitled to participate in the defense of such matter and to employ counsel at its expense to assist in such defense; provided, however,

that the indemnifying Party will have final decision-making authority regarding all aspects of the defense of any claim. The Party seeking indemnification will provide the indemnifying Party with such information and assistance as the indemnifying Party may reasonably request, at the expense of the indemnifying Party.

18.4 Settlement. Neither Party will be responsible nor bound by any settlement of any claim nor by any suit made without its prior written consent; provided, however, that the indemnified Party will not unreasonably withhold or delay such consent.

18.5 Limitation of Liability. [***].

18.6 Liability Cap. [***].

19. Product Recall; Adverse Events.

19.1 Recalls. As between COMPANY and FRESENIUS, COMPANY shall have sole discretion over whether and under what circumstances to require the recall of a Product. COMPANY will inform FRESENIUS promptly of any need or desire for recall of Product and FRESENIUS shall cooperate with and give all reasonable and timely assistance to COMPANY in connection therewith. [***].

19.2 Adverse Events. COMPANY will be solely responsible for adverse event reporting relating to Product (or any product containing or comprised of Product). In the event FRESENIUS receives or becomes aware of any adverse event information which may be related to Product (or any product containing or comprised of Product), FRESENIUS will immediately or as otherwise defined in the Quality Agreement provide COMPANY with all such information in English in the form and by the process required by COMPANY.

20. Intellectual Property.

20.1 Background Intellectual Property; Licenses. This Agreement does not affect the ownership of a Party's Background Intellectual Property which remains the property of such Party (or its licensors). FRESENIUS does not acquire a license or any other right to COMPANY's Background Intellectual Property except for the limited purpose of carrying out its duties and obligations under this Agreement and that such limited, non-exclusive, license will expire upon the completion of such duties and obligations or the termination or expiration of this Agreement, whichever is the first to occur. FRESENIUS hereby grants to COMPANY a non-exclusive, transferable (in conjunction with a permitted assignment under Section 26.7), sublicensable (to Affiliates of COMPANY), royalty-free, license to COMPANY and its Affiliates to use FRESENIUS Background Intellectual Property only to the extent necessary to distribute, offer for sale, sell, import, export, and otherwise dispose of Product, limited to the longer of the time this Agreement is in force or all Product supplied under this Agreement is used.

20.2 Improvements.

(a) "Improvements" means all discoveries, inventions, developments, modifications, innovations, updates, enhancements, improvements, writings or rights, and other Intellectual Property that are made, discovered, conceived, created, invented, developed, or reduced to practice in the performance of Services under this Agreement.

(b) All Improvements that relate solely to [***] will be the sole and exclusive property of FRESENIUS ("**FRESENIUS Improvements**"). To the extent that FRESENIUS Improvements relay to the Product, FRESENIUS will grant COMPANY and COMPANY hereby accepts a worldwide, perpetual, irrevocable, transferable, sub-licensable royalty-free license to the extent necessary to freely operate regarding those FRESENIUS Improvements. All other Improvements will be the sole and exclusive property of COMPANY ("**COMPANY Improvements**"). FRESENIUS will have a limited license to use Company Improvements on [***].

(c) FRESENIUS agrees (i) to promptly disclose all COMPANY Improvements; (ii) that all COMPANY Improvements will be the sole and exclusive property of COMPANY; and (iii) that FRESENIUS will assign and does assign all COMPANY Improvements to COMPANY (or its designee) without additional compensation to FRESENIUS. FRESENIUS will take such steps as COMPANY may reasonably request (at COMPANY'S expense) to vest in COMPANY (or its designee) ownership of the COMPANY Improvements. COMPANY will have the exclusive right and option, but not the obligation, to prepare, file, prosecute, maintain and defend at its sole expense, any patent applications or patents that claim and/or cover the COMPANY Improvements.

