MERRIMACK PHARMACEUTICALS INC
Form 10-Q
November 09, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2016

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number: 001-35409

Merrimack Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	04-3210530
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
One Kendall Square, Suite B7201	
Cambridge, MA	02139
(Address of principal executive offices)	(Zip Code)

(617) 441-1000

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company

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 November 4, 2016, there were 129,615,944 shares of Common Stock, $0.01 par value per share, outstanding.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “ similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- the market potential and our commercialization efforts for ONIVYDE®, which we market in the United States;
- our plans to develop and commercialize our clinical stage product candidates and diagnostics;
- our ongoing and planned discovery programs, preclinical studies and clinical trials;
- the timing of the completion of our clinical trials and the availability of results from such trials;
- our collaborations with Baxalta Incorporated, Baxalta US Inc. and Baxalta GmbH, which we collectively refer to as Baxalta, and PharmaEngine, Inc., or PharmaEngine, related to ONIVYDE;
- our ability to establish and maintain additional collaborations;
- the timing of and our ability to obtain and maintain regulatory approvals for our products and product candidates;
- the rate and degree of market acceptance and clinical utility of our products;
- our intellectual property position;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the potential advantages of our systems biology approach to drug research and development;
- the potential use of our systems biology approach in fields other than oncology; and
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in Part II, Item 1A. Risk Factors, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations or investments that we may make.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

NOTE REGARDING TRADEMARKS

ONIVYDE® is a trademark of Merrimack Pharmaceuticals, Inc. Any other trademarks, trade names and service marks referred to in this Quarterly Report on Form 10-Q are the property of their respective owners.

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PART I

FINANCIAL INFORMATION

Item 1.Financial Statements.

Merrimack Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets

(in thousands, except per share amounts)	September 30,	December 31,
(unaudited)	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	$ 36,463	$ 185,606
Marketable securities	12,003	—
Restricted cash	102	101
Accounts receivable, net	22,170	6,483
Inventory	14,770	3,717
Prepaid expenses and other current assets	4,109	5,487
Total current assets	89,617	201,394
Restricted cash	674	584
Property and equipment, net	17,564	21,915
Other assets	27	27
Intangible assets, net	6,922	7,355
Goodwill	3,605	3,605
Total assets	$ 118,409	$ 234,880
Liabilities, non-controlling interest and stockholders’ deficit		
Current liabilities:		
Accounts payable, accrued expenses and other	$ 49,699	$ 52,082
Deferred revenues	36,610	50,137
Deferred rent	1,974	1,527
Total current liabilities	88,283	103,746
Deferred revenues, net of current portion	36,328	51,197
Deferred rent, net of current portion	3,905	4,926
Deferred tax incentives, net of current portion	165	1,045
Long-term debt	216,871	257,655
Total liabilities	345,552	418,569
Commitments and contingencies		
Non-controlling interest	(361)	239
Stockholders’ deficit:		
Preferred stock, $0.01 par value: 10,000 shares authorized at September 30, 2016 and December 31, 2015; no shares issued or outstanding at September 30, 2016 or December 31, 2015	—	—
	1,294	1,159

Common stock, $0.01 par value: 200,000 shares authorized at September 30, 2016 and December 31, 2015; 129,435 and 115,871 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively		
Additional paid-in capital	693,449	617,145
Accumulated other comprehensive loss	(2)	—
Accumulated deficit	(921,523)	(802,232)
Total stockholders' deficit	(226,782)	(183,928)
Total liabilities, non-controlling interest and stockholders' deficit	$ 118,409	$ 234,880

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

Merrimack Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except per share amounts) (unaudited)	Three Months Ended September 30, 2016	2015	Nine Months Ended September 30, 2016	2015
Revenues:				
Product revenues, net	$14,493	$—	$37,312	$—
License and collaboration revenues	12,417	16,440	43,062	67,839
Other revenues	1,161	—	2,659	—
Total revenues	28,071	16,440	83,033	67,839
Costs and expenses:				
Cost of revenues	1,010	—	3,593	—
Research and development expenses	32,078	37,763	105,956	116,248
Selling, general and administrative expenses	18,048	16,956	56,523	38,460
Restructuring expenses	809	—	809	—
Total costs and expenses	51,945	54,719	166,881	154,708
Loss from operations	(23,874)	(38,279)	(83,848)	(86,869)
Other income and expenses:				
Interest income	64	13	258	93
Interest expense	(6,850)	(4,476)	(36,579)	(13,524)
Other income, net	385	356	278	580
Net loss	(30,275)	(42,386)	(119,891)	(99,720)
Net (loss) income attributable to non-controlling interest	(207)	208	(600)	412
Net loss attributable to Merrimack Pharmaceuticals, Inc.	$(30,068)	$(42,594)	$(119,291)	$(100,132)
Other comprehensive (loss) income:				
Unrealized (loss) gain on available-for-sale securities	(3)	6	(2)	74
Other comprehensive (loss) income	(3)	6	(2)	74
Comprehensive loss	$(30,071)	$(42,588)	$(119,293)	$(100,058)
Net loss per share available to common stockholders—basic and diluted	$(0.23)	$(0.38)	$(0.96)	$(0.91)
Weighted-average common shares used in computing net loss per share available to common stockholders—basic and diluted	129,212	112,417	123,832	109,928

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

Merrimack Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows

(in thousands) (unaudited)	Nine Months Ended September 30, 2016	2015
Cash flows from operating activities		
Net loss	$(119,891)	$(99,720)
Adjustments to reconcile net loss to net cash used in operating activities		
Non-cash interest expense	4,672	6,131
Non-cash loss on extinguishment of convertible notes due 2020	14,566	—
Loss on disposal of property and equipment	227	—
Gain on sale of property and equipment	(40)	—
Depreciation and amortization expense	5,210	4,320
Stock-based compensation expense	11,061	12,027
Changes in operating assets and liabilities:		
Accounts receivable	(15,687)	1,262
Inventory	(10,745)	—
Accounts payable, accrued expenses and other	(2,367)	335
Deferred revenues	(28,396)	(25,922)
Other assets and liabilities, net	2,046	(481)
Net cash used in operating activities	(139,344)	(102,048)
Cash flows from investing activities		
Purchases of marketable securities	(84,262)	—
Proceeds from sales and maturities of marketable securities	72,160	81,899
Purchases of property and equipment	(2,868)	(8,127)
Net cash (used in) provided by investing activities	(14,970)	73,772
Cash flows from financing activities		
Proceeds from exercise of options and warrants to purchase common stock	4,007	8,295
Proceeds from issuance of convertible promissory notes by Silver Creek Pharmaceuticals, Inc.	1,185	—
Proceeds from at the market offering, net of issuance costs	—	38,560
Proceeds from issuance of preferred stock by Silver Creek Pharmaceuticals, Inc.	—	2,083
Other financing activities, net	(21)	—
Net cash provided by financing activities	5,171	48,938
Net (decrease) increase in cash and cash equivalents	(149,143)	20,662
Cash and cash equivalents, beginning of period	185,606	35,688
Cash and cash equivalents, end of period	$36,463	$56,350
Non-cash investing and financing activities		
Purchases of property and equipment in accounts payable, accrued expenses and other	$105	$1,800
Receivables related to stock option exercises in prepaid expenses and other current assets	39	87
Receivables related to the sale of property and equipment in prepaid expenses and other current assets	40	—

Principal amount of convertible notes due 2020 converted into shares of common stock	64,209	—
Transaction costs related to conversion of convertible notes due 2020 in accounts payable, accrued expenses and other	148	—
Supplemental disclosure of cash flows		
Cash paid for interest	$13,851	$8,837

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

Merrimack Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Nature of the Business

Merrimack Pharmaceuticals, Inc. (the "Company") is a biopharmaceutical company discovering, developing and commercializing innovative medicines consisting of novel therapeutics paired with diagnostics for the treatment of cancer. The Company has one marketed therapeutic oncology product and multiple targeted therapeutic oncology candidates in clinical development. The Company's most advanced program is its therapeutic ONIVYDE, which it markets in the United States. In addition to ONIVYDE and its product candidates in clinical development, the Company has multiple product candidates in preclinical development and a discovery effort advancing additional candidate medicines. The Company has tailored ONIVYDE and its other product candidates to target specific disease mechanisms that its research suggests are common across many solid tumor types. The Company believes that ONIVYDE and its other product candidates have the potential to address major unmet medical needs. The Company also has an agreement to utilize its manufacturing expertise to develop, manufacture and exclusively supply bulk drug product to a third party, who will in turn process the drug into finished product and commercialize it globally following regulatory approval. The Company was incorporated in the Commonwealth of Massachusetts in 1993 and reincorporated in the State of Delaware in October 2010.

The Company is subject to risks and uncertainties common to companies in the biopharmaceutical industry, including, among other things, its ability to secure additional capital to fund operations, success of clinical trials, development by competitors of new technological innovations, dependence on collaborative arrangements, protection of proprietary technology, compliance with government regulations and dependence on key personnel. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel, infrastructure and extensive compliance reporting capabilities.

The Company has incurred significant expenses and operating losses to date, and it expects to continue to incur significant expenses and operating losses for at least the next several years. The accompanying condensed consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business.

The Company may seek additional funding through public or private debt or equity financings, or through existing or new collaboration arrangements. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into additional collaborative arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. Arrangements with collaborators or others may require the Company to relinquish rights to certain of its technologies or product candidates. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate its research and development programs or commercialization efforts, which could adversely affect its business prospects.

2. Basis of Presentation and Consolidation

The accompanying condensed consolidated financial statements as of September 30, 2016 and December 31, 2015, and for the three and nine months ended September 30, 2016 and 2015, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (the “SEC”) and generally accepted accounting principles in the United States of America (“GAAP”) for condensed consolidated financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, these condensed consolidated financial statements reflect all adjustments which are necessary for a fair statement of the Company’s financial position and results of its operations, as of and for the periods presented. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company’s Annual Report on Form 10-K for the year ended December 31, 2015 filed with the SEC on February 26, 2016.

The information presented in the condensed consolidated financial statements and related notes as of September 30, 2016, and for the three and nine months ended September 30, 2016 and 2015, is unaudited. The December 31, 2015 condensed consolidated balance sheet included herein was derived from the audited financial statements as of that date, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

Interim results for the nine months ended September 30, 2016 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2016, or any future period.

These condensed consolidated financial statements include the accounts of the Company and its majority owned subsidiary, Silver Creek Pharmaceuticals, Inc. (“Silver Creek”). All intercompany transactions and balances have been eliminated in consolidation.

As of September 30, 2016, the Company’s unrestricted cash and cash equivalents includes $0.4 million of cash and cash equivalents held by Silver Creek. This $0.4 million held by Silver Creek is designated for the operations of Silver Creek.

During the nine months ended September 30, 2015, Silver Creek issued and sold a total of 1.6 million shares of Silver Creek Series B preferred stock at a price per share of $1.35 to investors and received net proceeds of $2.1 million, after deducting issuance costs. No shares of Silver Creek Series B preferred stock were sold during the nine months ended September 30, 2016. The Company’s ownership of Silver Creek was 56% as of both September 30, 2016 and December 31, 2015. The change in the non-controlling interest related to Silver Creek was as follows:

(in thousands)	Non-Controlling Interest
Balance at December 31, 2015	$ 239
Net loss attributable to Silver Creek	(600)
Balance at September 30, 2016	$ (361)

(in thousands)	Non-Controlling Interest
Balance at December 31, 2014	$ 69
Net income attributable to Silver Creek	412
Balance at September 30, 2015	$ 481

3. Net Loss Per Common Share

Basic net loss per share is calculated by dividing the net loss available to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss available to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, convertible preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

As discussed in Note 10, “Borrowings,” in July 2013, the Company issued $125.0 million aggregate principal amount of 4.50% convertible notes due 2020 (the “Convertible Notes”) in an underwritten public offering. Following the repayment and satisfaction in full of the Company’s obligations to Hercules Technology Growth Capital, Inc. (“Hercules”) under its Loan and Security Agreement with Hercules (the “Loan Agreement”), which occurred in December 2015, upon any conversion of the Convertible Notes, the Convertible Notes may be settled, at the Company’s election, in cash, shares of the Company’s common stock or a combination of cash and shares of the Company’s common stock. For purposes of calculating the maximum dilutive impact, it is presumed that the conversion premium will be settled in common stock, inclusive of a contractual make-whole provision resulting from a fundamental change, and the resulting potential common shares included in diluted earnings per share if the effect is more dilutive. As of September 30, 2016, $60.8 million aggregate principal amount of the Convertible Notes remain outstanding.

The stock options, warrants and conversion premium on the Convertible Notes are excluded from the calculation of diluted loss per share because the net loss for the three and nine months ended September 30, 2016 and 2015 causes such securities to be anti-dilutive. Outstanding securities excluded from the calculation of diluted loss per share for the three and nine months ended September 30, 2016 and 2015 are shown in the chart below:

	Three and Nine Months Ended September 30,	
(in thousands)	2016	2015
Outstanding options to purchase common stock	21,000	19,436
Common stock warrants	—	370
Conversion of the Convertible Notes	12,158	25,000

4. License and Collaboration Agreements

Baxalta

On September 23, 2014, the Company and Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA entered into a license and collaboration agreement (the "Baxalta Agreement") for the development and commercialization of ONIVYDE outside of the United States and Taiwan (the "Licensed Territory"). In connection with Baxter International Inc.'s separation of the Baxalta business, the Baxalta Agreement was assigned to Baxalta Incorporated, Baxalta US Inc. and Baxalta GmbH (collectively, "Baxalta") during the second quarter of 2015. As part of the Baxalta Agreement, the Company granted Baxalta an exclusive, royalty-bearing right and license under the Company's patent rights and know-how to develop and commercialize ONIVYDE in the Licensed Territory. Baxalta is responsible for using commercially reasonable efforts to develop, obtain regulatory approvals for and, following regulatory approval, commercialize ONIVYDE in the Licensed Territory. A joint steering committee comprised of an equal number of representatives from each of Baxalta and the Company is responsible for approving changes to the global development plan for ONIVYDE, including all budgets, and overseeing the parties' development and commercialization activities with respect to ONIVYDE. Unless otherwise agreed, the Company will be responsible for conducting all clinical trials contemplated by the global development plan for ONIVYDE and manufacturing all clinical material needed for such trials. Baxalta also has the option to manufacture ONIVYDE, in which case the Company will perform a technology transfer of its manufacturing process to Baxalta.

Under the terms of the Baxalta Agreement, the Company received a $100.0 million upfront, nonrefundable cash payment in September 2014. In addition, the Company is eligible to receive from Baxalta (i) up to an aggregate of $100.0 million upon the achievement of specified research and development milestones, of which the Company has received $62.5 million from Baxalta through September 30, 2016, (ii) up to an aggregate of $520.0 million upon the achievement of specified regulatory milestones, of which the Company has received $30.0 million from Baxalta through September 30, 2016, and (iii) up to an aggregate of $250.0 million upon the achievement of specified sales milestones. Under the terms of the Baxalta Agreement, the Company will bear up to the first $98.8 million of costs related to the development of ONIVYDE for pancreatic cancer patients who have not previously received gemcitabine-based therapy; however, the Company expects most of these costs to be offset by payments received upon the achievement of clinical trial-related milestones. The Company and Baxalta will share equally all other clinical trial costs contemplated by the global development plan. The Company is also entitled to tiered, escalating royalties ranging from sub-teen double digits to low twenties percentages of net sales of ONIVYDE in the Licensed Territory.

If not terminated earlier by either party, the Baxalta Agreement will expire upon expiration of all royalty and other payment obligations of Baxalta under the Baxalta Agreement. Either party may terminate the Baxalta Agreement in the event of an uncured material breach by the other party. Baxalta may also terminate the Baxalta Agreement on a product-by-product, country-by-country or sub-territory-by-sub-territory basis or in its entirety, for its convenience, upon 180 days' prior written notice. In addition, the Company may terminate the Baxalta Agreement if Baxalta challenges or supports any challenge of the Company's licensed patent rights.

At the inception of the collaboration, the Company identified the following deliverables as part of the Baxalta Agreement: (i) license to develop and commercialize ONIVYDE in Baxalta's territories, (ii) discovery, research, development and manufacturing services required to complete ongoing clinical trials related to ONIVYDE, (iii) discovery, research, development and manufacturing services needed to complete future clinical trials in further indications related to ONIVYDE, (iv) the option to perform a technology transfer of the Company's manufacturing process related to the production of ONIVYDE to Baxalta and (v) participation on the joint steering committee.

The Company concluded that none of the deliverables identified at the inception of the collaboration has standalone value from the other undelivered elements. As such, all deliverables represent a single unit of accounting.

The Company has determined that the collaboration represents a services agreement and as such has estimated the level of effort expected to be completed as a result of providing the identified deliverables. The Company will recognize revenue from the nonrefundable upfront payment, forecasted non-substantive milestone payments and estimated payments related to discovery, research, development and technology transfer services based on proportional performance as effort is completed over the expected services period, which is estimated to be substantially complete by June 30, 2022. The Company will periodically review and, if necessary, revise the estimated service period related to its collaboration with Baxalta. As of September 30, 2016, the Company has achieved $62.5 million of the $90.0 million of forecasted non-substantive milestones that are included in the Company's proportional performance revenue recognition model and $30.0 million of the $530.0 million of substantive milestones that are included in the Baxalta Agreement.

Research, development and regulatory milestones that are considered substantive on the basis of the contingent nature of the milestone will be recognized as revenue in full in the period in which the associated milestone is achieved, assuming all other revenue

recognition criteria are met. All sales milestones will be accounted for in the same manner as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

During the second quarter of 2015, the European Medicines Agency ("EMA") accepted for review a Marketing Authorization Application ("MAA") filed by Baxalta for ONIVYDE. As a result of this acceptance, the Company recognized $20.0 million of revenue related to a substantive milestone payment owed from Baxalta. In August 2015, the Company achieved a $15.0 million milestone related to the submission of the protocol for the Company's Phase 2 clinical trial of ONIVYDE in front-line metastatic pancreatic cancer. This milestone is a non-substantive milestone, and revenue related to the achievement of this milestone will be recognized through the proportional performance revenue recognition model. In October 2015, the Company achieved an additional $47.5 million milestone related to the enrollment of the first patient in a Phase 2 clinical trial of ONIVYDE in front-line pancreatic cancer. This milestone is also a non-substantive milestone, and revenue related to the achievement of this milestone will be recognized through the proportional performance revenue recognition model. In the second quarter of 2016, the South Korean Ministry of Food and Drug Safety (the "MFDS") accepted for review a new drug application filed by Baxalta for ONIVYDE. As a result of this acceptance, the Company recognized $10.0 million of license and collaboration revenue related to a substantive milestone payment owed from Baxalta.

During the three and nine months ended September 30, 2016 and 2015, the Company recognized revenue based on the following components of the Baxalta Agreement:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
(in thousands)	2016	2015	2016	2015
Proportional performance revenue recognition model	$12,417	$16,440	$33,062	$47,839
Substantive milestones	—	—	10,000	20,000
Total	$12,417	$16,440	$43,062	$67,839

As of September 30, 2016 and December 31, 2015, the Company maintained the following assets and liabilities related to the Baxalta Agreement:

	September 30,	December 31,
(in thousands)	2016	2015
Accounts receivable, billed	$ 594	$ 1,336
Accounts receivable, unbilled	385	626
Deferred revenues	68,944	97,365

Of the $68.9 million of deferred revenues related to the Baxalta Agreement as of September 30, 2016, $36.6 million is classified as current in the condensed consolidated balance sheets based upon the Company's estimate of revenues that will be recognized under the proportional performance revenue recognition model as a result of effort expected to be completed within the next twelve months.

In February 2016, the Company and Baxalta entered into a commercial supply agreement (the "Baxalta Supply Agreement") pursuant to which the Company supplies ONIVYDE bulk drug substance to Baxalta and, at Baxalta's option, manages fill and finish activities conducted by a third-party contract manufacturer for Baxalta. The Company began supplying bulk drug substance under the Baxalta Supply Agreement during the second quarter of 2016 and recognized $1.2 million and $2.4 million of revenue during the three and nine months ended September 30, 2016, respectively. Revenue and cost of goods sold associated with the Baxalta Supply Agreement are included within "Other revenues" and "Cost of revenues" on the consolidated statements of operations and comprehensive loss.

