

# SECURITIES & EXCHANGE COMMISSION EDGAR FILING

## MEDICINES CO /DE

**Form: 10-Q**

**Date Filed: 2019-07-24**

Corporate Issuer CIK: 1113481

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended: June 30, 2019  
OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 (No Fee Required)

For the transition period from to

Commission file number 000-31191

**THE MEDICINES COMPANY**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**04-3324394**

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

**8 Sylvan Way**

**Parsippany, New Jersey**

(Address of principal executive offices)

**07054**

(Zip Code)

Registrant's telephone number, including area code: **(973) 290-6000**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
<b>Common Stock</b>	<b>MDCO</b>	<b>NASDAQ Global Select Market</b>

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "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 Exchange Act).

Yes  No

As of July 22, 2019, there were 79,350,047 shares of Common Stock, \$0.001 par value per share, outstanding (excluding 3,013,143 shares held in treasury).

**THE MEDICINES COMPANY**  
**QUARTERLY REPORT ON FORM 10-Q**  
**For the Quarterly Period Ended June 30, 2019**  
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**Part I. Financial Information**

**Item 1. Condensed Financial Statements**

**THE MEDICINES COMPANY**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(Unaudited, in thousands, except share and per share amounts)

	June 30, 2019	December 31, 2018
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 319,272	\$ 238,310
Short-term investment	4,407	2,627
Inventory, net	—	864
Prepaid expenses and other current assets	57,948	53,002
<b>Total current assets</b>	<b>381,627</b>	<b>294,803</b>
Fixed assets, net	7,874	8,872
Goodwill	200,571	200,571
Restricted cash	6,532	6,710
Contingent purchase price from sale of businesses	324,499	325,806
Other assets	35,170	4,924
<b>Total assets</b>	<b>\$ 956,273</b>	<b>\$ 841,686</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 4,331	\$ 695
Accrued expenses	52,066	57,716
Other current liabilities	7,567	—
<b>Total current liabilities</b>	<b>63,964</b>	<b>58,411</b>
Convertible senior notes	817,774	792,752
Other liabilities	36,406	12,787
<b>Total liabilities</b>	<b>918,144</b>	<b>863,950</b>
Stockholders' equity (deficit):		
Preferred stock, \$1.00 par value per share, 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.001 par value per share, 187,500,000 authorized; 82,338,481 issued and 79,325,338 outstanding at June 30, 2019 and 76,861,668 issued and 73,848,525 outstanding at December 31, 2018	82	77
Additional paid-in capital	1,633,308	1,452,975
Treasury stock, at cost; 3,013,143 shares at June 30, 2019 and December 31, 2018	(90,016)	(90,016)
Accumulated deficit	(1,500,644)	(1,380,724)
Accumulated other comprehensive loss	(4,601)	(4,576)
<b>Total stockholders' equity (deficit)</b>	<b>38,129</b>	<b>(22,264)</b>
<b>Total liabilities and stockholders' equity (deficit)</b>	<b>\$ 956,273</b>	<b>\$ 841,686</b>

See accompanying notes to condensed consolidated financial statements.

**THE MEDICINES COMPANY**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(Unaudited, in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net revenues	\$ —	\$ 1,667	\$ —	\$ 9,438
Operating expenses:				
Cost of revenues	—	2,931	—	5,668
Research and development	28,112	30,294	55,123	70,660
Selling, general and administrative	19,889	21,013	36,871	49,964
Total operating expenses	48,001	54,238	91,994	126,292
Loss from operations	(48,001)	(52,571)	(91,994)	(116,854)
Co-promotion and license income	—	254	—	482
Gain (loss) on short-term investment	2,057	(3,474)	1,791	(33,463)
Interest expense	(15,791)	(12,108)	(31,815)	(24,185)
Other income	1,687	1,053	2,108	3,422
Loss from continuing operations before income taxes	(60,048)	(66,846)	(119,910)	(170,598)
(Provision for) benefit from income taxes	(7)	12,393	(10)	31,309
Loss from continuing operations	(60,055)	(54,453)	(119,920)	(139,289)
Income from discontinued operations, net of tax	—	256	—	114,241
Net loss	\$ (60,055)	\$ (54,197)	\$ (119,920)	\$ (25,048)
Basic loss per common share:				
Loss from continuing operations	\$ (0.80)	\$ (0.74)	\$ (1.62)	\$ (1.89)
Earnings from discontinued operations	—	—	—	1.55
Basic loss per share	\$ (0.80)	\$ (0.74)	\$ (1.62)	\$ (0.34)
Diluted loss per common share:				
Loss from continuing operations	\$ (0.80)	\$ (0.74)	\$ (1.62)	\$ (1.89)
Earnings from discontinued operations	—	—	—	1.55
Diluted loss per share	\$ (0.80)	\$ (0.74)	\$ (1.62)	\$ (0.34)
Weighted average number of common shares outstanding:				
Basic	74,809	73,349	74,230	73,574
Diluted	74,809	73,349	74,230	73,574

See accompanying notes to condensed consolidated financial statements.

**THE MEDICINES COMPANY**  
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
*(In thousands)*

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net loss	\$ (60,055)	\$ (54,197)	\$ (119,920)	\$ (25,048)
Other comprehensive income (loss):				
Foreign currency translation adjustment	805	(123)	(25)	(594)
Amounts reclassified from accumulated other comprehensive loss	—	—	—	1,183
Other comprehensive income (loss)	805	(123)	(25)	589
Comprehensive loss	<u>\$ (59,250)</u>	<u>\$ (54,320)</u>	<u>\$ (119,945)</u>	<u>\$ (24,459)</u>

See accompanying notes to condensed consolidated financial statements.

**THE MEDICINES COMPANY**  
**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
*(In thousands)*

	Common Stock		Treasury Stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Comprehensive Income (Loss)	Stockholders' Equity (Deficit)
Balance at January 1, 2018	76,191	\$ 76	(3,013)	\$ (90,016)	\$1,377,393	\$ (1,257,356)	\$ (5,183)	\$ 24,914
Employee stock purchases	335	—			8,637			8,637
Issuance of restricted stock awards	35	—						—
Non-cash stock compensation					4,454			4,454
Adoption of new accounting standard related to revenue recognition						(210)		(210)
Net income						29,149		29,149
Currency translation adjustment							(471)	(471)
Amounts reclassified from accumulated other comprehensive income							1,183	1,183
Balance at March 31, 2018	76,561	\$ 76	(3,013)	\$ (90,016)	\$1,390,484	\$ (1,228,417)	\$ (4,471)	\$ 67,656
Employee stock purchases	130	—			3,274			3,274
Non-cash stock compensation					4,619			4,619
Net loss						(54,197)		(54,197)
Currency translation adjustment							(123)	(123)
Balance at June 30, 2018	76,691	\$ 76	(3,013)	\$ (90,016)	\$1,398,377	\$ (1,282,614)	\$ (4,594)	\$ 21,229
Balance at January 1, 2019	76,862	\$ 77	(3,013)	\$ (90,016)	\$1,452,975	\$ (1,380,724)	\$ (4,576)	\$ (22,264)
Employee stock purchases	33	—			672			672
Issuance of restricted stock awards	(10)	—						—
Non-cash stock compensation					4,446			4,446
Equity component of 2024 Notes issuance, net					2,452			2,452
Net loss						(59,865)		(59,865)
Currency translation adjustment							(830)	(830)
Balance at March 31, 2019	76,885	\$ 77	(3,013)	\$ (90,016)	\$1,460,545	\$ (1,440,589)	\$ (5,406)	\$ (75,389)
Employee stock purchases	211	—			5,438			5,438
Issuance of restricted stock awards	16	—						—
Non-cash stock compensation					5,747			5,747
Issuance of common stock	5,227	5			161,578			161,583
Net loss						(60,055)		(60,055)
Currency translation adjustment							805	805
Balance at June 30, 2019	82,339	\$ 82	(3,013)	\$ (90,016)	\$1,633,308	\$ (1,500,644)	\$ (4,601)	\$ 38,129

See accompanying notes to condensed consolidated financial statements.



**THE MEDICINES COMPANY**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
*(Unaudited, in thousands)*

	Six Months Ended June 30,	
	2019	2018
<b>Cash flows from operating activities:</b>		
Net loss	\$ (119,920)	\$ (25,048)
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	999	1,443
Amortization of debt discount	18,233	13,531
Unrealized foreign currency transaction losses, net	41	127
Stock compensation expense	10,193	9,073
Gain on sale of business	—	(168,955)
Gain on sale of assets	(500)	—
(Gain) loss on short-term investments	(1,780)	33,463
Reserve for excess or obsolete inventory	—	(394)
Changes in contingent purchase price	—	(258)
Changes in operating assets and liabilities:		
Accounts receivable	—	619
Inventory, net	863	2,258
Prepaid expenses and other assets	1,031	6,687
Accounts payable	3,656	(4,618)
Accrued expenses	(5,510)	(33,253)
Other current liabilities	—	(4,181)
Payments on contingent purchase price	—	(57)
Other liabilities	(5,904)	4,222
Net cash used in operating activities	<u>(98,598)</u>	<u>(165,341)</u>
<b>Cash flows from investing activities:</b>		
Proceeds from sale of assets	500	—
Purchases of fixed assets	—	(7)
Proceeds from sale of business	—	166,383
Net cash provided by investing activities	<u>500</u>	<u>166,376</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuances of common stock, net	6,111	11,913
Payments on contingent purchase price	—	(511)
Proceeds from the issuance of convertible senior notes	9,500	—
Proceeds from equity offering, net	161,583	—
Debt issuance costs	(280)	—
Net cash provided by financing activities	<u>176,914</u>	<u>11,402</u>
Effect of exchange rate changes on cash	<u>1,968</u>	<u>(1,374)</u>
Increase in cash, cash equivalents and restricted cash	80,784	11,063
Cash, cash equivalents and restricted cash at beginning of period	245,020	156,900
Cash, cash equivalents and restricted cash at end of period <sup>(a)</sup>	<u>\$ 325,804</u>	<u>\$ 167,963</u>
<b>Supplemental disclosure of cash flow information:</b>		
Interest paid	<u>\$ 10,534</u>	<u>\$ 10,534</u>

(a) The following table provides a reconciliation of cash, cash equivalents and restricted cash to amounts reported within the condensed consolidated balance sheet:

	June 30, 2019	June 30, 2018
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	\$ 319,272	162,530
Restricted cash	6,532	5,433
Total cash, cash equivalents and restricted cash at end of period	<u>\$ 325,804</u>	<u>\$ 167,963</u>

See accompanying notes to condensed consolidated financial statements.

**THE MEDICINES COMPANY**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)**

The Medicines Company® name and logo are registered trademarks or trademark applications of The Medicines Company in the United States and/or other countries. All other trademarks, service marks or other tradenames appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. References to “the Company,” “we,” “us” or “our” mean The Medicines Company, a Delaware corporation, and its subsidiaries.

### **1. Nature of Business**

The Medicines Company (the Company) is a biopharmaceutical company driven by its purpose to solve major medical, societal and economic challenges in healthcare. The Company has a singular focus on one of the greatest global healthcare challenges and burdens - that presented by cardiovascular disease, which remains the number one cause of death in the United States and worldwide. The leading cause of cardiovascular disease morbidity and mortality is atherosclerotic cardiovascular disease (ASCVD). The Company takes on that challenge by developing inclisiran, the investigational RNA interference (RNAi) therapeutic, that specifically inhibits production of proprotein convertase subtilisin/kexin type 9 (PCSK9), a key protein that controls LDL-cholesterol (LDL-C) levels. The Company believes inclisiran is uniquely suited to make a significant difference reducing risk in ASCVD. The Company has the right to develop, manufacture and commercialize inclisiran under its collaboration agreement with Alnylam Pharmaceuticals, Inc. (Alnylam).

### **2. Significant Accounting Policies**

The Company’s significant accounting policies are described in Note 2, “Significant Accounting Policies,” in the notes to the audited consolidated financial statements included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2018 (the 2018 Form 10-K).

#### ***Basis of Presentation***

The accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting solely of normal recurring adjustments, considered necessary for a fair presentation of the Company’s financial position, results of operations, comprehensive loss, and cash flows for the periods presented.

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned and majority owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. The Company has no unconsolidated subsidiaries.

The Company’s results of operations for the three and six months ended June 30, 2019 are not necessarily indicative of the results that may be expected from the Company for the entire fiscal year or any other quarter of the fiscal year ending December 31, 2019. These unaudited condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements included in the 2018 Form 10-K.

#### ***Going Concern***

Due to the divestiture of the Company’s rights to branded Angiomax in the United States to Sandoz Inc. (Sandoz) during 2018, the Company is no longer generating revenues from product sales. Prior to such divestiture, the Company’s revenues generated from product sales had been declining significantly since 2014 due to the introduction of generic competition against Angiomax and the divestiture of certain of the Company’s non-core products. The Company has incurred net losses and negative cash flows from operations since 2014 and had an accumulated deficit of \$1,500.6 million as of June 30, 2019. The Company expects to incur significant expenses and operating losses for the foreseeable future as it continues to develop, seek regulatory approval for and commercially launch inclisiran. On June 24, 2019, the Company filed a shelf registration statement on Form S-3 with the SEC, which was automatically effective upon filing. This shelf registration statement permits the Company to offer, from time to time, an unspecified amount of debt securities, common stock, preferred stock, depositary shares, purchase contracts, purchase units and warrants. On June 28, 2019, the Company sold an aggregate of 5,227,273 shares of its common stock, including the exercise in full by the underwriters of an option to purchase additional 681,818 shares of common stock, in an underwritten public offering at a price to the public of \$33.00 per share. We received net proceeds of approximately \$161.6 million from the sale of shares in the offering, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

**THE MEDICINES COMPANY**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) — (Continued)**

The Company believes that its existing cash and cash equivalents and short term investments of approximately \$323.7 million as of June 30, 2019, will be sufficient to satisfy the Company's anticipated operating and other funding requirements for the next twelve months from July 24, 2019 (the date of filing this Form 10-Q).

***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, costs, expenses and accumulated other comprehensive loss that are reported in the condensed consolidated financial statements and accompanying disclosures. Actual results may be different.

***Contingencies***

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company continually assesses litigation to determine if an unfavorable outcome would lead to a probable loss or reasonably possible loss which could be estimated. In accordance with the guidance of the Financial Accounting Standards Board (FASB) on accounting for loss contingencies, the Company accrues for all contingencies at the earliest date at which the Company deems it probable that a liability has been incurred and the amount of such liability can be reasonably estimated. If the estimate of a probable loss is a range and no amount within the range is more likely than another, the Company accrues the minimum of the range. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the litigation, including an estimable range, if possible.

***Research and Development***

Research and development costs are expensed as incurred. Clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. Payments for a product license prior to regulatory approval of the product and payments for milestones achieved prior to regulatory approval of the product are expensed in the period incurred as research and development. Milestone payments that do not represent payments of contingent purchase price from business combinations that are made in connection with regulatory approvals are capitalized and amortized to cost of revenue over the remaining useful life of the asset.

***Contingent Purchase Price From Sale of Business***

The Company has contingent assets for certain specified calendar year net sales milestones as part of the 2016 divestitures of its hemostasis portfolio consisting of PreveLeak, Raplixa and Recothrom (the Hemostasis Business) to wholly owned subsidiaries of Mallinckrodt plc (Mallinckrodt) and its non-core cardiovascular assets consisting of Kengreal, Cleviprex and rights to Argatroban for Injection (the Non-Core ACC Products) to Chiesi USA, Inc. (Chiesi USA) and its parent company Chiesi Farmaceutici S.p.A. (Chiesi), which in each case are reflected as contingent purchase price from sale of businesses on the accompanying condensed consolidated balance sheets. The Company also has contingent assets for royalties associated with the sale of the infectious disease business to Melinta, which is reflected as contingent purchase price from sale of business on the accompanying condensed consolidated balance sheets.

The Company will recognize any increases in the carrying amount when the milestones or royalties are achieved and reduce the carrying amount as payments are received. The Company will recognize an impairment of the carrying amount when it determines it is probable that the asset has been impaired and the amount of the loss can be reasonably estimated.

The Company noted no impairment on the carrying amount of the contingent assets. In addition, the Company determined that the fair values of these contingent payments to be received from Mallinckrodt, Chiesi and Melinta, respectively, are not readily determinable at June 30, 2019, as the estimated future net sales of each of the respective products are determined by the future actions of such parties.

**THE MEDICINES COMPANY**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) — (Continued)**

**Recent Accounting Pronouncements**

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)" (ASU No. 2016-02 or Topic 842) and subsequent ASUs issued in 2018 and 2019 that contained improvements to this guidance. This new guidance on leasing will require organizations that lease assets with lease terms of more than 12 months to recognize assets and liabilities for the rights and obligations created by those leases on their balance sheets. The Company adopted this new guidance on leasing on January 1, 2019. The Company elected the package of practical expedients upon transition that allows the Company not to reassess the lease classification for expired and existing leases, whether initial direct costs qualify for capitalization for any expired or existing leases or whether any expired contracts are or contain leases. Additionally, the Company elected the optional transition method that allows for a cumulative effect adjustment in the period of adoption and did not restate prior periods. The adoption of the new guidance on leasing resulted in the recognition of a right-of-use asset of \$34.9 million and lease obligations of \$41.2 million. The difference between the right-of-use assets and the lease obligations is primarily due to unamortized lease incentives and deferred rent related to the Company's operating leases at December 31, 2018.

The impact of the adoption of Topic 842 on the accompanying condensed consolidated balance sheet as of January 1, 2019 was as follows (in thousands):

	December 31, 2018	Adoption Adjustment	January 1, 2019
Other assets	\$ 4,924	\$ 34,925	\$ 39,849
Other current liabilities	\$ —	\$ 7,508	\$ 7,508
Other liabilities	\$ 12,787	\$ 27,417	\$ 40,204

The adoption of the new guidance did not have a material impact on the condensed consolidated statement of operations. For further details regarding the adoption of this standard see Note 16, "Leases."

In August 2018, the FASB issued ASU 2018-13, "Fair Value Measurement (Topic 820), Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement", which modifies disclosure requirements on fair value measurements. This ASU is effective for public companies for fiscal years and interim periods within those fiscal years beginning after December 15, 2019, with early adoption permitted. The Company expects to adopt this guidance when effective and is currently evaluating the effect that the updated standard will have on its consolidated financial statements and related disclosures.

**3. Stock Compensation Expense**

The Company recorded stock compensation expense of approximately \$5.7 million and \$4.6 million for the three months ended June 30, 2019 and 2018, respectively, and \$10.2 million and \$9.1 million for the six months ended June 30, 2019 and 2018, respectively. As of June 30, 2019, there was approximately \$60.1 million of total unrecognized compensation costs related to non-vested share-based employee compensation arrangements granted under the Company's equity compensation plans. The Company expects to recognize those costs, exclusive of \$39.7 million related to stock options which will vest upon the achievement of specified performance goals, over a weighted average period of 1.5 years.

During the six months ended June 30, 2019 and 2018, the Company issued a total of 262,504 and 602,820, respectively, of shares of its common stock upon the exercise of stock options, grants of restricted stock, and purchases under the Company's 2010 employee stock purchase plan (ESPP). Cash received from the exercise of stock options and purchases through the ESPP during the six months ended June 30, 2019 and 2018 was \$6.1 million and \$11.9 million, respectively, and is included within the financing activities section of the accompanying condensed consolidated statements of cash flows.

**4. Earnings (Loss) Per Share**

Basic loss per share is computed by dividing consolidated net (loss) income by the weighted average number of shares of common stock outstanding during the period, excluding unvested restricted common shares. The potentially dilutive effect of the Company's stock options, unvested restricted common stock, and convertible senior notes due 2022 (2022 Notes) on earnings per share is computed under the treasury stock method. In addition, the Company analyzes the potential dilutive effect of the convertible senior notes due 2023 (2023 Notes) and 2024 (2024 Notes) on earnings per share under the "if converted" method, in which it is assumed that the outstanding security converts into common stock at the beginning of the period, or at the time of issuance, if later.

**THE MEDICINES COMPANY**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) — (Continued)**

For periods of income from continuing operations when the effects are not anti-dilutive, diluted (loss) earnings per share is computed by dividing consolidated net (loss) income by the weighted average number of shares outstanding and the impact of all potential dilutive common shares, consisting primarily of stock options, unvested restricted common stock, shares issuable upon conversion of the 2022 Notes, 2023 Notes and 2024 Notes and stock purchase warrants.

For periods of loss from continuing operations, diluted loss per share is calculated similar to basic loss per share as the effect of including all potentially dilutive common share equivalents is anti-dilutive. Due to the periods of loss from continuing operations, the calculation of diluted loss per share for the three and six months ended June 30, 2019 excluded 16,278,260 and 15,877,586, respectively, of potentially dilutive stock options, warrants, restricted common shares, and shares issuable upon conversion of the 2022 Notes, 2023 Notes and 2024 Notes as their inclusion would have an anti-dilutive effect.

The calculation of diluted loss per share for the three and six months ended June 30, 2018 excluded 9,084,658 and 9,023,621, respectively, of potentially dilutive stock options, stock purchase warrants, restricted common shares, and shares issuable upon conversion of the 2022 Notes and 2023 Notes as their inclusion would have an anti-dilutive effect.

## **5. Income Taxes**

For the three months ended June 30, 2019 and 2018, the Company recorded a provision for income taxes of less than \$0.01 million and benefit from income taxes of \$12.4 million, respectively. The worldwide effective income tax rates for the Company for the three months ended June 30, 2019 and 2018 was 0.01% and 18.5%, respectively.

For the six months ended June 30, 2019 and 2018, the Company recorded a provision for income taxes of \$0.01 million and a benefit from income taxes of \$31.3 million, respectively. The worldwide effective income tax rates for the Company for the six months ended June 30, 2019 and 2018 was 0.01% and 18.4%, respectively.

For the three and six months ended June 30, 2019, the Company's income tax provision is primarily attributable to minimum state taxes and foreign taxes based on income.

For the three and six months ended June 30, 2018, the Company's benefit from income taxes is primarily attributable to the utilization of current period losses against a discrete provision for income taxes of \$51.2 million from the sale of the Company's infectious disease business. For further details regarding the sale of the infectious disease business see Note 15, "Discontinued Operations."