(d) COMPANY agrees (i) to promptly disclose all FRESENIUS Improvements; (ii) that all FRESENIUS Improvements will be the sole and exclusive property of FRESENIUS; and (c) that COMPANY will assign and does assign all FRESENIUS Improvements to FRESENIUS (or its designee) without additional compensation to COMPANY. COMPANY will take such steps as FRESENIUS may reasonably request (at FRESENIUS' expense) to vest in FRESENIUS (or its designee) ownership of the FRESENIUS Improvements. FRESENIUS will have the exclusive right and option, but not the obligation, to prepare, file, prosecute, maintain and defend at its sole expense, any patent applications or patents that claim and/or cover the FRESENIUS Improvements

21. Confidentiality.

21.1 The Receiving Party shall

(a) keep in strict confidence and in safe custody all Confidential Information of the Disclosing Party,

(b) use the Confidential Information only for the purpose of performing its obligations under this Agreement or the reasonable exercise of rights granted to it under this Agreement,

(c) not copy or otherwise reproduce any of the Confidential Information except as is reasonably necessary for the purpose of performing its obligations or reasonably exercising rights granted to it under this Agreement, and

(d) disclose the Confidential Information only to Entitled Persons.

21.2 "**Entitled Persons**" are only the statutory representatives, members of corporate bodies and employees, contractors, consultants and agents as well as the professional advisors of (a) the Receiving Party and (b) the Receiving Party's Affiliates, in each case with a need

to know and bound by written obligations of confidentiality and non-use no less restrictive than the terms of this Agreement. The Receiving Party shall (i) limit access to the Confidential Information to a minimum number of persons as necessary for the purpose of performing this Agreement (or exercise of rights granted under it) and (ii) advise all such persons of the confidentiality obligations at the time the Confidential Information is disclosed to them and (iii) procure that they comply with the terms of this Agreement as if they were a receiving party to it. The Receiving Party shall be liable for any non-compliance of such persons with the terms of this Agreement as if the Receiving Party was itself so non-compliant.

21.3 The Receiving Party's obligations under this Agreement shall not apply to Confidential Information which it can demonstrate, by admissible proof:

(a) was known to the Receiving Party at the date of disclosure of the Confidential Information by the Disclosing Party,

(b) is after the date of disclosure acquired by the Receiving Party in good faith from an independent third party who is not subject to any obligation of confidentiality in respect of such information,

(c) was at the time of its disclosure in the public knowledge or has become public knowledge during the term of this Agreement other than through a breach of this Agreement by the Receiving Party, or

(d) is independently developed by the Receiving Party without access to any of the Confidential Information.

21.4 If Confidential Information of the other Party is required to be disclosed by applicable law, judicial action of court of competent jurisdiction, regulation, the rules or regulations of a recognized stock exchange or listing authority, government department or agency or other regulatory authority, the Receiving Party will prior to any disclosure, promptly notify the Disclosing Party, and cooperate with it in its lawful measures of protection with regard to the Confidential Information prior to the actual disclosure, and any disclosure by the Receiving Party will be only to the extent legally required to make such disclosure.

21.5 Upon the Disclosing Party's written request (which for Confidential Information not needed by the Receiving Party to perform its obligations or exercise its rights) may be made at any time and at the Disclosing Party's sole and exclusive discretion, the Receiving Party shall, to the extent permissible under applicable law, promptly (i) return to the Disclosing Party any Confidential Information provided by or on behalf of the Disclosing Party to the Receiving Party in physical form, including, but not limited to, product samples, and otherwise (ii) destroy the Confidential Information. The Receiving Party shall not be obliged to delete automatically generated computer back-up or archival copies of the Confidential Information generated in the ordinary course of information system procedures, provided that except as expressly provided herein, the Receiving Party shall make no use of such copies and retain such copies under controlled locked files.

21.6 This Section 21 shall survive the effect of termination or expiry of this Agreement for [***] therefrom.

22. Non-Exclusivity.

22.1 FRESENIUS undertakes to manufacture and supply the Product non-exclusively to COMPANY.

23. Term and Termination.

23.1 This Agreement shall become effective as of the Effective Date and unless earlier terminated as permitted by this Agreement, shall remain in full force and effect for a period of [***] from the later of the Effective Date or the completion of all Services under all accepted Purchase Orders issued prior to the [***] of the Effective Date ("**Initial Term**"). The term of this Agreement shall automatically be extended for subsequent periods of [***] ("**Extension Term**") unless terminated by a Party [***] prior to the end of the Initial Term or prior to the end of each Extension Term.