PharmaEngine, Inc.

On May 5, 2011, the Company and PharmaEngine, Inc. ("PharmaEngine") entered into an assignment, sublicense and collaboration agreement (the "PharmaEngine Agreement") under which the Company reacquired rights in Europe and certain countries in Asia to ONIVYDE. In exchange, the Company agreed to pay PharmaEngine a nonrefundable, noncreditable upfront payment of $10.0 million and up to an additional $80.0 million in aggregate development and regulatory milestones and $130.0 million in aggregate sales milestones. PharmaEngine is also entitled to tiered royalties on net sales of ONIVYDE in Europe and certain countries in Asia. PharmaEngine is not responsible for any future development costs of ONIVYDE except those required specifically for regulatory approval in Taiwan.

On September 22, 2014, the Company amended the PharmaEngine Agreement to redefine sublicense revenue and reduce the portion of sublicense revenue that the Company is required to pay to PharmaEngine. As a result of this amendment, the Company

made a $7.0 million milestone payment to PharmaEngine in September 2014. Additionally, as a result of this amendment, a previously contingent $5.0 million milestone payment was paid to PharmaEngine in the second quarter of 2015. Prior to the amendment of the PharmaEngine Agreement, this milestone payment was contingent upon the award of certain specified regulatory designations. These milestone payments were recognized as research and development expense during the year ended December 31, 2014. In July 2015, the Company made an $11.0 million milestone payment to PharmaEngine in connection with the EMA's acceptance for review of an MAA for ONIVYDE, which occurred, and was recognized as research and development expense, in the second quarter of 2015. In June 2016, the Company also made a $10.0 million milestone payment to PharmaEngine in connection with the MFDS's acceptance for review of a new drug application for ONIVYDE, which occurred, and was recognized as research and development expense, in the second quarter of 2016.

During the three months ended September 30, 2016 and 2015, the Company recognized research and development expenses related to the PharmaEngine Agreement of less than $0.1 million and $0.1 million, respectively. During the nine months ended September 30, 2016 and 2015, the Company recognized research and development expenses related to the PharmaEngine Agreement of $10.1 million and $11.4 million, respectively.

In August 2015, the Company and PharmaEngine also entered into a commercial supply agreement (the "PharmaEngine Supply Agreement") pursuant to which the Company supplies ONIVYDE bulk drug substance to PharmaEngine. The Company began supplying bulk drug substance under the PharmaEngine Supply Agreement in the second quarter of 2016 and has recognized $0.3 million of revenue during the nine months ended September 30, 2016. No revenue related to the PharmaEngine Supply Agreement was recognized during the three months ended September 30, 2016. Revenue and cost of goods sold associated with the PharmaEngine Supply Agreement are included within "Other revenues" and "Cost of revenues" on the consolidated statements of operations and comprehensive loss.

Actavis

In November 2013, the Company and Watson Laboratories, Inc. ("Actavis") entered into a development, license and supply agreement (the "Actavis Agreement") pursuant to which the Company will develop, manufacture and exclusively supply the bulk form of doxorubicin HCl liposome injection (the "Initial Product") to Actavis. The Actavis Agreement was subsequently amended in January 2015 to transfer certain responsibilities from the Company to Actavis in exchange for reducing the aggregate milestone payments that the Company is eligible to receive by $0.4 million. Under the Actavis Agreement, Actavis is responsible for all costs related to finished product processing and global commercialization. Pursuant to the agreement, additional products may be developed for Actavis in the future, the identities of which will be mutually agreed upon. The Company is eligible to receive up to $15.1 million in milestone and development payments, as well as additional reimbursement for specific activities performed by the Company at the request of Actavis, of which $4.0 million in total has been received through September 30, 2016. The Company will also receive a mid-twenties percentage of net profits on global sales of the Initial Product and any additional products. The Company will manufacture and supply the Initial Product to Actavis in bulk form at an agreed upon unit price. In October 2016, the U.S. Food and Drug Administration accepted for review an Abbreviated New Drug Application filed by Actavis for the Initial Product.

The Actavis Agreement will expire with respect to the Initial Product and any additional products developed in the future ten years after Actavis' first sale of the applicable product, unless terminated earlier, and will automatically renew for additional two year periods thereafter unless either party provides notice of non-renewal. Either party may terminate the Actavis Agreement in the event of an uncured material breach or bankruptcy filing by the other party. Actavis may also terminate the Actavis Agreement for convenience in specified circumstances upon 90 days' prior written notice.

The Company applied revenue recognition guidance to determine whether the performance obligations under the Actavis Agreement, including the license, participation on steering committees, development services, and manufacturing and supply services could be accounted for separately or as a single unit of accounting. The Company determined that these obligations represent a single unit of accounting and will recognize revenue as product is supplied to Actavis. Therefore, the Company has recorded $4.0 million of billed and billable milestones and development expenses related to the Actavis Agreement as deferred revenue as of both September 30, 2016 and December 31, 2015. This revenue is expected to be recognized by the Company over the ten year period that begins after Actavis' first sale of the applicable product under the Actavis Agreement.

5. Product Revenue Reserves and Allowances

The following table summarizes activity in each of the product revenue reserve and allowance categories for the nine months ended September 30, 2016:

(in thousands)	Trade Allowances	Rebates and Chargeback Discounts	Product Returns	Other Incentives	Total
Balance at December 31, 2015	$ 138	$ 362	$ 32	$ 8	$540
Provisions related to sales in the current year	1,332	4,073	278	7	5,690
Adjustments related to sales in the prior year	—	(156)	—	—	(156)
Credits and payments made	(978)	(3,354)	(26)	(7)	(4,365)
Balance at September 30, 2016	$ 492	$ 925	$ 284	$ 8	$1,709

6. Fair Value of Financial Instruments

The carrying values of cash, restricted cash, prepaid expenses, accounts receivable, accounts payable and accrued expenses, and other short-term assets and liabilities approximate their respective fair values due to the short-term maturities of these assets and liabilities.

Fair value is an exit price, representing the amount that would be received from the sale of an asset or paid to transfer a liability in an orderly transaction between market participants. Fair value is determined based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect certain market assumptions. As a basis for considering such assumptions, GAAP establishes a three-tier value hierarchy, which prioritizes the inputs used to develop the assumptions and for measuring fair value as follows: (Level 1) observable inputs such as quoted prices in active markets for identical assets; (Level 2) inputs other than the quoted prices in active markets that are observable either directly or indirectly; and (Level 3) unobservable inputs in which there is little or no market data, which requires the Company to develop its own assumptions. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

Recurring Fair Value Measurements

The following tables show assets measured at fair value on a recurring basis as of September 30, 2016 and December 31, 2015:

	September 30, 2016		
(in thousands)	Level 1	Level 2	Level 3
Cash equivalents:			

Money market funds	$32,288	$—	$ —
Total cash equivalents	$32,288	$—	$ —
Marketable securities:			
Commercial paper	$—	$7,000	$ —
Corporate debt securities	—	5,003	—
Total marketable securities	$—	$12,003	$ —

	December 31, 2015		
(in thousands)	Level 1	Level 2	Level 3
Cash equivalents:			
Money market funds	$704	$ —	$ —
Total cash equivalents	$704	$ —	$ —

There were no changes in valuation techniques or transfers between the fair value measurement levels during the three or nine months ended September 30, 2016 or during the year ended December 31, 2015. There were no liabilities measured at fair value on a recurring basis as of September 30, 2016 or December 31, 2015.

Non-Recurring Fair Value Measurements

Certain assets, including in-process research and development intangible assets, may be measured at fair value on a non-recurring basis in periods subsequent to initial recognition. No non-recurring fair value measurements were required during the three or nine months ended September 30, 2016 or during the year ended December 31, 2015.

Other Fair Value Measurements

The estimated fair value of the Convertible Notes was $74.2 million as of September 30, 2016. The Company estimated the fair value of the Convertible Notes by using a quoted market rate in an inactive market, which is classified as a Level 2 input. The carrying value of the Convertible Notes was $46.0 million as of September 30, 2016 due to the bifurcation of the conversion feature of the Convertible Notes as described more fully in Note 10, “Borrowings.”

As discussed in Note 10, “Borrowings,” in December 2015, the Company closed a private placement of $175.0 million aggregate principal amount of 11.50% senior secured notes due 2022 (the “2022 Notes”). The Company estimated the fair value of the 2022 Notes by using publicly-available information related to one of the 2022 Notes borrower’s portfolio of debt investments based on unobservable inputs, which is classified as a Level 3 input. The estimated fair value of the 2022 Notes was $173.5 million as of September 30, 2016. The carrying value of the 2022 Notes was $169.7 million as of September 30, 2016.

As discussed in Note 10, “Borrowings,” Silver Creek issued $1.0 million of convertible promissory notes (the “Silver Creek Notes”) in May 2016. In August 2016, Silver Creek issued $0.2 million of additional Silver Creek Notes under the same terms as the May 2016 issuance. The Company estimated the fair value of the Silver Creek Notes using a probability-weighted valuation based upon the likelihood of Silver Creek Notes being converted to shares of Silver Creek equity, which is classified as a Level 3 input. The estimated fair value of the Silver Creek Notes was $1.2 million as of September 30, 2016. The carrying value of the Silver Creek Notes was also $1.2 million as of September 30, 2016.

7. Marketable Securities

The Company classifies marketable securities with a remaining maturity when purchased of greater than three months as available-for-sale. Available-for-sale securities may consist of U.S. government agency securities, commercial paper, corporate notes and bonds and certificates of deposit, which are maintained by an investment manager. Available-for-sale securities are carried at fair value, with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders’ deficit until realized. The amortized cost of securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Realized gains and losses are recognized within interest income.

Cash equivalents and marketable securities as of September 30, 2016 consisted of the following:

	September 30, 2016			
(in thousands)	Amortized	Unrealized	Unrealized	Fair

	Cost	Gains	Losses	Value
Cash equivalents:				
Money market funds	$32,288	$ —	$ —	$32,288
Total cash equivalents	$32,288	$ —	$ —	$32,288
Marketable securities:				
Commercial paper	$7,000	$ —	$ -	$7,000
Corporate debt securities	5,005	—	(2)	5,003
Total marketable securities	$12,005	$ —	$ (2)	$12,003

As of December 31, 2015, the Company maintained only cash equivalents comprised of money market funds.

There were no realized gains or losses on available-for-sale securities during the three or nine months ended September 30, 2016 or 2015. As of September 30, 2016, the Company held three securities that had been in an immaterial unrealized loss position for less than twelve months. The aggregate fair value of these three securities was $12.0 million. As of September 30, 2016, the Company did not intend to sell, and it was not more likely than not that the Company would be required to sell, the securities in an unrealized loss position before recovery of their amortized cost bases. As a result, the Company determined that there was no material change in the credit risk of the investments, and the Company did not hold any securities with an other-than-temporary-impairment as of September 30, 2016.

8. Inventory

Inventory as of September 30, 2016 and December 31, 2015 consisted of the following:

(in thousands)	September 30, 2016	December 31, 2015
Raw materials	$ 4,669	$ 900
Work in process	8,775	2,743
Finished goods	1,326	74
Total inventory	$ 14,770	$ 3,717

Inventory acquired prior to receipt of marketing approval of ONIVYDE was expensed as research and development expense as incurred. The Company began to capitalize the costs associated with the production of ONIVYDE upon receipt of approval from the U.S. Food and Drug Administration on October 22, 2015.

9. Accounts Payable, Accrued Expenses and Other

Accounts payable, accrued expenses and other as of September 30, 2016 and December 31, 2015 consisted of the following:

(in thousands)	September 30, 2016	December 31, 2015
Accounts payable	$ 8,114	$ 5,049
Accrued goods and services	13,602	14,295
Accrued clinical trial costs	11,495	12,764
Accrued drug purchase costs	35	7,460
Accrued payroll and related benefits	8,186	9,009
Accrued restructuring expenses	809	—
Accrued interest	6,447	3,041
Accrued dividends payable	19	19
Deferred tax incentives	992	445
Total accounts payable, accrued expenses and other	$ 49,699	$ 52,082

10. Borrowings

2022 Notes

On December 22, 2015, the Company closed a private placement of $175.0 million aggregate principal amount of 11.50% 2022 Notes. As a result of this placement, the Company received net proceeds of approximately $168.5 million, after deducting private placement and offering expenses payable by the Company. The 2022 Notes bear interest at a rate of 11.50% per year, payable semi-annually on June 15 and December 15 of each year, beginning on June 15, 2016. The Company will pay semi-annual installments of principal on the 2022 Notes of $21,875,000 each on June 15 and December 15 of each year, beginning on June 15, 2019. The 2022 Notes will mature on December 15, 2022, unless earlier redeemed or repurchased in accordance with their terms prior to such date.

The 2022 Notes are senior secured obligations of the Company and will be equal in right of payment to all existing and future pari passu indebtedness of the Company (including the Company's outstanding Convertible Notes), will be senior in right of payment to all existing and future subordinated indebtedness of the Company, will have the benefit of a security interest in the 2022 Notes collateral and will be junior in lien priority in respect of any asset-based lending collateral that secures any first priority lien obligations from time to time. The 2022 Notes contain customary covenants, including covenants that limit or restrict the Company's ability to incur liens, incur indebtedness, and make certain restricted payments, but do not contain covenants related to future financial performance. The 2022 Notes are secured by a first priority lien on substantially all of the Company's assets.

The Company assessed the 2022 Notes pursuant to Accounting Standards Codification ("ASC") 815, Derivatives and Hedging, to determine if any features necessitated bifurcation from the host instrument. The Company concluded that none of the embedded redemption features within the 2022 Notes require bifurcation as these features are clearly and closely related to the host instrument.

Debt issuance costs incurred by the Company are accounted for as a direct deduction to the carrying value of the 2022 Notes and are amortized to interest expense using the effective interest method over the life of the 2022 Notes. For the three and nine months ended September 30, 2016, interest expense related to the 2022 Notes was $5.2 million and $15.6 million, respectively.

Convertible Notes

In July 2013, the Company issued $125.0 million aggregate principal amount of Convertible Notes in an underwritten public offering. As a result of the Convertible Notes offering, the Company received net proceeds of approximately $120.6 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company.

The Convertible Notes bear interest at a rate of 4.50% per year, payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2014. The Convertible Notes are general unsecured senior obligations of the Company and rank (i) pari passu in seniority with respect to the 2022 Notes, (ii) senior in right of payment to any of the Company's indebtedness that is expressly subordinated in right of payment to the Convertible Notes, (iii) equal in right of payment to any of the Company's unsecured indebtedness that is not so subordinated, (iv) 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 (v) structurally junior to all indebtedness and other liabilities (including trade payables) of the Company's subsidiaries.

The Company separately accounted for the liability and equity components of the Convertible Notes by bifurcating gross proceeds between the indebtedness, or liability component, and the embedded conversion option, or equity component. This bifurcation was done by estimating an effective interest rate as of the date of issuance for similar notes which do not contain an embedded conversion option. The gross proceeds received from the issuance of the Convertible Notes less the initial amount allocated to the indebtedness resulted in a $53.8 million allocation to the embedded conversion option. The embedded conversion option was recorded in stockholders' deficit and as debt discount, to be subsequently amortized as interest expense over the term of the Convertible Notes. Underwriting discounts and commissions and offering expenses totaled $4.4 million and were allocated to the indebtedness and the embedded conversion option based on their relative values.

On April 13, 2016, the Company entered into separate, privately-negotiated conversion agreements (the "Conversion Agreements") with certain holders of the Convertible Notes. Under the Conversion Agreements, such holders agreed to convert an aggregate principal amount of $64.2 million of Convertible Notes held by them. The Company initially settled each $1,000 principal amount of Convertible Notes surrendered for conversion by delivering 136 shares of the Company's common stock on April 18, 2016. In total, the Company issued an aggregate of 8,732,152 shares of its common stock on this initial closing date. In addition, pursuant to the Conversion Agreements, at the additional closings (as defined in the Conversion Agreements), the Company issued an aggregate of 3,635,511 shares of the Company's common stock representing an aggregate of $27.7 million as additional payments in respect of the conversion of the Convertible Notes. The number of additional shares was determined based on the daily VWAP (as defined in the Conversion Agreements) of the Company's common stock for each of the trading days in the 10-day trading period following the date of the Conversion Agreements. The issuance of 12,367,663 total shares of the Company's common stock pursuant to the Conversion Agreements resulted in an increase to common stock and additional paid-in capital of $101.0 million.

As a result of the conversion, the Company recognized an overall loss on extinguishment of $14.6 million representing the difference between the total settlement consideration transferred to the holders that was attributed to the liability component of the Convertible Notes, based on the fair value of that component at the time of conversion, and the net carrying value of the liability. The loss on extinguishment was recorded as interest expense during the second quarter of 2016. The remaining settlement consideration transferred was allocated to the reacquisition of the embedded conversion option and recognized as a $39.8 million reduction of additional paid-in capital. Transaction costs incurred with third parties related to the conversion were allocated to the liability and equity components and resulted in an additional $0.2 million of interest expense and a $0.2 million reduction of additional paid-in capital.

The outstanding Convertible Notes will mature on July 15, 2020 (the "Maturity Date"), unless earlier repurchased by the Company or converted at the option of holders. Holders may convert their Convertible Notes at their option at any time prior to the close of business on the business day immediately preceding April 15, 2020 only under the following circumstances:

- during any calendar quarter commencing after September 30, 2013 (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 Convertible Notes) per $1,000 principal amount of Convertible 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 set forth in the indenture governing the Convertible Notes.

On or after April 15, 2020 until the close of business on the business day immediately preceding the Maturity Date, holders may convert their Convertible Notes at any time, regardless of the foregoing circumstances.

Following the repayment and satisfaction in full of the Company's obligations to Hercules under the Loan Agreement, which occurred in December 2015, upon any conversion of the Convertible Notes, the Convertible Notes may be settled, at the Company's election, in cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock.

The initial conversion rate of the Convertible Notes is 160 shares of the Company's common stock per $1,000 principal amount of Convertible Notes, which is equivalent to an initial conversion price of $6.25 per share of common stock. The conversion rate will be subject to adjustment in some events, but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the Maturity Date, the Company will increase the conversion rate for a holder who elects to convert its Convertible Notes in connection with such a corporate event in certain circumstances.

For the three months ended September 30, 2016 and 2015, interest expense related to the Convertible Notes was $1.7 million and $3.4 million, respectively. For the nine months ended September 30, 2016 and 2015, interest expense related to the Convertible Notes was $21.1 million and $10.3 million, respectively. As discussed above, interest expense for the nine months ended September 30, 2016 includes the loss on extinguishment of $14.6 million associated with the April 2016 conversion of the Convertible Notes as well as $0.2 million of related transaction costs.

Silver Creek Convertible Promissory Notes

In May 2016, Silver Creek issued an aggregate of $1.0 million of Silver Creek Notes. In August 2016, Silver Creek issued $0.2 million of additional Silver Creek Notes under the same terms as the May 2016 issuance. The Silver Creek Notes are automatically convertible into shares of Silver Creek equity under a variety of conversion scenarios. The Silver Creek Notes bear interest at 6% per annum and mature and convert, along with accrued interest, into Silver Creek Series B preferred stock at a conversion price of $1.35 per share on December 31, 2016. If, prior to maturity, Silver Creek enters into a sale or series of related sales of equity securities resulting in at least $4.0 million of gross proceeds, the Silver Creek Notes will convert into the equity securities sold at the lesser of the price paid per share for the equity securities or $1.60 per share. Principal and accrued interest related to the Silver Creek Notes may not be paid in cash by Silver Creek without the consent of the majority noteholders. The Silver Creek Notes are classified as non-current as of September 30, 2016, as it is not expected that the Silver Creek Notes will be settled in cash.