The Company considers all available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation allowance is needed to reduce its deferred tax assets to the amount that is more likely than not to be realized. The Company placed significant weight on the fact that the Company expects to be in a cumulative net book loss for the three-year period ending December 31, 2019 in recording valuation allowances on substantial portions of its deferred tax assets as of June 30, 2019.

The Company will continue to evaluate its ability to realize its deferred tax assets on a periodic basis and will adjust such amounts in light of changing facts and circumstances including, but not limited to, future projections of taxable income, tax legislation, rulings by relevant tax authorities, the progress of ongoing tax audits and the regulatory approval of products currently under development. Any additional changes to the valuation allowance recorded on deferred tax assets in the future would impact the Company's income taxes.

## **6. Cash and Cash Equivalents and Investments**

The Company considers all highly liquid investments purchased with original maturities at the date of purchase of three months or less to be cash equivalents. At June 30, 2019 and December 31, 2018, the Company had cash and cash equivalents of \$319.3 million and \$238.3 million, respectively, which consisted of cash of \$306.9 million and \$226.0 million, and money market funds with original maturities of less than three months of \$12.4 million and \$12.3 million at June 30, 2019 and December 31, 2018, respectively.

As of June 30, 2019 and December 31, 2018, the Company's common stock investment in Melinta had a readily determinable fair value of \$4.4 million and \$2.6 million, respectively. During the three and six months ended June 30, 2019, the Company recognized a gain of \$2.1 million and \$1.8 million, respectively, all of which was unrealized, in the accompanying condensed consolidated statements of operations, relating to the Company's investment in Melinta.

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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) — (Continued)**

During the three and six months ended June 30, 2018, the Company recognized losses of \$3.5 million and \$33.5 million, respectively, all of which was unrealized, in the accompanying condensed consolidated statements of operations, relating to the Company's investment in Melinta.

**Restricted Cash**

The Company had restricted cash of \$6.5 million and \$6.7 million at June 30, 2019 and December 31, 2018, respectively which included \$6.2 million and \$6.3 million, respectively, reserved for outstanding letters of credit associated with foreign taxes, and \$0.4 million and \$0.4 million, respectively, reserved for other U.S. operating expenses. These funds are invested in certificates of deposit.

**7. Fair Value Measurements**

The Company applies a fair value framework in order to measure and disclose its financial assets and liabilities. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. There are three levels of inputs that may be used to measure fair value:

- Level 1** Quoted prices in active markets for identical assets or liabilities. The Company's Level 1 assets consist of money market investments.
- Level 2** Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Fair values are determined by utilizing quoted prices for similar assets and liabilities in active markets or other market observable inputs such as interest rates and yield curves.
- Level 3** Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

*Financial assets and liabilities measured at fair value on a recurring basis*

Financial assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability.

Except for the Company's Level 2 liabilities which are discussed in Note 9, "Convertible Senior Notes," the following table sets forth the Company's assets and liabilities that are measured at fair value on a recurring basis at June 30, 2019 and December 31, 2018, by level, within the fair value hierarchy:

Assets and Liabilities	As of June 30, 2019				As of December 31, 2018			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of June 30, 2019	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2018
(in thousands)								
<b>Assets:</b>								
Cash equivalents	\$ 12,438	\$ —	\$ —	\$ 12,438	\$ 12,298	\$ —	\$ —	\$ 12,298
Short-term investment	4,407	—	—	4,407	2,627	—	—	2,627
<b>Total assets at fair value</b>	<b>\$ 16,845</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 16,845</b>	<b>\$ 14,925</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 14,925</b>

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**8. Inventory**

The major classes of inventory were as follows:

	June 30, 2019	December 31, 2018
	(in thousands)	
Raw materials	\$ —	\$ 864
Work-in-progress	—	—
Finished goods	—	—
Total	\$ —	\$ 864

The Company reviews inventory, including inventory purchase commitments, for slow moving or obsolete amounts based on expected product sales volume and provides reserves against the carrying amount of inventory as appropriate. If annual volume is less than expected, the Company may be required to make additional allowances for excess or obsolete inventory in the future.

**9. Convertible Senior Notes**

*Convertible Senior Notes Due 2024*

In December 2018 and January 2019, the Company issued, at par value, \$172.5 million aggregate principal amount of 3.5% 2024 Notes. The 2024 Notes bear cash interest at a rate of 3.5% per year, payable semi-annually on January 15 and July 15 of each year, beginning on July 15, 2019. The 2024 Notes will mature on January 15, 2024. The net proceeds to the Company from the offering were \$166.8 million after deducting commissions and the offering expenses payable by the Company.

The 2024 Notes are governed by an indenture (the 2024 Notes Indenture) with Wells Fargo Bank, National Association, a national banking association, as trustee (the 2024 Notes Trustee).

The 2024 Notes are senior unsecured obligations of the Company and will rank senior in right of payment to the Company's future indebtedness that is expressly subordinated in right of payment to the 2024 Notes; equal in right of payment to the Company's existing and future unsecured indebtedness that is not so subordinated; effectively junior in right of payment to any of the Company's secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all existing and future indebtedness and other liabilities (including trade payables) incurred by the Company's subsidiaries.

Holders may convert their 2024 Notes at their option at any time prior to the close of business on the business day immediately preceding October 15, 2023 only under the following circumstances:

- during any calendar quarter commencing on or after March 31, 2019 (and only during such calendar quarter), if the last reported sale price of the Company's 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;
- during the five business day period after any five consecutive trading day period (the measurement period) in which the trading price (as defined in the 2024 Notes Indenture) per \$1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day; or
- upon the occurrence of specified corporate events.

On or after October 15, 2023, until the close of business on the business day immediately preceding the maturity date, holders may convert their 2024 Notes at any time, regardless of the foregoing circumstances. Upon conversion, the Company will pay or deliver, as the case may be, cash, shares of the Company's common stock or a combination thereof, at the Company's option, based upon a daily conversion value calculated on a proportionate basis for each trading day in a 40 trading day observation period (as more fully described in the 2024 Notes Indenture). The conversion rate for the 2024 Notes was initially, and remains, 39.692

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shares of the Company's common stock per \$1,000 principal amount of the 2024 Notes, which is equivalent to an initial conversion price of approximately \$25.19 per share of the Company's common stock.

During the second quarter of 2019, the conditional conversion feature of the 2024 Notes was triggered based on the trading price of the Company's common stock during the second quarter of 2019, and the holders are currently entitled to convert the 2024 Notes through September 30, 2019. From July 1, 2019 through July 23, 2019, no holders of the 2024 Notes exercised their conversion option. In the event that the holders elect to convert their 2024 Notes, the Company intends to deliver shares of the Company's common stock. As of June 30, 2019 the value of the convertible portion of the 2024 Notes exceeds the principal amount by \$77.2 million.

If the Company undergoes a fundamental change (as defined in the 2024 Notes Indenture), subject to certain conditions, holders of the 2024 Notes may require the Company to repurchase for cash all or part of their 2024 Notes at a repurchase price equal to 100% of the principal amount of the 2024 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The 2024 Notes Indenture governing the 2024 Notes contains customary events of default with respect to the 2024 Notes, including that upon certain events of default (including the Company's failure to make any payment of principal or interest on the 2024 Notes when due and payable) occurring and continuing, the 2024 Notes Trustee by notice to the Company, or the holders of at least 25% in principal amount of the outstanding 2024 Notes by notice to the Company and the 2024 Notes Trustee, may, and the 2024 Notes Trustee at the request of such holders (subject to the provisions of the 2024 Notes Indenture) shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2024 Notes to be due and payable. In case of certain events of bankruptcy, insolvency or reorganization, involving the Company or a significant subsidiary, 100% of the principal of and accrued and unpaid interest on the 2024 Notes will automatically become due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately.

In accounting for the issuance of the 2024 Notes, the Company separated the 2024 Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The carrying amount of the equity component representing the conversion option was determined by deducting the fair value of the liability component from the par value of the 2024 Notes as a whole. The excess of the principal amount of the liability component over its carrying amount, referred to as the debt discount, is amortized to interest expense over the five-year term of the 2024 Notes. The equity component is not re-measured as long as it continues to meet the conditions for equity classification. The equity component related to the 2024 Notes was \$44.4 million and was recorded in additional paid-in capital on the accompanying consolidated balance sheet.

In accounting for the transaction costs related to the issuance of the 2024 Notes, the Company allocated the total costs incurred to the liability and equity components of the 2024 Notes based on their relative values. Transaction costs attributable to the liability component are amortized to interest expense over the five-year term of the 2024 Notes, and transaction costs attributable to the equity component are netted with the equity components in stockholders' equity. Additionally, the Company initially recorded a net deferred tax liability of \$12.5 million in connection with the 2024 Notes.

The 2024 Notes consist of the following:

Liability component	June 30, 2019	December 31, 2018
	(in thousands)	
Principal	\$ 172,500	\$ 163,000
Less: Debt discount, net(1)	(46,042)	(47,010)
<b>Net carrying amount</b>	<b>\$ 126,458</b>	<b>\$ 115,990</b>

(1) Included in the accompanying consolidated balance sheets within convertible senior notes (due 2024) and amortized to interest expense over the remaining life of the 2024 Notes using the effective interest rate method.

The fair value of the 2024 Notes was approximately \$274.1 million as of June 30, 2019. The Company estimates the fair value of its 2024 Notes utilizing market quotations for debt that have quoted prices in active markets. Since the 2024 Notes do not trade on a daily basis in an active market, the fair value estimates are based on market observable inputs based on borrowing rates currently available for debt with similar terms and average maturities, which are classified as Level 2 measurements within the



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fair value hierarchy. See Note 7, “Fair Value Measurements,” for definitions of hierarchy levels. As of June 30, 2019, the remaining contractual life of the 2024 Notes is approximately 4.5 years.

The following table sets forth total interest expense recognized related to the 2024 Notes:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Contractual interest expense	\$ 1,400	\$ —	\$ 2,918	\$ —
Amortization of debt discount	1,774	—	3,679	—
<b>Total</b>	<b>\$ 3,174</b>	<b>\$ —</b>	<b>\$ 6,597</b>	<b>\$ —</b>
Effective interest rate of the liability component	11.15%	—%	11.15%	—%

*Convertible Senior Notes Due 2023*

In June 2016, the Company issued, at par value, \$402.5 million aggregate principal amount of 2.75% 2023 Notes. The 2023 Notes bear cash interest at a rate of 2.75% per year, payable semi-annually on January 15 and July 15 of each year, beginning on January 15, 2017. The 2023 Notes will mature on July 15, 2023. The net proceeds to the Company from the offering were \$390.8 million after deducting the initial purchasers’ discounts and commissions and the offering expenses payable by the Company.

The 2023 Notes are governed by an indenture (the 2023 Notes Indenture) with Wells Fargo Bank, National Association, a national banking association, as trustee (the 2023 Notes Trustee).

The 2023 Notes are senior unsecured obligations of the Company and will rank senior in right of payment to the Company’s future indebtedness that is expressly subordinated in right of payment to the 2023 Notes; equal in right of payment to the Company’s existing and future unsecured indebtedness that is not so subordinated; effectively junior in right of payment to any of the Company’s secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all existing and future indebtedness and other liabilities (including trade payables) incurred by the Company’s subsidiaries.

Holders may convert their 2023 Notes at their option at any time prior to the close of business on the business day immediately preceding April 15, 2023 only under the following circumstances:

- during any calendar quarter commencing on or after September 30, 2016 (and only during such calendar quarter), if the last reported sale price of the Company’s 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;
- during the five business day period after any five consecutive trading day period (the measurement period) in which the trading price (as defined in the 2023 Notes Indenture) per \$1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company’s common stock and the conversion rate on each such trading day;
- during any period after the Company has issued notice of redemption until the close of business on the scheduled trading day immediately preceding the relevant redemption date; or
- upon the occurrence of specified corporate events.

On or after April 15, 2023, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their 2023 Notes at any time, regardless of the foregoing circumstances. Upon conversion, the Company will pay or deliver, as the case may be, cash, shares of the Company’s common stock or a combination thereof, at the Company’s option, based upon a daily conversion value calculated on a proportionate basis for each trading day in a 50 trading day observation period (as more fully described in the 2023 Notes Indenture). The conversion rate for the 2023 Notes was initially, and remains, 20.4198 shares of the Company’s common stock per \$1,000 principal amount of the 2023 Notes, which is equivalent to an initial conversion price of approximately \$48.97 per share of the Company’s common stock.

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The Company may not redeem the 2023 Notes prior to July 15, 2020. The Company may redeem for cash all or any portion of the 2023 Notes, at its option, on or after July 15, 2020 if the last reported sale price of its common stock has been at least 130% of the conversion price then in effect on the last trading day of, and for at least 19 other trading days (whether or not consecutive) during, any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption, at a redemption price equal to 100% of the principal amount of the 2023 Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. No redemption date may be designated that falls on or after the 52<sup>nd</sup> scheduled trading date prior to maturity. No sinking fund is provided for the 2023 Notes, which means that the Company is not required to redeem or retire the 2023 Notes periodically.

If the Company undergoes a fundamental change (as defined in the 2023 Notes Indenture), subject to certain conditions, holders of the 2023 Notes may require the Company to repurchase for cash all or part of their 2023 Notes at a repurchase price equal to 100% of the principal amount of the 2023 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The 2023 Notes Indenture governing the 2023 Notes contains customary events of default with respect to the 2023 Notes, including that upon certain events of default (including the Company's failure to make any payment of principal or interest on the 2023 Notes when due and payable) occurring and continuing, the 2023 Notes Trustee by notice to the Company, or the holders of at least 25% in principal amount of the outstanding 2023 Notes by notice to the Company and the 2023 Notes Trustee, may, and the 2023 Notes Trustee at the request of such holders (subject to the provisions of the 2023 Notes Indenture) shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2023 Notes to be due and payable. In case of certain events of bankruptcy, insolvency or reorganization, involving the Company or a significant subsidiary, 100% of the principal of and accrued and unpaid interest on the 2023 Notes will automatically become due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately.

In accounting for the issuance of the 2023 Notes, the Company separated the 2023 Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The carrying amount of the equity component representing the conversion option was determined by deducting the fair value of the liability component from the par value of the 2023 Notes as a whole. The excess of the principal amount of the liability component over its carrying amount, referred to as the debt discount, is amortized to interest expense over the seven-year term of the 2023 Notes. The equity component is not re-measured as long as it continues to meet the conditions for equity classification. The equity component related to the 2023 Notes is \$101.0 million and is recorded in additional paid-in capital on the accompanying condensed consolidated balance sheet.

In accounting for the transaction costs related to the issuance of the 2023 Notes, the Company allocated the total costs incurred to the liability and equity components of the 2023 Notes based on their relative values. Transaction costs attributable to the liability component are amortized to interest expense over the seven-year term of the 2023 Notes, and transaction costs attributable to the equity component are netted with the equity components in stockholders' equity. Additionally, the Company initially recorded a net deferred tax liability of \$33.5 million in connection with the 2023 Notes.

The 2023 Notes consist of the following:

Liability component	June 30, 2019	December 31, 2018
	(in thousands)	
Principal	\$ 402,500	\$ 402,500
Less: Debt discount, net <sup>(1)</sup>	(69,709)	(76,925)
Net carrying amount	<u>\$ 332,791</u>	<u>\$ 325,575</u>

<sup>(1)</sup> Included in the accompanying condensed consolidated balance sheets within convertible senior notes (due 2023) and amortized to interest expense over the remaining life of the 2023 Notes using the effective interest rate method.

The fair value of the 2023 Notes was approximately \$392.9 million as of June 30, 2019. The Company estimates the fair value of its 2023 Notes utilizing market quotations for debt that have quoted prices in active markets. Since the 2023 Notes do not trade on a daily basis in an active market, the fair value estimates are based on market observable inputs based on borrowing rates currently available for debt with similar terms and average maturities, which are classified as Level 2 measurements within the fair value hierarchy. See Note 7, "Fair Value Measurements," for definitions of hierarchy levels. As of June 30, 2019, the remaining contractual life of the 2023 Notes is approximately 4.0 years.

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The following table sets forth total interest expense recognized related to the 2023 Notes:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Contractual interest expense	\$ 2,767	\$ 2,767	\$ 5,534	\$ 5,534
Amortization of debt discount	3,619	3,351	7,216	6,682
<b>Total</b>	<b>\$ 6,386</b>	<b>\$ 6,118</b>	<b>\$ 12,750</b>	<b>\$ 12,216</b>
Effective interest rate of the liability component	7.5%	7.5%	7.5%	7.5%

*Capped call transactions*

In June 2016, the Company entered into capped call transactions with certain counterparties of the 2023 Notes or their respective affiliates or other financial institutions. The Company used approximately \$33.9 million of the net proceeds from the offering to pay the cost of the capped call transactions, which is included as a net reduction to additional paid-in capital on the accompanying condensed consolidated balance sheet.

The capped call transactions are expected to reduce the potential dilution with respect to shares of the Company's common stock upon any conversion of the 2023 Notes and/or offset any cash payments the Company is required to make in excess of the principal amount of converted 2023 Notes, as the case may be, if the market price of the Company's common stock is then greater than the strike price of the capped call transactions. Such reduction of potential dilution or offset of cash payments is subject to a cap based on the cap price of the capped call transactions. The cap price of the capped calls is currently \$64.68.

For any conversions of the 2023 Notes prior to the close of business on the 52<sup>nd</sup> scheduled trading day immediately preceding the stated maturity date of the 2023 Notes, including without limitation upon an acquisition of the Company or similar business combination, a corresponding portion of the capped calls will be terminated. Upon such termination, the portion of the capped calls being terminated will be settled at fair value (subject to certain limitations), as determined by the counterparties to the capped calls and no payments will be due from the Company to such counterparties. The capped calls expire on the earlier of (i) the last day on which any Convertible Securities remain outstanding and (ii) the second "Scheduled Trading Day" (as defined in the 2023 Notes Indenture) immediately preceding the "Maturity Date" (as defined in the 2023 Notes Indenture).

*Convertible Senior Notes Due 2022*

In January 2015, the Company issued, at par value, \$400.0 million aggregate principal amount of 2.5% convertible senior notes due 2022. The 2022 Notes bear cash interest at a rate of 2.5% per year, payable semi-annually on January 15 and July 15 of each year, beginning on July 15, 2015. The 2022 Notes will mature on January 15, 2022. The net proceeds to the Company from the offering were \$387.2 million after deducting the initial purchasers' discounts and commissions and the offering expenses payable by the Company.

The 2022 Notes are governed by an indenture (the 2022 Notes Indenture) with Wells Fargo Bank, National Association, a national banking association, as trustee (the 2022 Notes Trustee).

The 2022 Notes are senior unsecured obligations of the Company and will rank senior in right of payment to the Company's future indebtedness that is expressly subordinated in right of payment to the 2022 Notes; equal in right of payment to the Company's existing and future unsecured indebtedness that is not so subordinated; effectively junior in right of payment to any of the Company's secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all existing and future indebtedness and other liabilities (including trade payables) incurred by the Company's subsidiaries.

Holders may convert their 2022 Notes at their option at any time prior to the close of business on the business day immediately preceding October 15, 2021 only under the following circumstances:

- during any calendar quarter commencing on or after March 31, 2015 (and only during such calendar quarter), if the last reported sale price of the Company's 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;

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- during the five business day period after any five consecutive trading day period (the measurement period) in which the trading price (as defined in the 2022 Notes Indenture) per \$1,000 principal amount of 2022 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day;
- during any period after the Company has issued notice of redemption until the close of business on the scheduled trading day immediately preceding the relevant redemption date; or
- upon the occurrence of specified corporate events.

On or after October 15, 2021, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their 2022 Notes at any time, regardless of the circumstances described above. Upon conversion, the Company will pay cash up to the aggregate principal amount of the 2022 Notes to be converted and deliver shares of its common stock in respect of the remainder, if any, of its conversion obligation in excess of the aggregate principal amount of 2022 Notes being converted, subject to a daily share cap.

The conversion rate for the 2022 Notes was initially, and remains, 29.8806 shares of the Company's common stock per \$1,000 principal amount of the 2022 Notes, which is equivalent to an initial conversion price of approximately \$33.47 per share of the Company's common stock.

The Company may redeem for cash all or any portion of the 2022 Notes, at its option, on or after January 15, 2019 if the last reported sale price of its common stock has been at least 130% of the conversion price then in effect on the last trading day of, and for at least 19 other trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption, at a redemption price equal to 100% of the principal amount of the 2022 Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the 2022 Notes, which means that the Company is not required to redeem or retire the 2022 Notes periodically.

If the Company undergoes a "fundamental change" (as defined in the Indenture governing the 2022 Notes Indenture), subject to certain conditions, holders of the 2022 Notes may require the Company to repurchase for cash all or part of their 2022 Notes at a repurchase price equal to 100% of the principal amount of the 2022 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The 2022 Notes Indenture contains customary events of default with respect to the 2022 Notes, including that upon certain events of default (including the Company's failure to make any payment of principal or interest on the 2022 Notes when due and payable) occurring and continuing, the 2022 Notes Trustee by notice to the Company, or the holders of at least 25% in principal amount of the outstanding 2022 Notes by notice to the Company and the 2022 Notes Trustee, may, and the 2022 Notes Trustee at the request of such holders (subject to the provisions of the 2022 Notes Indenture) shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2022 Notes to be due and payable. In case of certain events of bankruptcy, insolvency or reorganization, involving the Company or a significant subsidiary, 100% of the principal of and accrued and unpaid interest on the 2022 Notes will automatically become due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately.

In accounting for the issuance of the 2022 Notes, the Company separated the 2022 Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The carrying amount of the equity component representing the conversion option was determined by deducting the fair value of the liability component from the par value of the 2022 Notes as a whole. The excess of the principal amount of the liability component over its carrying amount, referred to as the debt discount, is amortized to interest expense over the seven-year term of the 2022 Notes. The equity component is not re-measured as long as it continues to meet the conditions for equity classification. The equity component related to the 2022 Notes was \$88.9 million and was recorded in additional paid-in capital on the accompanying condensed consolidated balance sheets.