23.2 This Agreement, and any Product Schedule, may be terminated by a Party with written notice to the other Party under the following conditions:

(a) in the event of a material breach of this Agreement, or a Product Schedule, the non-breaching Party may terminate this Agreement, or the applicable Product Schedule if after [***] written notice from the non-breaching Party specifying the breach the other Party fails to cure such breach within the [***] period;

(b) if otherwise explicitly stated in this Agreement;

(c) if the other Party files a petition in bankruptcy or of insolvency, or is adjudicated insolvent, or takes advantage of the insolvency law in any state or country, or makes an assignment for the benefit of creditors, or a receiver, trustee or other court officer is applied for or appointed for its property (which, in the case of any involuntary proceeding or assignments, are not dismissed within [***]);

(d) by FRESENIUS if COMPANY undergoes a Change Of Control to a FRESENIUS Competitor (defined below). For this purpose, COMPANY shall notify FRESENIUS without undue delay of such Change Of Control and the identity of the then controlling FRESENIUS Competitor. In the event that FRESENIUS elects to exercise its right of termination under this Section 23.2(d), it must notify COMPANY within [***] of receipt of notice from COMPANY and unless a shorter period is agreed to with COMPANY, FRESENIUS will continue to supply COMPANY according to the terms of this Agreement and all its Attachments for [***] following the COMPANY's receipt of notice of termination from FRESENIUS. [***].

23.3 COMPANY will have the right, in its sole discretion, to terminate this Agreement or any Product Schedule upon written notice if (i) FRESENIUS fails to obtain or maintain any material governmental licenses or approvals required in connection with the Services and FRESENIUS fails to re-instate material governmental licenses or approvals within [***]; or (ii) the FDA or other Authority in the Territory does not approve Product (or any product containing or comprised of Product) for marketing or withdraws marketing approval upon [***] prior written notice to FRESENIUS. If COMPANY has agreed in a pending Product

Schedule to any minimum purchase quantity of Product, COMPANY shall remain responsible to purchase, prior to the effective date of such termination, [***].

23.4 Effect of Termination.

FRESENIUS will, upon receipt of a termination notice from COMPANY or any other termination of this Agreement by either Party as well as expiration of the Agreement term, promptly cease performance of the applicable Services and will take all reasonable steps to mitigate the out-of-pocket expenses incurred in connection therewith. In particular, FRESENIUS will use its best efforts to: immediately cancel, to the greatest extent possible, any third party obligations; promptly inform COMPANY of any irrevocable commitments made in connection with any pending Services prior to termination; promptly try to return to the vendor for a refund all unused, unopened materials in FRESENIUS' possession that are related to any pending Services; provided, that COMPANY will have the option, but not the obligation, to take possession of any such materials; promptly inform COMPANY of the cost of any remaining unused, unreturnable materials ordered pursuant to any pending Services, and either deliver such materials to COMPANY (or its designee) or properly dispose of them, as instructed by COMPANY at the expense of COMPANY; and perform only those services and activities mutually agreed upon by COMPANY and FRESENIUS as being necessary or advisable in connection with the close-out of any pending Services.

In case of COMPANY's termination other than for cause, or FRESENIUS' termination of the Agreement or this Product Schedule for cause, COMPANY shall pay compensation concerning the Product as follows:

(a) FRESENIUS' Price, as specified in Part C.1 of the relevant Product Schedule, as valid at the time of termination for all work in progress on non-ordered Product, including work on intermediates at the date of termination which are within COMPANY's binding Forecasts (Section 5 of the Agreement) or minimum purchase quantity (Section 5.3 of this Agreement); and

(b) FRESENIUS' direct costs for raw materials, intermediates and other materials in stock at the date of termination and purchased for the use in the manufacture of the Product. The compensation under this sub-paragraph (b) is given provided that:

(i) the raw materials, intermediates and other materials are to be used for Product volumes which are within COMPANY's Forecasts and for a period not exceeding [***];

(ii) the raw materials, intermediates and other materials cannot reasonably be used for other purposes by FRESENIUS; and

(ii) COMPANY is entitled to collect such raw materials, intermediates and other materials for its own use or sale, without additional charge.