Future Minimum Payments under Outstanding Borrowings

Future minimum payments under outstanding borrowings as of September 30, 2016 are as follows:

(in thousands)	Convertible Notes	2022 Notes
Remainder of 2016	$ —	$ 10,063
2017	2,736	20,125
2018	2,736	20,125
2019	2,736	62,617
2020 and thereafter	63,527	157,664
Total	71,735	270,594

Less interest	(10,943)	(95,594)
Less unamortized discount	(14,820)	(5,286)
Less current portion	—	—
Long-term debt	$ 45,972	$ 169,714

11. Restructuring Activities

On October 3, 2016, the Company announced a 22% reduction in headcount as part of a major corporate restructuring with the objective of prioritizing its research and development on a focused set of systems biology-derived oncology products and strengthening its financial runway. On this same date, the Company also announced the resignation of Robert Mulroy, the Company's former President and Chief Executive Officer.

Under this corporate restructuring, the Company recognized total restructuring expenses of $0.8 million during the three and nine months ended September 30, 2016 related to contractual termination benefits for employees with pre-existing severance arrangements. The Company also expects to incur approximately $4.0 million of additional restructuring expenses during the fourth quarter of 2016 related to one-time employee termination benefits. These one-time employee termination benefits are comprised of severance, benefits and related costs, all of which are expected to result in cash expenditures. The Company anticipates that the majority of these payments will be made during the fourth quarter of 2016.

The following table summarizes the charges related to the restructuring activities as of September 30, 2016:

(in thousands)	Expenses	Payments	Accrued restructuring expenses at September 30, 2016
Severance, benefits and related costs due to workforce reduction	$ 809	$ —	$ 809
Totals	$ 809	$ —	$ 809

12. Stock-Based Compensation

As of December 31, 2015, there were 2.5 million shares of common stock available to be granted under the Company's 2011 Stock Incentive Plan (the "2011 Plan"). The 2011 Plan is administered by the Company's board of directors and permits the Company to grant incentive and non-qualified stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards.

In February 2016, 4.1 million additional shares of common stock became available for grant to employees, officers, directors and consultants under the 2011 Plan. At September 30, 2016, there were 3.5 million shares remaining available for grant under the 2011 Plan.

During the nine months ended September 30, 2016 and 2015, the Company issued options to purchase 4.2 million and 3.3 million shares of common stock, respectively. These options generally vest over a three-year period for employees. Options granted to directors vest immediately.

The fair value of stock options granted to employees during the three and nine months ended September 30, 2016 and 2015 was estimated at the date of grant using the following assumptions:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Risk-free interest rate	1.1 – 1.4%	1.7 – 1.9%	1.1 – 1.5%	1.5 – 1.8%
Expected dividend yield	0%	0%	0%	0%
Expected term	5.8 years	5.8 – 5.9 years	5.0 – 5.8 years	5.0 – 5.9 years
Expected volatility	67%	67%	67 – 69%	66 – 67%

The Company uses the simplified method to calculate the expected term, as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term. The computation of expected volatility is based on the historical volatility of comparable companies from a representative peer group selected based on industry and market capitalization. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected life of the stock options. Management estimates expected forfeitures based on historical experience and recognizes compensation costs only for those equity awards expected to vest.

The Company recognized stock-based compensation expense during the three and nine months ended September 30, 2016 and 2015 as follows:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
(in thousands)	2016	2015	2016	2015
Employee awards:				
Research and development expense	$1,596	$2,116	$5,268	$6,451
Selling, general and administrative expense	1,663	1,565	6,100	5,519
Stock-based compensation expense for employee awards	3,259	3,681	11,368	11,970
Stock-based compensation expense for non-employee awards	—	9	1	57
Less: stock-based compensation expense capitalized to inventory	(88)	—	(308)	—
Total stock-based compensation expense	$3,171	$3,690	$11,061	$12,027

The following table summarizes stock option activity during the nine months ended September 30, 2016:

(in thousands, except per share amounts)	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2015	19,211	$ 5.72	6.24	$ 47,963
Granted	4,189	$ 5.57		
Exercised	(1,196)	$ 3.37		
Forfeited	(1,204)	$ 6.89		
Outstanding at September 30, 2016	21,000	$ 5.76	6.01	$ 26,505
Vested and expected to vest at September 30, 2016	20,658	$ 5.75	5.96	$ 26,271
Exercisable at September 30, 2016	15,691	$ 5.40	5.14	$ 23,323

The weighted-average grant date fair value per share of stock options granted during the three months ended September 30, 2016 and 2015 was $3.07 and $6.19, respectively. The weighted-average grant date fair value per share of stock options granted during the nine months ended September 30, 2016 and 2015 was $3.32 and $5.83, respectively.

The aggregate intrinsic value is calculated as the difference between the exercise price of the stock options and the fair value of the underlying common stock. The aggregate intrinsic value of stock options exercised during the three months ended September 30, 2016 and 2015 was $1.1 million and $3.8 million, respectively. The aggregate intrinsic value of stock options exercised during the nine months ended September 30, 2016 and 2015 was $3.8 million and $27.6 million, respectively.

As of September 30, 2016, there was $18.4 million of total unrecognized stock-based compensation expense related to unvested employee stock awards. The Company expects to recognize this expense over a weighted-average period of approximately 1.9 years.

13. Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, “Revenue from Contracts with Customers (Topic 606),” which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. This guidance was originally effective for interim and annual periods beginning after December 15, 2016 and allows for adoption using a full retrospective method, or a modified retrospective method. Early adoption was originally not permitted. Subsequent to the issuance of ASU 2014-09, the FASB also issued the following updates related to ASC 606, Revenue from Contracts with Customers:

- In August 2015, the FASB issued ASU 2015-14, “Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date,” whereby the effective date for the new revenue standard was deferred by one year. As a result of ASU 2015-14, the new revenue standard is now effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017, and early adoption is now permitted for annual periods beginning after December 15, 2016, including interim periods within that annual period.

- In March 2016, the FASB issued ASU 2016-08, "Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)," to clarify the implementation guidance on principal versus agent considerations.
- In April 2016, the FASB issued ASU 2016-10, "Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing," to clarify the principle for determining whether a good or service is "separately identifiable" from other promises in the contract and to clarify the categorization of licenses of intellectual property.
- In May 2016, the FASB issued ASU 2016-12, "Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Technical Expedients," to clarify guidance on transition, determining collectibility, non-cash consideration and the presentation of sales and other similar taxes.

The Company is currently evaluating the potential impact that the adoption of this guidance and the related transition guidance may have on the consolidated financial statements, including the adoption method to be utilized.

In August 2014, the FASB issued ASU 2014-15, "Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern," outlining management's responsibility to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued and providing guidance on determining when and how to disclose going concern uncertainties in the financial statements. This guidance will be effective for annual and interim reporting periods ending after December 15, 2016, and early adoption is permitted. The Company expects that the adoption of this guidance will only impact the notes to the consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, "Financial Statements – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Liabilities," which contains a number of provisions related to the measurement, presentation and disclosure of financial instruments. This guidance will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within those annual periods. Early adoption of this guidance is not permitted with the exception of certain specific presentation requirements that are not currently applicable to the Company. The Company does not anticipate a material impact to the consolidated financial statements as a result of the adoption of this guidance.

In February 2016, the FASB issued ASU 2016-02, "Leases (Topic 842)," which supersedes all existing lease accounting guidance within ASC 840, Leases. The new standard requires that lease assets and lease liabilities be recognized by lessees for those leases previously classified as operating leases under ASC 840, with limited exceptions. This update also creates a new definition of a lease and provides guidance as to whether a contract is or contains a lease. This guidance will be effective for annual reporting periods beginning after December 15, 2018, including interim periods within those annual reporting periods, and early adoption is permitted. The Company is currently evaluating the potential impact that the adoption of this guidance may have on the consolidated financial statements.

In March 2016, the FASB issued ASU 2016-06, "Derivatives and Hedging (Topic 815): Contingent Put and Call Options in Debt Instruments," which clarifies the requirements for assessing whether contingent call or put options that can accelerate the repayment of principal on debt instruments are clearly and closely related to their debt hosts. This guidance will be effective for annual reporting periods beginning after December 15, 2016, including interim periods within those annual reporting periods, and early adoption is permitted. The Company does not anticipate a material impact to the consolidated financial statements as a result of the adoption of this guidance.

In March 2016, the FASB issued ASU 2016-09, "Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting," which simplifies several areas of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either liabilities or equity and classification of excess tax benefits on the statement of cash flows. This guidance also permits a new entity-wide accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures

when they occur. This guidance will be effective for annual reporting periods beginning after December 15, 2016, including interim periods within those annual reporting periods, and early adoption is permitted. An entity that elects early adoption must adopt all of the amendments in the same period. The Company is currently evaluating the potential impact that the adoption of this guidance may have on the consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, “Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,” which represents a new credit loss standard that will change the impairment model for most financial assets and certain other financial instruments. Specifically, this guidance will require entities to utilize a new “expected loss” model as it relates to trade and other receivables. In addition, entities will be required to recognize an allowance for estimated credit losses on available-for-sale debt securities, regardless of the length of time that a security has been in an unrealized loss position. This guidance will be effective for annual reporting periods beginning after December 15, 2019, including interim periods within those

annual reporting periods, and early adoption is permitted. The Company is currently evaluating the potential impact that the adoption of this guidance may have on the consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, “Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments,” which is intended to reduce diversity in practice in how entities present certain types of cash transactions in the statement of cash flows. This guidance also clarifies how the predominance principle should be applied when classifying cash receipts and cash payments that have attributes of more than one class of cash flows. This guidance will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within those annual reporting periods, and early adoption is permitted. An entity that elects early adoption must adopt all of the amendments in the same period. The Company does not anticipate a material impact to the consolidated financial statements as a result of the adoption of this guidance.

Other accounting standards that have been issued by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company’s consolidated financial statements upon adoption.

14. Subsequent Event

On November 8, 2016, the Company entered into a Loan and Security Agreement (the “Credit Agreement”) with BioPharma Credit Investments IV Sub, LP (“Pharmakon”) pursuant to which a credit facility of an aggregate principal amount of at least $15.0 million and up to $25.0 million is available. The credit facility is available at any time through March 15, 2017 upon the Company’s request. If the Company borrows under the Credit Agreement, the credit facility will bear interest at an annual rate of 11.50%.

In connection with the Credit Agreement, the Company granted Pharmakon a security interest in all inventory and accounts receivable. The Credit Agreement also contains certain representations, warranties and non-financial covenants. In addition, the Credit Agreement grants Pharmakon an option during the two years following funding of the credit facility to participate in a future financing at an amount up to the lesser of 25% of the total amount financed or $50.0 million.

As of the date of filing, no amounts had been borrowed under the Credit Agreement.

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

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the notes to those financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and management’s discussion and analysis of financial condition and results of operations for the year ended December 31, 2015 included in our Annual Report on Form 10-K. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth in Part II, Item 1A. Risk Factors of this Quarterly Report on Form 10-Q, which are incorporated herein by reference, our actual results may differ materially from those anticipated in these

forward-looking statements.

Overview

We are a biopharmaceutical company discovering, developing and commercializing innovative medicines consisting of novel therapeutics paired with diagnostics for the treatment of cancer. We were founded by a team of scientists from The Massachusetts Institute of Technology and Harvard University who sought to develop a systems biology-based approach to biomedical research. The core of our approach to systems biology is to apply multidisciplinary and multitechnology capabilities to build functional and predictive computational models of biological systems, such as cell signaling networks, that allow us to engineer treatments that are directed at the mechanisms of disease. We view cancer as a complex engineering challenge. Through systems biology, which brings together the fields of biology, computing and engineering, we aim to decrease uncertainty in drug development and clinical validation, and move discovery efforts beyond trial and error. Our mission is to employ these insights to provide patients, physicians and the healthcare system with the medicines, tools and information to deliver integrated healthcare solutions that improve both the quality of outcomes and the efficiency of care.

We have one marketed therapeutic oncology product and multiple targeted therapeutic oncology candidates in clinical development. Our most advanced program is our therapeutic ONIVYDE, which we market in the United States. On October 22, 2015, the U.S. Food and Drug Administration, or FDA, and the Taiwan Food and Drug Administration, or TFDA, approved the use of ONIVYDE in combination with fluorouracil, or 5-FU, and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy in the United States and Taiwan, respectively. In addition, on October 18, 2016, the European Commission granted Marketing Authorization to our collaboration partner Baxalta for ONIVYDE in combination with 5-FU and leucovorin for the treatment of adult patients with metastatic adenocarcinoma of the pancreas who have progressed following gemcitabine-based therapy.

In addition to ONIVYDE and our product candidates in clinical development, we have multiple product candidates in preclinical development and a discovery effort advancing additional candidate medicines. We have tailored ONIVYDE and our other product candidates to target specific disease mechanisms that our research suggests are common across many solid tumor types. We believe that ONIVYDE and our other product candidates have the potential to address major unmet medical needs.

We have devoted substantially all of our resources to our drug discovery and development efforts, including advancing our systems biology approach, conducting clinical trials for our product candidates, protecting our intellectual property, preparing for and initiating the commercial launch of ONIVYDE and providing general and administrative support for these operations. We began to generate revenue from product sales for the first time in the fourth quarter of 2015 and, to date, have financed our operations primarily through private placements of our convertible preferred stock, collaborations, public offerings of our securities, secured debt financings and sales of ONIVYDE.

On April 13, 2016, we entered into separate, privately-negotiated conversion agreements, or the conversion agreements, with certain holders of our 4.50% convertible notes due 2020, or the convertible notes. The execution of the conversion agreements resulted in the conversion of an aggregate principal amount of $64.2 million of convertible notes and the issuance of 12,367,663 shares of our common stock. See Note 10, “Borrowings,” in the accompanying notes to the condensed consolidated financial statements for additional information.

On October 3, 2016, we announced a 22% reduction in headcount as part of a major corporate restructuring with the objective of prioritizing our research and development on a focused set of systems biology-derived oncology products and strengthening our financial runway. On this same date, we also announced the resignation of Robert Mulroy, our former President and Chief Executive Officer. See Note 11, “Restructuring Activities,” in the accompanying notes to the condensed consolidated financial statements for additional information.

In connection with our corporate restructuring, we initiated a strategic review of our pipeline, including a clinical and financial prioritization of our programs. This review may result in amendments to our ongoing clinical trials and other changes to our programs. We expect to complete this review by the end of 2016. In the absence of clinical trial amendments, we believe that the data readouts of trials for our lead product candidates, including potentially MM-302, MM-121 and ONIVYDE in front-line metastatic pancreatic cancer, will likely extend beyond our prior guidance. As part of our strategic review, we will continue to assess these data timelines and the potential impact of any such clinical trial amendments.

On November 8, 2016, we entered into a Loan and Security Agreement, or the Credit Agreement, with BioPharma Credit Investments IV Sub, LP, or Pharmakon, pursuant to which a credit facility of an aggregate principal amount of at least $15.0 million and up to $25.0 million is available to us. The credit facility is available at any time through March 15, 2017 upon our request. No amounts have yet been borrowed under the Credit Agreement.

As of September 30, 2016, we had unrestricted cash and cash equivalents and marketable securities of $48.5 million. We believe that at our currently forecasted spending rates, our existing financial resources, together with anticipated net product revenues and net royalty payments from sales of ONIVYDE, the net milestone payments and reimbursements we expect to receive under our Baxalta collaboration and access to our credit facility, will be sufficient to fund our operations into 2018. In addition, we have the ability to further manage spending as needed.

We have never been profitable and, as of September 30, 2016, we had an accumulated deficit of $921.5 million. Our net loss was $30.3 million and $119.9 million for the three and nine months ended September 30, 2016, respectively, and $42.4 million and $99.7 million for the three and nine months ended September 30, 2015, respectively. We expect to continue to incur significant expenses and operating losses for at least the next several years. We expect to continue

to incur significant research and development expenses in connection with our ongoing activities, particularly as we continue the research, development and clinical trials of our product candidates, including multiple simultaneous clinical trials for certain product candidates, some of which have entered or we expect will be entering late stage clinical development. In addition, in connection with supporting commercial sales of ONIVYDE and with seeking and possibly obtaining regulatory approval of any of our other product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. Until such time, if ever, as we can generate sufficient product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, licensing arrangements and other marketing and distribution arrangements. We also could engage in discussions with third parties regarding partnerships, joint ventures, combinations or divestitures of one or more of our businesses as we seek to further the development of our research programs, improve our cash position and maximize stockholder value. There can be no assurance as to the timing, terms or consummation of any financing, collaboration, licensing arrangement or other marketing and distribution arrangement, partnership, joint venture, combination or divestiture. We may be unable to raise capital when needed or on attractive terms, which would force us to delay, limit, reduce or terminate our research and development programs or commercialization efforts. We will need to generate significant revenues to achieve profitability, and we may never do so.

Strategic Partnerships, Licenses and Collaborations

Baxalta

On September 23, 2014, we entered into a license and collaboration agreement with Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, which we refer to as the Baxalta agreement, for the development and commercialization of ONIVYDE outside of the United States and Taiwan, or the licensed territory. In connection with Baxter International Inc.'s separation of the Baxalta business, the Baxalta agreement was assigned to Baxalta during the second quarter of 2015. As part of the Baxalta agreement, we granted Baxalta an exclusive, royalty-bearing right and license under our patent rights and know-how to develop and commercialize ONIVYDE in the licensed territory. Baxalta is responsible for using commercially reasonable efforts to develop, obtain regulatory approvals for and, following regulatory approval, commercialize ONIVYDE in the licensed territory. A joint steering committee comprised of an equal number of representatives from each of Baxalta and us is responsible for approving changes to the global development plan for ONIVYDE, including all budgets, and overseeing the parties' development and commercialization activities with respect to ONIVYDE. Unless otherwise agreed, we will be responsible for conducting all clinical trials contemplated by the global development plan for ONIVYDE and manufacturing all clinical material needed for such trials. Baxalta also has the option to manufacture ONIVYDE, in which case we will perform a technology transfer of our manufacturing process to Baxalta.

Under the terms of the Baxalta agreement, we received a $100.0 million upfront, nonrefundable cash payment in September 2014. In addition, we are eligible to receive from Baxalta (i) up to an aggregate of $100.0 million upon the achievement of specified research and development milestones, of which we have received $62.5 million from Baxalta through September 30, 2016, (ii) up to an aggregate of $520.0 million upon the achievement of specified regulatory milestones, of which we have received $30.0 million from Baxalta through September 30, 2016, and (iii) up to an aggregate of $250.0 million upon the achievement of specified sales milestones. Under the terms of the Baxalta agreement, we will bear up to the first $98.8 million of costs related to the development of ONIVYDE for pancreatic cancer patients who have not previously received gemcitabine-based therapy; however, we expect most of these costs to be offset by payments received upon the achievement of clinical trial-related milestones. We will share equally with Baxalta all other clinical trial costs contemplated by the global development plan. We are also entitled to tiered, escalating royalties ranging from sub-teen double digits to low twenties percentages of net sales of ONIVYDE in the licensed territory.

If not terminated earlier by either party, the Baxalta agreement will expire upon expiration of all royalty and other payment obligations of Baxalta under the Baxalta agreement. Either party may terminate the Baxalta agreement in the event of an uncured material breach by the other party. Baxalta may also terminate the Baxalta agreement on a product-by-product, country-by-country or sub-territory-by-sub-territory basis or in its entirety, for its convenience, upon 180 days' prior written notice. In addition, we may terminate the Baxalta agreement if Baxalta challenges or supports any challenge of our licensed patent rights.

Under the Baxalta agreement, Baxalta has also agreed that, subject to limited exceptions, until September 23, 2017, neither Baxalta nor any of its affiliates will (i) effect or seek, offer or propose to effect, or cause or participate in or in any way advise, assist or encourage any other person to effect or seek, offer or propose to effect or cause or participate in, any acquisition of any of our securities or assets, any tender or exchange offer, merger or other business combination involving us, any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to us, or any solicitation of proxies or consents to vote any of our voting securities, (ii) form, join or in any way participate in a group with respect to any of our securities, (iii) otherwise act, alone or in concert with others, to seek to control or influence our management, board of directors or policies, (iv) take any action that might force us to make a public announcement regarding any of the foregoing or (v) enter into any agreements, discussions or arrangements with any third party with respect to any of the foregoing.