In accounting for the transaction costs related to the issuance of the 2022 Notes, the Company allocated the total costs incurred to the liability and equity components of the 2022 Notes based on their relative values. Transaction costs attributable to the liability component are amortized to interest expense over the seven-year term of the 2022 Notes, and transaction costs attributable to the

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equity component are netted with the equity components in stockholders' equity. Additionally, the Company initially recorded a net deferred tax liability of \$31.8 million in connection with the 2022 Notes.

The 2022 Notes consist of the following:

Liability component	June 30, 2019	December 31, 2018
	(in thousands)	
Principal	\$ 399,997	\$ 399,997
Less: Debt discount, net <sup>(1)</sup>	(41,472)	(48,810)
Net carrying amount	<u>\$ 358,525</u>	<u>\$ 351,187</u>

<sup>(1)</sup> Included in the accompanying condensed consolidated balance sheets within convertible senior notes (due 2022) and amortized to interest expense over the remaining life of the 2022 Notes using the effective interest rate method.

The fair value of the 2022 Notes was approximately \$476.1 million as of June 30, 2019. The Company estimates the fair value of its 2022 Notes utilizing market quotations for debt that have quoted prices in active markets. Since the 2022 Notes do not trade on a daily basis in an active market, the fair value estimates are based on market observable inputs based on borrowing rates currently available for debt with similar terms and average maturities, which are classified as Level 2 measurements within the fair value hierarchy. See Note 7, "Fair Value Measurements," for definitions of hierarchy levels. As of June 30, 2019, the remaining contractual life of the 2022 Notes is approximately 2.5 years. As of June 30, 2019 the value of the convertible portion of the 2022 Notes exceeds the principal amount by \$15.5 million.

The following table sets forth total interest expense recognized related to the 2022 Notes:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Contractual interest expense	\$ 2,500	\$ 2,500	\$ 5,000	\$ 5,000
Amortization of debt discount	3,679	3,434	7,338	6,848
Total	<u>\$ 6,179</u>	<u>\$ 5,934</u>	<u>\$ 12,338</u>	<u>\$ 11,848</u>
Effective interest rate of the liability component	6.5%	6.5%	6.5%	6.5%

#### 10. Accumulated Other Comprehensive Loss

The following tables provide a reconciliation of the components of accumulated other comprehensive loss, net of tax, attributable to the Company for the three and six months ended June 30, 2019 and 2018 :

	Three Months Ended June 30,			
	2019		2018	
	Foreign currency translation adjustment	Total	Foreign currency translation adjustment	Total
	(in thousands)			
Balance at beginning of period	\$ (5,406)	\$ (5,406)	\$ (4,471)	\$ (4,471)
Other comprehensive income (loss)	805	805	(123)	(123)
Total other comprehensive income (loss)	<u>805</u>	<u>805</u>	<u>(123)</u>	<u>(123)</u>
Balance at end of period	<u>\$ (4,601)</u>	<u>\$ (4,601)</u>	<u>\$ (4,594)</u>	<u>\$ (4,594)</u>

**THE MEDICINES COMPANY**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) — (Continued)**

	Six Months Ended June 30,			
	2019		2018	
	Foreign currency translation adjustment	Total	Foreign currency translation adjustment	Total
	(in thousands)			
Balance at beginning of period	\$ (4,576)	\$ (4,576)	\$ (5,183)	\$ (5,183)
Other comprehensive loss before reclassifications	(25)	(25)	(594)	(594)
Amounts reclassified from accumulated other comprehensive loss <sup>(1)</sup>	—	—	1,183	1,183
Total other comprehensive (loss) income	(25)	(25)	589	589
Balance at end of period	\$ (4,601)	\$ (4,601)	\$ (4,594)	\$ (4,594)

(1) See Note 15, "Discontinued Operations," for a discussion of this reclassification of foreign currency translation adjustment.

### 11. Segment and Geographic Information

The Company manages its business and operations as one segment and is focused on inclisiran as a transformative treatment for ASCVD. The Company allocates resources and assesses financial performance on a consolidated basis. In August 2018, the Company divested its rights to branded Angiomax in the United States to Sandoz, as a result, it no longer has any marketed products.

The geographic segment information provided below is classified based on the major geographic regions in which the Company operates. Long-lived assets are comprised of the Company's noncurrent assets.

	June 30, 2019		December 31, 2018	
	(\$ in thousands)			
Long-lived assets:				
United States	\$ 569,052	99.0%	\$ 541,268	99.0%
Europe	5,594	1.0%	5,615	1.0%
Total long-lived assets	\$ 574,646	100.0%	\$ 546,883	100.0%

### 12. Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for loss contingencies when available information indicates that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the litigation, including an estimable range, if possible.

The Company is currently party to certain legal proceedings, which are principally contractual litigation matters related to license agreements and divestiture agreements. The Company has assessed such legal proceedings and recorded a loss contingency of \$5.2 million during 2018 as a result of settlement of the litigation with Biogen Idec (Biogen) related to Angiomax under the Company's license agreement with Biogen. For all other matters the Company does not believe that it is probable that a liability has been incurred or that the amount of any potential liability can be reasonably estimated. As a result, the Company did not record a loss contingency related to any of these matters. While it is not possible to determine the outcome of these matters, the Company believes that the resolution of all such matters will not have a material adverse effect on its financial position or liquidity, but could possibly be material to its results of operations in any one accounting period.

### 13. Restructuring

#### *2018 Workforce Reduction*

In October 2017, the Company announced its intention to commence a series of workforce reductions, independent of the divestiture of the Company's infectious disease business (the Workforce Reductions), to improve efficiencies and better align its costs and structure. The Workforce Reductions and the infectious disease business divestiture resulted in the Company reducing its personnel to less than 60 full time employees at such time. Upon signing release agreements, affected employees received the

**THE MEDICINES COMPANY**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) — (Continued)**

Company's severance package, including reduction payments and fully paid health care coverage and outplacement services for six months to a year. The impacted employees were eligible to receive severance payments in specified amounts, health benefits and outplacement services. For the three and six months ended June 30, 2019, there were no material restructuring charges. For the three months ended June 30, 2018, the Company recorded \$0.3 million, \$3.3 million, and \$2.5 million in costs of revenue, research and development and selling, general and administrative expenses, respectively, in the accompanying condensed consolidated statement of operations based on responsibilities of the impacted employees.

For the six months ended June 30, 2018, the Company recorded \$0.8 million, \$4.1 million, and \$8.4 million in costs of revenue, research and development and selling, general and administrative expenses, respectively, in the accompanying condensed consolidated statement of operations based on responsibilities of the impacted employees.

The following table sets forth details regarding the activities described above during the six months ended June 30, 2019 :

	Balance as of January 1, 2019	Expenses, Net	Cash	Noncash	Balance as of June 30, 2019
	(in thousands)				
2018 Workforce reduction	\$ 2,334	\$ —	\$ (2,151)	\$ (77)	\$ 106

**14. Related Party Transactions**

**Arrangements Involving the Company's Executive Officers**

In January 2018, Christopher Cox, the Company's former executive vice president and chief corporate development officer, rejoined the law firm Cadwalader, Wickersham & Taft, LLP (Cadwalader) as a partner. During 2018, Mr. Cox remained employed with the Company and continued to lead certain company functions and initiatives, including corporate strategy, business development and investor relations. In March 2019, Mr. Cox separated from the Company and rejoined Cadwalader on a full-time basis. Stephen Rodin, the Company's executive vice president, general counsel and secretary, has been, and will continue to be, responsible for the retention and management of outside counsel. Since 2015, the Company has retained Cadwalader as corporate and transactional legal counsel. The Company and Cadwalader had agreed on certain procedures to address potential conflicts that could have arisen out of Mr. Cox's dual roles from January 2018 to March 2019.

**15. Discontinued Operations**

*Sale of Infectious Disease Business*

On January 5, 2018, the Company completed the sale of its infectious disease business, consisting of the products Vabomere, Orbactiv and Minocin IV and line extensions thereof, and substantially all of the assets related thereto, other than certain pre-clinical assets, to Melinta. At the completion of the sale, the Company received approximately \$166.4 million and 3,313,702 shares of Melinta common stock having a market value, based on Melinta's closing share price on January 5, 2018, of approximately \$54.5 million. The Company's common stock investment in Melinta was recorded as a short-term investment with a readily determinable fair value at June 30, 2019 of \$4.4 million on the accompanying condensed consolidated balance sheet. See Note 6 "Cash, Cash Equivalents and Investments" for further details.

In addition, the Company is entitled to receive a cash payment payable 12 months following the closing of the transaction equal to \$25.0 million and a cash payment payable 18 months following the closing of the transaction equal to \$25.0 million. On January 5, 2018 the fair value of such payments was approximately \$45.9 million, of which \$23.3 million was originally recorded in prepaid expenses and other current assets and \$22.6 million was originally recorded in other assets on the condensed consolidated balance sheet. Such fair value was estimated using a discounted cash flow model and was classified as a Level 3 fair value measurement due to the use of significant unobservable inputs. See Note 7, "Fair Value Measurements," for definitions of hierarchy levels. The excess of the cash payments payable to the Company over the initial fair value was amortized to interest income over the 12 and 18 month periods using the effective interest rate method. As of June 30, 2019, the carrying amounts of these assets of \$50.0 million approximate their fair value due to the short term nature of the payments.

The Company is also entitled to tiered royalty payments of 5% to 25% on worldwide net sales of (a) Vabomere and (b) Orbactiv and Minocin IV, collectively. On January 5, 2018, the fair value of these contingent payments to be received from Melinta was \$246.2 million and was recorded as contingent purchase price from sale of businesses in the accompanying condensed consolidated balance sheet. Substantially all of the fair value was estimated using Monte Carlo simulation models to compute contractual payments which were present valued using a risk-adjusted discount rate. The Company classified this as a Level 3 fair value



**THE MEDICINES COMPANY**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) — (Continued)**

measurement due to the use of these significant unobservable inputs. See Note 7, “Fair Value Measurements,” for definitions of hierarchy levels.

In addition, Melinta assumed the Company’s obligation to make potential milestone payments due under the Company’s acquisition agreement with Rempex Pharmaceuticals, Inc. (Rempex) related to regulatory and sales based milestones of up to \$35 million and \$120 million, respectively. This is inclusive of a \$30 million milestone payment to the former owners of the infectious disease business (Vabomere Milestone Payment), achieved upon receipt of regulatory approval of Vabomere by the European Medicines Agency. As regulatory approval was received by Melinta in November 2018, the Vabomere Milestone Payment is due. The Company remains ultimately responsible to pay the Vabomere Milestone Payment under its agreement with the former owners of the infectious disease business; however the Company believes that it is responsible for such payment only if the former owners of the infectious disease business are unable to collect from Melinta after exercising due diligence in attempting to collect from Melinta before seeking to collect from the Company. In December 2018, Melinta filed a complaint in the Court of Chancery of the State of Delaware alleging that the Company breached certain representations and warranties in the purchase and sale agreement pursuant to which Melinta acquired the Company’s infectious disease business. In connection with the lawsuit, Melinta is seeking indemnification under the purchase and sale agreement and notified the Company that it would not be paying the Vabomere Milestone Payment or the two \$25 million deferred payments due to the Company under the purchase and sale agreement because Melinta believes it has the right to set-off such payments against its claimed damages in its lawsuit. The Company contested Melinta’s indemnification and right of set-off assertions. The Company has contested Melinta’s position, and on December 28, 2018, January 22, 2019 and July 16, 2019, the Company sent demand letters to Melinta regarding its failure to pay the Vabomere Milestone Payment, the first deferred payment and the second deferred payment, respectively. Relatedly, on January 7, 2019, the Company received a letter on behalf of Fortis Advisors LLC, (Fortis), in its capacity as the representative for the interests of former equity holders of Rempex, demanding that the Company pay the Vabomere Milestone Payment. On January 28, 2019, the Company notified Fortis that, while the Company agrees it is ultimately responsible for the Vabomere Milestone Payment even though the payment was assumed by Melinta, the Company believes it is responsible for such payment only if Fortis is unable to collect from Melinta after exercising due diligence in attempting to collect from Melinta before seeking to collect from the Company. On March 28, 2019, Fortis filed a complaint in the Court of Chancery of the State of Delaware against Melinta and the Company regarding the non-payment of the Vabomere Milestone Payment. On April 18, 2019, the Company filed an answer to Fortis’s complaint and a crossclaim against Melinta, alleging breach of contract and requesting that the Court order Melinta to fulfill its obligations under the purchase and sale agreement, including complying with payment obligations in connection with the Vabomere Milestone Payment, among other relief. That same day, Melinta filed a motion to dismiss Fortis’s complaint, and filed its opening brief in support of that motion on May 31, 2019. On May 8, 2019, Melinta filed its answer to the Company’s crossclaim. On May 20, 2019, Fortis filed both a motion for partial judgment on the pleadings against the Company and its brief in support of that motion. On June 21, 2019, the Company filed both a motion for judgment on the pleadings against Melinta and a combined answering and opening brief, which both opposed Fortis’s motion for partial judgment on the pleadings and supported the Company’s affirmative motion for judgment on the pleadings against Melinta. Oral argument on Fortis’s Motion for Partial Judgment on the Pleadings is currently scheduled for September 19, 2019. Briefing in both the Fortis and Melinta matters has continued, and is presently ongoing. Although the Company will vigorously contest Fortis’s claims on the basis that they must first exercise due diligence in attempting to collect the Vabomere Milestone Payment from Melinta before they seek to collect from the Company, litigation is subject to inherent uncertainty. The Company believes Melinta’s claims are meritless and it will vigorously defend any and all claims brought against itself by Melinta and seek full payment by Melinta of its obligations under the purchase and sale agreement.

Financial results of the infectious disease business are presented as “Income (loss) from discontinued operations, net of tax” on the accompanying condensed consolidated statements of operations for the three and six months ended June 30, 2018 .

The following table presents key financial results of the infectious disease business included in “Income (loss) from discontinued operations, net of tax” for the three and six months ended June 30, 2018 .



**THE MEDICINES COMPANY**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) — (Continued)**

	Three Months Ended June 30, 2018	Six Months Ended June 30, 2018
	(In thousands)	
Net product revenues	\$ (81)	\$ (107)
Operating expenses:		
Cost of revenue	(17)	197
Research and development	98	510
Selling, general and administrative	(19)	3,077
Total operating expenses	62	3,784
Loss from operations	(143)	(3,891)
Gain from sale of business	—	168,955
Other income, net	484	410
Income from discontinued operations before income taxes	341	165,474
Benefit from income taxes	85	51,233
Income from discontinued operations, net of tax	\$ 256	\$ 114,241

Cumulative translation adjustment (CTA) gains or losses of foreign subsidiaries related to divested businesses are reclassified into income once the liquidation of the respective foreign subsidiaries is substantially complete. At the completion of the sale of the infectious disease business, the Company reclassified \$1.2 million of CTA gains from accumulated comprehensive loss to the Company's results of discontinued operations. This amount was included in gain from sale of business for the six months ended June 30, 2018.

Disposition related costs during the six months ended June 30, 2018 of approximately \$11.9 million for advisory, legal and regulatory fees incurred in connection with the sale of the infectious disease business were recorded in the gain from the sale of the business.

The significant cash flow items from discontinued operations for the six months ended June 30, 2018 were as follows:

	Six months ended June 30, 2018
	(In thousands)
Gain on sale of business	\$ (168,955)
Proceeds from sale of business	166,383

## 16. Leases

The Company leases its principal office in Parsippany, New Jersey, U.S. The lease for the Parsippany office covers 173,146 square feet and expires January 2024. The Company also leases 63,000 square feet of office and laboratory space in San Diego, California. This lease expires in September 2028. On January 11, 2018, the Company entered into an agreement to sublease 32,039 square feet of the office and laboratory space in San Diego. On August 24, 2018, the Company entered into an agreement to sublease the remaining office and laboratory space in San Diego. The sublease agreements have initial terms of 84 months and 48 months, respectively.

The Company recognizes lease expense on a straight-line basis over the lease term. For lease agreements entered into or reassessed after the adoption of Topic 842, the Company elected to account for non-lease components associated with its leases and lease components as a single lease component.

**THE MEDICINES COMPANY**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) — (Continued)**

The Company's lease and sublease portfolio consists of operating leases and are included on the accompanying condensed consolidated balance sheet as follows:

	June 30, 2019
	(in thousands)
Other assets	\$ 32,696
<b>Liabilities</b>	
Other current liabilities	\$ 7,567
Other liabilities	31,319
Total Lease Liabilities	\$ 38,886

Equipment leases with an initial term of 12 months or less are not recorded on the accompanying condensed consolidated balance sheet. The Company recognizes rent expense for these leases on a straight-line basis over the lease term and is not material.

The Company recognizes a right-of-use asset, which represents the Company's right to use the underlying asset for the lease term, and a lease liability, which represents the present value of the Company's obligation to make payments arising over the lease term. The present value of the lease payments are calculated using an incremental borrowing rate as the Company's leases do not provide an implicit interest rate. The Company's weighted average discount rate and lease terms for its operating leases as of June 30, 2019 was 8.61% and 7.1 years, respectively.

For the three months ended June 30, 2019, the Company recorded operating lease costs and sublease income of \$1.9 million and \$0.8 million, respectively, in selling, general and administrative expenses, in the accompanying condensed consolidated statements of operations.

For the six months ended June 30, 2019, the Company recorded operating lease costs and sublease income of \$3.9 million and \$1.5 million, respectively, in selling, general and administrative expenses, in the accompanying condensed consolidated statements of operations.

The accompanying statement of cash flows includes \$2.5 million in net cash used in operating activities, related to net cash payments for operating leases.

The Company's operating lease payments for the remainder of 2019 is expected to be \$3.9 million, and for the years ended December 31, 2020, 2021, 2022, 2023 and thereafter are expected to be \$8.6 million, \$8.7 million, \$8.8 million, \$6.6 million and \$15.4 million, respectively, inclusive of interest of approximately \$12.9 million.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and accompanying notes included elsewhere in this Quarterly Report on Form 10-Q. In addition to the historical information, the discussion in this Quarterly Report on Form 10-Q contains certain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated by the forward-looking statements due to our critical accounting estimates discussed below and important factors set forth in this Quarterly Report on Form 10-Q, including under "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q.*

### Overview

#### ***Our Business***

We are a biopharmaceutical company driven by our purpose solve major medical, societal and economic challenges in healthcare. We have a singular focus on one of the greatest global healthcare challenges and burdens - that presented by cardiovascular disease, which remains the number one cause of death in the United States and worldwide. The leading cause of cardiovascular disease morbidity and mortality is atherosclerotic cardiovascular disease, or ASCVD. We take on that challenge

by developing inclisiran, the investigational RNA interference, or RNAi, therapeutic, that specifically inhibits production of proprotein convertase subtilisin/kexin type 9, or PCSK9, a key protein that controls LDL-cholesterol, or LDL-C, levels. We believe inclisiran is uniquely suited to make a significant difference reducing risk in ASCVD. We have the right to develop, manufacture and commercialize inclisiran under our collaboration agreement with Alnylam Pharmaceuticals, Inc., or Alnylam.

On August 22, 2018, we completed the sale of our rights to branded Angiomax in the United States to Sandoz Inc., or Sandoz, for \$9.9 million. Following such divestiture, we no longer market any products. Historically, our revenues have been generated primarily from sales of Angiomax in the United States, but competition from generic versions of Angiomax following the loss of market exclusivity in the United States in July 2015 and in Europe in August 2015 resulted in a significant decline in revenue from Angiomax prior to our divestiture of the product. Based on our current business, we expect to incur net losses for the foreseeable future.

### ***Inclisiran Clinical Development***

We expect to start reporting data readouts for the pivotal Phase 3 clinical trials for inclisiran, ORION-11, ORION-9 and ORION-10, in the second half of the third quarter of 2019. We submitted a promissory abstract for a late-breaking science session at the European Society of Cardiology's ESC Congress 2019, Paris, to present efficacy, tolerability and safety data from ORION-11, which was accepted for presentation on September 2, 2019. In addition, in July 2019 the Independent Data Monitoring Committee, or IDMC, for the ORION-9, ORION-10 and ORION-11 clinical trials completed its seventh planned review of un-blinded safety and efficacy data. The IDMC recommended that the trials continue as designed and conducted, without modification.

### ***Business Development Activity***

*Sale of Angiomax.* On August 22, 2018, we completed the sale of our rights to branded Angiomax in the United States to Sandoz for \$9.9 million. Prior to the divestiture, Sandoz had been selling an authorized generic of Angiomax (bivalirudin) as of July 2, 2015 pursuant to a supply and distribution agreement with us. As a result of the divestiture, Sandoz is the holder of the new drug application, or NDA, for Angiomax in the United States and will be responsible for manufacturing and supply of Angiomax in the second quarter of 2019. In February 2019, we sold our rights to branded Angiomax in Canada to Sandoz AG for \$0.5 million and, as a result of the transaction, Sandoz AG is the holder of the marketing authorization for Angiomax in Canada and is responsible for manufacturing and supply of Angiomax.

*Sale of Infectious Disease Products.* On January 5, 2018, we completed the sale of our infectious disease portfolio, consisting of the products Vabomere, Orbactiv and Minocin IV and line extensions thereof, and substantially all of the assets related thereto, other than certain pre-clinical assets, to Melinta Therapeutics, Inc., or Melinta. At the completion of the sale, we received approximately \$166.4 million and 3,313,702 shares of Melinta common stock having a market value, based on Melinta's closing share price on June 30, 2019, of approximately \$4.4 million. In addition, we are entitled to receive (i) a cash payment that was due 12 months following the closing of the transaction equal to \$25 million; (ii) a cash payment payable 18 months following the closing of the transaction equal to \$25 million; and (iii) tiered royalty payments of 5% to 25% on worldwide net sales of (a) Vabomere and (b) Orbactiv and Minocin IV, collectively, and Melinta assumed potential milestone payments due under our agreement with Rempex Pharmaceuticals, Inc., or Rempex. None of the future payments due from Melinta are secured by collateral and we are currently in litigation with Melinta with respect to its obligations to us. See Part II, Item 1 *Legal Proceedings* of this Quarterly Report on Form 10-Q for a description of our litigation related to Melinta.