23.5 Neither termination nor expiry of this Agreement shall release either Party from fulfilling any obligations which may have been incurred prior to any such termination or expiry. Sections 1, 2.5 (last two sentences), 2.7, 5.3, 6.2 (last sentence only), 7, 9, 10, 12, 13, 15.2 (last sentence) and 15.4, 16 through 21, 23.2(d), 23.4 through 23.7, 24 through 26 shall survive

expiration or termination of this Agreement, as shall any other provision which due to its nature is intended to survive.

23.6 Every termination of this Agreement requires a written notice by registered mail or other permitted method as set forth in this Agreement.

23.7 This Section 23 applies for the term and termination of any individual Product Schedule as well, as long as the term or the termination is not regulated differently in the Product Schedule.

24. Representations and Warranties.

24.1 FRESENIUS Representations and Warranties. FRESENIUS represents and warrants to COMPANY that:

(a) it has the full power and right to enter into this Agreement and that there are no outstanding agreements, assignments, licenses, encumbrances or rights of any kind held by other parties, private or public, that are inconsistent with the provisions of this Agreement;

(b) the execution and delivery of this Agreement by FRESENIUS has been authorized by all requisite corporate or company action and this Agreement is and will remain a valid and binding obligation of FRESENIUS, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors;

(c) the Services will be performed with requisite care, skill and diligence, by individuals who are appropriately trained and qualified; and in accordance with Applicable Laws and industry standards, and Services under a Product Schedule will be performed in accordance with all applicable provisions of this Agreement and the Quality Agreement, including the Specifications made known to FRESENIUS in writing prior to execution of such Product Schedule.

(d) to the best of FRESENIUS' knowledge, the use of the FRESENIUS Background Intellectual Property of FRESENIUS in the conduct and the provision of the Services will not violate any patent, trade secret or other proprietary or intellectual property rights of any third party and it will promptly notify COMPANY in writing should it become aware of any claims asserting such violation;

(e) at the time of delivery to COMPANY, the Product Manufactured under this Agreement (i) will have been Manufactured in accordance with GMP and all other Applicable Laws, the Manufacturing Process, the applicable Quality Agreement, and Specifications; (ii) will not be adulterated or misbranded under the FDCA or other Applicable Laws; and (iii) will not have been produced in violation of any applicable provisions of the Austrian labor laws, as amended; and

(f) FRESENIUS, its Affiliates, approved subcontractors, and each of their respective officers and directors, as applicable, and any person used by FRESENIUS, its Affiliates or approved subcontractors to perform Services under this Agreement: (a) have not been debarred and are not subject to a pending debarment pursuant to section 306 of the United States Food, Drug and Cosmetic Act, 21 U.S.C. § 335a; (b) are not ineligible

to participate in any federal and/or state healthcare programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. 1320a-7b(f)); (c) are not disqualified by any government or regulatory authorities from performing specific services, and are not subject to a pending disqualification proceeding; and (d) have not been convicted of a criminal offense related to the provision of healthcare items or services and are not subject to any such pending action. FRESENIUS will notify COMPANY immediately if FRESENIUS, its Affiliates, or approved subcontractors, or any person used to perform Services under this Agreement, or any of their respective officers or directors, as applicable, is subject to the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending, or to the best of FRESENIUS' knowledge, is threatened.

(g) FRESENIUS has adhered to, and shall continue to adhere to, the provisions of the U.S. Foreign Corrupt Practices Act of 1977, as amended, codified at 15 U.S.C. §§ 78dd-1, et seq. ("**FCPA**"), and to any other applicable anti-corruption or anti-kickback legislation. Neither FRESENIUS nor any of its or its affiliates employees, directors, officers, subcontractors, consultants, agents, or representatives (collectively, "**Representatives**") has engaged or in the future shall engage in any activity that is prohibited by the FCPA, including bribery, kickbacks, payoffs, or other corrupt business practices. FRESENIUS further represents, warrants and covenants that it and its Representatives have not offered, paid, or authorized, and will not offer, pay, or authorize, directly or indirectly, any payment of money or anything of value to a foreign official (as that term is defined by the FCPA) to improperly seek to influence any foreign official or Authority, or foreign government entity decision-making to gain a commercial or other advantage for COMPANY.