At the inception of the collaboration, we identified the following deliverables as part of the Baxalta agreement: (i) license to develop and commercialize ONIVYDE in Baxalta's territories, (ii) discovery, research, development and manufacturing services required to complete ongoing clinical trials related to ONIVYDE, (iii) discovery, research, development and manufacturing services needed to complete future clinical trials in further indications related to ONIVYDE, (iv) the option to perform a technology transfer of our manufacturing process related to the production of ONIVYDE to Baxalta and (v) participation on the joint steering committee.

We concluded that none of the deliverables identified at the inception of the collaboration has standalone value from the other undelivered elements. As such, all deliverables represent a single unit of accounting.

We have determined that the collaboration represents a services agreement and, as such, have estimated the level of effort expected to be completed as a result of providing the identified deliverables. We will recognize revenue from the nonrefundable upfront payment, forecasted non-substantive milestone payments and estimated payments related to discovery, research, development and technology transfer services based on proportional performance as effort is completed over the expected services period, which is estimated to be substantially complete by June 30, 2022. We will periodically review and, if necessary, revise the estimated service period related to our collaboration with Baxalta. As of September 30, 2016, we have achieved $62.5 million of the $90.0 million of

forecasted non-substantive milestones that are included in our proportional performance revenue recognition model and $30.0 million of the $530.0 million of substantive milestones that are included in the Baxalta agreement.

Research, development and regulatory milestones that are considered substantive on the basis of the contingent nature of the milestone will be recognized as revenue in full in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. All sales milestones will be accounted for in the same manner as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

During the second quarter of 2015, the European Medicines Agency, or EMA, accepted for review a Marketing Authorization Application, or MAA, filed by Baxalta for ONIVYDE. As a result of this acceptance, we recognized $20.0 million of revenue related to a substantive milestone payment owed from Baxalta. In August 2015, we achieved a $15.0 million milestone related to the submission of the protocol for our Phase 2 clinical trial of ONIVYDE in front-line metastatic pancreatic cancer. This milestone is a non-substantive milestone, and revenue related to the achievement of this milestone will be recognized through the proportional performance revenue recognition model. In October 2015, we achieved an additional $47.5 million milestone related to the enrollment of the first patient in a Phase 2 clinical trial of ONIVYDE in front-line pancreatic cancer. This milestone is also a non-substantive milestone, and revenue related to the achievement of this milestone will be recognized through the proportional performance revenue recognition model. In the second quarter of 2016, the South Korean Ministry of Food and Drug Safety, or MFDS, accepted for review a new drug application filed by Baxalta for ONIVYDE. As a result of this acceptance, we recognized $10.0 million of revenue related to a substantive milestone payment owed from Baxalta.

During the three and nine months ended September 30, 2016 and 2015, we recognized revenue based on the following components of the Baxalta agreement:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
(in thousands)	2016	2015	2016	2015
Proportional performance revenue recognition model	$12,417	$16,440	$33,062	$47,839
Substantive milestones	—	—	10,000	20,000
Total	$12,417	$16,440	$43,062	$67,839

As of September 30, 2016 and December 31, 2015, we maintained the following assets and liabilities related to the Baxalta agreement:

	September 30,	December 31,
(in thousands)	2016	2015
Accounts receivable, billed	$ 594	$ 1,336
Accounts receivable, unbilled	385	626
Deferred revenues	68,944	97,365

Of the $68.9 million of deferred revenues related to the Baxalta agreement as of September 30, 2016, $36.6 million is classified as current in our condensed consolidated balance sheets based upon our estimate of revenues that will be recognized under the proportional performance revenue recognition model as a result of effort expected to be completed within the next twelve months.

In February 2016, we entered into a commercial supply agreement with Baxalta pursuant to which we supply ONIVYDE bulk drug substance to Baxalta and, at Baxalta's option, manage fill and finish activities conducted by a third-party contract manufacturer for Baxalta.

Actavis

In November 2013, we entered into a development, license and supply agreement with Watson Laboratories, Inc., or Actavis, which we refer to as the Actavis agreement, pursuant to which we will develop, manufacture and exclusively supply the bulk form of doxorubicin HCl liposome injection, or the initial product, to Actavis. The Actavis agreement was subsequently amended in January 2015 to transfer certain responsibilities from us to Actavis in exchange for reducing the aggregate milestone payments that we are eligible to receive by $0.4 million. Under the Actavis agreement, Actavis is responsible for all costs related to finished product processing and global commercialization. Pursuant to the Actavis agreement, we have also agreed to develop additional products for Actavis in the future, the identities of which will be mutually agreed upon. We are eligible to receive up to $15.1 million in milestone and development payments, as well as additional reimbursement for specific activities performed by us at the request of Actavis, of which $4.0 million in total has been received through September 30, 2016. We will also receive a mid-twenties percentage of net profits on global sales of the initial product and any additional products. We will manufacture and supply the initial product to Actavis

in bulk form at an agreed upon unit price. In October 2016, the FDA accepted for review an Abbreviated New Drug Application, or ANDA, filed by Actavis for the initial product.

The Actavis agreement will expire with respect to the initial product and any additional products developed in the future ten years after Actavis' first sale of the applicable product, unless terminated earlier, and will automatically renew for additional two year periods thereafter unless either party provides notice of non-renewal. Either party may terminate the Actavis agreement in the event of an uncured material breach or bankruptcy filing by the other party. Actavis may also terminate the agreement for convenience in specified circumstances upon 90 days' prior written notice.

We applied revenue recognition guidance to determine whether the performance obligations under this collaboration, including the license, participation on steering committees, development services, and manufacturing and supply services, could be accounted for separately or as a single unit of accounting. We determined that these obligations represent a single unit of accounting and will recognize revenue as product is supplied to Actavis. Therefore, we have recorded $4.0 million of total billed and billable milestones and development expenses related to the Actavis agreement as deferred revenue as of both September 30, 2016 and December 31, 2015. We expect to recognize this revenue over the ten year period that begins after Actavis' first sale of applicable product under the Actavis agreement.

Financial Obligations Related to the License and Development of ONIVYDE

In September 2005, Hermes BioSciences, Inc., or Hermes, which we acquired in October 2009, entered into a license agreement with PharmaEngine under which PharmaEngine received an exclusive license to research, develop, manufacture and commercialize ONIVYDE in Europe and certain countries in Asia. In May 2011, we entered into a new agreement with PharmaEngine, which we refer to as the PharmaEngine agreement, under which we reacquired all previously licensed rights for ONIVYDE, other than rights to commercialize ONIVYDE in Taiwan. As a result, we had the exclusive right to commercialize ONIVYDE in all territories in the world, except for Taiwan, where PharmaEngine has an exclusive commercialization right. Upon entering into the May 2011 agreement with PharmaEngine, we paid PharmaEngine a $10.0 million upfront license fee. In addition, we made a milestone payment of $5.0 million to PharmaEngine in connection with dosing the first patient in our Phase 3 clinical trial of ONIVYDE, which occurred and was paid in the first quarter of 2012.

On September 22, 2014, we amended the PharmaEngine agreement to redefine sublicense revenue and reduce the portion of sublicense revenue that we are required to pay to PharmaEngine. As a result of this amendment, we made a $7.0 million milestone payment to PharmaEngine. Additionally, as a result of this amendment, a previously contingent $5.0 million milestone payment was paid in the second quarter of 2015. Prior to the amendment of the PharmaEngine agreement, this milestone payment was contingent upon the award of certain specified regulatory designations. These milestone payments were recognized as research and development expense during the year ended December 31, 2014.

Since entering into the PharmaEngine agreement, we have paid PharmaEngine an aggregate of $48.0 million in upfront license fees and milestone payments, including an $11.0 million milestone payment made in July 2015 in connection with the EMA's acceptance for review of an MAA for ONIVYDE, which occurred, and was recognized as research and development expense, in the second quarter of 2015, and a $10.0 million milestone payment made in June 2016 in connection with the MFDS's acceptance for review of a new drug application for ONIVYDE, which occurred, and was recognized as research and development expense, in the second quarter of 2016. In addition to these amounts, we could also be required to pay PharmaEngine up to an additional $50.0 million in aggregate regulatory milestones, $38.5 million in sublicense fees and $130.0 million in aggregate sales milestones, in each case with respect to Europe and certain countries in Asia. PharmaEngine is also entitled to tiered royalties on net sales of ONIVYDE in Europe and certain countries in Asia. The royalty rates under the PharmaEngine agreement range from high single digits up to the low teens as a percentage of our net sales of ONIVYDE in these territories. Under the

PharmaEngine agreement, we are responsible for all future development costs of ONIVYDE except those required specifically for regulatory approval in Taiwan. During the three months ended September 30, 2016 and 2015, we recognized research and development expenses related to the PharmaEngine agreement of less than $0.1 million and $0.1 million, respectively. During the nine months ended September 30, 2016 and 2015, we recognized research and development expenses related to the PharmaEngine agreement of $10.1 million and $11.4 million, respectively.

In August 2015, we also entered into a commercial supply agreement with PharmaEngine pursuant to which we supply ONIVYDE bulk drug substance to PharmaEngine.

Financial Operations Overview

Revenues

The majority of our revenue to date has been derived from license fees, milestone payments and research, development, manufacturing and other payments received from collaborations, as well as from sales of ONIVYDE. In the future, we may generate revenue from a combination of product sales, license fees, milestone payments and research, development and manufacturing payments from collaborations and royalties from the sales of products developed under licenses of our intellectual property.

Upon the FDA's approval of ONIVYDE in the fourth quarter of 2015, we began selling ONIVYDE within the United States. For the three and nine months ended September 30, 2016, we recognized net product revenues of $14.5 million and $37.3 million, respectively. We estimate our net product revenues by deducting from our gross product revenues trade allowances, estimated rebates and chargeback discounts, estimated reserves for product returns and estimated costs of other incentives offered to patients. We expect such net product revenues to increase in future periods as ONIVYDE continues to gain market penetration.

Beginning in the second quarter of 2016, we began to recognize revenue related to the commercial supply of ONIVYDE bulk drug substance to Baxalta and PharmaEngine. For the three and nine months ended September 30, 2016, we recognized commercial supply revenues of $1.2 million and $2.7 million, respectively. Such revenue is categorized as "Other revenues" within our consolidated statements of operations and comprehensive loss. We expect that other revenues will increase in the future as we continue to provide commercial supply of ONIVYDE bulk drug substance to Baxalta and PharmaEngine. After selling through lots that were previously expensed due to being manufactured prior to ONIVYDE receiving FDA approval, we expect other revenues to generate a gross margin in the mid-single digits.

We expect that license and collaboration revenues recognized under the Baxalta agreement will fluctuate in future periods depending on the achievement of research and development and regulatory milestones.

Cost of revenues

Cost of revenues consists of manufacturing costs of product sold both commercially and under our commercial supply agreements with Baxalta and PharmaEngine, including shipping and handling costs, as well as costs associated with inventory reserves or write-downs. We began to capitalize costs associated with the production of ONIVYDE upon receipt of FDA approval on October 22, 2015. Costs incurred prior to receipt of marketing approval of ONIVYDE were expensed as research and development expenses.

We expect that our cost of revenues related to net product revenues and other revenues will fluctuate in future periods depending on our revenue mix as well as when the components of the specific ONIVYDE lots sold were produced. Certain lots of ONIVYDE were previously expensed due to being manufactured prior to ONIVYDE receiving FDA approval and therefore will not have cost of revenues associated with their sale. This benefit is expected to continue through 2017; however, the time period over which this reduced-cost inventory is consumed will depend on a number of factors, including the amount of future ONIVYDE sales, the ultimate use of this inventory in either commercial sales, clinical development or other research activities, and the ability to utilize inventory prior to its expiration date.

Research and development expenses

Research and development expenses consist of the costs associated with our research and discovery activities, including investment in our systems biology approach, conduct of preclinical studies and clinical trials, manufacturing

development efforts and activities related to regulatory filings. Our research and development expenses consist of:

- employee salaries and related expenses, which include stock-based compensation and benefits for the personnel involved in our drug discovery and development activities;
- external research and development expenses incurred under agreements with third-party contract research organizations and investigative sites;
- manufacturing material expense for in-house manufacturing and third-party manufacturing organizations and consultants, including costs associated with manufacturing product prior to product approval;
- license fees for and milestone payments related to in-licensed products and technologies; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment, and laboratory and other supplies.

We expense research and development costs as incurred. Conducting a significant amount of research and development is central to our business model. Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of late stage clinical trials. We expect to maintain or increase our research and development expenses for the foreseeable future as we continue to develop our clinical stage product candidates and further advance our preclinical products and earlier stage research and development projects. Such future research and development expenses will include additional regulatory milestone payments that we are required to make under the PharmaEngine agreement.

We use our employee and infrastructure resources across multiple research and development programs. We track expenses related to our most advanced product candidates on a per project basis. Accordingly, we allocate internal employee-related and infrastructure costs, as well as third-party costs, to each of these programs. We do not allocate to particular development programs either stock-based compensation expense or expenses related to preclinical programs. Costs that are not directly attributable to specific clinical programs, such as wages related to shared laboratory services, travel and employee training and development, are not allocated and are considered general research and discovery expenses.

The following table summarizes our principal product development programs, including the research and development expenses allocated to each clinical product candidate, for the three and nine months ended September 30, 2016 and 2015:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
(in thousands)	2016	2015	2016	2015
ONIVYDE	$4,221	$6,575	$22,389	$31,102
MM-302	4,229	4,315	14,636	12,990
MM-121	4,302	3,922	14,341	7,548
MM-141	5,489	2,929	9,715	9,838
MM-151	1,019	1,440	2,842	3,874
Companion therapeutics program	345	636	2,936	1,414
Preclinical, general research and discovery	10,877	15,830	33,829	43,028
Stock-based compensation	1,596	2,116	5,268	6,454
Total research and development expenses	$32,078	$37,763	$105,956	$116,248

The development, regulatory and clinical expenses related to the Actavis agreement are included within our preclinical, general research and discovery expenses.

ONIVYDE

ONIVYDE has been approved by the FDA, TFDA and European Commission in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy. In October 2015, we enrolled the first patient in a Phase 2 clinical trial of ONIVYDE in front-line metastatic pancreatic cancer. This trial is designed to assess the safety and efficacy of the combination of ONIVYDE plus 5-FU and leucovorin, with or without the addition of oxaliplatin, versus nab-paclitaxel and gemcitabine in patients with previously untreated, metastatic pancreatic adenocarcinoma. In May

2016, we announced the initiation of a Phase 1 clinical trial of ONIVYDE plus 5-FU and leucovorin in combination with MM-151 in patients with RAS wild-type metastatic colorectal cancer. We are also collaborating with several investigators to conduct additional trials of ONIVYDE, including in a Phase 1 clinical trial utilizing a high concentration formulation of ONIVYDE in patients with glioma and a Phase 1 clinical trial in pediatric solid tumors.

As described above, we have paid PharmaEngine upfront license fees and milestone payments under the PharmaEngine agreement. We have recorded research and development expenses related to these upfront license fees and milestone payments to PharmaEngine of less than $0.1 million and $0.1 million during the three months ended September 30, 2016 and 2015, respectively, and $10.1 million and $11.4 million for the nine months ended September 30, 2016 and 2015, respectively.

MM-302

In August 2014, we initiated a global, open-label, randomized Phase 2 clinical trial of MM-302 in combination with trastuzumab (Herceptin®) in patients with ErbB2 (HER2) positive, locally advanced or metastatic breast cancer. Prior to initiating the Phase 2 clinical trial of MM-302, we conducted a Phase 1 clinical trial of MM-302 in patients with advanced ErbB2 (HER2) positive breast cancer. We reported final results from this trial in April 2015.

MM-121 (seribantumab)

In February 2015, we initiated a global, open-label, biomarker-selected, randomized Phase 2 clinical trial of MM-121 in combination with docetaxel or pemetrexed versus docetaxel or pemetrexed alone in patients with heregulin positive, locally advanced or metastatic non-small cell lung cancer. In December 2015, we announced an amendment to the trial, including a change in primary endpoint from progression free survival to overall survival.

MM-141 (istiratumab)

In May 2015, we initiated a randomized, double-blinded, placebo-controlled Phase 2 clinical trial of MM-141 in combination with nab-paclitaxel and gemcitabine, versus nab-paclitaxel and gemcitabine alone in patients with newly diagnosed metastatic pancreatic cancer who have high serum levels of free IGF-1. We have completed a multi-arm Phase 1 clinical trial evaluating the safety and tolerability of MM-141 as a monotherapy and in combination with everolimus or with nab-paclitaxel and gemcitabine in patients with advanced solid tumors.

MM-151

We have completed a Phase 1 clinical trial of MM-151 as a monotherapy and in combination with irinotecan in patients with solid tumors.

Companion therapeutics program

We are investigating combinations of our therapeutic oncology candidates, including MM-151 in combination with MM-121 in heregulin positive tumors, MM-151 in combination with MM-141 in IGF-1-positive tumors, and MM-151 in combination with a MEK inhibitor (trametinib) in KRAS/NRAS-mutant tumors.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of salaries and other related costs for personnel, including stock-based compensation expenses and benefits, in our commercial, legal, intellectual property, business development, finance, information technology, corporate communications, investor relations and human resources departments. Other selling, general and administrative expenses include costs to support commercial sales, employee training and development, board of directors costs, depreciation, insurance expenses, facility-related costs not otherwise included in research and development expense, professional fees for legal services, including patent-related expenses, and accounting and information technology services. We expect to maintain selling, general and administrative expense in future periods as we continue to support the development and commercialization of our clinical products.

Restructuring expenses

As a result of the corporate restructuring activities described above, we recognized total restructuring expenses of $0.8 million during the three and nine months ended September 30, 2016 related to contractual termination benefits for employees with pre-existing severance arrangements. We also expect to incur approximately $4.0 million of additional restructuring expenses during the fourth quarter of 2016 related to one-time employee termination benefits. These one-time employee termination benefits are comprised of severance, benefits and related costs, all of which are expected to result in cash expenditures. We anticipate that the majority of these payments will be made during the fourth quarter of 2016.

Interest expense

Interest expense consists primarily of cash and non-cash interest related to our convertible notes and our 11.50% senior secured notes due 2022, or the 2022 notes.

As a result of the conversion agreements entered into on April 13, 2016, we recognized a one-time $14.6 million non-cash loss on extinguishment during the second quarter of 2016. This loss on extinguishment was recorded as a component of interest expense. Transaction costs incurred with third parties directly related to the conversion were allocated to the liability and equity components, resulting in additional interest expense recognized of $0.2 million during the second quarter of 2016. We expect that interest expense will decrease in subsequent periods as compared to the nine months ended September 30, 2016 due to the one-time loss on extinguishment recognized in the second quarter of 2016, as well as an overall reduction in outstanding long-term debt as a result of the conversion.

Other income

Other income consists primarily of the recognition of tax incentives and other income or expense-related items.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which we have prepared in accordance with the rules and regulations of the Securities and Exchange Commission, or the SEC, and generally accepted accounting principles in the United States, or GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. Estimates include revenue recognition, including the estimated percentage of billable expenses in any particular budget period, periods of meaningful use of licensed products, estimated service periods and services to be completed under a collaboration, estimates used in accounting for revenue separability and recognition, estimates of discounts and allowances related to commercial sales of ONIVYDE, estimates utilized in the valuation of inventory, useful lives with respect to long-lived assets and intangible assets, accounting for stock-based compensation, contingencies, intangible assets, goodwill, in-process research and development, tax valuation reserves and accrued expenses. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies and the methodologies and assumptions we apply under them have not materially changed since February 26, 2016, the date we filed our Annual Report on Form 10-K for the year ended December 31, 2015. For more information on our critical accounting policies, refer to our Annual Report on Form 10-K for the year ended December 31, 2015.

Results of Operations

Comparison of the three months ended September 30, 2016 and 2015

	Three Months Ended September 30,	
(in thousands)	2016	2015
Product revenues, net	$14,493	$—
License and collaboration revenues	12,417	16,440
Other revenues	1,161	—
Cost of revenues	(1,010)	—
Research and development expenses	(32,078)	(37,763)
Selling, general and administrative expenses	(18,048)	(16,956)
Restructuring expenses	(809)	—
Loss from operations	(23,874)	(38,279)
Interest income	64	13
Interest expense	(6,850)	(4,476)

Other income, net	385	356
Net loss	$(30,275)	$(42,386)

Product revenues, net

We commenced product sales of ONIVYDE in the fourth quarter of 2015 subsequent to approval by the FDA. For the three months ended September 30, 2016, we recognized net product revenues of $14.5 million. No net product revenues were recognized during the three months ended September 30, 2015.