In October 2018, we divested certain pre-clinical infectious disease assets not acquired by Melinta, which included the funding agreement with the Biomedical Advanced Research and Development Authority, or BARDA, of the U.S. Department of Health and Human Services, or HHS. The assets were purchased by Qpex Biopharma, Inc., or Qpex, a new company formed by a syndicate of venture firms led by New Enterprise Associates and accompanied by Adams Street Partners, LYZZ Capital, Hatteras Venture Partners and Stanford University Draper Fund. At the completion of the sale, we received approximately \$2.8 million and are entitled to receive up to \$29 million upon the achievement of certain milestones related to the pre-clinical assets. In addition, Qpex assumed potential milestone payments due under our agreement with Rempex related to the development of the pre-clinical assets.

*Sale of Non-Core Cardiovascular Products.* On June 21, 2016, we completed the sale of Cleviprex, Kengreal and rights to Argatroban for Injection, which we refer to collectively as Non-Core ACC Assets, to Chiesi USA, Inc., or Chiesi USA, and its parent company Chiesi Farmaceutici S.p.A., or Chiesi. Under the terms of the purchase and sale agreement, Chiesi and Chiesi USA acquired our Non-Core ACC Assets and related assets, and assumed substantially all of the liabilities arising out of the operation of the businesses and the acquired assets after closing, including any obligations with respect to future milestones relating to each of the products. At the completion of the sale, we received approximately \$263.8 million in cash, which included the value of product inventory, and may receive up to an additional \$480.0 million in the aggregate following the achievement of certain

specified calendar year net sales milestones with respect to net sales of each of Cleviprex and Kengreal. As part of the transaction to sell Non-Core ACC Assets, we sublicensed to Chiesi all of our rights to Cleviprex and Kengreal under our license from AstraZeneca AB, or AstraZeneca. Subsequent to the completion of the sale, these sublicenses from us to Chiesi were terminated, Chiesi purchased from AstraZeneca all or substantially all of AstraZeneca's assets relating to Cleviprex and Kengreal, the parties released certain claims against one another, and we paid Chiesi \$7.5 million.

**Sale of Hemostasis Business.** On February 1, 2016, we completed the sale of our hemostasis business, consisting of PreveLeak, Raplixa and Recothrom products to wholly-owned subsidiaries of Mallinckrodt plc, or Mallinckrodt. Under the terms of the purchase and sale agreement, Mallinckrodt acquired all of the outstanding equity of Tenaxis Medical, Inc. and ProFibrin B.V. and assets exclusively related to the Recothrom product. Mallinckrodt assumed all liabilities arising out of Mallinckrodt's operation of the businesses and the acquired assets after closing, including all obligations with respect to milestones relating to the PreveLeak and Raplixa products. At the completion of the sale, we received approximately \$174.1 million in cash from Mallinckrodt, and may receive up to an additional \$235.0 million in the aggregate following the achievement of certain specified calendar year net sales milestones with respect to net sales of PreveLeak and Raplixa. The amount paid at closing was subject to a post-closing purchase price adjustment process with respect to the Recothrom inventory and the net working capital of the hemostasis business as of the date of the closing. In the first quarter of 2018, Mallinckrodt announced it would no longer commercialize Raplixa and sold Recothrom and PreveLeak to Baxter International Inc., or Baxter, with Baxter assuming the sales milestones associated with PreveLeak.

**Alnylam License Agreement.** In February 2013, we entered into a license and collaboration agreement with Alnylam to develop, manufacture and commercialize therapeutic products targeting the PCSK9 gene based on certain of Alnylam's RNA interference technology. Under the terms of the agreement, we obtained the exclusive, worldwide right under Alnylam's technology to develop, manufacture and commercialize PCSK9 products for the treatment, palliation and/or prevention of all human diseases. We paid Alnylam \$25.0 million in an initial license payment and agreed to pay up to \$180.0 million in success-based development, regulatory and commercialization milestones. In December 2014, we paid a development milestone payment of \$10.0 million based upon the initiation of a Phase 1 clinical trial for inclisiran and in January 2018 we paid a development milestone payment of \$20.0 million based upon the initiation of our phase 3 study for inclisiran. In addition, Alnylam will be eligible to receive scaled double-digit royalties based on annual worldwide net sales of PCSK9 products by us or our affiliates and sublicensees. Royalties to Alnylam are payable on a product-by-product and country-by-country basis until the last to occur of the expiration of patent rights in the applicable country that cover the applicable product, the expiration of non-patent regulatory exclusivities for such product in such country, and the twelfth anniversary of the first commercial sale of the product in such country. The royalties are subject to reduction in specified circumstances. We are also responsible for paying royalties, and in some cases milestone payments, owed by Alnylam to its licensors with respect to intellectual property covering these products. Alnylam was responsible for developing the lead product through the end of the first Phase 1 clinical trial and to supply the lead product for the first Phase 1 clinical trial and the first phase 2 clinical trial. Alnylam bore the costs for these activities. We are responsible for all other development, manufacturing and commercialization activities under the agreement.

### **Workforce Restructuring**

In 2017 and 2018, we conducted a series of workforce reductions, as described below. Upon signing release agreements, affected employees have received a severance package, including reduction payments and fully paid health care coverage and outplacement services for six months to a year.

In June 2017, in connection with our voluntary discontinuation and withdrawal of Ionsys from the market in the United States, we commenced a workforce reduction, which resulted in the reduction of 57 employees, which represented approximately 15% of our workforce.

Commencing in December 2017 and continuing through 2018, we implemented a series of workforce reductions to focus on inclisiran, improve efficiencies and better align costs and structure. Through December 31, 2018, 136 employees were terminated and 136 employees were transferred as part of the sale of the infectious disease business unit to Melinta. These workforce reductions are expected to reduce headcount costs included in operating expenses by approximately \$74.0 million on an annualized basis.

### **Shelf Registration Statement and Equity Financing**

On June 24, 2019, we filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission, or SEC, which was automatically effective upon filing. This shelf registration statement permits us to offer, from time to time, an unspecified amount of debt securities, common stock, preferred stock, depositary shares, purchase contracts, purchase units and warrants. On June 28, 2019, we sold an aggregate of 5,227,273 shares of our common stock, including the exercise in full by the underwriters of an option to purchase additional 681,818 shares of common stock, in an underwritten public offering at a price to the public of

\$33.00 per share. We received net proceeds of approximately \$161.6 million from the sale of shares in the offering, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

### **Convertible Senior Note Offerings**

#### *2024 Notes*

On December 18, 2018, we completed our private offering of \$150.0 million aggregate principal amount of our 3.50% convertible senior notes due 2024, or the 2024 notes, and entered into an indenture with Wells Fargo Bank, National Association, a national banking association, as trustee, governing the 2024 notes. On December 28, 2018 and January 11, 2019, we completed the sale of an additional \$13.0 million and \$9.5 million, respectively, in aggregate principal amount of the 2024 notes pursuant to exercises of the initial purchaser's option to purchase additional notes to cover over-allotments. The additional notes have the same terms in all respects as the 2024 notes. The net proceeds from the offering (inclusive of the full exercise of the over-allotment option) were \$166.8 million, after deducting the commissions and our offering expenses.

The 2024 notes bear cash interest at a rate of 3.50% per year, payable semi-annually on January 15 and July 15 of each year, beginning on July 15, 2019. The 2024 notes will mature on January 15, 2024. The 2024 notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, incurrence of other indebtedness, or issuance or repurchase of securities by us.

Holders may convert their 2024 notes at their option at any time prior to the close of business on the business day immediately preceding October 15, 2023 only under the following circumstances: (1) during any calendar quarter commencing on or after March 31, 2019 (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, or measurement period, in which the trading price, as defined in the indenture governing the 2024 notes, per \$1,000 principal amount of 2024 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. Based on the trading price of our common stock during the second quarter of 2019, the conditional conversion feature of the 2024 notes has been triggered for the third quarter of 2019. On or after October 15, 2023, until the close of business on business day immediately preceding the maturity date, holders may convert their 2024 notes at any time, regardless of the foregoing circumstances. Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election based upon a daily conversion value calculated on a proportionate basis for each trading day in a 40 trading day observation period (as more fully described in the 2024 notes indenture).

The conversion rate for the 2024 notes was initially, and remains, 39.692 shares of our common stock per \$1,000 principal amount of the 2024 notes, which is equivalent to an initial conversion price of approximately \$25.19 per share of our common stock. The conversion rate and the conversion price are subject to customary adjustments for certain events, including, but not limited to, the issuance of certain stock dividends on our common stock, the issuance of certain rights or warrants, subdivisions, combinations, distributions of capital stock, indebtedness, or assets, cash dividends and certain issuer tender or exchange offers, as described in the indenture governing the 2024 notes.

If we undergo a fundamental change, as defined in the indenture governing the 2024 notes, subject to certain conditions, holders of the 2024 notes may require us to repurchase for cash all or part of their 2024 notes at a repurchase price equal to 100% of the principal amount of the 2024 notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. Following certain corporate transactions that constitute a change of control, we would increase the conversion rate for a holder who elects to convert the 2024 notes in connection with such change of control in certain circumstances.

The 2024 notes are our senior unsecured obligations and will rank senior in right of payment to our future indebtedness that is expressly subordinated in right of payment to the 2024 notes; equal in right of payment to our existing and future unsecured indebtedness that is not so subordinated (including the 2022 notes and 2023 notes); effectively junior in right of payment to any of our secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all existing and future indebtedness and other liabilities (including trade payables) incurred by our subsidiaries.

The indenture governing the 2024 notes contains customary events of default with respect to the 2024 notes, including that upon certain events of default (including our failure to make any payment of principal on the 2024 notes when due and payable or our failure to make any interest payment on the 2024 notes when due and payable and such failure continues for a period of thirty days) occurring and continuing, the trustee for the 2024 notes by notice to us, or the holders of at least 25% in principal amount of the outstanding 2024 notes by notice to us and the trustee for the 2024 notes, may, and the trustee at the request of such holders (subject to the provisions of the indenture governing the 2023 notes) shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2024 notes to be due and payable. In case of certain events of bankruptcy, insolvency or

reorganization, involving us or a significant subsidiary, 100% of the principal of and accrued and unpaid interest on the 2024 notes will automatically become due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately.

### *2023 Notes*

On June 10, 2016, we completed our private offering of \$402.5 million aggregate principal amount of our 2.75% convertible senior notes due 2023, or the 2023 notes, and entered into an indenture with Wells Fargo Bank, National Association, a national banking association, as trustee, governing the 2023 notes. The net proceeds from the offering were \$390.8 million, after deducting the initial purchasers' discounts and commissions and our offering expenses.

The 2023 notes bear cash interest at a rate of 2.75% per year, payable semi-annually on January 15 and July 15 of each year, beginning on January 15, 2017. The 2023 notes will mature on July 15, 2023. The 2023 notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, incurrence of other indebtedness, or issuance or repurchase of securities by us.

Holders may convert their 2023 notes at their option at any time prior to the close of business on the business day immediately preceding April 15, 2023 only under the following circumstances: (1) during any calendar quarter commencing on or after September 30, 2016 (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, or measurement period, in which the trading price, as defined in the indenture governing the 2023 notes, per \$1,000 principal amount of 2023 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; (3) during any period after we have issued notice of redemption until the close of business on the scheduled trading day immediately preceding the relevant redemption date; or (4) upon the occurrence of specified corporate events. On or after April 15, 2023, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their 2023 notes at any time, regardless of the foregoing circumstances. Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election based upon a daily conversion value calculated on a proportionate basis for each trading day in a 50 trading day observation period (as more fully described in the 2023 notes indenture).

The conversion rate for the 2023 notes was initially, and remains, 20.4198 shares of our common stock per \$1,000 principal amount of the 2023 notes, which is equivalent to an initial conversion price of approximately \$48.97 per share of our common stock. The conversion rate and the conversion price are subject to customary adjustments for certain events, including, but not limited to, the issuance of certain stock dividends on our common stock, the issuance of certain rights or warrants, subdivisions, combinations, distributions of capital stock, indebtedness, or assets, cash dividends and certain issuer tender or exchange offers, as described in the indenture governing the 2023 notes.

We may not redeem the 2023 notes prior to July 15, 2020. We may redeem for cash all or any portion of the 2023 notes, at our option, on or after July 15, 2020 if the last reported sale price of our common stock has been at least 130% of the conversion price then in effect on the last trading day of, and for at least 19 other trading days (whether or not consecutive) during, any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption, at a redemption price equal to 100% of the principal amount of the 2023 notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. However, no redemption date may be designated that falls on or after the 52nd scheduled trading date prior to maturity. No sinking fund is provided for the 2023 notes, which means that we are not required to redeem or retire the 2023 notes periodically.

If we undergo a fundamental change, as defined in the indenture governing the 2023 notes, subject to certain conditions, holders of the 2023 notes may require us to repurchase for cash all or part of their 2023 notes at a repurchase price equal to 100% of the principal amount of the 2023 notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. Following certain corporate transactions that constitute a change of control, we would increase the conversion rate for a holder who elects to convert the 2023 notes in connection with such change of control in certain circumstances.

The 2023 notes are our senior unsecured obligations and will rank senior in right of payment to our future indebtedness that is expressly subordinated in right of payment to the 2023 notes; equal in right of payment to our existing and future unsecured indebtedness that is not so subordinated (including the 2022 notes); effectively junior in right of payment to any of our secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all existing and future indebtedness and other liabilities (including trade payables) incurred by our subsidiaries.

The indenture governing the 2023 notes contains customary events of default with respect to the 2023 notes, including that upon certain events of default (including our failure to make any payment of principal on the 2023 notes when due and payable

or our failure to make any interest payment on the 2023 notes when due and payable and such failure continues for a period of thirty days) occurring and continuing, the trustee for the 2023 notes by notice to us, or the holders of at least 25% in principal amount of the outstanding 2023 notes by notice to us and the trustee for the 2023 notes, may, and the trustee at the request of such holders (subject to the provisions of the indenture governing the 2023 notes) shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2023 notes to be due and payable. In case of certain events of bankruptcy, insolvency or reorganization, involving us or a significant subsidiary, 100% of the principal of and accrued and unpaid interest on the 2023 notes will automatically become due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately.

#### *Capped Call Transactions*

To minimize the impact of potential dilution upon conversion of the 2023 notes, we entered into capped call transactions separate from the issuance of the 2023 notes with certain counterparties. The capped calls have a strike price of \$48.97 per share and a cap price of \$64.68 per share and are exercisable when and if the 2023 notes are converted. If upon conversion of the 2023 notes, the price of our common stock is above the strike price of the capped calls, the counterparties will deliver shares of our common stock and/or cash with an aggregate value equal to the difference between the price of our common stock at the conversion date and the strike price, multiplied by the number of shares of our common stock related to the capped calls being exercised. We paid \$33.9 million for these capped call transactions.

For any conversions of the 2023 notes prior to the close of business on the 52nd scheduled trading day immediately preceding the stated maturity date of the 2023 notes, including without limitation upon an acquisition of us or similar business combination, a corresponding portion of the capped calls will be terminated. Upon such termination, the portion of the capped calls being terminated will be settled at fair value (subject to certain limitations), as determined by the counterparties to the capped calls and no payments will be due from us to such counterparties. The capped calls expire on the earlier of (i) the last day on which any Convertible Securities remain outstanding and (ii) the second "Scheduled Trading Day" (as defined in the indenture) immediately preceding the "Maturity Date" (as defined in the indenture).

#### *2022 Notes*

On January 13, 2015, we completed our private offering of \$400.0 million aggregate principal amount of our 2.50% convertible senior notes due 2022, or the 2022 notes, and entered into an indenture with Wells Fargo Bank, National Association, a national banking association, as trustee, governing the 2022 notes. The aggregate principal amount of 2022 notes sold reflects the exercise in full by the initial purchasers of the 2022 notes of their option to purchase up to an additional \$50.0 million in aggregate principal amount of the 2022 notes. The net proceeds from the offering were \$387.2 million, after deducting the initial purchasers' discounts and commissions and our offering expenses.

The 2022 notes bear cash interest at a rate of 2.50% per year, payable semi-annually on January 15 and July 15 of each year, beginning on July 15, 2015. The 2022 notes will mature on January 15, 2022. The 2022 notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, incurrence of other indebtedness, or issuance or repurchase of securities by us.

Holders may convert their 2022 notes at their option at any time prior to the close of business on the business day immediately preceding October 15, 2021 only under the following circumstances: (1) during any calendar quarter commencing on or after March 31, 2015 (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, or measurement period, in which the trading price, as defined in the indenture governing the 2022 notes, per \$1,000 principal amount of 2022 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; (3) during any period after we have issued notice of redemption until the close of business on the scheduled trading day immediately preceding the relevant redemption date; or (4) upon the occurrence of specified corporate events.

On or after October 15, 2021, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their 2022 notes at any time, regardless of the foregoing circumstances. Upon conversion, we will pay cash up to the aggregate principal amount of the 2022 notes to be converted and deliver shares of our common stock in respect of the remainder, if any, of its conversion obligation in excess of the aggregate principal amount of 2022 notes being converted, subject to a daily share cap, as described in the indenture governing the 2022 notes. Holders of 2022 notes will not receive any additional cash payment or additional shares representing accrued and unpaid interest, if any, upon conversion of a note, except in limited circumstances. Instead, accrued but unpaid interest will be deemed to be paid by the cash and shares, if any, of our common stock, together with any cash payment for any fractional share, paid or delivered, as the case may be, upon conversion of a 2022 note.



The conversion rate for the 2022 notes was initially, and remains, 29.8806 shares of our common stock per \$1,000 principal amount of the 2022 notes, which is equivalent to an initial conversion price of approximately \$33.47 per share of our common stock. The conversion rate and the conversion price are subject to customary adjustments for certain events, including, but not limited to, the issuance of certain stock dividends on our common stock, the issuance of certain rights or warrants, subdivisions, combinations, distributions of capital stock, indebtedness, or assets, cash dividends and certain issuer tender or exchange offers, as described in the indenture governing the 2022 notes.

We may redeem for cash all or any portion of the 2022 notes, at our option, on or after January 15, 2019 if the last reported sale price of our common stock has been at least 130% of the conversion price then in effect on the last trading day of, and for at least 19 other trading days (whether or not consecutive) during, any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption, at a redemption price equal to 100% of the principal amount of the 2022 notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the 2022 notes, which means that we are not required to redeem or retire the 2022 notes periodically.

If we undergo a fundamental change, as defined in the indenture governing the 2022 notes, subject to certain conditions, holders of the 2022 notes may require us to repurchase for cash all or part of their 2022 notes at a repurchase price equal to 100% of the principal amount of the 2022 notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. Following certain corporate transactions that constitute a change of control, we would increase the conversion rate for a holder who elects to convert the 2022 notes in connection with such change of control in certain circumstances.

The 2022 notes are our senior unsecured obligations and will rank senior in right of payment to our future indebtedness that is expressly subordinated in right of payment to the 2022 notes; equal in right of payment to our existing and future unsecured indebtedness that is not so subordinated (including the 2023 notes); effectively junior in right of payment to any of our secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all existing and future indebtedness and other liabilities (including trade payables) incurred by our subsidiaries.

The indenture governing the 2022 notes contains customary events of default with respect to the 2022 notes, including that upon certain events of default (including our failure to make any payment of principal or interest on the 2022 notes when due and payable) occurring and continuing, the trustee for the 2022 notes by notice to us, or the holders of at least 25% in principal amount of the outstanding 2022 notes by notice to us and the trustee for the 2022 notes, may, and the trustee at the request of such holders (subject to the provisions of the indenture governing the 2022 notes) shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2022 notes to be due and payable. In case of certain events of bankruptcy, insolvency or reorganization, involving us or a significant subsidiary, 100% of the principal of and accrued and unpaid interest on the 2022 notes will automatically become due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately.

### ***U.S. Healthcare Reform***

We are continually evaluating the impact of healthcare reform-related programs and regulations on our business. As of the date of this Quarterly Report on Form 10-Q, we have not identified any provisions that currently materially impact our business and results of operations. However, the potential impact of healthcare reform measures on our business and results of operations is inherently difficult to predict because many of the details regarding the implementation of this legislation have not been determined. In addition, the impact on our business and results of operations may change as and if our business evolves. President Trump and HHS Secretary Azar have announced support for regulatory provisions that would limit a number of healthcare reform programs initiated under the Obama administration, and have proposed or are considering additional reforms. It remains unclear whether these reforms will include similar limitations affecting reimbursement, although scrutiny over drug pricing and government costs is expected to continue. Similarly, efforts in Congress to reform Medicare and Medicaid may impact the pharmaceutical and healthcare industries.



**Results of Operations**

Three and Six Months Ended June 30, 2019 Compared to Three and Six Months Ended June 30, 2018

*Net Revenues:*

Net revenues decreased for the three and six months ended June 30, 2019, as a result of the divestiture of our rights to branded Angiomax in the United States and Canada to Sandoz, which had been selling an authorized generic of Angiomax (bivalirudin) as of July 2, 2015 pursuant to a supply and distribution agreement with us. As a result, we no longer have any marketed products.

	Three Months Ended June 30,				Six Months Ended June 30,			
	2019	2018	Change \$	Change %	2019	2018	Change \$	Change %
	(in thousands)				(in thousands)			
Net revenues	\$ —	\$ 1,667	\$ (1,667)	(100.0)%	\$ —	\$ 9,438	\$ (9,438)	(100.0)%

*Cost of Revenues:*

As described above, in August 2018, we divested our rights to branded Angiomax in the United States to Sandoz, which had been selling an authorized generic of Angiomax (bivalirudin) as of July 2, 2015 pursuant to a supply and distribution agreement with us. As a result, we no longer have any marketed products, and have not incurred any cost of revenues for the three and six months ended June 30, 2019.