24.2 COMPANY Representations and Warranties. COMPANY represents and warrants to FRESENIUS that:

(a) it has the full power and right to enter into this Agreement and that there are no outstanding agreements, assignments, licenses, encumbrances or rights held by other parties, private or public, that are inconsistent with the provisions of this Agreement;

(b) the execution and delivery of this Agreement by COMPANY has been authorized by all requisite corporate action and this Agreement is and will remain a valid and binding obligation of COMPANY, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors;

(c) to the best of COMPANY's knowledge, the use of the COMPANY Background Intellectual Property in the conduct and the provision of the Services will not violate any patent, trade secret or other proprietary or intellectual property rights of any third party and it will promptly notify FRESENIUS in writing should it become aware of any claims asserting such violation

(d) to the best of Company's knowledge, Supplied Materials are, at the time of delivery, free from liens, defects, and in accordance with authorization from all relevant Authorities and with all specifications agreed to by the Parties for the Supplied Materials.

24.3 Disclaimer of Other Representations and Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR

EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT.

25. Force Majeure.

25.1 Neither Party hereto shall be responsible or liable in any way for failure or delay in carrying out the terms of the Agreement resulting from any cause or circumstance beyond its reasonable control (a "**Force Majeure**"), including, but not limited to, fire, flood, other natural disasters, war, and civil commotion, provided that the Party so affected shall give prompt notice thereof to the other Party.

25.2 No failure or delay set out in this Section shall terminate this Agreement, and each Party shall complete its obligations hereunder as promptly as reasonably practicable following cessation of the cause or circumstance of such failure or delay, provided, however, that if any of the above force majeure events continue to exist for more than [***] after the date of any notice given with regard thereto, either Party may terminate this Agreement with notice to the other.

26. Miscellaneous.

26.1 This Agreement constitutes the entire agreement between the Parties pertaining to the subject matter hereof and supersedes all prior agreements and understandings of the Parties with respect thereto. For avoidance of doubt, nothing in this Agreement changes the Development and Clinical Manufacturing Agreement dated [***], together with any amendments thereto. This Agreement may be amended, including this section, only by an amendment in writing that is signed by an authorized representative of each Party. All Exhibits referred to in this Agreement are intended to be and are hereby specifically incorporated into and made a part of this Agreement. If there is any inconsistency between a Product Schedule or between any other Exhibit on the one hand and this Agreement on the other hand, the terms of this Agreement shall govern.

All Exhibits are listed as follows:

Exhibit 1: Product Schedule(s).
Exhibit 2: Form of Purchase Order

26.2 The general terms and conditions of either of the Parties shall not be applicable even if they are contained in or referred to in any Purchase Order, order confirmation or other correspondence.

26.3 If any provision of this Agreement is determined, by a court with proper jurisdiction, to be invalid, illegal or unenforceable, the remaining provisions of this Agreement, to the extent permitted by law, shall remain in full force and effect. The Parties shall agree on a valid, legal or enforceable provision in lieu of the invalid, illegal or unenforceable provision that reflects the Parties' intentions at the time of entering into this Agreement. The same shall apply if the Parties have, unintentionally, failed to address a certain matter in this Agreement.

26.4 No failure on the part of any Party to exercise or delay in exercising any right hereunder shall be deemed a waiver thereof except with respect to an express written waiver relating

to a particular matter for a particular period of time signed by an authorized representative of the waiving Party, as applicable.

26.5 All notices hereunder shall be made in writing in the English language to the persons at the addresses set forth below, or such other person or address as may be designated by the respective Party to the other Party in the same manner. All notices must be given by (a) personal delivery, with receipt acknowledged; or (b) prepaid certified or registered mail, return receipt requested; or (c) prepaid recognized next business day or express delivery service. Notices will be effective upon receipt or at a later date stated in the notice.