License and collaboration revenues

License and collaboration revenues were $12.4 million for the three months ended September 30, 2016 compared to $16.4 million for the three months ended September 30, 2015, a decrease of $4.0 million, or 24%. Revenue recognized during both periods was comprised solely of revenue recognized under the proportional performance revenue recognition model. The decrease was primarily attributable to significant work performed during the three months ended September 30, 2015 as we completed the Phase 3 clinical trial of ONIVYDE and prepared for regulatory approval by the FDA.

Other revenues

We began recognizing other revenues in the second quarter of 2016 when we first supplied ONIVYDE bulk drug substance to Baxalta and PharmaEngine. Other revenues were $1.2 million for the three months ended September 30, 2016, all of which were related to ONIVYDE bulk drug substance sales to Baxalta. No other revenues were recognized during the three months ended September 30, 2015.

Cost of revenues

We began recognizing cost of revenues for the first time in the fourth quarter of 2015 subsequent to the approval of ONIVYDE by the FDA. We recognized $1.0 million of cost of revenues during the three months ended September 30, 2016. This was comprised of $0.2 million of costs related to net product revenues and $0.8 million of costs related to other revenues. No cost of revenues was recognized during the three months ended September 30, 2015.

Research and development expenses

Research and development expenses were $32.1 million for the three months ended September 30, 2016 compared to $37.8 million for the three months ended September 30, 2015, a decrease of $5.7 million, or 15%. This decrease was primarily attributable to:

- $2.4 million of decreased ONIVYDE expenses primarily due to manufacturing campaigns that took place during the three months ended September 30, 2015 as well as the winding down of our Phase 3 clinical trial that supported the approval of ONIVYDE by the FDA; and
- $5.0 million of decreased expenses related to preclinical, general research and discovery as a result of our cost management efforts and the timing of manufacturing campaigns for our preclinical programs.

These decreases were partially offset by $2.6 million of increased MM-141 expenses related to the May 2015 initiation of a Phase 2 clinical trial of MM-141 in metastatic pancreatic cancer.

Selling, general and administrative expenses

Selling, general and administrative expenses were $18.0 million for the three months ended September 30, 2016 compared to $17.0 million for the three months ended September 30, 2015, an increase of $1.1 million, or 6%. This increase was primarily attributable to $1.1 million of increased expenses to support commercial sales of ONIVYDE.

Restructuring expenses

We recognized restructuring expenses of $0.8 million during the three months ended September 30, 2016 related to our corporate restructuring activities described above. No restructuring expenses were recognized during the three months ended September 30, 2015.

Interest expense

Interest expense was $6.9 million for the three months ended September 30, 2016 compared to $4.5 million for the three months ended September 30, 2015, an increase of $2.4 million, or 53%. This increase was primarily attributable to interest expense related to our 2022 notes that were issued in December 2015, offset by a decrease in interest expense related to our previously outstanding loans payable to Hercules Technology Growth Capital, Inc., or Hercules, that were repaid in full during December 2015.

Comparison of the nine months ended September 30, 2016 and 2015

	Nine Months Ended September 30,	
(in thousands)	2016	2015
Product revenues, net	$37,312	$—
License and collaboration revenues	43,062	67,839
Other revenues	2,659	—
Cost of revenues	(3,593)	—
Research and development expenses	(105,956)	(116,248)
Selling, general and administrative expenses	(56,523)	(38,460)
Restructuring expenses	(809)	—
Loss from operations	(83,848)	(86,869)
Interest income	258	93
Interest expense	(36,579)	(13,524)
Other income, net	278	580
Net loss	$(119,891)	$(99,720)

Product revenues, net

We commenced product sales of ONIVYDE in the fourth quarter of 2015 subsequent to approval by the FDA. For the nine months ended September 30, 2016, we recognized net product revenues of $37.3 million. No net product revenues were recognized during the nine months ended September 30, 2015.

License and collaboration revenues

License and collaboration revenues were $43.1 million for the nine months ended September 30, 2016 compared to $67.8 million for the nine months ended September 30, 2015, a decrease of $24.8 million, or 37%. This decrease was primarily attributable to the achievement of $10.0 million of substantive milestones during the nine months ended September 30, 2016 as compared to the achievement of $20.0 million of substantive milestones during the nine months ended September 30, 2015, as well as a decrease in revenue recognized under the proportional performance revenue recognition model. This decrease was primarily attributable to significant work performed during the nine months ended September 30, 2015 as we completed the Phase 3 clinical trial of ONIVYDE and prepared for regulatory approval by the FDA.

Other revenues

We began recognizing other revenues in the second quarter of 2016 when we began supplying ONIVYDE bulk drug substance to Baxalta and PharmaEngine. Other revenues were $2.7 million for the nine months ended September 30, 2016, comprised of $2.4 million of revenue related to ONIVYDE bulk drug substance sold to Baxalta and $0.3 million of revenue related to ONIVYDE bulk drug substance sold to PharmaEngine. No other revenues were recognized during the nine months ended September 30, 2015.

Cost of revenues

We began recognizing cost of revenues for the first time in the fourth quarter of 2015 subsequent to the approval of ONIVYDE by the FDA. We recognized $3.6 million of cost of revenues during the nine months ended September 30, 2016, comprised of $1.8 million of costs related to net product revenues and $1.8 million of costs related to other revenues. No cost of revenues was recognized during the nine months ended September 30, 2015.

Research and development expenses

Research and development expenses were $106.0 million for the nine months ended September 30, 2016 compared to $116.2 million for the nine months ended September 30, 2015, a decrease of $10.3 million, or 9%. This decrease was primarily attributable to:

- $8.7 million of decreased ONIVYDE expenses primarily due to manufacturing campaigns that took place during the nine months ended September 30, 2015 as well as the winding down of our Phase 3 clinical trial that supported the approval of ONIVYDE by the FDA; and
- $9.2 million of decreased spend related to preclinical, general research and discovery as a result of our cost management efforts and the timing of manufacturing campaigns for our preclinical programs.

These decreases were partially offset by:

- $6.8 million of increased MM-121 expenses related to the February 2015 initiation of a Phase 2 clinical trial of MM-121 in non-small cell lung cancer; and
- $1.6 million of increased MM-302 expenses related to increased activity in our Phase 2 clinical trial of MM-302 in locally advanced or metastatic breast cancer.

Selling, general and administrative expenses

Selling, general and administrative expenses were $56.5 million for the nine months ended September 30, 2016 compared to $38.5 million for the nine months ended September 30, 2015, an increase of $18.1 million, or 47%. This increase was primarily attributable to $13.5 million of increased expenses to support commercial sales of ONIVYDE as well as increased labor and labor-related expenses and facility-related costs required to support our overall growth.

Restructuring expenses

We recognized restructuring expenses of $0.8 million during the nine months ended September 30, 2016 related to our corporate restructuring activities described above. No restructuring expenses were recognized during the nine months ended September 30, 2015.

Interest expense

Interest expense was $36.6 million for the nine months ended September 30, 2016 compared to $13.5 million for the nine months ended September 30, 2015, an increase of $23.1 million, or 170%. This increase was primarily attributable to a one-time non-cash charge of $14.6 million associated with the induced conversion of an aggregate principal amount of $64.2 million of our convertible notes in April 2016 as well as interest expense related to our 2022 notes that were issued in December 2015, offset by a decrease in interest expense related to our previously outstanding loans payable to Hercules that were repaid in full during December 2015.

Liquidity and Capital Resources

Sources of liquidity

We have financed our operations to date primarily through private placements of our convertible preferred stock, collaborations, public offerings of our securities, secured debt financings and sales of ONIVYDE. Through September 30, 2016, we have received $268.2 million from the sale of convertible preferred stock and warrants, $126.7 million of net proceeds from the sale of common stock in our initial public offering and July 2013 follow-on underwritten public offering, $38.6 million of net proceeds from our 2015 “at the market offering” program, or the ATM offering, $39.6 million of net proceeds from a secured debt financing, $120.6 million of net proceeds from the issuance of the convertible notes in our July 2013 underwritten public offering, $168.5 million of net proceeds from the issuance of the 2022 notes, $452.0 million of upfront license fees, milestone payments, reimbursement of research and development costs and manufacturing services and other payments from our collaborations and $22.4 million of cash receipts related to ONIVYDE sales. We have also entered into an arrangement to use our manufacturing capabilities to manufacture drug product on behalf of Actavis, for which we have received $4.0 million in upfront fees and reimbursements as of September 30, 2016. As of September 30, 2016, we had unrestricted cash and cash equivalents and marketable securities of $48.5 million.

As of September 30, 2016, within our unrestricted cash and cash equivalents, $0.4 million was cash and cash equivalents held by our majority owned subsidiary, Silver Creek Pharmaceuticals, Inc., or Silver Creek, which is consolidated for financial reporting purposes. This $0.4 million held by Silver Creek is designated for the operations

of Silver Creek.

Cash flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,	
(in thousands)	2016	2015
Net cash used in operating activities	$(139,344)	$(102,048)
Net cash (used in) provided by investing activities	(14,970)	73,772
Net cash provided by financing activities	5,171	48,938
Net (decrease) increase in cash and cash equivalents	$(149,143)	$20,662

Operating activities

Cash used in operating activities of $139.3 million during the nine months ended September 30, 2016 was primarily a result of our $119.9 million net loss and changes in operating assets and liabilities of $55.1 million. The change in operating assets and liabilities during the nine months ended September 30, 2016 was primarily driven by increases in accounts receivable and inventory related to the commercialization and sale of ONIVYDE, offset by a decrease in deferred revenue related to the Baxalta agreement. These decreases were offset by $35.7 million of non-cash items, including a $14.6 million non-cash loss on extinguishment related to the April 2016 conversion of a portion of our convertible notes, $11.1 million of stock-based compensation expense and $4.7 million in non-cash interest expense. Cash used in operating activities of $102.0 million during the nine months ended September 30, 2015 was primarily a result of our net loss of $99.7 million and changes in operating assets and liabilities of $24.8 million. The change in operating assets and liabilities during the nine months ended September 30, 2015 was primarily driven by a decrease in deferred revenue related to the Baxalta agreement, offset by an increase in accounts receivable. These decreases were offset by $22.5 million of non-cash items, including $12.0 million of stock-based compensation expense and $6.1 million in non-cash interest expense.

Investing activities

Cash used in investing activities of $15.0 million during the nine months ended September 30, 2016 was primarily due to purchases of marketable securities of $84.3 million in addition to $2.9 million of property and equipment purchases, offset by proceeds from sales and maturities of marketable securities of $72.2 million. Cash provided by investing activities of $73.8 million during the nine months ended September 30, 2015 was primarily due to maturities of marketable securities of $81.9 million, partially offset by $8.1 million of property and equipment purchases.

Financing activities

Cash provided by financing activities of $5.2 million during the nine months ended September 30, 2016 was primarily due to $4.0 million of proceeds received from the exercise of common stock options and $1.2 million of proceeds received from the issuance of convertible promissory notes by Silver Creek. Cash provided by financing activities of $48.9 million during the nine months ended September 30, 2015 was primarily due to $38.6 million of net proceeds from the ATM offering, $8.3 million of proceeds received from the exercise of common stock options and warrants and $1.2 million of proceeds received from the issuance of convertible preferred stock by Silver Creek.

Borrowings and other liabilities

In December 2015, we closed a private placement of $175.0 million aggregate principal amount of 2022 notes. The 2022 notes bear interest at a rate of 11.50% per year, payable semi-annually on June 15 and December 15 of each year, beginning on June 15, 2016. We will pay semi-annual installments of principal on the 2022 notes of $21,875,000 each, subject to adjustment as provided in the 2022 notes, on June 15 and December 15 of each year, beginning on June 15, 2019. The 2022 notes will mature on December 15, 2022, unless earlier redeemed or repurchased in accordance with their terms prior to such date. See Note 10, “Borrowings,” in the accompanying notes to the condensed consolidated financial statements for additional information.

In July 2013, we issued convertible notes in the aggregate principal amount of $125.0 million. The convertible notes are convertible into common stock upon satisfaction of certain conditions. The convertible notes bear interest at a fixed rate of 4.50% per year, payable semiannually in arrears on January 15 and July 15 of each year. The convertible notes will mature on July 15, 2020 unless earlier repurchased by us or converted at the option of holders. On April 13, 2016, we entered into conversion agreements with certain holders of our convertible notes. Under the conversion agreements, such holders agreed to convert an aggregate principal amount of $64.2 million of convertible notes held by them. See Note 10, “Borrowings,” in the accompanying notes to the condensed consolidated financial statements for additional information.

Funding requirements

We have incurred significant expenses and operating losses to date, and we expect to continue to incur significant expenses and operating losses for at least the next several years. We anticipate that we will continue to incur significant expenses as we:

- initiate or continue clinical trials of our most advanced product candidates;
- continue the research and development of our other product candidates;
- seek to discover additional product candidates;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- continue to support our sales, marketing and distribution infrastructure and scale up manufacturing capabilities to meet commercial demand for ONIVYDE and other products for which we may seek regulatory approval; and
- continue to provide the operational, financial and management information systems and personnel to support our product development and continued commercialization.

We believe that at our currently forecasted spending rates, our existing financial resources, together with anticipated net product revenues and net royalty payments from sales of ONIVYDE, the net milestone payments and reimbursements we expect to receive under our Baxalta collaboration and access to our credit facility, will be sufficient to fund our operations into 2018. In addition, we have the ability to further manage spending as needed. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, and the extent to which we utilize collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future capital requirements will depend on many factors, including:

- the amount of net product revenues realized from ONIVYDE commercial sales;
- the amount of royalty and profit sharing revenue from our collaboration partners;
- the progress and results of the clinical trials of our most advanced product candidates;
- the success of our collaborations with Baxalta and PharmaEngine related to ONIVYDE and any future collaborations with other parties that we may enter into;
- the timing and amount of anticipated milestone payments and cost sharing reimbursements related to ONIVYDE that we may receive from Baxalta;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs, timing and outcome of regulatory review of our current and future product candidates;
- the costs of commercial activities, including product sales, marketing, manufacturing and distribution;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the extent to which we acquire or invest in businesses, products and technologies;
- our ability to establish and maintain commercial manufacturing arrangements for the manufacture of drug product on behalf of third-party pharmaceutical companies; and
- our ability to establish and maintain additional collaborations on favorable terms, particularly marketing and distribution arrangements for oncology product candidates outside the United States and Europe.

Until such time, if ever, as we can generate sufficient product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, licensing arrangements and other marketing and distribution arrangements. We also could engage in discussions with third parties regarding partnerships, joint ventures, combinations or divestitures of one or more of our businesses as we seek to further the development of our research programs, improve our cash position and maximize stockholder value. There can be no assurance as to the timing, terms or consummation of any financing, collaboration, licensing arrangement or other marketing and

distribution arrangement, partnership, joint venture, combination or divestiture. We do not have any committed external sources of funds, other than our collaboration with Baxalta for the development and commercialization of ONIVYDE, which is terminable by Baxalta for convenience upon 180 days' prior written notice, and under

our development, license and supply agreement with Actavis, which is terminable by Actavis for convenience in specified circumstances upon 90 days' prior written notice. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. For example, if we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

Our contractual obligations and commitments were reported in our Annual Report on Form 10-K for the year ended December 31, 2015, which was filed with the SEC on February 26, 2016. As described in more detail above and within Note 10, "Borrowings," in the accompanying notes to the condensed consolidated financial statements, we entered into conversion agreements with certain holders of our convertible notes on April 13, 2016. Under the conversion agreements, such holders agreed to convert an aggregate principal amount of $64.2 million of convertible notes held by them, and we are no longer obligated to repay this principal amount or related interest. There have been no other material changes from the contractual obligations and commitments previously disclosed in our Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-09, "Revenue from Contracts with Customers (Topic 606)," which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. This guidance was originally effective for interim and annual periods beginning after December 15, 2016 and allows for adoption using a full retrospective method, or a modified retrospective method. Early adoption was originally not permitted. Subsequent to the issuance of ASU 2014-09, the FASB also issued the following updates related to Accounting Standards Codification, or ASC, 606, Revenue from Contracts with Customers:

- In August 2015, the FASB issued ASU 2015-14, "Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date," whereby the effective date for the new revenue standard was deferred by one year. As a result of ASU 2015-14, the new revenue standard is now effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017, and early adoption is now permitted for annual periods beginning after December 15, 2016, including interim periods within that annual period.
- In March 2016, the FASB issued ASU 2016-08, "Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)," to clarify the implementation guidance on principal versus agent considerations.

- In April 2016, the FASB issued ASU 2016-10, “Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing,” to clarify the principle for determining whether a good or service is “separately identifiable” from other promises in the contract and to clarify the categorization of licenses of intellectual property.
- In May 2016, the FASB issued ASU 2016-12, “Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Technical Expedients,” to clarify guidance on transition, determining collectibility, non-cash consideration and the presentation of sales and other similar taxes.

We are currently evaluating the potential impact that the adoption of this guidance and the related transition guidance may have on our consolidated financial statements, including the adoption method to be utilized.

In August 2014, the FASB issued ASU 2014-15, “Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern,” outlining management’s responsibility to perform interim and annual assessments of an entity’s ability to continue as a going concern within one year of the date the financial statements are issued and providing guidance on determining when and how to disclose going concern uncertainties in the financial statements. This guidance will be effective for annual and interim reporting periods ending after December 15, 2016, and early adoption is permitted. We expect that the adoption of this guidance will only impact the notes to our consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, “Financial Statements – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Liabilities,” which contains a number of provisions related to the measurement, presentation and disclosure of financial instruments. This guidance will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within those annual periods. Early adoption of this guidance is not permitted with the exception of certain specific presentation requirements that are not currently applicable to us. We do not anticipate a material impact to our consolidated financial statements as a result of the adoption of this guidance.

In February 2016, the FASB issued ASU 2016-02, “Leases (Topic 842),” which supersedes all existing lease accounting guidance within ASC 840, Leases. The new standard requires that lease assets and lease liabilities be recognized by lessees for those leases previously classified as operating leases under ASC 840, with limited exceptions. This update also creates a new definition of a lease and provides guidance as to whether a contract is or contains a lease. This guidance will be effective for annual reporting periods beginning after December 15, 2018, including interim periods within those annual reporting periods, and early adoption is permitted. We are currently evaluating the potential impact that the adoption of this guidance may have on our consolidated financial statements.

In March 2016, the FASB issued ASU 2016-06, “Derivatives and Hedging (Topic 815): Contingent Put and Call Options in Debt Instruments,” which clarifies the requirements for assessing whether contingent call or put options that can accelerate the repayment of principal on debt instruments are clearly and closely related to their debt hosts. This guidance will be effective for annual reporting periods beginning after December 15, 2016, including interim periods within those annual reporting periods, and early adoption is permitted. We do not anticipate a material impact to our consolidated financial statements as a result of the adoption of this guidance.

In March 2016, the FASB issued ASU 2016-09, “Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting,” which simplifies several areas of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either liabilities or equity and classification of excess tax benefits on the statement of cash flows. This guidance also permits a new entity-wide accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures when they occur. This guidance will be effective for annual reporting periods beginning after December 15, 2016, including interim periods within those annual reporting periods, and early adoption is permitted. An entity that elects early adoption must adopt all of the amendments in the same period. We are currently evaluating the potential impact that the adoption of this guidance may have on our consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, “Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,” which represents a new credit loss standard that will change the impairment model for most financial assets and certain other financial instruments. Specifically, this guidance will require entities to utilize a new “expected loss” model as it relates to trade and other receivables. In addition, entities will be required to recognize an allowance for estimated credit losses on available-for-sale debt securities, regardless of the length of time that a security has been in an unrealized loss position. This guidance will be effective for annual reporting periods beginning after December 15, 2019, including interim periods within those annual reporting periods, and early adoption is permitted. We are currently evaluating the potential impact that the adoption of this guidance may have on

our consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, “Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments,” which is intended to reduce diversity in practice in how entities present certain types of cash transactions in the statement of cash flows. This guidance also clarifies how the predominance principle should be applied when classifying cash receipts and cash payments that have attributes of more than one class of cash flows. This guidance will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within those annual reporting periods, and early adoption is permitted. An entity that elects early adoption must adopt all of the amendments in the same period. We do not anticipate a material impact to our consolidated financial statements as a result of the adoption of this guidance.