Cost of revenues during the three and six months ended June 30, 2018 were \$2.9 million and \$5.7 million, or 175.8% and 60.1% of net revenues, respectively, and consisted of:

- expenses in connection with the manufacture of our products sold, including expenses related to excess inventory offset by the positive impact of sales of previously reserved units;
- logistics costs related to Angiomax and Ionsys, including distribution, storage, and handling costs;
- royalty expenses under our agreement with Biogen Idec, or Biogen, and Health Research Inc. related to Angiomax; and
- expenses associated with severance and other exit costs

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	% of Total	2018	% of Total
	(in thousands)		(in thousands)	
Manufacturing/Logistics	\$ 2,924	99.8%	\$ 5,530	97.6%
Royalties	7	0.2%	138	2.4%
Total cost of revenues	\$ 2,931	100.0%	\$ 5,668	100.0%

**Research and Development Expenses:**

	Three Months Ended June 30,				Six Months Ended June 30,			
	2019	% of Total	2018	% of Total	2019	% of Total	2018	% of Total
	(in thousands)		(in thousands)		(in thousands)		(in thousands)	
<b>Marketed products</b>								
Total marketed products	\$ —	—%	\$ 106	0.3%	\$ 2	—%	\$ 254	0.4%
<b>Research and development product candidates</b>								
Inclisiran	25,680	91.3%	24,575	81.1%	52,024	94.4%	61,197	86.6%
Other	2,432	8.7%	5,613	18.5%	3,097	5.6%	9,209	13.0%
Total research and development product candidates	28,112	100.0%	30,188	99.7%	55,121	100.0%	70,406	99.6%
Total research and development expenses	\$ 28,112	100%	\$ 30,294	100.0%	\$ 55,123	100.0%	\$ 70,660	100.0%

Research and development expenses decreased by \$2.2 million during the three months ended June 30, 2019 compared to the three months ended June 30, 2018. The decrease in research and development expenses during the three months ended June 30, 2019 is primarily attributed to a \$3.2 million decrease in clinical trial spending associated with other programs discontinued or withdrawn, partially offset by an increase in clinical trial spending for inclisiran of \$1.1 million.

Research and development expenses decreased by \$15.5 million during the six months ended June 30, 2019 compared to the six months ended June 30, 2018. The decrease in research and development expenses during the six months ended June 30, 2019 is primarily due to costs associated with the clinical trials for inclisiran of \$9.2 million and \$6.1 million due to other programs discontinued or withdrawn.

**Selling, General and Administrative Expenses:**

	Three Months Ended June 30,				Six Months Ended June 30,			
	2019	2018	Change \$	Change %	2019	2018	Change \$	Change %
	(in thousands)				(in thousands)			
Selling, marketing and promotional	\$ 5,619	1,971	\$ 3,648	185.1 %	\$ 9,884	\$ 5,052	\$ 4,832	95.6 %
General corporate and administrative	14,270	19,042	(4,772)	(25.1)%	26,987	44,912	(17,925)	(39.9)%
Total selling, general and administrative expenses	\$ 19,889	\$ 21,013	\$ (1,124)	(5.3)%	\$ 36,871	\$ 49,964	\$ (13,093)	(26.2)%

Selling, general and administrative expenses decreased by \$1.1 million during the three months ended June 30, 2019 compared to the three months ended June 30, 2018. General corporate and administrative expenses decreased by \$4.8 million during the three months ended June 30, 2019, primarily attributed to workforce reduction costs as a result of restructuring efforts initiated in the prior year and lower general and corporate infrastructure costs. Selling, marketing and promotional expenses increased by \$3.6 million during this period primarily due to pre-commercialization efforts related to inclisiran.

Selling, general and administrative expenses decreased by \$13.1 million during the six months ended June 30, 2019 compared to the six months ended June 30, 2018. General corporate and administrative expenses decreased by \$17.9 million during the six months ended June 30, 2019. The decrease is primarily due to workforce reduction costs as a result of the restructuring initiatives discussed above and lower general and corporate infrastructure costs. Selling, marketing and promotional expenses increased by \$4.8 million during this period primarily due to pre-commercialization efforts related to inclisiran.

*Co-promotion and License Income:*

	Three Months Ended June 30,				Six Months Ended June 30,			
	2019	2018	Change \$	Change %	2019	2018	Change \$	Change %
	(in thousands)				(in thousands)			
Co-promotion and license income	\$ —	\$ 254	\$ (254)	(100.0)%	\$ —	\$ 482	\$ (482)	(100.0)%

Co-promotion and license income decreased by \$0.3 million and \$0.5 million during the three and six months ended June 30, 2019 as compared to the three and six months ended June 30, 2018, respectively. In the three and six months ended June 30, 2018, license income included \$0.2 million and \$0.5 million related to our collaboration agreement with SciClone Pharmaceuticals related to Angiomax in China, where services have been fully rendered through December 31, 2018.

*Gain (Loss) on Short-term Investment:*

	Three Months Ended June 30,				Six Months Ended June 30,			
	2019	2018	Change \$	Change %	2019	2018	Change \$	Change %
	(in thousands)				(in thousands)			
Gain (loss) on short-term investment	\$ 2,057	\$ (3,474)	\$ 5,531	*	\$ 1,791	\$ (33,463)	\$ 35,254	*

\* Represents a change in excess of 100%

Gain (loss) on short-term investment increased by \$5.5 million and \$35.3 million during the three and six months ended June 30, 2019 as compared to the three and six months ended June 30, 2018, respectively. The gain on short-term investment relates to the non-cash change in fair value associated with our common stock ownership in Melinta. In connection with the sale of our infectious disease business, we received 3,313,702 shares of Melinta common stock having a market value, based on Melinta's closing share price on January 5, 2018, of approximately \$54.5 million. During the first quarter of 2019, Melinta initiated a 5-1 reverse stock split. As a result, we now hold 662,740 shares of Melinta common stock as of June 30, 2019. The change in short-term investments was derived based on the market value of Melinta's common stock as of June 30, 2019 and 2018, respectively.

*Interest Expense:*

	Three Months Ended June 30,				Six Months Ended June 30,			
	2019	2018	Change \$	Change %	2019	2018	Change \$	Change %
	(in thousands)				(in thousands)			
Interest expense	\$ 15,791	\$ 12,108	\$ 3,683	30.4%	\$ 31,815	\$ 24,185	\$ 7,630	31.5%

During the three and six months ended June 30, 2019, we recorded approximately \$15.8 million and \$31.8 million, respectively, in interest expense related to the 2022 notes, 2023 notes and 2024 notes as compared to \$12.1 million and \$24.2 million in interest expense related to the 2022 notes and 2023 notes during the three and six months ended June 30, 2018, respectively. The increase in interest expense in the three and six months ended June 30, 2019 compared to the three and six months ended June 30, 2018 is due to the 2024 notes which we completed in January 2019, and non-cash interest expense associated with the 2022 notes and 2023 notes.

*Other Income:*

	Three Months Ended June 30,				Six Months Ended June 30,			
	2019	2018	Change \$	Change %	2019	2018	Change \$	Change %
	(in thousands)				(in thousands)			
Other income	\$ 1,687	\$ 1,053	\$ 634	60.2%	\$ 2,108	\$ 3,422	\$ (1,314)	(38.4)%

Other income, which is comprised of interest income related to payments associated with the sale of our infectious disease business, interest income and gains and losses on foreign currency transactions, increased by \$0.6 million during the three months ended June 30, 2019 compared to the three months ended June 30, 2018 and decreased by \$1.3 million during the six months ended June 30, 2019 compared to the six months ended June 30, 2018, respectively.

The increase compared to the three months ended June 30, 2018 is primarily due to foreign currency gains partially offset by the accretion related to payments associated with the sale of our infectious disease products incurred in the prior year.

The decrease compared to the six months ended June 30, 2018 is primarily due to the accretion related to payments associated with the sale of our infectious disease products incurred in the prior year.

*(Provision) Benefit from Income Taxes:*

	Three Months Ended June 30,				Six Months Ended June 30,			
	2019	2018	Change \$	Change %	2019	2018	Change \$	Change %
	(in thousands)				(in thousands)			
(Provision for) benefit from income taxes	\$ (7)	\$ 12,393	\$ (12,400)	*	\$ (10)	\$ 31,309	\$ (31,319)	*

\* Represents a change in excess of 100%

For the three months ended June 30, 2019, we recorded a provision for income taxes of less than \$0.0 million as compared to a benefit from income taxes of \$12.4 million, for the three months ended June 30, 2018. Our worldwide effective income tax rates for the three months ended June 30, 2019 and 2018 was approximately less than 1% and 18.5%, respectively.

For the six months ended June 30, 2019, we recorded a provision for income taxes of less than \$0.0 million as compared to a benefit from income taxes of \$31.3 million for the six months ended June 30, 2018. Our worldwide effective income tax rates for the six months ended June 30, 2019 and 2018 was approximately less than 1% and 18.4%, respectively.

For the three and six months ended June 30, 2019, our provision for income taxes is primarily attributable to minimum state taxes and foreign taxes based on income.

For the three and six months ended June 30, 2018, our benefit for income taxes is primarily attributable to the utilization of current period losses against a discrete provision of \$51.2 million from the sale of our infectious disease business. For further details regarding the sale of the infectious disease business see Note 15, "Discontinued Operations," in the accompanying notes to condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

*Income from Discontinued Operations, Net Of Tax:*

	Three Months Ended June 30,				Six Months Ended June 30,			
	2019	2018	Change \$	Change %	2019	2018	Change \$	Change %
	(in thousands)				(in thousands)			
Income from discontinued operations, net of tax	\$ —	\$ 256	\$ (256)	(100)%	\$ —	\$ 114,241	\$ (114,241)	(100)%

Income from discontinued operations for the three and six months ended June 30, 2018 is attributed to the gain on the sale of our infectious disease business. For details on discontinued operations, see Note 15, "Discontinued Operations," in the accompanying notes to condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

**Liquidity and Capital Resources**

*Sources of Liquidity*

Since our inception, we have financed our operations principally through revenues from sales of Angiomax and our other products, product divestitures and the sale of common stock, convertible promissory notes and warrants. Revenue from sales of Angiomax has decreased significantly in recent years due to generic competition. In August 2018, we divested our rights to branded Angiomax in the United States to Sandoz, which had been selling an authorized generic of Angiomax (bivalirudin) as of July 2, 2015 pursuant to a supply and distribution agreement with us. As a result, we no longer have any marketed products. We had \$319.3 million and \$4.4 million in cash and cash equivalents and short term investments, respectively, as of June 30, 2019.

### *Cash Flows*

As of June 30, 2019, we had \$325.8 million in cash, cash equivalents and restricted cash as compared to \$245.0 million as of December 31, 2018. The increase in cash, cash equivalents and restricted cash in the six months ended June 30, 2019 was due primarily to \$98.6 million of net cash used in operating activities, partially offset by \$0.5 million and \$176.9 million of net cash provided by investing activities and financing activities, respectively.

Net cash used in operating activities was \$98.6 million and \$165.3 million for the six months ended June 30, 2019 and 2018, respectively. The cash used in operating activities during the six months ended June 30, 2019 is primarily due to a net loss of \$119.9 million and changes in working capital items of \$5.9 million, partially offset by increases in non-cash items of \$27.2 million. Non-cash items primarily consist of amortization of debt discount, stock compensation expense, depreciation and amortization and change in fair value of short-term investments.

Net cash provided by investing activities was \$0.5 million in the six months ended June 30, 2019, which was due to proceeds from the sale of assets of \$0.5 million. Net cash provided by investing activities was \$166.4 million in the six months ended June 30, 2018, which was due to proceeds from the sale of the infectious disease business of \$166.4 million.

Net cash provided by financing activities was \$176.9 million in the six months ended June 30, 2019, which was primarily due to \$161.6 million of net proceeds from our equity offering, \$9.5 million of proceeds from the issuance of convertible debt and \$6.1 million of proceeds from issuance of common stock and purchases of stock under our employee stock purchase plan. Net cash provided by financing activities was \$11.4 million in the six months ended June 30, 2018, which was primarily due to \$11.9 million of proceeds from issuance of common stock and purchases of stock under our employee stock purchase plan, partially offset by \$0.5 million in payments of contingent purchase price.

### *Funding Requirements*

We expect to devote substantial financial resources to our research and development efforts, clinical trials, nonclinical and preclinical studies and regulatory approvals and to our commercialization and manufacturing programs associated with inclisiran. We also will require cash to pay interest on the \$400.0 million aggregate principal amount of the 2022 notes, the \$402.5 million aggregate principal amount of the 2023 notes, and \$172.5 million aggregate principal amount of the 2024 notes, and to make principal payments on the 2022 notes, 2023 notes and 2024 notes at maturity or upon conversion (other than the 2023 notes and 2024 notes upon conversion, in which case we will have the option to settle entirely in shares of our common stock).

In addition, as part of our business development strategy, we generally structure our license agreements and acquisition agreements so that a significant portion of the total license or acquisition cost is contingent upon the successful achievement of specified development, regulatory or commercial milestones. As a result, we will require cash to make payments upon achievement of these milestones under the license agreements and acquisition agreements to which we are a party. As of July 24, 2019, we may have to make contingent cash payments upon the achievement of specified development, regulatory or commercial milestones of up to \$150.0 million for the license and collaboration agreement with Alnylam. Of this amount, \$50.0 million relates to regulatory approval milestones and \$100.0 million relates to commercial milestones. We had additional contingent cash payments relating to pre-clinical infectious disease assets acquired in our Rempex acquisition (which were not divested in the Melinta transactions), but the obligations for such payments were assumed by Qpex in its acquisition of the pre-clinical infectious disease assets in October 2018.

Of the total potential milestone payment obligations, based on our anticipated timeline for the achievement of regulatory and commercial milestones, we do not expect that we would make any milestone payments under our license and collaboration agreement with Alnylam during 2019.

We continually evaluate our liquidity requirements, capital needs and availability of resources in view of, among other things, alternative sources and uses of capital, debt service requirements, the cost of debt and equity capital and estimated future operating cash flow. We may raise additional capital; enter into licenses or collaborations with third parties to develop and commercialize inclisiran; sell assets, including asset sales of products or businesses that generate a material portion of our revenue; restructure or refinance outstanding debt; repurchase material amounts of outstanding debt or equity; or take a combination of such steps or other steps to increase or manage our liquidity and capital resources. Any such actions or steps could have a material effect on us.

Our future capital requirements will depend on many factors, including:

- the progress, level, timing and cost of our research and development activities related to our clinical trials and non-clinical studies with respect to inclisiran;

- whether we develop and commercialize inclisiran on our own or through licenses and collaborations with third parties and the terms and timing of such arrangements, if any;
- the extent to which our submissions and planned submissions for regulatory approval of inclisiran are approved on a timely basis, if at all;
- if inclisiran receives regulatory approval, the extent to which it is commercially successful;
- the extent to which we are able to realize additional funds through our sources of liquidity from the Melinta transaction or from the future payments, if any, which we are entitled from Melinta due to the sale of the infectious disease business and connected to our ongoing litigation with Melinta;
- the continuation or termination of third-party manufacturing, distribution and sales and marketing arrangements;
- the size, cost and effectiveness of our sales and marketing programs, including scaling our operations in anticipation of a potential launch of inclisiran;
- the amounts of our payment obligations to third parties with respect to inclisiran;
- our ability to defend and enforce our intellectual property rights; and
- our ability to defend ourselves and prevail in current and, if any, future litigation matters.

With respect to both our short-term and long-term cash requirements, if our existing cash resources, together with cash that we generate from other sources, are insufficient to satisfy our product launch, research and development and other funding requirements, including obligations under our convertible notes, we will need to sell additional equity or debt securities, or seek additional financing through other arrangements, any of which could be material. Any sale of additional equity or convertible debt securities may result in dilution to our stockholders. Public or private financing may not be available in amounts or on terms acceptable to us, if at all. If we seek to raise funds through collaboration or licensing arrangements with third parties, we may be required to relinquish rights to inclisiran that we would not otherwise relinquish or grant licenses on terms that may not be favorable to us. Moreover, our ability to obtain additional debt financing may be limited by the 2022 notes, 2023 notes and the 2024 notes, market conditions or otherwise. If we are unable to obtain additional financing or otherwise increase our cash resources, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could adversely affect our business, financial condition and operating results.

#### *Certain Contingencies*

We may be, from time to time, a party to various disputes and claims arising from normal business activities. We accrue for loss contingencies when available information indicates that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated. In the cases where we believe that a reasonably possible loss exists, we disclose the facts and circumstances of the litigation, including an estimable range, if possible.

Currently, we are party to the legal proceedings described in Part II, Item 1. Legal Proceedings, of this Quarterly Report on Form 10-Q, which are principally contractual litigation matters related to license agreements and divestiture agreements. We have assessed such legal proceedings and recorded a loss contingency of \$5.2 million, consisting of an upfront payment of \$1.2 million and additional payments of \$4 million, in the aggregate, on June 30, 2020 and June 30, 2021, as a result of settlement of the Biogen matter discussed therein. For all other matters we do not believe that it is probable that a liability has been incurred and the amount of such liability can be reasonably estimated. As a result, we have not recorded a loss contingency related to these legal proceedings. Particularly with respect to the litigation related to a company license agreement, we are presently unable to predict the outcome of such lawsuit or to reasonably estimate the possible loss, or range of potential losses, if any, related to such lawsuit. While it is not possible to determine the outcome of the matters described in Part II, Item 1, Legal Proceedings, of this Quarterly Report on Form 10-Q, we believe it is possible that the resolution of all such matters could have a material adverse effect on our business, financial condition or results of operations.

#### **Contractual Obligations**

Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. These include commitments related to royalties, milestone payments, and other contingent payments due under

our license and acquisition agreements, purchases of inventory of our products, research and development service agreements, income tax contingencies, operating leases, selling, general and administrative obligations and leased office space for our principal office in Parsippany, New Jersey and our leased office space in San Diego, California, royalties, and milestone payments and other contingent payments due under our license and acquisition agreements as of June 30, 2019.

During the quarter ended June 30, 2019 there were no material changes outside the ordinary course of business to the specified contractual obligations set forth in the contractual obligations table included in our Annual Report on Form 10-K for the year ended December 31, 2018.

### **Application of Critical Accounting Estimates**

The discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements. The preparation of these financial statements requires us to make estimates and judgments that affect our reported assets and liabilities, revenues and expenses, and other financial information. Actual results may differ significantly from these estimates under different assumptions and conditions. In addition, our reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

We regard an accounting estimate or assumption underlying our financial statements as a “critical accounting estimate” where:

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and
- the impact of the estimates and assumptions on financial condition or operating performance is material.

Our significant accounting policies are more fully described in Note 2, “Significant Accounting Policies,” of our unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q and Note 2 of our audited consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2018. Not all of these significant accounting policies, however, require that we make estimates and assumptions that we believe are “critical accounting estimates.” We believe that our estimates relating to share-based compensation, income taxes and contingent purchase price from sale of business described under the caption “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations - Application of Critical Accounting Estimates” in our Annual Report on Form 10-K for the year ended December 31, 2018 are “critical accounting estimates.” Please refer to Note 2, “Significant Accounting Policies,” in the accompanying notes to the condensed consolidated financial statements for a discussion on changes to certain accounting policies during the six months ended June 30, 2019.

### **Recent Accounting Pronouncements**

Refer to Note 2, “Significant Accounting Policies,” in the accompanying notes to the condensed consolidated financial statements for a discussion of recent accounting pronouncements.

### **Forward-Looking Information**

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. For this purpose, any statements contained herein regarding our strategy, future operations, financial position, liquidity, future revenue, projected costs, prospects, plans and objectives of management, other than statements of historical facts, are forward-looking statements. The words “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations expressed or implied in our forward-looking statements. There are a number of important factors that could cause actual results, levels of activity, performance or events to differ materially from those expressed or implied in the forward-looking statements we make. These important factors include our “critical accounting estimates” described in Part I, Item 2 of this Quarterly Report on Form 10-Q and the factors set forth under the caption “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q. Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change, and readers should not rely on those forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, creditworthiness, financing, exchange rates or other factors. Our primary market risk exposure relates to changes in interest rates in our cash and cash equivalents. We place our investments in high-quality financial instruments, primarily money market funds, corporate debt securities, asset backed securities and U.S. government agency notes with maturities of less than two years, which we believe are subject to limited interest rate and credit risk. We currently do not hedge interest rate exposure. At June 30, 2019, we held \$319.3 million in cash and cash equivalents, which had an average interest rate of approximately 0.91%. A 10% change in such average interest rate would have had an approximate \$0.3 million impact on our annual interest income. At June 30, 2019, all cash and cash equivalents were due on demand and 96.8% was held in the United States.

Most of our transactions are conducted in U.S. dollars. We do have certain agreements with parties located outside the United States. Transactions under certain of these agreements are conducted in U.S. dollars, subject to adjustment based on significant fluctuations in currency exchange rates. Transactions under certain other of these agreements are conducted in the local foreign currency, however as of June 30, 2019 they were not material.

### **Item 4. Controls and Procedures**

#### *Disclosure Controls and Procedures*

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2019. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2019, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

#### *Changes in Internal Control over Financial Reporting*

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended June 30, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



## Part II. Other Information

### Item 1. Legal Proceedings

From time to time we are party to legal proceedings in the course of our business in addition to those described below. We do not, however, expect such other legal proceedings to have a material adverse effect on our business, financial condition or results of operations.

#### ***Melinta Litigation***

In December 2018, Melinta filed a complaint in the Court of Chancery of the State of Delaware alleging that we breached certain representations and warranties in the purchase and sale agreement pursuant to which Melinta acquired our infectious disease business. In connection with the lawsuit, Melinta is seeking indemnification under the purchase and sale agreement and notified us that it would not be paying a \$30 million milestone payment to the former owners of the infectious disease business, which we referred to as the Vabomere Milestone Payment, or the two \$25 million deferred payments due to us under the purchase and sale agreement because Melinta believes it has the right to set-off such payments against its claimed damages in its lawsuit. We have contested Melinta's indemnification and right of set-off assertions. On January 9, 2019, we filed a motion to dismiss Melinta's complaint against us, and on March 15, 2019, we filed our opening brief in support of that motion. On April 23, 2019, Melinta filed an amended complaint containing additional allegations to support their purported claims against us. On May 3, 2019 we filed a motion to dismiss Melinta's amended complaint against us, and on June 10, 2019, we filed our opening brief in support of that motion. The deadline for Melinta's answering brief in opposition to our motion to dismiss is August 2, 2019, and the deadline for our reply brief in further support of our motion is September 6, 2019. Oral argument on our motion to dismiss Melinta's amended complaint is currently scheduled for September 19, 2019. Although we believe Melinta's claims are meritless and we will vigorously defend any and all claims brought against us by Melinta and seek full payment by Melinta of its obligations under the purchase and sale agreement, litigation is subject to inherent uncertainty.