For FRESENIUS:
[***]

For COMPANY:
AMAG Pharmaceuticals, Inc.
1100 Winter Street
Waltham, MA 02451
U.S.A.
Attn: Vice President of Technical Operations

With a copy to:

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

26.6 Nothing in this Agreement is intended to create an agency relationship, partnership or joint venture between the Parties. The relationship among the Parties is that of independent contractors. Neither COMPANY nor FRESENIUS shall present itself as affiliated with the other Party and nothing herein shall be construed as to grant either Party the right to refer to the other as a business partner or use the other's trademarks and logos, unless specifically agreed upon in writing. This Agreement does not create an employer-employee relationship between COMPANY on the one hand and FRESENIUS or any employee, subcontractors, Affiliate of FRESENIUS, or any FRESENIUS personnel on the other.

26.7 Neither this Agreement nor any rights or obligations hereunder may be assigned or transferred by either Party, in whole or in part, without the prior written consent of the other Party, except that a Party may assign this Agreement and its rights and obligations hereunder without the consent of the other Party to: (a) an Affiliate of such Party or (b) subject to the provisions in Section 23 regarding a Change of Control, any person or entity that acquires all or a substantial portion of the stock or assets, or line of business which the Product relates to, to such Party. Any purported assignment in violation of the preceding sentence will be void. Any permitted assignee will assume the rights and obligations of its assignor under this Agreement.

26.8 This Agreement shall be governed by and construed in accordance with the laws of Switzerland without regard to its principles of conflicts of law. The United Nations Convention on Contracts for the International Sale of Goods (CISG) and the 1974 Convention on the Limitation Period in the International Sale of Goods, as amended by that certain Protocol, done at Vienna on April 11, 1980 are excluded and shall not apply to this Agreement, including for clarity, Product Schedules, Purchase Order, or deliveries based hereon or thereon.

26.9 Disputes.

(a) The Parties will try to settle their differences amicably between themselves. Except for any disputes which are subject to Section 16.4, if any claim, dispute, or controversy of whatever nature arising out of or relating to this Agreement, including the performance or alleged non-performance of a Party of its obligations under this Agreement arises between the Parties (each a "**Dispute**"), a Party will, before initiating any proceedings pursuant to subsection b) of this Section, notify the other Party in writing of such Dispute. If the Parties are unable to resolve the Dispute within [***] of receipt of the written notice by the other Party, such dispute will be referred to an executive officer of COMPANY and an executive officer of FRESENIUS, or their designees, who will meet in person at least once and use their good faith efforts to resolve the Dispute within [***] after such referral.

(b) [***].

(c) [***].

26.10 Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

26.11 [***].

26.12 Headings. The headings used in this Agreement have been inserted for convenience of reference only and do not define or limit the provisions hereof. The Appendices to this Agreement are incorporated herein by reference and will be deemed a part of this Agreement.

26.13 Singular Terms. Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice-versa.

26.14 Additional Interpretations. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires, the words "**include**", "**includes**" and "**including**" will be deemed to be followed by the phrase "**but not limited to**", "**without limitation**", or words of similar import.

26.15 Counterparts. This Agreement may be executed in one or more counterparts, all of which shall constitute one and the same agreement. The Agreement becomes valid only after the duly authorised representatives of both Parties have signed it.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the authorized representatives of the Parties have duly executed this Agreement as of the Effective Date.

SIGNED for and on behalf of

Fresenius Kabi Austria GmbH

/s/ Heinz Riesner
Signature

Name: Heinz Riesner

Title: General Manager

SIGNED for and on behalf of

AMAG Pharmaceuticals, Inc.

/s/ William K. Heiden
Signature

Name: William K. Heiden

Title: CEO

SIGNED for and on behalf of

Fresenius Kabi Austria GmbH

/s/ Tanja Greve
Signature

Name: Tanja Greve
Title: Executive Vice President/CFO/GMP

SIGNED for and on behalf of
Fresenius Kabi Austria GmbH

/s/ Stefan Czvitkovich
Signature

Name: Stefan Czvitkovich
Title: Director PP Sterile Pharmaceuticals

Exhibit 31.1

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: November 2, 2018

/s/ William K. Heiden

William K. Heiden

President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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: November 2, 2018

/s/ Edward Myles

Edward Myles

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

Exhibit 32.1

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 September 30, 2018 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)

November 2, 2018

Exhibit 32.2

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 September 30, 2018 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)

November 2, 2018