Other accounting standards that have been issued by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on our consolidated financial statements upon adoption.

Item 3.Quantitative and Qualitative Disclosures About Market Risk.

We invest in a variety of financial instruments, principally cash deposits, money market funds, securities issued by the U.S. government and its agencies and corporate debt securities. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk.

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates, particularly because our investments are in short-term marketable securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability and intention to hold our investments until maturity, and therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio.

We do not currently have any auction rate or mortgage-backed securities. We do not believe our cash, cash equivalents and marketable securities have significant risk of default or illiquidity, however we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value.

The convertible notes bear interest at a fixed rate of 4.50% per year, payable semi-annually in arrears on January 15 and July 15 of each year, beginning on January 15, 2014. As a result, we are not subject to interest rate risk with respect to the convertible notes.

The 2022 notes bear interest at a fixed rate of 11.50% per year, payable semi-annually in arrears on June 15 and December 15 of each year, beginning on June 15, 2016. As a result, we are not subject to interest rate risk with respect to the 2022 notes.

Item 4.Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2016. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are 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 recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. 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 September 30, 2016, 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 three months ended September 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II

OTHER INFORMATION

Item 1A.Risk Factors.

The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see page 1 of this Quarterly Report on Form 10-Q for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net loss was $119.9 million for the nine months ended September 30, 2016, $147.8 million for the year ended December 31, 2015 and $83.6 million for the year ended December 31, 2014. As of September 30, 2016, we had an accumulated deficit of $921.5 million. To date, we have financed our operations primarily through private placements of our convertible preferred stock, collaborations, public offerings of our securities, secured debt financings and sales of ONIVYDE. We have devoted substantially all of our efforts to research and development, including clinical trials and recently to commercialization of our first product, ONIVYDE. We have not completed development of or commercialized any other therapeutic product candidates or diagnostics other than ONIVYDE. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

- initiate or continue clinical trials of our most advanced product candidates;
- continue the research and development of our other product candidates;
- seek to discover additional product candidates;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- continue to support our sales, marketing and distribution infrastructure and scale up manufacturing capabilities to meet the commercial demand for ONIVYDE and other products for which we may seek regulatory approval; and
- continue to provide the operational, financial and management information systems and personnel to support our product development and continued commercialization.

To become and remain profitable, we must succeed in developing and commercializing products with significant market potential. This will require us to be successful in a range of challenging activities, including discovering product candidates, completing preclinical testing and clinical trials of our product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling those products for which we may seek regulatory approval. We are only in the preliminary stages of some of these activities for most of our product candidates, and our commercial activities for ONIVYDE are still at an early stage. We may never succeed in these activities and may never generate revenues that are significant or large enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

Our substantial indebtedness may limit cash flow available to invest in the ongoing needs of our business.

We currently have, and will continue to have, a significant amount of indebtedness. In July 2013, we issued $125.0 million aggregate principal amount of 4.50% convertible notes due 2020, or convertible notes, and in December 2015, we issued $175.0 million aggregate principal amount of 11.50% senior secured notes due 2022, or 2022 notes. In April 2016, certain holders of the convertible notes agreed to convert an aggregate of $64.2 million of convertible notes held by them into shares of our common stock. We could in the future incur additional indebtedness beyond such amounts.

Our substantial debt combined with our other financial obligations and contractual commitments could have significant 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 adverse changes in general economic, industry and market conditions;
- obligating us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- 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 competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We intend to satisfy our current and future debt service obligations with our existing cash and cash equivalents and marketable securities and funds from external sources. However, we may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt. Funds from external sources may not be available on acceptable terms, if at all. In addition, a failure to comply with the covenants under our existing debt instruments could result in an event of default under those instruments. In the event of an acceleration of amounts due under our debt instruments as a result of an event of default, including upon the occurrence of an event that would reasonably be expected to have a material adverse effect on our business, operations, properties, assets or condition or a failure to pay any amount due, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness. In addition, the covenants under our existing debt instruments and the pledge of our assets as collateral limit our ability to obtain additional debt financing.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our obligations.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. We currently do not generate cash flow from operations and, in the future, our business may not generate cash flow from operations sufficient to service our debt and make necessary capital expenditures. 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 or debt financing on terms that may be unfavorable to us or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities at all or engage in these activities on desirable terms, which could result in a default on our debt obligations or future indebtedness.

We will need substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need substantial additional funding in connection with our continuing operations. We expect our research and development expenses to continue to increase in connection with our ongoing activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. In addition, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution related to ONIVYDE and any other product for which we obtain regulatory approval in the future. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or commercialization efforts.

We believe that at our currently forecasted spending rates, our existing financial resources, together with anticipated net product revenues and net royalty payments from sales of ONIVYDE, the net milestone payments and reimbursements we expect to receive under our Baxalta collaboration and access to our credit facility, will be sufficient to fund our operations into 2018. In addition, we have the ability to further manage spending as needed. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, and the extent to which we utilize collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future capital requirements will depend on many factors, including:

- the amount of net product revenues realized from ONIVYDE commercial sales;
- the amount of royalty and profit sharing revenue from our collaboration partners;

- the progress and results of the clinical trials of our most advanced product candidates;
- the success of our collaborations with Baxalta and PharmaEngine related to ONIVYDE and any future collaborations with other parties that we may enter into;
- the timing and amount of anticipated milestone payments and cost sharing reimbursements related to ONIVYDE that we may receive from Baxalta;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs, timing and outcome of regulatory review of our current and future product candidates;
- the costs of commercial activities, including product sales, marketing, manufacturing and distribution;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the extent to which we acquire or invest in businesses, products and technologies;
- our ability to establish and maintain commercial manufacturing arrangements for the manufacture of drug product on behalf of third-party pharmaceutical companies; and
- our ability to establish and maintain additional collaborations on favorable terms, particularly marketing and distribution arrangements for oncology product candidates outside the United States and Europe.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data required to obtain regulatory approval and, even if regulatory approval is obtained, achieve product sales of any of our product candidates other than ONIVYDE. In addition, ONIVYDE or any of our other product candidates, if approved, may not achieve commercial success. We began commercializing ONIVYDE under the brand name ONIVYDE in the United States in the fourth quarter of 2015. If we fail to generate sufficient revenues from the sale of ONIVYDE or the commercialization of any of our product candidates, we will need to continue to rely on additional financing to achieve our business objectives.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We do not have any committed external source of funds, other than under our collaboration with Baxalta for the development and commercialization of ONIVYDE, which is terminable by Baxalta for convenience upon 180 days' prior written notice, and under our development, license and supply agreement with Actavis, which is terminable by Actavis for convenience in specified circumstances upon 90 days' prior written notice. Other sources of funds may not be available or, if available, may not be available on terms satisfactory to us and could result in significant stockholder dilution.

Until such time, if ever, as we can generate sufficient product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, licensing arrangements and other marketing and distribution arrangements. We also could engage in discussions with third parties regarding partnerships, joint ventures, combinations or divestitures of one or more of our businesses as we seek to further the development of our research programs, improve our cash position and maximize stockholder value. There can be no assurance as to the timing, terms or consummation of any financing, collaboration, licensing arrangement or other marketing and distribution arrangement, partnership, joint venture, combination or divestiture.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and these covenants may also require us to attain certain levels of financial performance and we may not be able to do so; any such failure may result in the acceleration of such debt and the foreclosure by our creditors on the collateral we used to secure the debt. The debt issued in a debt

financing would also be senior to our outstanding shares of capital stock, and may rank equally with or senior to the convertible notes and the 2022 notes, upon our liquidation. Our existing indebtedness and the pledge of our assets as collateral limit our ability to obtain additional debt financing. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be

required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our investments are subject to risks that could result in losses.

We invest our cash in a variety of financial instruments, principally securities issued by the U.S. government and its agencies, investment grade corporate bonds, including commercial paper, and money market instruments. All of these investments are subject to credit, liquidity, market and interest rate risk. Such risks, including the failure or severe financial distress of the financial institutions that hold our cash, cash equivalents and investments, may result in a loss of liquidity, impairment to our investments, realization of substantial future losses, or a complete loss of the investments in the long-term, which may have a material adverse effect on our business, results of operations, liquidity and financial condition. In order to manage the risk to our investments, we maintain an investment policy that, among other things, limits the amount that we may invest in any one issue or any single issuer and requires us to only invest in high credit quality securities.

Risks Related to the Development and Commercialization of Our Product Candidates

We depend heavily on the successful commercialization of ONIVYDE and the success of our clinical stage product candidates. All of our product candidates other than ONIVYDE are still in preclinical and clinical development. Clinical trials of our product candidates may not be successful. If we are unable to successfully commercialize ONIVYDE or our other product candidates, or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of ONIVYDE and our other clinical stage product candidates for the treatment of various types of cancer. All of our product candidates, including ONIVYDE in indications beyond those for which it has already received marketing approval, are still in preclinical and clinical development. Our ability to generate meaningful product revenues will depend heavily on the successful commercialization of ONIVYDE and development of our product candidates. The success of ONIVYDE and our product candidates, which include both our therapeutic product candidates and diagnostic candidates, will depend on several factors, including the following:

- successful enrollment in, and completion of, preclinical studies and clinical trials;
- receipt of marketing approvals from the FDA and similar regulatory authorities outside the United States for our product candidates, including our diagnostics;
- establishing commercial manufacturing capabilities, either by building such facilities ourselves or making arrangements with third-party manufacturers;
- launching commercial sales of any approved products, whether alone or in collaboration with others;
- acceptance of any approved products by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- a continued acceptable safety profile of any products following approval; and
- qualifying for, maintaining, enforcing and defending intellectual property rights and claims.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize ONIVYDE and our other product candidates, which would materially harm our business.

For example, in connection with our corporate restructuring, we initiated a strategic review of our pipeline, including a clinical and financial prioritization of our programs. This review may result in amendments to our ongoing clinical trials and other changes to our programs. We expect to complete this review by the end of 2016. In the absence of clinical trial amendments, we believe that the data readouts of trials for our lead product candidates, including

potentially MM-302, MM-121 and ONIVYDE in front-line metastatic pancreatic cancer, will likely extend beyond our prior guidance. As part of our strategic review, we will continue to assess these data timelines and the potential impact of any such clinical trial amendments.

Even though the ONIVYDE regimen has been approved for marketing by the FDA, TFDA and European Commission, we or Baxalta may never receive approval to commercialize ONIVYDE in other parts of the world.

We have out-licensed the rights for the development and commercialization of ONIVYDE outside of the United States and Taiwan. In order to market our products outside of the United States, we or our collaboration partners must comply with numerous and varying regulatory requirements of other jurisdictions regarding safety and efficacy. Approval procedures vary among

jurisdictions and can involve product testing and administrative review periods different from, and greater than, those in the United States. Potential risks include that the regulatory authorities may not:

- deem our products safe and effective;
- find the data from clinical trials sufficient to support approval;
    - approve of manufacturing processes and facilities; or
- approve our products for any or all indications for which approval is sought.

If ONIVYDE fails to receive marketing approval in other parts of the world, our business may be materially harmed.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Even though ONIVYDE has been approved for marketing by the FDA, TFDA and European Commission in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy, we may never receive approval to commercialize our other product candidates in the United States or other jurisdictions, or to commercialize ONIVYDE in other parts of the world or for other indications. Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and successful interim results of a clinical trial do not necessarily predict successful final results.

We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding of a lack of clinical response or a finding that the patients are being exposed to unacceptable health risks;
    - regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates, diagnostics or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

For example, in February 2015, we stopped enrolling patients in our Phase 2 clinical trial of MM-111, a bispecific antibody product candidate, for the treatment of advanced gastric, esophageal and gastroesophageal junction cancers

prior to full enrollment based on a recommendation from the Data Safety Monitoring Board for that clinical trial, which cited shorter progression free survival on the treatment arm relative to the control arm in the overall patient population. We do not plan to invest in additional development of MM-111 at this time. In our previous Phase 2 clinical trial of MM-121 in patients with non-small cell lung cancer, two of the three cohorts (Groups A and C) failed to meet their primary endpoints, and the third cohort (Group B) did not pass its planned interim

analysis and ceased enrolling patients. Additionally, we did not meet the primary endpoints in our previous Phase 2 clinical trials of MM-121 in patients with ovarian cancer or in patients with breast cancer, although our ongoing biomarker analysis in each trial identified a potential subpopulation of patients benefiting from MM-121 in combination with either paclitaxel or exemestane, respectively.

Preclinical and clinical data may not be predictive of the success of later clinical trials, and are often susceptible to varying interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications that are not as broad as intended;
- have the product removed from the market after obtaining marketing approval;
- be subject to additional post-marketing testing requirements;
- be subject to restrictions on how the product is distributed or used; or
- be unable to obtain reimbursement for use of the product.

Delays in testing or approvals may result in increases to our product development costs. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all.

Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidates and may harm our business and results of operations.

If serious adverse or undesirable side effects are identified during the development of our product candidates or following their approval and commercialization, we may need to modify or abandon our development or marketing of such product or product candidate.

All of our product candidates, other than ONIVYDE in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy, are still in preclinical or clinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval, and it is impossible to ensure that safety or efficacy issues will not arise following regulatory approval. Currently marketed therapies for solid tumors are generally limited to some extent by their toxicity. Use of our product candidates as monotherapies in clinical trials also has resulted in adverse events consistent in nature with other marketed therapies. When used in combination with other marketed or investigational therapies, our product candidates may exacerbate adverse events associated with the other therapy. If our products or product candidates, either alone or in combination with other therapies, result in undesirable side effects or have characteristics that are unexpected, we may need to modify or abandon their development or marketing. For instance, the label for ONIVYDE contains a boxed warning with respect to severe neutropenia and severe diarrhea, which must be clearly conveyed in all marketing materials. Physicians' perceptions of the risks conveyed by the ONIVYDE boxed warning could impact their willingness to prescribe ONIVYDE.

If we experience delays in the enrollment of patients in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to obtain a statistically significant result as required by the FDA or other regulatory authorities. In addition, many of our competitors have ongoing clinical trials for product candidates that could be competitive with our product candidates. Patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates or rely upon treatment with existing therapies that may preclude them from eligibility for our clinical trials.

Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of the company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

In general, we forecast enrollment for our clinical trials based on experience from previous clinical trials and monitor enrollment to be able to make adjustments to clinical trials when appropriate, including as a result of slower than expected enrollment that we experience from time to time in our clinical trials. For example, we experienced slower than expected enrollment in our Phase 2 clinical trial of MM-121 in combination with exemestane for hormone receptor positive breast cancer. In response, we revised the entry criteria for the clinical trial to correspond with changes in clinical practice and also expanded the number of sites and countries participating in the clinical trial. It is possible that slow enrollment in other clinical trials in the future could require us to make similar adjustments. If these adjustments do not overcome problems with slow enrollment, we could experience significant delays or abandon the applicable clinical trial altogether.

If we are unable to successfully develop diagnostics for our therapeutic product candidates, or experience significant delays in doing so, we may not realize the full commercial potential of our therapeutics.

An important component of our business strategy is to develop, either alone or together with third parties, in vitro or in vivo diagnostics for each of our therapeutic product candidates. There has been limited success to date industry-wide in developing diagnostics, in particular in vitro diagnostics. To be successful, we will need to address a number of scientific, technical, regulatory and logistical challenges.

All of our diagnostic candidates are in preclinical or clinical development. We have limited experience in the development of diagnostics and may not be successful in developing appropriate diagnostics to pair with any of our therapeutic product candidates that receive marketing approval. The FDA and similar regulatory authorities outside the United States are generally expected to regulate in vitro companion diagnostics as medical devices and in vivo companion diagnostics as drugs. In each case, companion diagnostics require separate regulatory approval prior to commercialization. Given our limited experience in developing diagnostics, we expect to rely in part on third parties for their design, development and manufacture. If we, or any third parties that we engage to assist us, are unable to successfully develop diagnostics for our therapeutic product candidates, or experience delays in doing so, the development of our therapeutic product candidates may be adversely affected, our therapeutic product candidates may not receive marketing approval and we may not realize the full commercial potential of any therapeutics that receive marketing approval. As a result, our business would be harmed, possibly materially.

Any of our product candidates that receive regulatory approval may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even though ONIVYDE has received marketing approval, it, or any of our other product candidates that receive marketing approval, may nonetheless not gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of ONIVYDE and our other product candidates, if approved for commercial sale, will depend on a number of factors that may be uncertain or subjective, including:

- the prevalence and severity of any side effects;
- efficacy and potential advantages or disadvantages compared to alternative treatments;
- the price we charge for our product candidates;
- convenience and ease of administration compared to alternative treatments;

- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- our ability to successfully develop diagnostics that effectively identify patient populations likely to benefit from treatment with our therapeutic products;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

If we are unable to effectively educate healthcare professionals or enter into agreements with third parties to sell and market our products, we may not be successful in commercializing ONIVYDE or any other product candidates for which we receive marketing approval.

ONIVYDE is the first product that we are commercializing. We have no prior experience in the sale, marketing or distribution of therapeutic products. To achieve commercial success for any approved product, we must either build a field organization or outsource this function to third parties. We have established an organization to educate healthcare professionals on ONIVYDE in the United States. We expect that Baxalta and PharmaEngine will market and sell ONIVYDE in the rest of the world in the jurisdictions in which they receive marketing approval. Our commercialization plans for our other therapeutic candidates will depend in part on any future collaborations into which we may enter.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, we have a small field force of clinically trained professionals who are charged with educating healthcare professionals about ONIVYDE and Merrimack. This differs from the traditional field model in that it is neither a traditional field sales force nor a traditional medical science liaison role. While we believe that our field strategy will better meet the needs of our customers, this strategy may not be effective.

We also may not be successful entering into arrangements with third parties to sell and market our product candidates or doing so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

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

The development and commercialization of new therapeutic and diagnostic products is highly competitive. We face competition with respect to ONIVYDE and our other product candidates, and will face competition with respect to any products that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Several large pharmaceutical and biotechnology companies currently market and sell products for the treatment of the solid tumor indications for which we are developing our product candidates. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of these competitors are attempting to develop therapeutics for our target indications.

We are developing our product candidates for the treatment of solid tumors. There are a variety of available therapies marketed for solid tumors. In many cases, these drugs are administered in combination to enhance efficacy. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis, including the active ingredients in ONIVYDE and MM-302. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. This may make it difficult for us to achieve our business strategy of replacing existing therapies with our product candidates.

There are also a number of products in late stage clinical development to treat solid tumors. Our competitors may develop products that are more effective, safer, more convenient or less costly than any that we are developing or that would render ONIVYDE or our other product candidates obsolete or non-competitive. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. In addition, our ability to compete may be affected because in many cases insurers or other third-party payors seek to

encourage the use of generic products. There are many generic products currently on the market for the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

ONIVYDE or any of our product candidates that we successfully commercialize may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new therapeutic and diagnostic products, including ONIVYDE, vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our ability to commercialize ONIVYDE and any other approved products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors, including government payors such as Medicare and Medicaid, private health insurers and managed care organizations. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. The federal government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as ONIVYDE and the other product candidates that we are developing and could have a material adverse effect our net revenue and results.

Third-party payors decide which drugs they will pay for and establish reimbursement and co-pay levels. The growing emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider our products to be cost-effective 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. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Even with clinical trials, our product candidates may be considered less safe, less effective or less cost-effective than other products, and third-party payors may not provide coverage and reimbursement for our products or any of our product candidates that we commercialize, in whole or in part.

The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on a formulary, which might not include all of the approved drugs for a particular indication, and a payor’s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved.