On December 28, 2018, we sent a demand letter to Melinta regarding its failure to pay the Vabomere Milestone Payment. On January 7, 2019, we received a letter on behalf of Fortis Advisors LLC, or Fortis, in its capacity as the representative for the interests of former equity holders of Rempex Pharmaceuticals, Inc., or Rempex, demanding that we pay the Vabomere Milestone Payment. On January 28, 2019, we notified Fortis that, while we agree that we are ultimately responsible for the Vabomere Milestone Payment even though it was assumed by Melinta, we believe that we are responsible for such payment only if Fortis is unable to collect from Melinta after exercising due diligence in attempting to collect from Melinta before seeking to collect from us. On March 28, 2019, Fortis filed a complaint in the Court of Chancery of the State of Delaware against Melinta and us regarding the non-payment of the Vabomere Milestone Payment. On April 18, 2019, we filed an answer to Fortis's complaint and a crossclaim against Melinta, alleging breach of contract and requesting that the Court order Melinta to fulfill its obligations under the purchase and sale agreement, including complying with payment obligations in connection with the Vabomere Milestone Payment, among other relief. That same day, Melinta filed a motion to dismiss Fortis's complaint, and filed its opening brief in support of that motion on May 31, 2019. On May 8, 2019, Melinta filed its answer to our crossclaim. On May 20, 2019, Fortis filed both a motion for partial judgment on the pleadings against us and its brief in support of that motion. On June 21, 2019, we filed both our motion for judgment on the pleadings against Melinta and our combined answering and opening brief, which both opposed Fortis's motion for partial judgment on the pleadings and supported our affirmative motion for judgment on the pleadings against Melinta. The deadline for Melinta's answering brief in opposition to our motion is August 7, 2019, and the deadline for our reply brief in further support of our motion is September 11, 2019. Oral argument on both Fortis's motion for partial judgment on the pleadings and our motion for judgment on the pleadings is currently scheduled for September 19, 2019. Although we will vigorously contest Fortis's claims on the basis that they must first exercise due diligence in attempting to collect the Vabomere Milestone Payment from Melinta before they seek to collect from us, litigation is subject to inherent uncertainty.

#### ***SymBio Arbitration***

On October 11, 2017, SymBio Pharmaceuticals Limited, or SymBio, filed a Request for Arbitration with the International Chamber of Commerce's International Court of Arbitration against us and our wholly owned subsidiary, Incline Therapeutics, Inc., or Incline. In the Request for Arbitration, SymBio claims that we failed to provide adequate assurances of performance of, or, alternatively, have rendered ourselves unable to perform, our obligations under the license agreement between us, Incline and SymBio relating to the development and commercialization of lonsys in Japan. As a result, SymBio seeks compensatory damages in an amount of \$82 million. On December 15, 2017, we filed an Answer and Counterclaim denying SymBio's allegations, asserting defenses to SymBio's claims, and bringing a counterclaim for breach of contract. We are seeking compensatory damages in an

amount of \$10 million. The arbitration process is ongoing. We intend to defend ourselves vigorously in this matter and pursue all relief to which we are entitled.

### ***Silence Therapeutics Litigation***

In October 2017, Silence Therapeutics plc and Silence Therapeutics GmbH, which we refer to together as Silence, served a claim in the High Court of Justice, Chancery Division, Patents Court in the United Kingdom, naming The Medicines Company UK Ltd., our wholly owned subsidiary, Alnylam and Alnylam UK Limited, as co-defendants. In Silence's claim, it sought a determination that it is entitled to supplementary protection certificates, or SPCs, based on Silence's European Patent No. 2,258,847, or the '847 patent, and the prospective European regulatory approvals for inclisiran and for certain of Alnylam's product candidates. This was based on Silence's assertion that inclisiran and the cited Alnylam product candidates fall within the scope of the '847 patent. An SPC is an intellectual property right that could extend the life of the Silence patent in relation to a specified product for a period of up to five additional years bringing the expiration date up to 2028. In addition, Silence sought costs, interest and other unspecified relief. On October 31, 2017, we acknowledged service of the claim served by Silence and on November 30, 2017, submitted substantive defenses to the claim.

On October 27, 2017, we and Alnylam filed and served a claim against Silence in the High Court seeking revocation of the '847 patent, as well as a declaration of non-infringement by inclisiran and certain of Alnylam's product candidates of the '847 patent, and costs and interest among other potential remedies. On November 14, 2017, Silence filed a defense to our claim along with counterclaims alleging infringement of the '847 patent by inclisiran and certain of Alnylam's product candidates. On December 11, 2017, we filed an answer and defense to the counterclaims.

The High Court had listed the trial for 10 days which was to be heard in a window starting on December 3, 2018 for all claims between Silence, Alnylam and us. However, on June 29, 2018, Silence withdrew the proceedings it issued against us seeking a determination that it is entitled to SPCs based on the '847 patent and the prospective European regulatory approvals for inclisiran. In the remaining revocation and infringement proceedings based on the '847 patent, on July 2, 2018, Silence filed an application for an order for permission to amend the '847 patent. At the same time Silence confirmed to us that it will no longer assert that inclisiran falls within the scope of the '847 patent in the UK. In light of these developments, a UK Court Order was issued by which the Court declared that no act done in the UK with respect to inclisiran would infringe the '847 patent. Silence was also ordered to pay our legal costs in defending Silence's claim and our costs in commencing the revocation action in response. The trial between Silence and Alnylam was scheduled to continue without us and to be heard in December 2018.

In parallel to the above High Court proceedings, on December 14, 2017 we also commenced opposition proceedings at the European Patent Office, or EPO, seeking revocation of the '847 patent. Alnylam and Sanofi also each commenced opposition proceedings for the revocation of the '847 patent at the EPO. Also, on October 16, 2018 we commenced opposition proceedings at the EPO seeking revocation of European Patent No. 1,857,547, or the '547 patent, which was recently granted by the EPO to Silence and is in the same patent family as the '847 patent.

On December 9, 2018, Silence and Alnylam entered into a settlement and license agreement pursuant to which Alnylam received a global license to Silence's relevant intellectual property for all current and future Alnylam products, including inclisiran, for a low royalty on Alnylam's ONPATTRO product in the European Union through 2023. The settlement does not contain any milestones or royalty payments due to Silence with respect to inclisiran. In connection with the settlement, we entered into an agreement with Alnylam and Silence to discontinue all of our pending litigation against Silence and EPO oppositions of Silence's patents, and we agreed to forgo any reimbursement of legal costs from Silence. Under our collaboration agreement with Alnylam, we received a license from Alnylam covering the license rights granted to Alnylam from Silence with no additional milestone payments or royalties.

On February 15, 2019, in accordance with the terms of the agreement with Alnylam and Silence, we withdrew from the opposition proceedings at the EPO in respect of both the '847 patent and the '547 patent. As a result there are no ongoing proceedings in the United Kingdom, at the EPO or elsewhere in Europe between us and Silence.

## **Biogen Idec Litigation**

On September 15, 2015, Biogen notified us that after completing an audit of our books and records for the fourth quarter of 2014, Biogen believed it was owed additional royalties relating to Angiomax under our license agreement with Biogen. On September 23, 2015, we filed suit against Biogen in the United States District Court for the District of New Jersey seeking, inter alia, declaratory judgments that we have satisfied our obligations under the license agreement. On November 12, 2015, Biogen answered the complaint denying our claims and asserting counterclaims for breach of contract. In February 2017, Biogen's claim for audit costs was voluntarily dismissed. Following settlement discussions, the parties agreed to settle the case and entered into a joint stipulation and order of dismissal with prejudice. As part of the settlement, we made an upfront payment of \$1.2 million upon entering into the settlement agreement and agreed to make additional payments of \$4 million, in the aggregate, on June 30, 2020 and June 30, 2021.

### **Item 1A. Risk Factors**

*Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below in addition to the other information included or incorporated by reference in this Quarterly Report on Form 10-Q. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could decline. In addition to the risk factors identified under the captions below, the operation and results of our business are subject to risks and uncertainties identified elsewhere in this Quarterly Report on Form 10-Q as well as general risks and uncertainties such as those relating to general economic conditions and demand in the market for our products.*

#### **Risks Related to Development, Approval and Commercialization of Inclisiran**

***We are almost entirely dependent on the success of inclisiran, our only drug candidate, which is currently in Phase 3 of clinical development, and we cannot be certain that inclisiran will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.***

Following our divestiture of Angiomax in the United States to Sandoz, we no longer market any products and we may never be able to develop inclisiran as a marketable product. We expect that a substantial majority of our efforts and expenditures over the next few years will be devoted to inclisiran.

Accordingly, our future business, including the ability to generate revenue, finance our operations and repay our indebtedness, depends almost entirely on the successful development, regulatory approval and commercialization of inclisiran. We cannot be certain that inclisiran will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market inclisiran in the United States until it receives approval of an NDA from the FDA, or in any foreign countries until they receive the requisite approval from such countries. Obtaining approval of an NDA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of a drug candidate for many reasons, including:

- we may not be able to demonstrate that inclisiran is safe and effective as a treatment for our targeted indications to the satisfaction of the FDA;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- a clinical research organization, or CRO, that we retain to conduct clinical trials or any other third parties involved in the conduct of trials may take actions outside of our control that materially adversely impact our clinical trials;
- the FDA may not find the data from pre-clinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of inclisiran outweigh the safety risks;

- the FDA may disagree with our interpretation of data from our pre-clinical studies and clinical trials or may require that we conduct additional studies or trials;
- the FDA may not accept data generated at our clinical trial sites;
- if our NDA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the advisory committee may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy as a condition to approval;
- the FDA may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the FDA may change its approval policies or adopt new regulations.

If inclisiran gains regulatory approval, the commercial launch will require significant efforts from us. Our ability to successfully commercially launch inclisiran will depend on our ability to:

- train, deploy and support a qualified sales force to market and sell our newly launched product;
- have third parties manufacture and release the product in sufficient quantities;
- implement and maintain agreements with wholesalers and distributors;
- receive adequate levels of coverage and reimbursement for the product from governments and third-party payors;
- develop and execute marketing and sales strategies and programs for the product; and
- enter into suitable partnerships with third parties, as needed, to provide a viable platform to commercialize the product.

We expect that the revenues from inclisiran, if approved, will represent nearly all of our revenues in the future. As a result, if we are unable to successfully commercialize inclisiran, our business, results of operations and financial condition would be materially harmed.

***We will need substantial additional funds to support our operations, and amounts we previously expected to be paid to us by Melinta may not be received and additional funding may not be available to us on acceptable terms, or at all.***

We are focused on the advancement of our product candidate, inclisiran. The completion of the development and the potential commercialization of inclisiran, should it receive regulatory approval, will require that we obtain substantial additional funds.

Due to the divestiture of our rights to branded Angiomax in the United States to Sandoz during the three months ended September 30, 2018, we are no longer generating revenues from product sales. Prior to such divestiture, our revenues generated from product sales had been declining significantly since 2014 due to the introduction of generic competition to Angiomax and the divestiture of certain of our non-core products. We have incurred net losses and negative cash flows from operations since 2014 and had an accumulated deficit of approximately \$1.5 billion as of June 30, 2019. We expect to incur significant expenses and operating losses for the foreseeable future as we continue to develop, seek regulatory approval for and potentially commercializes inclisiran.

Melinta has significant payment commitments to us, including a \$25 million deferred payment which was due on January 7, 2019 and an additional \$25 million deferred payment due July 8, 2019, and quarterly payments based on net sales of Orbactiv and Minocin and, subject to a \$50 million annual net sales threshold, Vabomere. In addition, Melinta assumed our obligation to make a \$30 million milestone payment to the former owners of the infectious disease business, which we refer to as the Vabomere Milestone Payment, upon receipt of regulatory approval of Vabomere by the European Medicines Agency, which approval was received by Melinta in November 2018. We remain ultimately responsible to pay the Vabomere Milestone Payment under our agreement with the former owners of the infectious disease business; however we believe that we are responsible for such payment only if the former owners of the infectious disease business are unable to collect from Melinta after exercising due diligence in

attempting to collect from Melinta before seeking to collect from us. In December 2018, Melinta filed a complaint in the Court of Chancery of the State of Delaware alleging that we breached certain representations and warranties in the purchase and sale agreement pursuant to which Melinta acquired our infectious disease business. In addition, in March 2019, Fortis, the representative the former owners of the infectious disease business, filed a complaint in the Court of Chancery of the State of Delaware against Melinta and us regarding the non-payment of the Vabomere Milestone Payment. In connection with Melinta's lawsuit, Melinta is seeking indemnification under the purchase and sale agreement and notified us that it would not be paying the Vabomere Milestone Payment or the two \$25 million deferred payments due to us under the purchase and sale agreement because Melinta believes it has the right to set-off such payments against its claimed damages in its lawsuit. Although we believe Melinta's claims are meritless and we will vigorously defend any and all claims brought against us by Melinta and seek full payment by Melinta of its obligations under the purchase and sale agreement, litigation is subject to inherent uncertainty. See Part II, Item 1. *Legal Proceedings* of this Quarterly Report on Form 10-Q for a description of our litigation related to Melinta and Fortis.

Although we believe that following the completion of our June 2019 equity offering our existing cash and cash equivalents (assuming no sale of the Melinta shares of common stock that we own), will be sufficient to satisfy our anticipated operating and other funding requirements for the next twelve months from July 24, 2019 (the date of this Form 10-Q), including the receipt of clinical results from our ongoing Phase III trial of inclisiran and our anticipated submission of an NDA with the FDA and a European Marketing Authorization with the EU, we may need funds as a result of any negative outcomes in our pending litigation matters or other events outside our control.

***If we are unable to successfully develop our business infrastructure and operations, our ability to generate future product revenue will be adversely affected and our business, results of operations and financial condition may be adversely affected.***

We need to properly scale our internal organization and infrastructure to accommodate the development and, upon approval, commercialization of inclisiran. To manage our future growth and the breadth and complexity of our activities, we need to properly invest in personnel, infrastructure, information management systems and other operational resources. If we are unable to scale global operations successfully and in a timely manner, the growth of our business may be limited. Developing our business infrastructure and operations may be more difficult, more expensive or take longer than we anticipate.

Future development of our business infrastructure and operations could strain our operational, human and financial resources. In order to manage the development of our business infrastructure and global operations, we must:

- continue to improve operating, administrative, and information systems;
- accurately predict future personnel and resource needs to meet contract commitments;
- track the progress of ongoing projects;
- attract and retain qualified management, sales, professional, scientific and technical operating personnel; and
- enter into suitable partnerships with third parties, as needed, to provide a viable platform to commercialize inclisiran.

If we do not take these actions and are not able to manage our business, then our operations may be less successful than anticipated.

## **Risks Related to Our Financial Results**

***We have a history of net losses and may not achieve profitability in future periods.***

We have incurred net losses in many years and on a cumulative basis since our inception, and we expect to continue to incur net losses. As of June 30, 2019, we had an accumulated deficit of approximately \$1.5 billion. In those periods in which we were able to achieve profitability, our profitability was based on revenue from sales of Angiomax, and a substantial majority of our historic revenue has been generated from sales of Angiomax in the United States. However, in August 2018 we divested Angiomax in the United States to Sandoz following a period of generic competition for Angiomax that commenced in the United States in July 2015 and in Europe in August 2015.

We expect to make substantial expenditures to further develop and commercialize inclisiran, including costs and expenses associated with research and development, clinical trials, nonclinical and preclinical studies, regulatory approvals and commercialization. We will need to generate significant revenue in future periods from inclisiran in order to achieve and maintain profitability. If we are unable to generate significant revenue, we may not achieve profitability in future periods. Our ability to

generate future revenue will be substantially dependent on our ability to successfully commercialize inclisiran. If we fail to achieve profitability within the time frame expected by investors or securities analysts, the market price of our common stock may decline.

***We need to raise additional capital. If we are unable to obtain such capital on favorable terms or at all, we will not be able to execute on our business plans and our business, financial condition and results of operations will be adversely affected.***

At June 30, 2019, we had approximately \$319.3 million in cash and cash equivalents. We expect to devote substantial financial resources to our research and development efforts, clinical trials, nonclinical and preclinical studies and regulatory approvals and to our commercialization and manufacturing programs associated with inclisiran. We also will require cash to pay interest on the \$172.5 million aggregate principal amount of 2024 notes, the \$400.0 million aggregate principal amount of the 2022 notes and the \$402.5 million aggregate principal amount of the 2023 notes, and to make principal payments on the 2024 notes, 2022 notes and 2023 notes at maturity or upon conversion (other than the 2023 and 2024 notes upon conversion, in which case we will have the option to settle entirely in shares of our common stock).

In addition, as of July 24, 2019, our total potential milestone payment obligations related to development, regulatory and commercial milestones for inclisiran, assuming all milestones are achieved in accordance with the terms of our license and collaboration agreement with Alnylam, would be \$150.0 million. Of this amount, \$50.0 million relates to regulatory approval milestones and \$100.0 million relates to commercial milestones. We had additional contingent cash payments relating to pre-clinical infectious disease assets acquired in our Rempex acquisition (and which were not divested in the Melinta transactions), but the obligations for such payments were assumed by Qpex in its acquisition of the pre-clinical infectious disease assets in October 2018. In addition, even though Melinta assumed our obligation to make the Vabomere Milestone Payment, we remain ultimately responsible to pay the Vabomere Milestone Payment under our agreement with the former owners of the infectious disease business; however we believe that we are responsible for such payment only if the former owners of the infectious disease business are unable to collect from Melinta after exercising due diligence in attempting to collect from Melinta before seeking to collect from us. See Part II, Item 1. *Legal Proceedings* of this Quarterly Report on Form 10-Q for a description of our litigation related to Melinta and Fortis.

In addition, of the total potential milestone payment obligations, based on our anticipated timeline for the achievement of development, regulatory and commercial milestones, we do not expect that we would make milestone payments under our license agreement and collaboration agreement with Alnylam during 2019.

We continually evaluate our liquidity requirements, capital needs and availability of resources in view of, among other things, alternative sources and uses of capital, debt service requirements, the cost of debt and equity capital and estimated future operating cash flow. We may raise additional capital; generate cash proceeds from entering into collaboration agreements with respect to inclisiran; restructure or refinance outstanding debt; repurchase material amounts of outstanding debt or equity; or take a combination of such steps or other steps to increase or manage our liquidity and capital resources. Any such actions or steps could have a material effect on us.

Our future capital requirements will depend on many factors, including:

- the progress, level, timing and cost of our research and development activities related to our clinical trials and non-clinical studies with respect to inclisiran;
- whether we develop and commercialize inclisiran on our own or through licenses and collaborations with third parties and the terms and timing of such arrangements, if any;
- the extent to which our submissions and planned submissions for regulatory approval of inclisiran are approved on a timely basis, if at all;
- if inclisiran receives regulatory approval, the extent to which it is commercially successful;
- the extent to which we are able to realize additional funds through our sources of liquidity from the Melinta transaction or from the future payments, if any, which we are entitled from Melinta due to the sale of the infectious disease business and connected to our ongoing litigation with Melinta;
- the continuation or termination of third-party manufacturing, distribution and sales and marketing arrangements;
- the size, cost and effectiveness of our sales and marketing programs, including scaling our operations in anticipation of a potential launch of inclisiran;

- the amounts of our payment obligations to third parties with respect to incisiran;
- our ability to defend and enforce our intellectual property rights; and
- our ability to defend ourselves and prevail in current and, if any, future litigation matters.

With respect to both our short-term and long-term cash requirements, if our existing cash resources, together with cash that we generate from sales of our products and other sources, are insufficient to satisfy our research and development, clinical trial, product commercialization and other funding requirements, including obligations under our convertible notes, we will need to sell additional equity or debt securities, engage in asset sales, engage in other strategic transactions, or seek additional financing through other arrangements, any of which could be material. Any sale of additional equity or convertible debt securities may result in dilution to our stockholders. Public or private financing may not be available in amounts or on terms acceptable to us, if at all. If we seek to raise funds through collaboration or licensing arrangements with third parties, we may be required to relinquish rights to products, products in development or technologies that we would not otherwise relinquish or grant licenses on terms that may not be favorable to us. Moreover, our ability to obtain additional debt financing may be limited by the 2024 notes, the 2022 notes and the 2023 notes, market conditions or otherwise. If we are unable to obtain additional financing or otherwise increase our cash resources, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could adversely affect our business, financial condition and operating results.

***If we seek to raise additional capital by selling equity or debt securities or through other arrangements in the future, our stockholders could be subject to dilution and we may become subject to financial restrictions and covenants, which may limit our activities.***

If we determine that raising capital would be in the interest of the company and our stockholders, we may seek to sell equity or debt securities or seek financing through other arrangements. Any sale of equity or debt securities may result in dilution to our stockholders and increased liquidity requirements. Debt financing may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. Our ability to comply with these financial restrictions and covenants could be dependent on our future performance, which is subject to prevailing economic conditions and other factors, including factors that are beyond our control such as foreign exchange rates, interest rates and changes in the level of competition. Failure to comply with the financial restrictions and covenants would adversely affect our business, financial condition and operating results.

***We have been subject to securities class action litigation and may be subject to similar or other litigation in the future, which may divert management's attention and have a material adverse effect on our business, financial condition and results of operations.***

In February 2014, a class action lawsuit was filed against us and certain of our current and former officers alleging, among other things, that we and certain of our current and former officers violated federal securities laws because we and certain current and former officers allegedly made misrepresentations or did not make proper disclosures regarding the results of clinical trials which tested the efficacy and safety of one of our recently divested products. On February 12, 2016, the parties executed a stipulation for a proposed class settlement, subject to court approval, and on June 7, 2016, the court granted final approval of the settlement.

There may be additional suits or proceedings brought in the future. Monitoring and defending against legal actions, whether or not meritorious, is time-consuming for our management and detracts from our ability to fully focus our internal resources on our business activities, and we cannot predict how long it may take to resolve these matters. In addition, we may incur substantial legal fees and costs in connection with litigation. Although we have insurance, coverage could be denied or prove to be insufficient.

***We may be limited in our ability to utilize, or may not be able to utilize, deferred tax assets to reduce our future tax liability.***

We are subject to income taxes in the United States and numerous foreign jurisdictions. The amount of income taxes we owe is subject to the application of tax laws in jurisdictions in which we file. Changes in current or future laws or regulations, the imposition of new or changed tax laws or regulations or new related interpretations by taxing authorities in the jurisdictions in which we file could materially adversely affect our financial condition, results of operations, and cash flows.

Our future income tax liability may be significantly reduced by tax credits and net operating loss carryforwards available to us under the applicable tax codes. However, utilization of these net operating loss and tax credit carryforwards is dependent upon our achieving profitable results. At December 31, 2018, we had a valuation allowance that fully offset our net deferred tax assets.



If a corporation experiences an “ownership change,” Sections 382 and 383 of the Code (as defined herein) provide annual limitations with respect to the ability of the corporation to utilize its net operating loss (as well as certain built-in losses) and tax credit carryforwards against future U.S. taxable income. In general, an ownership change may result from transactions increasing the ownership of certain stockholders in the stock of the corporation by more than 50 percentage points over a three-year testing period. Certain of our tax attributes are subject to limitations as a result of historic ownership changes. Our use of net operating loss and tax credit carryforwards may be further limited by Section 382 of the Code as a result of any future ownership changes. In this event, we could owe significantly more tax, and could owe tax sooner than we would if we were able to fully use our net operating loss.

## Risks Related to Our Notes

***We have incurred substantial indebtedness, and our leverage and maintenance of high levels of indebtedness may adversely affect our business, financial condition and results of operations. Servicing this debt, including the 2022 notes, the 2023 notes and the 2024 notes, will require a significant amount of cash, and we may not have sufficient cash flow from our business to pay the interest on or principal of the 2022 notes, the 2023 notes, the 2024 notes or other debt we may incur.***

We have incurred a significant amount of indebtedness and we may incur additional indebtedness in the future. Our maintenance of this level of indebtedness could have adverse consequences, including:

- requiring us to dedicate a substantial portion of cash flow from operations to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;
- increasing our vulnerability to general adverse economic, industry and market conditions;
- limiting our ability to obtain additional financing in the future or engage in certain strategic transactions without securing bondholder consent;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a possible competitive disadvantage to less leveraged competitors and competitors that have less debt, better debt servicing options or better access to capital resources.

In addition, our ability to make scheduled payments of the principal of, to pay interest on or to refinance the remaining amount outstanding under the 2022 notes, the 2023 notes or the 2024 notes depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt, including the notes. If we are unable to generate cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be unfavorable to us or highly dilutive, any of which may be material to the holders of our common stock. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at the time we seek to refinance such indebtedness. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

***We may not have the ability to raise the funds necessary to settle conversions of the 2022 notes or to repurchase the 2022 notes, the 2023 notes or 2024 notes upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion of the 2022 notes or repurchase of the 2022 notes, 2023 notes or 2024 notes.***

Holders of the 2022 notes, the 2023 notes and the 2024 notes will have the right to require us to repurchase their notes upon the occurrence of a fundamental change, as defined in the applicable indenture, at a repurchase price equal to 100% of their principal amount, plus accrued and unpaid interest, if any, as described in the applicable indenture. In addition, upon conversion of the 2022 notes, we will be required to make with respect to each \$1,000 in principal amount of notes converted cash payments of at least the lesser of \$1,000 and the sum of the daily conversion values as described in the applicable indenture. Upon conversion of the 2023 notes and the 2024 notes, we will have the option to settle such conversions in cash, shares of our common stock or a combination thereof. However, we may not have enough available cash or be able to obtain financing at the time we are required to repurchase notes, to pay the notes at maturity or to pay cash upon conversions of such notes. In addition, our ability to repurchase notes or to pay cash upon conversions of such notes may be limited by law, by regulatory authority or by agreements governing our existing indebtedness (including, in the case of the 2022 notes, the 2023 notes or the 2024 notes, the indenture governing any



other series of notes) and future indebtedness. Our failure to repurchase notes at a time when the repurchase is required by the applicable indenture or to pay any cash payable on future conversions of the notes as required by the applicable indenture would constitute a default under the applicable indenture. A default under the applicable indenture governing the 2022 notes, the 2023 notes or 2024 notes, or the fundamental change itself could also lead to a default under agreements governing our existing indebtedness (including, in the case of the 2022 notes, the 2023 notes or 2024 notes, the indenture governing any other series of notes) and future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the notes or make cash payments upon conversions thereof.

***The conditional conversion feature of the 2022 notes, the 2023 notes or the 2024 notes, if triggered, may adversely affect our financial condition and operating results.***

In the event the conditional conversion feature of the 2022 notes, the 2023 notes or the 2024 notes is triggered, holders of such notes will be entitled to convert the notes at any time during specified periods at their option, which are set forth in the applicable indenture. Based on the trading price of our common stock during the second quarter of 2019, the conditional conversion feature of the 2024 notes has been triggered for the third quarter of 2019. If one or more holders elect to convert their 2024 notes, or the 2023 notes when convertible, we have the option to settle conversions entirely in cash, in common stock or a combination thereof. With respect to the 2022 notes, if one or more holders elect to convert their 2022 notes, we would be required, with respect to each \$1,000 principal amount of 2022 notes, to make cash payments equal to the lesser of \$1,000 and the sum of the daily conversion values, which could adversely affect our liquidity. If the holders of all of the 2022 notes were able to exercise their conversion option, we would not have sufficient cash to satisfy our payment obligations with respect to all of the 2022 notes and meet our anticipated funding requirements for a year from July 24, 2019 (the date of filing this Form 10-Q). In addition, even if holders do not elect to convert the 2022 notes, we are required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the notes as a current rather than long-term liability, which results in a material reduction of our net working capital.

***The accounting method for convertible debt securities that may be settled in cash, such as the 2022 notes, the 2023 notes and 2024 notes, could have a material effect on our reported financial results.***

Under Accounting Standards Codification 470-20, "Debt with Conversion and Other Options", which we refer to as ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments that may be settled entirely or partially in cash upon conversion (such as the 2022 notes, the 2023 notes and the 2024 notes) in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the 2022 notes, the 2023 notes and the 2024 notes is that the equity component is required to be included in the additional paid in capital section of stockholders' equity on our consolidated balance sheet, and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the 2022 notes, the 2023 notes and the 2024 notes. As a result, we will be required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the notes to their face amount over the term of the 2022 notes, the 2023 notes and the 2024 notes. We will report lower net income in our financial results because ASC 470-20 will require interest to include both the current period's amortization of the debt discount and the instrument's coupon interest, which could adversely affect our reported or future financial results, the market price of our common stock and the trading price of the 2022 notes, the 2023 notes and the 2024 notes.

In addition, under certain circumstances, convertible debt instruments that may be settled entirely or partly in cash (such as the 2022 notes) are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess are issued. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable to use the treasury stock method in accounting for the shares issuable upon conversion of the 2022 notes, then our diluted earnings per share would be adversely affected.

#### **Additional Risks Related to Commercialization**

***We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.***

Our industry is highly competitive. Competitors in the United States and other countries include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology firms, universities and other research institutions. Many of

our competitors are substantially larger than we are and have substantially greater research and development capabilities and experience, and greater manufacturing, marketing and financial resources, than we do.

Our competitors may develop, market or license products or novel technologies that are more effective, safer, more convenient or less costly than any that are being developed by us, or may obtain marketing approval for their products from the FDA or equivalent foreign regulatory bodies more rapidly than we may obtain approval for ours. There are well established products, including in many cases generic products, that are approved and marketed for the indications for which we are developing inclisiran. In addition, competitors are developing products for such markets and indications. A description of the competition for inclisiran is included in "Part I, Item 1. *Business-Competition*" of our Annual Report on Form 10-K for the year ended December 31, 2018.

We expect inclisiran to compete on the basis of product efficacy, safety, ease of administration, price and economic value compared to drugs used in current practice or currently being developed. If we are not successful in demonstrating these attributes, physicians and other key healthcare decision makers may choose other products over our products, switch from our products to new products or choose to use our products only in limited circumstances, which could adversely affect our business, financial condition and results of operations.

***If reimbursement by government payers or other third-party payers is not available or limited for our products, pricing is delayed or set at unfavorable levels or access to our products is reduced or terminated by governmental and other third-party payers, our ability to generate revenue would be adversely affected.***

Acceptable levels of coverage and reimbursement of drug treatments by government payers, such as Medicare and Medicaid programs, private health insurers and other organizations, have a significant effect on our ability to successfully commercialize our products. Reimbursement in the United States, Europe or elsewhere may not be available for any products we may develop or, if already available, may be decreased in the future. We may not get reimbursement or reimbursement may be limited if government payers, private health insurers and other organizations are influenced by the prices of existing drugs in determining whether our products will be reimbursed and at what levels. If reimbursement is not available or is available only at limited levels, we may not be able to commercialize our products, or may not be able to obtain a satisfactory financial return on our products.

In certain countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals and the level of reimbursement are subject to governmental control. In some countries, pricing and reimbursement are set with limited, if any, participation in the process by the marketing authorization holder. In addition, it can take an extended period of time after the receipt of initial approval of a product to establish and obtain reimbursement or pricing approval. Reimbursement approval also may be required at the individual patient level, which can lead to further delays. In addition, in some countries, it may take an extended period of time to collect payment even after reimbursement has been established. If prices are set at unsatisfactory levels, such prices may negatively impact our revenues from sales in those countries. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world, but have been most drastic in the European Union. Further, a number of European Union countries use drug prices from other countries of the European Union as "reference prices" to help determine pricing in their own countries. Consequently, a downward trend in drug prices for some countries could contribute to similar occurrences elsewhere. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

Third-party payers, including Medicare and Medicaid, increasingly are challenging prices charged for and the cost-effectiveness of medical products and services and they increasingly are limiting both coverage and the level of reimbursement for drugs. If these third-party payers do not consider our products to be economically beneficial compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. Third-party payers may provide coverage, but place stringent limitations on such coverage, such as requiring alternative treatments to be tried first. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. There exists a broader trend in health care in which the government and other payors are seeking to move from individualized "fee for service" payments toward a system focused on "bundled" payments for more comprehensive packages of services and episodes of care. Also, the trend toward managed health care in the United States and the changes in health insurance programs may result in lower prices for pharmaceutical products and health care reform.

Health care reform measures such as those outlined above, and others consistent with these trends, could, among other things, increase pressure on pricing. Additionally, health care reform efforts undertaken during the Trump administration may result in additional reductions in Medicare, Medicaid and other healthcare funding. In addition to federal legislation, state legislatures and foreign governments have also shown significant interest in implementing cost-containment programs, including price controls,

restrictions on reimbursement and requirements for substitution of generic products. The establishment of limitations on patient access to our drugs, adoption of price controls and cost-containment measures in new jurisdictions or programs, and adoption of more restrictive policies in jurisdictions with existing controls and measures could adversely impact our business and future results. If governmental organizations and third-party payers do not consider our products to be cost-effective compared to other available therapies, they may not reimburse providers or consumers of our products or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis.

***Use or misuse of our products may result in serious injuries or even death to patients and may subject us to significant claims for product liability. If we are unable to obtain insurance at acceptable costs and adequate levels or otherwise protect ourselves against potential product liability claims, we could be exposed to significant liability.***

Our business exposes us to potential significant product liability risks which are inherent in the testing, manufacturing, marketing and sale of human healthcare products. Product liability claims might be made by patients in clinical trials, consumers, health care providers or pharmaceutical companies or others that sell our products. These claims may be made even with respect to those products that are manufactured in licensed and regulated facilities or otherwise possess regulatory approval for commercial sale or study.

These claims could expose us to significant liabilities that could prevent or interfere with the development or commercialization of our products. Product liability claims could require us to spend significant time and money in litigation or pay significant damages. With respect to our commercial sales and our clinical trials, we are covered by product liability insurance in the amount of \$20.0 million per occurrence and \$20.0 million annually in the aggregate on a claims-made basis. This coverage may not be adequate to cover all or any product liability claims that we face.

As we continue to develop inclisiran, we may wish to increase our product liability insurance. Product liability coverage is expensive. In the future, we may not be able to maintain or obtain such product liability insurance on reasonable terms, at a reasonable cost or in sufficient amounts to protect us against losses due to product liability claims.

***We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.***

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on our ability to attract and retain qualified personnel for the acquisition, development and commercialization activities we conduct or sponsor. If we lose one or more of the members of our senior management or other key employees or consultants, our ability to implement successfully our business strategy could be seriously harmed. Our ability to replace these key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to acquire, develop and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate such additional personnel.

#### **Risks Related to our Dependence on Third Parties for Manufacturing, Research and Development, and Distribution Activities**

***We do not have manufacturing or supply capabilities and are completely dependent on third parties for the manufacture and supply of inclisiran. We depend on a limited number of suppliers for the production of bulk drug substance for inclisiran and to carry out fill-finish activities. If any of these suppliers does not or cannot fulfill its manufacturing or supply obligations to us, our ability to conduct clinical trials of inclisiran could be impaired and our business could be harmed.***

We do not manufacture inclisiran and do not plan to develop any capacity to manufacture it. We currently rely on a limited number of manufacturers and other third parties for bulk substance and to carry out fill-finish activities for inclisiran. We expect to continue this manufacturing strategy for the foreseeable future.

In the event that any third-party is unable or unwilling to carry out its respective manufacturing or supply obligations or terminates or refuses to renew its arrangements with us, we may be unable to obtain alternative manufacturing or supply on commercially reasonable terms on a timely basis or at all. In such cases, the third-party manufacturers have made no commitment to supply the drug product to us on a long-term basis and could reject our purchase orders. Only a limited number of manufacturers are capable of manufacturing inclisiran. Consolidation within the pharmaceutical manufacturing industry could further reduce the number of manufacturers capable of producing our products, or otherwise affect our existing contractual relationships.

If we were required to transfer manufacturing processes to other third-party manufacturers and we were able to identify an alternative manufacturer, we would still need to satisfy various regulatory requirements. Satisfaction of these requirements could

cause us to experience significant delays in receiving an adequate supply of inclisiran and could be costly. Moreover, we may not be able to transfer processes that are proprietary to the manufacturer. Any delays in the manufacturing process may adversely impact our ability to supply product for clinical trials of inclisiran, which could affect our ability to complete clinical trials of inclisiran on a timely basis and our ability to meet commercial demand for inclisiran, if approved, on a timely basis.

***If third parties on whom we rely to manufacture and support the development and commercialization of inclisiran do not fulfill their obligations or we are unable to establish or maintain such arrangements, the development and commercialization of our products may be terminated or delayed, and the costs of development and commercialization may increase.***

Our development and commercialization strategy involves entering into arrangements with corporate and academic collaborators, contract research organizations, distributors, third-party manufacturers, licensors, licensees and others to conduct development work, manage or conduct our clinical trials, manufacture our products and market and sell our products outside of the United States. We do not have the expertise or the resources to conduct many of these activities on our own and, as a result, are particularly dependent on third parties in many areas.

We may not be able to establish and maintain arrangements to develop, manufacture and, if approved, commercialize inclisiran or any additional product candidates or products we may acquire on terms that are acceptable to us. Any current or future arrangements for development and commercialization may not be successful. If we are not able to establish or maintain agreements relating to inclisiran or any additional products or product candidates we may acquire, our results of operations would be materially adversely affected.

Third parties may not perform their obligations as expected. The amount and timing of resources that third parties devote to developing, manufacturing and commercializing our products are not within our control. Our collaborators may develop, manufacture or commercialize, either alone or with others, products and services that are similar to or competitive with the products that are the subject of the collaboration with us. Furthermore, our interests may differ from those of third parties that manufacture or commercialize our products. Our collaborators may reevaluate their priorities from time to time, including following mergers and consolidations, and change the focus of their development, manufacturing or commercialization efforts. Disagreements that may arise with these third parties could delay or lead to the termination of the development or commercialization of our product candidates, or result in litigation or arbitration, which would be time consuming and expensive.

If any third party that manufactures or supports the development or commercialization of our products breaches or terminates its agreement with us, fails to commit sufficient resources to our collaboration or conduct its activities in a timely manner, or fails to comply with regulatory requirements, such breach, termination or failure could:

- delay or otherwise adversely impact the manufacturing, development or commercialization of inclisiran or any additional products or product candidates that we may acquire or develop;
- require us to seek a new collaborator or undertake unforeseen additional responsibilities or devote unforeseen additional resources to the manufacturing, development or commercialization of our products; or
- result in the termination of the development or commercialization of our products.

***Our reliance on third-party manufacturers and suppliers to supply inclisiran may increase the risk that we will not have appropriate supplies of the product or that sanctions may be imposed on us or the manufacturer due to a manufacturer's failure to comply with regulation requirements, either of which could adversely affect our business, results of operations and financial condition.***

Reliance on third-party manufacturers and suppliers entails risks to which we would not be subject if we manufactured inclisiran ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing or supply agreement by the third party; and
- the possible termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

Inclisiran may compete with products of third parties for access to manufacturing facilities. If we are not able to obtain adequate supplies of our products, it will be more difficult for us to compete effectively and develop inclisiran.

Our manufacturers are subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to evaluate compliance with the FDA's current good manufacturing practices, or cGMP, regulations and other governmental regulations and corresponding foreign standards. We cannot be certain that our present or future manufacturers will be able to comply with cGMP regulations and other FDA regulatory requirements or similar regulatory requirements outside the United States. We do not control compliance by our manufacturers with these regulations and standards. Failure of our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on the manufacturer or us, including fines and other monetary penalties, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products in development, delays, suspension or withdrawal of approvals, suspension of clinical trials, license revocation, seizures or recalls of products in development or products, interruption of production, warning letters, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of inclisiran.

***We may depend on collaborations with third parties for the development and commercialization of inclisiran. If those collaborations, if entered into, are not successful, we may not be able to capitalize on the market potential of inclisiran.***

We may seek to develop and commercialize inclisiran through a variety of types of collaboration arrangements. Our likely collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We may not be able to enter into these types of arrangements on a timely basis, on favorable terms or at all. Our ability to enter into such arrangements with respect to inclisiran that are subject to licenses may be limited by the terms of those licenses. If we do enter into any such arrangements with any third parties in the future, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of inclisiran. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving inclisiran could pose a number of risks to us, including:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of inclisiran or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon inclisiran, repeat or conduct new clinical trials or require a new formulation of inclisiran for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products in development if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or otherwise expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or products in development or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable products and products in development.

Collaboration agreements may not lead to development or commercialization of products in development in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

***If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages or subject to fines and penalties.***

Prior to our divestiture of our pre-clinical infectious disease assets to Qpex, we conducted research and development activities that involved the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials and viruses. In addition, our operations produced hazardous waste products. Federal, state and local laws and regulations in the United States and Canada govern the use, manufacture, storage, handling and disposal of hazardous materials. With respect to research and development activities conducted prior to our divestiture of our pre-clinical infectious disease assets, we may incur liability as a result of contamination or injury resulting from hazardous materials, which could exceed our resources. We have only limited insurance for liabilities arising from hazardous materials.

#### **Additional Risks Related to Regulatory Matters**

***Clinical trials of product candidates are expensive and time-consuming, and the results of these trials are uncertain. If we are unable to conduct clinical trials that continue to demonstrate the safety and efficacy of inclisiran on a timely basis, then our costs of developing inclisiran may increase and we may not be able to obtain regulatory approval for inclisiran on a timely basis or at all.***

Before we can obtain regulatory approvals to market inclisiran, we will be required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of such product for such indication.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in pre-clinical testing or early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. An unexpected result in one or more of our clinical trials can occur at any stage of testing. For example, in November 2016, we voluntarily discontinued our clinical development program for MDCO-216, an investigational cholesterol efflux promoter, and in August 2017 we voluntarily discontinued our clinical development program for MDCO-700, an investigational anesthetic agent.

We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us from receiving regulatory approval or commercializing our inclisiran, including:

- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials which even if undertaken cannot ensure we will gain approval;
- data obtained from pre-clinical testing and clinical trials may be subject to varying interpretations, which could result in the FDA or other regulatory authorities deciding not to approve a product in a timely fashion, or at all;
- the cost of clinical trials may be greater than we currently anticipate;
- regulators, ethics committees or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we, or the FDA or other regulatory authorities, might suspend or terminate a clinical trial at any time on various grounds, including a finding that participating patients are being exposed to unacceptable health risks. For example, we have in the past voluntarily suspended enrollment in one of our clinical trials to review an interim analysis of safety data from the trial; and
- the effects of inclisiran may not be the desired effects or may include undesirable side effects or inclisiran may have other unexpected characteristics.

The rate of completion of clinical trials depends in part upon the rate of enrollment of patients. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. Delays in patient enrollment in any of our current or future clinical trials may result in increased costs and program delays.

***If we or the contract manufacturers manufacturing inclisiran fail to comply with the extensive regulatory requirements to which we, our contract manufacturers and inclisiran are subject, the development of inclisiran could be jeopardized and we could be subject to penalties.***

The research, testing, manufacturing, labeling, safety, advertising, promotion, storage, sales, distribution, import, export and marketing, among other things, of our products, both before and after approval, are subject to extensive regulation by governmental authorities in the United States, Europe and elsewhere throughout the world. Both before and after approval of a product, quality control and manufacturing procedures must conform to cGMP. Regulatory authorities, including the FDA, periodically inspect manufacturing facilities to assess compliance with cGMP. Our failure or the failure of contract manufacturers to comply with the laws administered by the FDA, the EMA or other governmental authorities could result in, among other things, any of the following:

- delay in approving or refusal to approve a product;
- product recall or seizure;
- suspension or withdrawal of an approved product from the market;
- delays in, suspension of or prohibition of commencing, clinical trials of inclisiran;
- interruption of production;
- operating restrictions;
- untitled or warning letters;
- injunctions;
- fines and other monetary penalties;
- the imposition of civil or criminal penalties;
- disruption of importing and exporting activities; and
- unanticipated expenditures.