We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of,

ONIVYDE and any other product for which we obtain marketing approval. Third-party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. In addition, coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. Thus, even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. The marketability of any products for which we receive regulatory approval for commercial sale may also suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize ONIVYDE or any other product candidate that we successfully develop.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. Centers for Medicare & Medicaid Services, or CMS, surveys and publishes retail community pharmacy acquisition cost information in the National Average Drug Acquisition Cost files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. Changes in these reimbursement mechanisms may have an adverse effect on our revenue.

Moreover, there may be significant delays in obtaining reimbursement for ONIVYDE and any other approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future weakening of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and appropriate payment rates from both government-funded and private payors for new products that we develop could therefore have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of ONIVYDE and any other products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and an even greater risk related to the commercial sale of ONIVYDE and any other products that we may develop. If we cannot successfully defend ourselves against claims that ONIVYDE or our other product candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for ONIVYDE or any other products or product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical trials;
- significant costs to defend the related litigation;
- substantial monetary awards to patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently hold $10.0 million in product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any or every liability that may arise.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

We have based our research and development efforts on our systems biology approach to biomedical research. Notwithstanding our large investment to date and anticipated future expenditures in our proprietary approach to research and development, we may fail to address or develop product candidates or indications based on other

scientific approaches that may offer greater commercial potential or for which there is a greater likelihood of success.

We also may not be successful in our efforts to identify or discover new or additional product candidates through our systems biology approach. Research programs to identify new product candidates require substantial technical, financial and human resources. These research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development.

If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have otherwise been more advantageous for us to retain sole development and commercialization rights.

We plan to establish separately funded companies for the development of product candidates using our systems biology approach in some areas outside the oncology field. These companies may not be successful in the development and commercialization of any product candidates.

We plan to apply our systems biology approach to multiple additional disease areas outside the oncology field. We expect to do so in some cases through the establishment of separately funded companies. For example, we established Silver Creek to research and develop regenerative medicines to repair the heart using our systems biology approach. Silver Creek has received separate funding from investors other than us. Although we are the current majority owner of Silver Creek, in the future we may not be the majority owner of or control Silver Creek or other companies that we establish. If in the future we do not control Silver Creek or any future similar company that we establish, Silver Creek or such other companies could take actions that we do not endorse or with which we disagree, such as using our systems biology approach in a way that reflects adversely on us. In addition, these companies may have difficulty raising additional funds and could encounter any of the risks in developing and commercializing product candidates to which we are subject.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and radioactive and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We also store certain low level radioactive waste at our facilities until the materials can be properly disposed of. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological, hazardous or radioactive materials.

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Fluctuations in foreign currency exchange rates could substantially increase the costs of our clinical trial programs.

A significant portion of our clinical trial activities are conducted outside of the United States, and associated costs may be incurred in the local currency of the country in which the trial is being conducted, which costs could be subject to fluctuations in foreign exchange rates. At present, we do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. A decline in the value of the U.S. dollar against currencies in geographies in which we conduct clinical trials could have a negative impact on our research and development costs. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our development costs.

Risks Related to Our Dependence on Third Parties

The successful commercialization and continued development of ONIVYDE depends substantially on our collaboration with Baxalta. If Baxalta is unable or unwilling to commercialize or further develop ONIVYDE, or experiences significant delays in doing so, our business will be materially harmed.

In September 2014, we entered into a license and collaboration agreement with Baxalta for the development and commercialization of ONIVYDE. Prior to this collaboration, we did not have a history of working with Baxalta, nor do we have a history of working with Shire plc, which acquired Baxalta in June 2016. The collaboration involves a complex allocation of rights, provides for milestone payments to us based on the achievement of specified development, regulatory and commercial sale milestones, and provides us with royalty-based revenue if ONIVYDE is successfully commercialized. We cannot predict the success of the collaboration.

Under our license and collaboration agreement, Baxalta has significant control over the conduct and timing of development and commercialization efforts with respect to ONIVYDE outside of the United States. We have little control over the amount, timing and quality of resources that Baxalta devotes to the development or commercialization of ONIVYDE outside of the United States. If

Baxalta fails to devote sufficient financial and other resources to the future development or commercialization of ONIVYDE outside of the United States, the development and commercialization of ONIVYDE outside of the United States would be delayed or could fail. This would result in a delay in our receiving milestone payments or royalties with respect to ONIVYDE outside of the United States or in our not receiving such milestone payments or royalties at all.

If we lose Baxalta as a collaborator in the development or commercialization of ONIVYDE, our business will be materially harmed.

Baxalta has the right to terminate our agreement for the development and commercialization of ONIVYDE, in whole or with respect to specified territories, at any time and for any reason, upon 180 days' prior written notice. Baxalta also has the right to terminate our agreement if we fail to cure a material breach of our agreement within a specified cure period, or fail to diligently pursue a cure if such a breach is not curable within such period.

If Baxalta terminates our agreement at any time, whether on the basis of our uncured material breach or for any other reason, it would delay or prevent our further development of ONIVYDE and materially harm our business and could accelerate our need for additional capital. In particular, we would have to fund the future clinical development and commercialization of ONIVYDE outside of the United States on our own, seek another collaborator or licensee for such clinical development and commercialization, or abandon the future clinical development and commercialization of ONIVYDE outside of the United States.

Additionally, in June 2016, Baxalta was acquired by Shire plc. The change of control of Baxalta may adversely affect our collaborative relationship or the commercialization of ONIVYDE in the partnered territories. Such a change in control may result in a reprioritization of ONIVYDE within Baxalta's portfolio, or Baxalta failing to maintain the financial or other resources necessary to continue supporting its commercialization of ONIVYDE.

We may depend on collaborations with third parties for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

Depending on our capital requirements, development and commercialization costs, need for additional therapeutic expertise and other factors, it is possible that we will enter into additional development and commercialization arrangements with respect to either oncology product candidates or product candidates in other therapeutic areas. In particular, while we expect to apply our systems biology approach to other disease areas through arrangements similar to Silver Creek, it is also possible that we will seek to enter into licensing agreements or other types of collaborations for the application of our systems biology approach.

Our likely collaborators for any distribution, marketing, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We will have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. 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 our product candidates, including our collaboration with Baxalta, pose the following risks to us:

- 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 our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their 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 a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates 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;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;

- 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 proprietary information or expose us to potential litigation;
- disputes may arise between us and the collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated, such as the termination of our license and collaboration agreement with Sanofi effective December 17, 2014, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If a present or future 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 are not able to establish additional collaborations, we may have to alter our development plans.

Our product development programs, the commercialization of ONIVYDE and the potential commercialization of any other approved product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. We may also be restricted under existing collaboration agreements from entering into agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, we may have to curtail the development of a particular product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We do not independently conduct clinical trials of our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to perform this function. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other international regulatory agencies require us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that adverse event data are reported within required timeframes, that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical trials are protected. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully

commercialize our product candidates.

We also rely on other third parties to store and distribute supplies for our clinical trials. Any performance failure on the part of our existing or future distributors could delay clinical development or regulatory approval of our product candidates or commercialization of our products or cause us to incur additional costs, producing additional losses and depriving us of potential product revenue.

We also intend to utilize diagnostics in several of our current and planned clinical trials, including current clinical trials of MM-121 and MM-141, to preselect patients who will receive specified treatment regimens. We will rely on third-party laboratories to test

patient samples in connection with such diagnostics. Any failure on the part of these laboratories to properly perform such testing could jeopardize those clinical trials and delay or prevent the approval of the associated therapeutic candidate.

Risks Related to the Manufacturing of Our Product Candidates

We have limited experience in manufacturing our product candidates. We will need to upgrade and expand our manufacturing facility and augment our manufacturing personnel and processes in order to meet our business plans. If we fail to do so, we may not have sufficient drug product to meet our clinical development and commercial requirements.

We have a manufacturing facility located at our corporate headquarters in Cambridge, Massachusetts. We manufacture drug substance at this facility that we use for commercial sales of ONIVYDE, research and development purposes and for clinical trials of our product candidates. We have limited experience in manufacturing products at a commercial scale. Our current facility may not be sufficient to permit expanded manufacture of ONIVYDE or our other product candidates for Phase 3 clinical trials or commercial sale. In order to meet our business plan, which contemplates our internally manufacturing drug substance for most of our clinical trials for all or a significant portion of our commercial requirements, we will need to upgrade and expand our manufacturing facilities, add manufacturing personnel and ensure that validated processes are consistently implemented in our facilities. The upgrade and expansion of our facilities will require additional regulatory approvals. In addition, it will be costly and time-consuming to expand our facilities and recruit necessary additional personnel. If we are unable to expand our facilities in compliance with regulatory requirements or to hire additional necessary manufacturing personnel, we may encounter delays or additional costs in achieving our research, development and commercialization objectives, including in obtaining regulatory approvals of our product candidates, which could materially damage our business and financial position.

If our manufacturing facility is damaged or destroyed or production at this facility is otherwise interrupted, our business and prospects would be negatively affected and our commercialization efforts may be materially harmed.

If the manufacturing facility at our corporate headquarters or the equipment in it is damaged or destroyed, we may not be able to quickly or economically replace our manufacturing capacity or replace it at all. If such an event occurs, the supply of ONIVYDE and our other product candidates would be interrupted. In the event of a temporary or protracted loss of this facility or equipment, we might not be able to transfer manufacturing to a third party and could lose potential revenue from the sales of ONIVYDE and any other products for which we obtain regulatory approval. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need FDA approval before selling ONIVYDE or any other products manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales of ONIVYDE and any other products that are approved by the FDA.

Currently, we maintain insurance coverage against damage to our property and equipment and to cover business interruption and research and development restoration expenses. If we have underestimated our insurance needs with respect to an interruption in our clinical manufacturing of our product candidates, we may not be able to cover our losses.

Any other interruption of production at our manufacturing facility also could damage our business. For example, in 2009, we experienced a viral contamination at this facility that required that we shut the facility entirely for decontamination. Because of this contamination, the FDA placed a partial clinical hold on our investigational new drug application for MM-121 until we submitted supporting documentation to the FDA regarding our

decontamination procedures. Although we were able to resolve this issue, with the FDA lifting the partial clinical hold in April 2010, other companies have experienced similar contamination problems, and we could experience a similar problem in the future that is more difficult to resolve.

We expect to continue to contract with third parties for at least some aspects of the production of ONIVYDE and our other product candidates for commercial sale and clinical trials. This increases the risk that we will not have sufficient quantities of ONIVYDE or our other product candidates at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We currently rely on third-party manufacturers for some aspects of the production of ONIVYDE and our other product candidates, including the production of MM-121 and fill-finish and labeling activities for ONIVYDE and our other product candidates. In addition, while we believe that our existing manufacturing facility or additional facilities that we build will be sufficient to meet our requirements for manufacturing a significant portion of drug substance for our research and development activities, we may need to rely on third-party manufacturers for some of these requirements, particularly later stage clinical trials of our antibody product candidates, and, at least in the near term, for commercial supply of ONIVYDE and any other products for which we obtain marketing approval.

In connection with the termination of our license and collaboration agreement with Sanofi for the development and commercialization of MM-121 in 2014, we assumed an agreement with a third-party manufacturer for the manufacture of MM-121. We do not have any other agreements with third-party manufacturers for the clinical supply to us of ONIVYDE or commercial supply to us of ONIVYDE or any other product candidates, and we may be unable to conclude such agreements or to do so on acceptable terms. Reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, or Quality System Regulation, or QSR, or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates.

Any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. Because there are a limited number of manufacturers that operate under cGMP or QSR regulations and that might be capable of manufacturing for us, we may not have access to such manufacturers.

We currently rely on single suppliers for the resins, media and filters that we use for our manufacturing process. We purchase these materials from our suppliers on a purchase order basis and do not have long-term supply agreements in place. Any performance failure or refusal to supply on the part of our existing or future suppliers could delay clinical development, marketing approval or commercialization of our products. If our current suppliers cannot perform as agreed, we may be required to replace one or more of these suppliers. Although we believe that there may be a number of potential long-term replacements to each supplier, we may incur added costs and delays in identifying and qualifying any such replacements.

We likely will rely upon third-party manufacturers to provide us with necessary reagents and instruments to develop, test and manufacture our in vitro diagnostics. Currently, many reagents are marketed as Research Use Only products under FDA regulations.

Our potential future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

We rely on third parties to perform various tasks related to the manufacturing of our product candidates. Compliance by such third parties with regulations of the FDA or other regulatory bodies cannot be assured, which could adversely impact our ability to supply our product candidates.

Although we perform much of the bulk manufacturing for ONIVYDE and our other product candidates, we rely on third parties to perform the fill-finish and packaging steps. If any of those third parties were to fail to be in compliance with regulations of the FDA or other regulatory bodies, our ability to supply ONIVYDE and our other product candidates could be adversely impacted.

For instance, in 2010, a former fill-finish third-party contractor that we used to fill and package MM-121 experienced FDA inspection issues with its quality control processes that resulted in a formal warning letter from the FDA. As a

result, we pulled some MM-121 from clinical trial sites and replaced it with MM-121 that was filled by a different contractor. This restocking resulted in a few patients missing one or two doses of MM-121. It is possible that we could experience similar issues with other contractors.

Risks Related to Our Intellectual Property

If we fail to fulfill our obligations under our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to a number of intellectual property license agreements with third parties, including with respect to MM-302, MM-121, MM-141 and MM-151, and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that our future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate these agreements, in which event we might not be able to develop and market any product that is covered by these agreements. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms. The occurrence of such events could materially harm our business.

If we are unable to obtain and maintain patent protection for our technology and products, or if our licensors are unable to obtain and maintain patent protection for the technology or products that we license from them, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be adversely affected.

Our success depends in large part on our and our licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if third parties who license patents to us fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued that protect our technology or products or that effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. Under the America Invents Act enacted in 2011, the United States moved to this first to file system in early 2013 from the previous system under which the first to make the claimed invention was entitled to the patent. We may become involved in opposition, interference or derivation proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are

commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to initiate infringement lawsuits, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the enforceable proprietary rights of third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. 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.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to our patented technology and products, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. In addition, any of these parties may breach the agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We may not be able to obtain, maintain or protect proprietary rights necessary for the continued development and commercialization of our products, product candidates and research technologies, including as a result of challenges from companies who seek to sell generic versions of ONIVYDE after expiration of our orphan drug exclusivity but prior to our ONIVYDE patent expiration.

Our commercial success depends in large part on obtaining and maintaining U.S. and foreign patent protection for our products, our product candidates and our research technologies and successfully enforcing and defending these patents against third-party challenges, including with respect to generic challenges. The validity of our patents in one or more jurisdictions may be challenged by third parties, resulting in our patents being deemed invalid, unenforceable or narrowed in scope, which could compromise the scope or duration of our exclusive rights in the relevant product, product candidate or technology. For example, the validity of a U.S. patent can be challenged in the U.S. Patent and Trademark Office (e.g., through an Inter Partes Review and/or Post Grant Review Proceeding) and/or in U.S. federal district court.

In addition, our patents on ONIVYDE may also be challenged in a federal court in connection with a third party's ANDA or a Section 505(b)(2) new drug application, or NDA, seeking FDA approval to market a generic version of ONIVYDE, resulting in a patent challenge to one or more patents listed in the Orange Book for ONIVYDE. This patent challenge can result in one or more of those Orange Book patents for ONIVYDE being deemed uninfringed, invalid, unenforceable and/or narrowed in scope, which could compromise the scope or duration of our exclusive rights in the relevant product. An ANDA or Section 505(b)(2) NDA can be filed at any time after FDA approval of ONIVYDE. Other challenges to a patent may be mounted without regard to the date of an FDA approval.

Our patents as issued or as subsequently limited by any litigation might not contain claims that are sufficiently broad to prevent others from circumventing our patent protection and utilizing our technologies. For instance, the issued patents relating to ONIVYDE and our product candidates may be limited to a particular indication and/or composition and may not cover similar compositions that have similar clinical properties. Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual property. Also, our pending patent applications may not issue, and we may not receive any additional patents. We cannot be sure that our patents and patent applications, including our own and those that we have rights to under licenses from third parties, will adequately protect our intellectual property for a number of reasons, including, among other things, the following: (i) the patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions; (ii) the actual protection afforded by a patent can vary from country to country and may depend upon the type of patent, the scope of its coverage and the availability of legal remedies in the country; (iii) the laws of foreign countries in which we market our products may afford little or no effective protection to our intellectual property, thereby easing our competitors' ability to compete with us in such countries; (iv) intellectual property laws and regulations and legal standards relating to the validity, scope and enforcement of patents covering pharmaceutical and biotechnological inventions are continually developing and changing, both in the United States and in other important markets outside the United States; (v) third parties may challenge, infringe, circumvent or seek to invalidate existing or future patents owned by or licensed to us; and (vi) the coverage claimed in a patent application can be significantly reduced before the patent is issued, and, as a consequence, our and our partners' patent applications may result in patents with narrower coverage than we desire or have planned for.

Risks Related to Regulatory Approval of Our Product Candidates

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates, including our clinical stage product candidates, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping,

labeling, storage, approval, advertising, promotion, sale and distribution, import, export, sampling and marketing are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. On October 22, 2015, we received approval from the FDA and the TFDA to market ONIVYDE in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy in the United States and Taiwan, respectively, and on October 18, 2016, Baxalta received approval from the European Commission to market ONIVYDE in combination with 5-FU and leucovorin for the treatment of metastatic adenocarcinoma of the pancreas in adult patients who have progressed following gemcitabine-based therapy. ONIVYDE is our first and only product candidate to receive regulatory approval. We have only limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party contract research organizations to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA and other regulatory agencies for each therapeutic indication to establish the product candidate’s safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA or other regulatory agencies. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or

unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

The process of obtaining regulatory approvals is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based on a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, changes in regulatory review for each submitted product application or approval of other products for the same indication may cause delays in the approval or rejection of an application. Regulatory agencies have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we pursue development of a diagnostic to identify patients who are likely to benefit from a therapeutic product, failure to obtain approval for the diagnostic may prevent or delay approval of the therapeutic product.

We are attempting to develop diagnostics to identify patients who are likely to benefit from our therapeutic product candidates. We currently rely on and expect to continue to rely on third parties for much of the development, testing and manufacturing of our diagnostics. We will likely rely on such third parties to also obtain any required regulatory approval for and then commercially supply such diagnostics. All of our diagnostic candidates are in preclinical or clinical development. We have very limited experience in the development of diagnostics and, even with the help of third parties with greater experience, may fail to obtain the required diagnostic product marketing approval, which could prevent or delay approval of the therapeutic product.

In July 2014, the FDA issued final guidance that stated that if safe and effective use of a therapeutic depends on an in vitro diagnostic, then the FDA generally will not approve the therapeutic unless the FDA approves or clears this “in vitro companion diagnostic device” at the same time that the FDA approves the therapeutic. The approval or clearance of the in vitro diagnostic most likely will occur through the FDA’s Center for Devices and Radiological Health Office of In Vitro Diagnostics and Radiological Health. Even with the issuance of the final guidance, the FDA’s expectations for in vitro companion diagnostics remain unclear in some respects. The FDA’s developing expectations will affect our in vitro diagnostics. In particular, the FDA may limit our ability to use retrospective data, otherwise disagree with our approaches to trial design, biomarker qualification, clinical and analytical validity and clinical utility, or make us repeat aspects of the trial or initiate new trials.

Because our diagnostic candidates are at an early stage of development, we cannot yet know what the FDA will require for any of these tests. For several of our clinical stage product candidates, namely MM-121, MM-141, and MM-151, we are attempting to develop an in vitro diagnostic that will help identify patients likely to benefit from the therapy. Whether the FDA will consider these in vitro diagnostics to be “in vitro companion diagnostic devices” that require simultaneous approval or clearance with the therapeutics will depend on whether the FDA views the diagnostics to be essential to the safety and efficacy of these therapeutics.

Based on the FDA’s past practice with companion diagnostics, if we are successful in developing a diagnostic for any of our clinical stage product candidates, we would expect that FDA approval of an in vitro companion diagnostic, or possibly an in vivo companion diagnostic, would be required for approval and subsequent commercialization of each such therapeutic product candidate. We are not aware of any currently available diagnostics that, if necessary, would otherwise allow us to proceed with the approval and subsequent commercialization of our product candidates despite a delay in or failure of our attempts to develop diagnostics.

For ONIVYDE and MM-302, although we are also investigating possible in vitro diagnostics, we are currently developing in vivo diagnostics in the form of imaging agents that may help identify patients more likely to benefit from the therapy. Imaging agents for diagnostic use would most likely be regulated as drugs by the FDA's Center for Drug Evaluation and Research and, as such, would be generally subject to the regulatory requirements applicable to other new drug candidates. Alternatively, several in vivo imaging agents have been regulated as medical devices by FDA's Center for Devices and Radiological Health. Although the FDA has not issued guidance with respect to the simultaneous approval of in vivo diagnostics and therapeutics, it is possible that the FDA will apply a standard similar to that for in vitro diagnostics.

Because we expect to rely on third parties for various aspects of the development, testing and manufacture, as well as for regulatory approval for and commercial supply, of our diagnostics, the commercial success of any of our product candidates that require a diagnostic will be tied to and dependent on the continued ability of such third parties to make the diagnostic commercially available on reasonable terms in the relevant geographies.

If we fail to maintain orphan drug exclusivity or designation for ONIVYDE or MM-141, we will have to rely on other rights and protections for these product candidates.

We have obtained orphan drug exclusivity in the United States for ONIVYDE for the treatment of pancreatic cancer and orphan medicinal product designation in the European Union for ONIVYDE for the treatment of pancreatic cancer. In addition, we have obtained orphan drug designation in the United States for MM-141 for the treatment of pancreatic cancer. In the United States, under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

In the United States, the company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for that indication for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application, including a full NDA, to market the same drug for the same orphan indication, except in limited circumstances. For purposes of small molecule drugs, the FDA defines the term “same drug” to mean a drug that contains the same active molecule and that is intended for the same use as the approved orphan drug. Orphan drug exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

The EMA grants orphan medicinal product designation to promote the development of products that may offer therapeutic benefits for life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the European Union. Orphan medicinal product designation from the EMA provides ten years of marketing exclusivity following drug approval, subject to reduction to six years if the designation criteria are no longer met.

Our therapeutic product candidates for which we intend to seek approval as biological or drug products may face competition sooner than expected.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Health Care and Education Reconciliation Act of 2010, or the Health Care Reform Law, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on their similarity to existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until twelve years after the original branded product was approved under a biologics license application, or BLA. The BPCIA is complex and has yet to be fully interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning is subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of our products approved as a biological product under a BLA should qualify for the twelve year period of exclusivity. However:

- a potential competitor could seek and obtain approval of its own BLA during our exclusivity period instead of seeking approval of a biosimilar version; and
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the FDA could consider a particular product candidate which contains both drug and biological product components to be a drug subject to review pursuant to an NDA, and therefore eligible for a significantly shorter marketing exclusivity period as provided under the Drug Price Competition and Patent Term Restoration Act of 1984.

Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear and will depend on a number of marketplace and regulatory factors that are still developing.

In addition, a drug product approved under an NDA, such as ONIVYDE, could face generic competition earlier than expected. The enactment of the Generic Drug User Fee Amendments of 2012 as part of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, established a user fee program that will generate hundreds of millions of dollars in funding for the FDA's generic drug review program. Funding from the user fee program, along with performance goals that the FDA negotiated with the generic drug industry, could significantly decrease the timeframe for FDA review and approval of generic drug applications.

Failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our products abroad.

We intend to market our products, including ONIVYDE, either ourselves or with commercialization partners, both within and outside the United States. This may increase the risks described below with respect to our compliance with foreign regulations.

In order to market and sell ONIVYDE and our other products in the European Union and many other jurisdictions, we or our commercialization partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing, including sometimes additional testing in children. The time required to obtain approval in foreign countries may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be sold in that country. We or our commercialization partners may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We or our commercialization partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

Any product for which we obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

ONIVYDE and any other product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP or QSR requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in actions such as:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the marketing of a product;
- restrictions on product distribution;
- requirements to conduct post-marketing clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of our products;

- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDASIA provides the FDA with new inspection authorities. A drug or biologic will be considered adulterated, with possible resulting civil and criminal penalties, if the owner or operator of the establishment where it is made, processed, packed or held delays, denies, limits or refuses inspection. The FDASIA also replaces the biennial inspection schedule for drugs and biologics with a risk-based inspection schedule. The law grants the FDA authority to require a drug or biologics manufacturer to provide, in advance or instead of an inspection, and at the manufacturer's expense, any records or other information that the agency may otherwise inspect at the facility. The FDASIA also permits the FDA to share inspection information with foreign governments under certain circumstances. The FDASIA is complex and has yet to be fully interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

The FDASIA also provides the FDA with additional authority to exercise against manufacturers of drugs or biologics that are not adhering to pediatric study requirements, which apply even if the manufacturer is not seeking to market the drug or biologic to pediatric patients. As of April 2013, the FDA must issue non-compliance letters to companies who do not meet the pediatric study requirements. Any company receiving a non-compliance letter would have an opportunity to respond, and the non-compliance letter and company response would become publicly available.

Future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval.

For example, in March 2010, President Obama signed into law the Health Care Reform Laws, which were intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, provide benefits for patients within a coverage gap in the Medicare Part D prescription drug program, implement rules regarding prescription drug benefits under the health insurance exchanges and changes to the Medicare Drug Rebate program, expand the Public Health Service's, or PHS', 340B drug pricing program, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. These changes impact existing government healthcare programs and are resulting in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. Further, the Health Care Reform Laws impose a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners.

Some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level, as is permitted under the Health Care Reform Laws. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales, business and financial condition. Where Medicaid patients receive insurance coverage under any of the new options made available through the Health Care Reform Laws, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues. In addition, the federal government has also announced delays in the implementation of key provisions of the Health Care Reform Laws, including the employer mandate. The implications of these delays for our sales, business and financial condition, if any, are not yet clear.

The Health Care Reform Laws appear likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Moreover, legislative changes to the Health Care Reform Laws remain possible. We expect that the Health Care Reform Laws, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products or to successfully commercialize our product candidates.

If we fail to comply with our reporting and payment obligations under U.S. governmental pricing programs, we could be required to reimburse government programs for underpayments and could pay penalties, sanctions and fines which could have a material adverse effect on our business, financial condition and results of operations.

As a condition of reimbursement for ONIVYDE and any other product approved by the FDA, various U.S. federal and state healthcare programs require that we calculate and report certain pricing information to U.S. federal and state healthcare agencies. For example, we are required to provide average selling price information to CMS on a quarterly basis in order to compute Medicare Part B payment rates. Price reporting and payment obligations are highly complex and vary among products and programs. The calculation of average selling price includes a number of inputs from contracts with wholesalers, specialty distributors, group purchasing organizations and other customers. We are also required to make an assessment of whether these agreements are deemed to be for bona fide services and that the services are deemed to be at fair market value in our industry and for our products. Our processes for estimating amounts due under these governmental pricing programs involve subjective decisions. As a result, our price reporting calculations are subject to the risk of errors and our methodologies for calculating these prices could be challenged under the federal False Claims Act or other laws. In addition, the Health Care Reform Laws modified the rules related to certain price reports and expanded the scope of pharmaceutical product sales to which Medicaid rebates apply, among other things. Uncertainty exists currently, as many of the specific determinations necessary to implement this new legislation have yet to be decided and communicated to industry participants. This uncertainty in the interpretation of the legislation increases the chances of an error in price reporting, which could in turn lead to a legal challenge, restatement or investigation. If we become subject to investigations, restatements or other inquiries concerning our compliance with price reporting laws and regulations, we could be required to pay or be

subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on our business, financial condition and results of operations.

We participate in and have certain price reporting obligations to the Medicaid Drug Rebate program and other governmental pricing programs, and we have obligations to report average sales price under the Medicare program. Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by governmental or regulatory agencies and the courts. For example, the Medicaid rebate amount is computed each quarter based on our submission to the CMS of our average manufacturer price, or AMP, and best price for the quarter. If we become aware that our reporting for prior quarters was incorrect, or has changed as a result of recalculation of the pricing data, we will be obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due. Such restatements and recalculations would serve to increase our costs for complying with the laws and regulations governing the Medicaid rebate program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the price that we will be required to charge certain safety net providers under the PHS 340B drug pricing program.

We are liable for errors associated with our submission of pricing data and for overcharging government payers. For example, in addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false AMP or best price information to the government, we may be liable for civil monetary penalties in the amount of $100,000 per item of false information. Our failure to submit monthly/quarterly AMP and best price data on a timely basis could result in a civil monetary penalty of $10,000 per day for each day the submission is late beyond the due date. In the event that CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our products. In addition, if we overcharge the government in connection with our Federal Supply Schedule, or FSS, contract or under any other government program, we will be required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges could result in allegations against us under the federal civil False Claims Act and other laws and regulations.

CMS and the Office of Inspector General of the U.S. Department of Health and Human Services have pursued manufacturers that were alleged to have failed to report these data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

If we overcharge the government in connection with our FSS contract or the Tricare retail pharmacy program, whether due to a misstated Federal Ceiling Price or otherwise, we would be required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations.

Unexpected refunds to the federal government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Risks Related to Commercialization of Our Product Candidates

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. If we are found to have improperly promoted off-label uses, we may become subject to significant fines and other liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted for off-label uses, we may become subject to significant government fines and other related liability. For example, the U.S. government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into complex multi-year corporate integrity agreements and/or non-prosecution agreements that can impose significant restrictions and other burdens on the affected companies.

In addition, incentives under applicable U.S. laws encourage employees and physicians to report violations of rules governing promotional activities for pharmaceutical products. These incentives could lead to so called whistleblower lawsuits as part of which such persons seek to collect a portion of moneys allegedly overbilled to government agencies due to, for example, promotion of pharmaceutical products beyond labeled claims. Such lawsuits, whether with or without merit, are typically time consuming and costly to defend. Such suits may also result in related stockholder lawsuits, which are also costly to defend.

Our relationships with customers and payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of ONIVYDE and any other products for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute ONIVYDE and any other products for which we obtain marketing approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward the purchasing, leasing, ordering or arranging for the purchase, order or recommendation of any item or service reimbursable under Medicare, Medicaid, or other federal healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other, and violations are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor;
- the federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Government enforcement agencies and private whistleblowers have initiated investigations or brought private lawsuits against pharmaceutical companies for a variety of allegedly improper promotional or marketing activities, such as allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates; allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; or engaging in promotion for "off-label" uses. Additionally, the Health Care Reform Laws amended the federal False Claims Act such that a violation of the federal anti-kickback statute can serve as a basis for liability under the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA, makes it a crime to knowingly and willfully execute or attempt to execute a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies reimbursable under Medicare and Medicaid to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals, as well as physician ownership and investment interests, and provides for public reporting of the data reported by manufacturers;
- the U.S. Foreign Corrupt Practices Act prohibits U.S. companies and their representatives from paying, offering to pay, promising or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate for the purpose of obtaining or retaining business or to otherwise obtain favorable treatment or influence a person working in an official capacity, and encompasses many healthcare professionals in many countries under the definition of a foreign government official;

- the Bribery Act, which applies to U.S. companies such as ourselves that conduct business in the United Kingdom, proscribes giving and receiving bribes in the public and private sectors, bribing a foreign public official and failing to have adequate procedures to prevent employees and other agents from giving bribes; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. In addition, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government. Other states require pharmaceutical manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures, or prohibit certain marketing-related activities including the provision of gifts, meals or other items to certain healthcare providers.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also harm our financial condition. Responding to government investigations or whistleblower lawsuits, defending any claims raised, and any resulting fines, damages, penalties, settlement payments or administrative actions, as well as any related actions brought by stockholders or other third parties, could have a material impact on our reputation, business and financial condition and divert the attention of our management from operating our business.

Our corporate compliance efforts cannot guarantee that we are in compliance with all potentially applicable regulations.

The development, manufacturing, pricing, sales, coverage and reimbursement of our products, together with our general operations, are and will be subject to extensive regulation by federal, state and other authorities within the United States and numerous entities outside of the United States. While we have implemented a corporate compliance program based on what we believe are the current best practices, we cannot provide any assurance that governmental authorities will find that our business practices comply with current or future administrative or judicial interpretations of potentially applicable laws and regulations. If we fail to comply with any of these laws and regulations, we could be subject to a range of regulatory actions, including suspension or termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of ONIVYDE or other products from the market, significant fines, disqualification or debarment from participation in federally-funded healthcare programs or other sanctions or litigation, any of which events may have a significant adverse impact on our business.

Risks Related to Data Protection and Cybersecurity

Our failure to comply with 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 are subject to data protection laws and regulations that address privacy and data security. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws govern the collection, use, disclosure and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions, which could include civil or criminal penalties, private litigation and/or adverse publicity and could negatively affect our operating results and business. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under HIPAA. We could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information in a manner that is not authorized or permitted.

Significant disruptions of information technology systems or security breaches could adversely affect our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, among other things, trade secrets or other intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, and the large amounts of confidential information stored on those systems, make such systems vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors, and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information.

Significant disruptions of our information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or the prevention of access to,

confidential information, including, among other things, trade secrets or other intellectual property, proprietary business information and personal information, and could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, require us to comply with federal and/or state breach notification laws and foreign law equivalents, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business.

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain our key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive and scientific teams. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

Our corporate restructuring and the associated headcount reduction announced in October 2016 may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

On October 3, 2016, we announced a 22% reduction in headcount as part of a major corporate restructuring with the objective of prioritizing our research and development on a focused set of systems biology-derived oncology products and strengthening our financial runway. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. We also cannot guarantee that we will not have to undertake additional headcount reductions or restructuring activities in the future. Furthermore, our restructuring plan may be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, or increase difficulties in our day-to-day operations. Our headcount reductions could also harm our ability to attract and retain qualified management, scientific, clinical, manufacturing and sales and marketing personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our product candidates in the future.

We have entered into and may continue to enter into or seek to enter into business combinations and acquisitions which may be difficult to integrate, disrupt our business, divert management attention or dilute stockholder value.

As part of our business strategy, we may enter into business combinations and acquisitions. Although we acquired Hermes in October 2009, we have limited experience in making acquisitions. In addition, acquisitions are typically accompanied by a number of risks, including:

- the difficulty of integrating the operations and personnel of the acquired companies;
- the potential disruption of our ongoing business and distraction of management;
- potential unknown liabilities and expenses;
- the failure to achieve the expected benefits of the combination or acquisition;
- the maintenance of acceptable standards, controls, procedures and policies; and
- the impairment of relationships with employees as a result of any integration of new management and other personnel.

If we are not successful in completing acquisitions that we may pursue in the future, we would be required to reevaluate our business strategy and we may have incurred substantial expenses and devoted significant management time and resources in seeking

to complete the acquisitions. In addition, with future acquisitions, we could use substantial portions of our available cash as all or a portion of the purchase price. As we did for the acquisition of Hermes, we could also issue additional securities as consideration for these acquisitions, which could cause our stockholders to suffer significant dilution.

Risks Related to Our Common Stock

Our executive officers, directors and principal stockholders maintain the ability to significantly influence all matters submitted to stockholders for approval.

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock, in the aggregate, beneficially own a large portion of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could allow, delay or prevent an acquisition of our company on terms that other stockholders may desire.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions:

- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Further, the repurchase right under the convertible notes in connection with a fundamental change (as defined therein) and any increase in the conversion rate in connection with a make-whole fundamental change could also discourage a potential acquirer.

Our stock price has been and may in the future be volatile, which could cause holders of our common stock to incur substantial losses.

Our stock price has been and in the future may be subject to substantial price volatility. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders could incur substantial losses. The market price for our common stock may be influenced by many factors, including:

- our ability to successfully commercialize ONIVYDE in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy;
- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patents or other proprietary rights;
- the recruitment or departure of key personnel;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- activism by any single large stockholder or combination of stockholders;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

The indenture governing our 11.50% senior secured notes due 2022 imposes significant operating and financial restrictions on us and our subsidiaries that may prevent us from pursuing certain business opportunities and restrict our ability to operate our business.

On December 22, 2015, we issued $175.0 million in aggregate principal amount of 11.50% senior secured notes due 2022. The indenture governing the 2022 notes contains covenants that restrict our and our subsidiaries' ability to take various actions, including, among other things:

- the incurrence of debt;
- the issuance of our preferred stock;
- the payment of dividends, the repurchase of shares and making certain other restricted payments;
- the prepayment, redemption or repurchase of subordinated debt;
- the sale, lease or transfer of property and assets;
- engaging in transactions with affiliates; and
- the making of investments other than those permitted by the indenture.

The indenture specifies a number of events of default, some of which are subject to applicable grace or cure periods, including, among other things, non-payment defaults, covenant defaults, cross-defaults to other material indebtedness, bankruptcy and insolvency defaults, and non-payment of material judgments.

Our ability to comply with these covenants will likely be affected by many factors, including events beyond our control, and we may not satisfy those requirements. Our failure to comply with our obligations could result in an event of default under our other indebtedness and the acceleration of our other indebtedness, in whole or in part, could result in an event of default under the indenture governing the 2022 notes.

The restrictions contained in the indenture governing the 2022 notes could also limit our ability to plan for or react to market conditions, meet capital needs or otherwise restrict our activities or business plans and adversely affect our ability to finance our operations, enter into acquisitions or to engage in other business activities that would be in our interest.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for holders of our common stock.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of our existing debt agreements limit our ability to pay dividends, and the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for holders of our common stock for the foreseeable future.

Future sales of shares of our common stock, including by us or our directors and executive officers or shares issued upon the exercise of currently outstanding options, or upon conversion of our outstanding convertible notes, could cause the market price of our common stock to drop significantly, even if our business is doing well.

A substantial portion of our outstanding common stock can be traded without restriction at any time. In addition, a portion of our outstanding common stock is currently restricted as a result of federal securities laws, but can be sold at any time subject to applicable volume limitations. As such, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, by us or others, could reduce the market price of our common stock. In addition, we have a significant number of shares that are subject to outstanding options, and we may issue shares of our common stock upon conversion of our outstanding convertible notes. The exercise of these options or the issuance of shares of our common stock upon conversion of our outstanding convertible notes and the subsequent sale of the underlying common stock could cause a further decline in our stock price. For instance, in April 2016, we issued an aggregate of 12,367,663 shares of our common stock to certain holders of our convertible notes who had agreed to convert an aggregate of $64.2 million of convertible notes. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. We cannot predict the size of future issuances or the effect, if any, that any future issuances may have on the market price for our common stock.

Item 5. Other Information

On November 8, 2016, we entered into a Loan and Security Agreement, or the Credit Agreement, with BioPharma Credit Investments IV Sub, LP, or Pharmakon, pursuant to which a credit facility of an aggregate principal amount of at least $15.0 million and up to $25.0 million is available to us. The credit facility is available at any time through March 15, 2017 upon our request and upon compliance with certain additional funding conditions.

If we borrow under the Credit Agreement, the credit facility will bear interest at an annual rate of 11.50%. The Credit Agreement provides for quarterly interest-only payments for two years and repayment of all of the outstanding principal balance of the loan on the second anniversary of the funding date. In addition, we paid a fee of $0.4 million upon entry into the Credit Agreement. At our option, we may elect to prepay all of the outstanding credit facility with prepayment of all interest that would otherwise have accrued through the full remaining term of the loan. The credit facility is also subject to mandatory prepayment, with a comparable prepayment of interest, upon the occurrence of

certain events, including specified changes of control, asset sales and certain debt incurrences and refinancings.

In connection with the Credit Agreement, we granted Pharmakon a security interest in all of our inventory and accounts receivable. The Credit Agreement also contains certain representations, warranties and non-financial covenants. In addition, the Credit Agreement grants Pharmakon an option during the two years following funding of the credit facility to participate in future financings at an amount up to the lesser of 25% of the total amount financed or $50.0 million.

Item 6.Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by 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.

MERRIMACK
PHARMACEUTICALS, INC.

Date: November 9, 2016 By: /s/ Yasir B. Al-Wakeel
Yasir B. Al-Wakeel
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1+	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2+	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Database
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

*Filed herewith.
+Furnished herewith.