***We may incur significant liability if it is determined that we are engaging in pre-approval promotion or, if approved, promoting the “off-label” use of inclisiran.***

Physicians may prescribe drug products for uses that are not described in the product's labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and other regulatory agencies do restrict communications on the subject of off-label use. Companies may not promote drugs for off-label uses. In addition, the FDA prohibits the promotion of drugs that have not yet been approved or cleared for any use. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and products for which marketing approval has not been obtained. A company that is found to have engaged in pre-approval promotion and promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the regulatory restrictions on pre-approval promotion and off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products. We engage in medical education activities and communicate with investigators and potential investigators regarding our clinical trials. If the FDA or another regulatory or enforcement authority determines that our communications regarding inclisiran are not in compliance with the relevant regulatory requirements, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.



***If we do not comply with federal, state and foreign laws and regulations relating to the health care business, we could face substantial penalties.***

We and our customers are subject to extensive regulation by the federal government, and the governments of the states and foreign countries in which we may conduct our business. In the United States, the laws that directly or indirectly affect our ability to operate our business include the following:

- the Federal Anti-Kickback Law, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service for which payment may be made under federal health care programs such as Medicare and Medicaid;
- other Medicare laws and regulations that prescribe the requirements for coverage and payment for services performed by our customers, including the amount of such payment;
- the Federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;
- the Federal False Statements Act, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with delivery of or payment for health care benefits, items or services; and
- various state laws that impose similar requirements and liability with respect to state healthcare reimbursement and other programs.

If our operations are found to be in violation of any of the laws and regulations described above or any other law or governmental regulation to which we or our customers are or will be subject, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations. Similarly, if our customers are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

***Failure to comply with the U.S. Foreign Corrupt Practices Act, or FCPA, as well as the anti-bribery laws of the nations in which we conduct business, could subject us to penalties and other adverse consequences.***

We are subject to the FCPA, which generally prohibits U.S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business and requires companies to maintain accurate books and records and internal controls, including at foreign-controlled subsidiaries. In addition, we are subject to other anti-bribery laws of the nations in which we conduct business that apply similar prohibitions as the FCPA. Our employees or other agents may engage in prohibited conduct without our knowledge under our policies and procedures and the FCPA and other anti-bribery laws that we may be subject to for which we may be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

#### **Risks Related to Our Intellectual Property**

***If we breach any of the agreements under which we license rights to products or technology from others, we could lose license rights that are material to our business or be subject to claims by our licensors.***

We license rights to products and technology that are important to our business, and we expect to enter into additional licenses in the future. For instance, we have exclusively licensed patents and patent applications from Alnylam covering RNAi therapeutics. Under our agreement with Alnylam, we are subject to a range of commercialization and development, sublicensing, royalty, patent prosecution and maintenance, insurance and other obligations.

Any failure by us to comply with any of these obligations or any other breach by us of our license agreements could give the licensor the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for



damages. Any such termination or claim could have a material adverse effect on our financial condition, results of operations, liquidity or business. Even if we contest any such termination or claim and are ultimately successful, such dispute could lead to delays in the development or commercialization of potential products and result in time-consuming and expensive litigation or arbitration. In addition, on termination we may be required to license to the licensor any related intellectual property that we developed.

***If we are unable to obtain or maintain protection for the intellectual property relating to our products, the value of our products will be adversely affected.***

The patent positions of pharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual issues. We cannot be certain that our patents and patent applications, including our own and those that we have rights to through licenses from third parties, will adequately protect our intellectual property and value of our products. Our success protecting our intellectual property depends significantly on our ability to:

- obtain and maintain U.S. and foreign patents, including defending those patents against adverse claims;
- secure patent term extension for the patents covering our approved products;
- protect trade secrets;
- operate without infringing the proprietary rights of others; and
- prevent others from infringing our proprietary rights.

We may not have any additional patents issued from any patent applications that we own or license. If additional patents are granted, the claims allowed may not be sufficiently broad to protect our technology. In addition, issued patents that we own or license may be challenged in contested proceedings such as opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings and may be narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products, and we may not be able to obtain patent term extension to prolong the terms of the principal patents covering our approved products. Changes in patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the value of patents, once obtained, and with regard to our ability to obtain patents in the future. Depending on decisions by the U.S. Congress, the federal courts, and the U.S. Patent and Trademark Office, or PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that others have not filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications.

We exclusively license patents and patent applications for inclisiran. The patents covering inclisiran are currently set to expire at various dates.

*Inclisiran.* We have exclusively licensed from Alnylam patents and patent applications covering RNAi therapeutics targeting PCSK9 for the treatment of hypercholesterolemia and other human diseases for purposes of developing and commercializing such RNAi therapeutics. In November 2018, the PTO issued U.S. Patent No. 10,125,369, or the '369 patent. The '369 patent contains claims directed to specific compositions of the inclisiran product we are developing and methods of administering such compositions and is set to expire in August 2034 (not including any patent term or pediatric extensions). In addition, some of the patents licensed from Alnylam are directed to general RNAi technology, RNAi compositions including compositions of the inclisiran product, and methods of treatment using such RNAi compositions, which expire between 2020 and 2029 in the United States. In addition, we and Alnylam have filed and are prosecuting a number of patent applications in the United States and in certain foreign countries.

We plan to file applications for patent term extension for inclisiran upon its approval. If we do not receive patent term extensions for the periods requested by us or at all, our patent protection for inclisiran could be limited.

With respect to the portfolio of patents licensed from Alnylam, it is possible that one or more companies hold patent rights that could be asserted against us or patent rights to which we may need a license. If a court rules that we infringe such patent rights that have been asserted against us and/or we are not able to obtain a license on reasonable terms, we may be forced to pay license fees set by the court or may be unable to market inclisiran, which in either case could have a material adverse effect on our business. For example, in October 2017 Silence served a claim in the High Court of Justice, Chancery Division, Patents Court in the United Kingdom, naming The Medicines Company UK Ltd., our wholly owned subsidiary, Alnylam and Alnylam UK Limited, as co-defendants. In Silence's claim, it sought a determination that it is entitled to SPCs based on its '847 patent and the prospective European regulatory approvals for inclisiran and for certain of Alnylam's product candidates. This was based on Silence's assertion that inclisiran and the cited Alnylam product candidates fall within the scope of the '847 patent. Following briefing and additional claims by the parties, the High Court had listed the trial for 10 days which was to be heard in a window starting on December 3, 2018 for all claims between Silence, Alnylam and us. However, on June 29, 2018, Silence withdrew the proceedings it issued against us seeking a determination that it is entitled to SPCs based on the '847 patent and the prospective European regulatory approvals for inclisiran. The trial between Silence and Alnylam was scheduled to continue without us and to be heard in December 2018. On December 9, 2018, Silence and Alnylam entered into a settlement and license agreement pursuant to which Alnylam received a global license to Silence's relevant intellectual property for all current and future Alnylam products, including inclisiran, for a low royalty on Alnylam's ONPATTRO product in the European Union through 2023. The settlement does not contain any milestones or royalties payments due to Silence with respect to inclisiran. In connection with the settlement, we entered into an agreement with Alnylam and Silence to discontinue all of our pending litigation against Silence and EPO oppositions of Silence's patents, and we agreed to forgo any reimbursement of legal costs from Silence. Under our collaboration agreement with Alnylam, we received a license from Alnylam covering the license rights granted to Alnylam from Silence with no additional milestone payments or royalties. See Part II, Item 1. *Legal Proceedings* of this Quarterly Report on Form 10-Q for a full description of our litigation with Silence.

In addition to seeking to enforce our patent rights, we have in the past and may in the future seek to enforce our other intellectual property rights, including, for example, our trademark rights in order to prevent third parties from using the same or confusingly similar trademarks. We may not be successful in enforcing such rights and preventing such use. Further, certain of our trademark rights are licensed to us by third parties and, in certain circumstances, on a non-exclusive basis, which does not afford us the right to prevent third parties from using such trademarks. Failure to adequately pursue and enforce our intellectual property rights could damage our brands, enable others to compete with our products and impair our competitive position.

***If we are not able to keep our trade secrets confidential, our technology and information may be used by others to compete against us.***

We rely significantly upon unpatented proprietary technology, information, processes and know-how. We seek to protect this information by confidentiality agreements and invention assignment agreements with our employees, consultants and other third-party contractors, as well as through other security measures. We may not have adequate remedies for any breach by a party to these confidentiality agreements or invention assignment agreements. In addition, our competitors may learn or independently develop our trade secrets. If our confidential information or trade secrets become publicly known, they may lose their value to us.

***If we infringe or are alleged to infringe intellectual property rights of third parties, our business may be adversely affected.***

Our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents or patent applications under which we do not hold licenses or other rights. Third parties may own or control these patents and patent applications in the United States and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose or be required to seek a license from the third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including reexamination, inter partes review, post-grant review, and interference proceedings declared by the PTO and opposition proceedings in the EPO, regarding intellectual property rights with respect to our products and technology. Patent litigation and other proceedings may also absorb significant management time. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

***Cyber security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.***

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect and store confidential and sensitive electronic information on our networks and in our data centers. This information includes, among other things, our intellectual property and proprietary information, the confidential information of our collaborators and licensees, and the personally identifiable information of our employees. It is important to our operations and business strategy that this electronic information remains secure and is perceived to be secure. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, and the volume of data we retain, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches and other cyber-attacks. Information security risks have significantly increased in recent years in part due to the proliferation of new technologies and the increased sophistication and activities of organized crime, hackers, terrorists and other external parties, including foreign state actors. Network and information systems-related events affecting our systems, or those of third parties upon which our business relies, such as computer compromises, cyber threats and attacks, computer viruses, worms or other destructive or disruptive software, process breakdowns, denial of service attacks, malicious social engineering or other malicious activities, or any combination of the foregoing, as well as power outages, equipment failure, natural disasters (including extreme weather), terrorist activities, war, human or technological error or malfeasance that may affect such systems, could result in disruption of our business and/or loss, corruption or improper disclosure of personal data, business information, including intellectual property, or other confidential information. In addition, any design or manufacturing defects in, or the improper implementation of, hardware or software applications we develop or procure from third parties could unexpectedly compromise information security.

A security breach or privacy violation that leads to disclosure or modification of or prevents access to personally identifiable information or other protected information could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. Similarly, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information.

We have not experienced any material losses to date relating to cyber-attacks or other information security breaches, but there can be no assurance that we will not incur such losses in the future. While we have developed and implemented security measures and internal controls that are designed to protect personal data, business information, including intellectual property, and other confidential information, to prevent data loss, and to prevent or detect security breaches, such security measures cannot provide absolute security and may not be successful in preventing these events from occurring, particularly given that techniques used to access, disable or degrade service, or sabotage systems change frequently, and any network and information systems-related events could require us to expend significant resources to remedy such event.

***Failure to comply with health and data protection laws and regulations could lead to government enforcement actions, private litigation and/or adverse publicity and could negatively affect our operating results and business.***

We may receive, generate and store sensitive information, such as employee and patient data. In addition, we actively seek access to medical information, including patient data, through research and development partnerships and collaborations or otherwise. We have legal and contractual obligations regarding the protection of confidentiality and appropriate use of personal data. We and any potential collaborators may be subject to federal, state, local and foreign laws and regulations that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data. In the United States, numerous

federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH. Depending on the facts and circumstances, we could be subject to civil, criminal and administrative penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Several foreign jurisdictions, including the European Union, its member states, among others, have adopted legislation and regulations that increase or change the requirements governing the collection, use, disclosure and transfer of the personal information of individuals in these jurisdictions. In the United States, the state of California enacted legislation, the California Consumer Privacy Act, or CCPA, effective January 1, 2020, that increases the requirements governing the collection, use, disclosure and transfer of the personal information of individuals in the state of California. These laws and regulations are complex and change frequently, at times due to changes in political climate, and existing laws and regulations are subject to different and conflicting interpretations, which adds to the complexity of processing personal data from these jurisdictions. These laws have the potential to increase costs of compliance, risks of noncompliance and penalties for noncompliance. The Regulation 2016/679, known as the General Data Protection Regulation, or GDPR, as well as European Union member state implementing legislations, apply to the collection and processing of personal data, including health-related information, by companies located in the European Union, or in certain circumstances, by companies located outside of the European Union and processing personal information of individuals located in the European Union. These laws impose strict obligations on the ability to process personal data, including health-related information, in particular in relation to their collection, use, disclosure and transfer. For example, the GDPR prohibits the transfer of personal data to countries outside of the European Economic Area, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Although there are legal mechanisms to allow for the transfer of personal data from the EEA to the United States, they are subject to legal challenges and uncertainty about compliance with European Union data protection laws remains. The GDPR has increased our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional potential mechanisms to ensure compliance with the new European Union data protection rules.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions, which could include civil, criminal and administrative penalties, private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

## **Risks Related to Our Common Stock**

### ***Fluctuations in our operating results could affect the price of our common stock.***

Our operating results may vary from period to period based on factors, including the timing, expenses and results of clinical trials, announcements regarding clinical trial results and product introductions by us or our competitors, the availability and timing of third-party reimbursement, sales and marketing expenses and the timing of regulatory approvals. If our operating results do not meet the expectations of investors and securities analysts as a result of these or other factors, the trading price of our common stock will likely decrease.

### ***The capped call transactions we entered into in connection with the 2023 notes may affect the price of our common stock.***

In connection with the sale of the 2023 notes, we entered into capped call transactions with the initial purchasers of the 2023 notes, their affiliates and other financial institutions, whom we refer to as hedge counterparties.

In connection with establishing their hedges of the capped call transactions, the hedge counterparties or their affiliates entered into various derivative transactions with respect to our common stock. These parties may modify their hedge positions in the future by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common

stock or other securities of ours in the secondary market transactions prior to the maturity of the 2023 notes (and are likely to do so during any observation period related to a conversion of the 2023 notes). These activities could cause a decrease or avoid an increase in the market price of our common stock.

***We are subject to counterparty risk with respect to the capped call transactions.***

The counterparties to the capped call transactions we entered into in connection with the issuance of our 2023 notes are financial institutions (including affiliates of Goldman Sachs & Co. LLC and J.P. Morgan Securities LLC), and we will be subject to the risk that the counterparties might default under the capped call transactions. Our exposure to the credit risk of the counterparties will not be secured by any collateral. Global economic conditions have from time to time resulted in the actual or perceived failure or financial difficulties of many financial institutions, including the bankruptcy filing by Lehman Brothers Holdings Inc. and its various affiliates. If a counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim equal to our exposure at that time under our transactions with that counterparty. Our exposure will depend on many factors but, generally, the increase in our exposure will be correlated to the increase in the market price and in the volatility of our common stock. In addition, upon a default by a counterparty, we may suffer adverse tax consequences and more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of any counterparty. These activities could cause a decrease or avoid an increase in the market price of our common stock.

***Our stock price has been and may in the future be volatile. This volatility may make it difficult for you to sell common stock when you want or at attractive prices.***

Our common stock has been and in the future may be subject to substantial price volatility. From January 1, 2015 to July 23, 2019, the last reported closing price of our common stock ranged from a high of \$55.95 per share to a low of \$16.69 per share. The value of your investment could decline due to the effect upon the market price of our common stock of any of the following factors, many of which are beyond our control:

- announcements of results of clinical trials or nonclinical studies by us or third parties relating to inclisiran or products of our competitors or of regulatory proceedings by us or our competitors;
- approval or rejection of submissions for marketing approval for inclisiran;
- changes in securities analysts' estimates of our financial performance;
- changes in valuations of similar companies;
- variations in our operating results;
- acquisitions and strategic partnerships;
- announcements of technological innovations or new commercial products by us or our competitors or the filing of abbreviated NDAs, NDAs or biologic license applications for products competitive with ours;
- changes in governmental regulations;
- developments in patent rights or other proprietary rights;
- the extent to which our products are commercially successful globally;
- developments in our ongoing litigation and significant new litigation;
- developments or issues with our contract manufacturers;
- changes in our management; and
- general market conditions.

We believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance. If our revenues in any particular period do not meet expectations, we may not be able to adjust our expenditures in that period.

which could cause our operating results to suffer. If our operating results in any future period fall below the expectations of securities analysts or investors, our stock price may fall by a significant amount.

The stock markets in general, and The Nasdaq Global Select Market and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations recently. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors may adversely affect the market price of our common stock, regardless of our actual operating performance.

***Our corporate governance structure, including provisions in our certificate of incorporation and by-laws and Delaware law, may prevent a change in control or management that security holders may consider desirable.***

The General Corporation Law of the State of Delaware and our certificate of incorporation and by-laws contain provisions that might enable our management to resist a takeover of our company or discourage a third party from attempting to take over our company. These provisions include:

- Section 203 of the Delaware General Corporation Law, which provides that we may not enter into a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in the manner prescribed in Section 203;
- our board of directors has the authority to issue, without a vote or action of stockholders, up to 5,000,000 shares of a new series of preferred stock and to fix the price, rights, preferences and privileges of those shares, each of which could be superior to the rights of holders of our common stock;
- our directors may be removed with or without cause by the affirmative vote of the holders of at least 75% of the votes which all stockholders would be entitled to cast in any annual election of directors;
- the size of our board of directors is determined by resolution of the board of directors;
- any vacancy on our board of directors, however occurring, including a vacancy resulting from an enlargement of our board, may only be filled by vote of a majority of our directors then in office, even if less than a quorum;
- only our board of directors may call special meetings of stockholders;
- our by-laws may be amended, altered or repealed by (i) the affirmative vote of a majority of our directors, subject to any limitations set forth in the by-laws, or (ii) the affirmative vote of the holders of at least 75% of the votes which all the stockholders would be entitled to cast in any annual election of directors;
- stockholders must provide us with advance notice, and certain information specified in our by-laws, in connection with nominations or proposals by such stockholder for consideration at an annual meeting;
- stockholders may not take any action by written consent in lieu of a meeting; and
- our certificate of incorporation may only be amended or repealed by the affirmative vote of a majority of our directors and the affirmative vote of the holders of at least 75% of the votes which all the stockholders would be entitled to cast in any annual election of directors (and plus any separate class vote that might in the future be required pursuant to the terms of any series of preferred stock that might be outstanding at the time any of these amendments are submitted to stockholders).

These provisions could have the effect of delaying, deferring, or preventing a change in control of us or a change in our management that stockholders may consider favorable or beneficial. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock or our other securities.

***Our business could be negatively affected as a result of the actions of activist shareholders.***

Proxy contests have been waged against many companies in the biopharmaceutical industry over the last few years. If faced with a proxy contest, we may not be able to successfully defend against the contest, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest because:

- responding to proxy contests and other actions by activist shareholders may be costly and time-consuming and may disrupt our operations and divert the attention of management and our employees;
- perceived uncertainties as to our future direction may result in our inability to consummate potential acquisitions, collaborations or in-licensing opportunities and may make it more difficult to attract and retain qualified personnel and business partners; and
- if individuals are elected to our board of directors with a specific agenda different from ours, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

***Sales of additional shares of our common stock, including by us of our directors and officers following expiration or early release of the lock-up entered into in connection with the June 2019 equity offering, could cause the price of our common stock to decline.***

Sales of substantial amounts of our common stock in the public market, or the availability of such shares for sale, by us or others, including the issuance of common stock upon exercise of outstanding options, could adversely affect the price of our common stock. In connection with the June 2019 equity offering, we have agreed to a lock-up for a period of 90 days following such offering, and our directors and officers have entered into lock-up agreements for a period of 90 days following the offering. We and our directors and officers may be released from lock-up prior to the expiration of the lock-up period at the discretion of Goldman Sachs & Co. LLC and J.P. Morgan Securities LLC on behalf of the underwriters. Upon expiration or earlier release of the lock-up, we and our directors and officers may sell shares into the market, which could adversely affect the market price of shares of our common stock. In addition, during the lock-up period and thereafter, sales of shares held by our directors and officers are permitted under trading plans, as in effect as of the date of the applicable lock-up agreement, established pursuant to Rule 10b5-1 of the Exchange Act.

**Item 6. Exhibits**

Exhibits

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits filed as part of this Quarterly Report on Form 10-Q, which Exhibit Index is incorporated herein by this reference.

**SIGNATURES**

Pursuant to the requirements 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.

**THE MEDICINES COMPANY**

Date: July 24, 2019

By: /s/ Christopher J. Visioli

Christopher J. Visioli

Chief Financial Officer

(Principal Financial and Accounting Officer)



## EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
<a href="#">10.1</a>	Underwriting Agreement, dated as of June 25, 2019, by and among the registrant, Goldman Sachs & Co. LLC and J.P. Morgan Securities LLC (incorporated by reference to Exhibit 1.1 to the registrant's current report on Form 8-K, filed June 28, 2019)
<a href="#">31.1</a>	Chief Executive Officer Certification pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
<a href="#">31.2</a>	Chief Financial Officer Certification pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
<a href="#">32.1</a>	Chief Executive Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
<a href="#">32.2</a>	Chief Financial Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from The Medicines Company Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Comprehensive Loss, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements.*

\* The XBRL instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

## CERTIFICATIONS

I, Mark Timney, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of The Medicines Company;
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 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 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 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.

/s/ Mark Timney

Mark Timney  
Chief Executive Officer

Dated: July 24, 2019

## CERTIFICATIONS

I, Christopher J. Visioli, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of The Medicines Company;
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 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 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 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.

/s/ Christopher J. Visioli

Christopher J. Visioli  
Chief Financial Officer

Dated: July 24, 2019

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

In connection with the Quarterly Report on Form 10-Q of The Medicines Company (the "Company") for the period ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark Timney, Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (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.

By: /s/ Mark Timney

Mark Timney

Chief Executive Officer

Dated: July 24, 2019

A signed original of this written statement required by Section 906 has been provided to The Medicines Company and will be retained by The Medicines Company and furnished to the SEC or its staff upon request

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 on Form 10-Q of The Medicines Company (the "Company") for the period ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Christopher Visioli, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (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.

By: /s/ Christopher Visioli

Christopher Visioli  
Chief Financial Officer

Dated: July 24, 2019

A signed original of this written statement required by Section 906 has been provided to The Medicines Company and will be retained by The Medicines Company and furnished to the SEC or its staff upon request