MERRIMACK PHARMACEUTICALS INC
Form 10-Q
August 04, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

OR

o 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 x No o

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 x No o

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

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

As of July 29, 2016, there were 129,240,796 shares of Common Stock, $0.01 par value per share, outstanding.

TABLE OF CONTENTS

PART I

FINANCIAL INFORMATION

i

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.

1

PART I

FINANCIAL INFORMATION

Item 1.Financial Statements.

Merrimack Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets

(in thousands, except per share amounts)	June 30,	December 31,
(unaudited)	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	$21,491	$185,606
Marketable securities	61,176	—
Restricted cash	101	101
Accounts receivable, net	19,325	6,483
Inventory	12,321	3,717
Prepaid expenses and other current assets	4,619	5,487
Total current assets	119,033	201,394
Restricted cash	674	584
Property and equipment, net	19,614	21,915
Other assets	27	27
Intangible assets, net	7,066	7,355
Goodwill	3,605	3,605
Total assets	$150,019	$234,880
Liabilities, non-controlling interest and stockholders' deficit		
Current liabilities:		
Accounts payable, accrued expenses and other	$44,796	$52,082
Deferred revenues	44,157	50,137
Deferred rent	1,935	1,527
Total current liabilities	90,888	103,746
Deferred revenues, net of current portion	39,900	51,197
Deferred rent, net of current portion	4,423	4,926
Deferred tax incentives, net of current portion	822	1,045
Long-term debt	215,544	257,655
Total liabilities	351,577	418,569
Commitments and contingencies		
Non-controlling interest	(154)	239
Stockholders' deficit:		
Preferred stock, $0.01 par value: 10,000 shares authorized at June 30, 2016 and December 31, 2015; no shares issued or outstanding at June 30, 2016 or December 31, 2015	—	—

Common stock, $0.01 par value: 200,000 shares authorized at June 30, 2016 and December 31, 2015; 128,991 and 115,871 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	1,290	1,159
Additional paid-in capital	688,760	617,145
Accumulated other comprehensive income	1	—
Accumulated deficit	(891,455)	(802,232)
Total stockholders' deficit	(201,404)	(183,928)
Total liabilities, non-controlling interest and stockholders' deficit	$150,019	$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

	Three Months Ended		Six Months Ended	
(in thousands, except per share amounts) (unaudited)	June 30, 2016	2015	June 30, 2016	2015
Revenues:				
Product revenues, net	$12,851	$—	$22,819	$—
License and collaboration revenues	19,332	36,558	30,645	51,399
Other revenues	1,498	—	1,498	—
Total revenues	33,681	36,558	54,962	51,399
Costs and expenses:				
Cost of revenues	1,872	—	2,583	—
Research and development expenses	40,996	42,806	73,878	78,485
Selling, general and administrative expenses	20,680	12,315	38,475	21,504
Total costs and expenses	63,548	55,121	114,936	99,989
Loss from operations	(29,867)	(18,563)	(59,974)	(48,590)
Other income and expenses:				
Interest income	122	34	194	80
Interest expense	(21,149)	(4,482)	(29,729)	(9,048)
Other (expense) income, net	(64)	110	(107)	224
Net loss	(50,958)	(22,901)	(89,616)	(57,334)
Net (loss) income attributable to non-controlling interest	(208)	(123)	(393)	204
Net loss attributable to Merrimack Pharmaceuticals, Inc.	$(50,750)	$(22,778)	$(89,223)	$(57,538)
Other comprehensive income:				
Unrealized gain on available-for-sale securities	15	21	1	68
Other comprehensive income	15	21	1	68
Comprehensive loss	$(50,735)	$(22,757)	$(89,222)	$(57,470)
Net loss per share available to common stockholders—basic and diluted	$(0.40)	$(0.21)	$(0.74)	$(0.53)
Weighted-average common shares used in computing net loss per share available to common stockholders—basic and diluted	126,161	109,975	121,112	108,662

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)	Six Months Ended June 30, 2016	2015
Cash flows from operating activities		
Net loss	$(89,616)	$(57,334)
Adjustments to reconcile net loss to net cash used in operating activities		
Non-cash interest expense	3,505	4,038
Non-cash loss on extinguishment of convertible notes due 2020	14,566	—
Loss on disposal of property and equipment	227	—
Depreciation and amortization expense	3,020	2,092
Stock-based compensation expense	7,891	8,337
Changes in operating assets and liabilities:		
Accounts receivable	(12,842)	1,711
Inventory	(8,384)	—
Accounts payable, accrued expenses and other	(7,072)	7,474
Deferred revenues	(17,277)	(26,502)
Other assets and liabilities, net	1,556	527
Net cash used in operating activities	(104,426)	(59,657)
Cash flows from investing activities		
Purchases of marketable securities	(84,262)	—
Proceeds from sales and maturities of marketable securities	23,000	53,963
Purchases of property and equipment	(2,050)	(4,105)
Net cash (used in) provided by investing activities	(63,312)	49,858
Cash flows from financing activities		
Proceeds from exercise of options and warrants to purchase common stock	2,598	6,542
Proceeds from issuance of convertible promissory notes by Silver Creek Pharmaceuticals, Inc.	1,025	—
Proceeds from issuance of preferred stock by Silver Creek Pharmaceuticals, Inc.	—	1,233
Net cash provided by financing activities	3,623	7,775
Net decrease in cash and cash equivalents	(164,115)	(2,024)
Cash and cash equivalents, beginning of period	185,606	35,688
Cash and cash equivalents, end of period	$21,491	$33,664
Non-cash investing and financing activities		
Purchases of property and equipment in accounts payable, accrued expenses and other	$434	$2,060
Receivables related to stock option exercises in prepaid expenses and other current assets	13	160
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	169	—
Supplemental disclosure of cash flows		
Cash paid for interest	$12,484	$4,946

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 June 30, 2016 and December 31, 2015, and for the three and six months ended June 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 June 30, 2016, and for the three and six months ended June 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 six months ended June 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 June 30, 2016, the Company’s unrestricted cash and cash equivalents includes $0.7 million of cash and cash equivalents held by Silver Creek. This $0.7 million held by Silver Creek is designated for the operations of Silver Creek.

During the six months ended June 30, 2015, Silver Creek issued and sold a total of 1.0 million shares of Silver Creek Series B preferred stock at a price per share of $1.35 to investors and received net proceeds of $1.2 million, after deducting issuance costs. No shares of Silver Creek Series B preferred stock were sold during the six months ended June 30, 2016. The Company’s ownership of Silver Creek was 56% as of both June 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	(393)
Balance at June 30, 2016	$ (154)

(in thousands)	Non-Controlling Interest
Balance at December 31, 2014	$ 69
Net income attributable to Silver Creek	204
Balance at June 30, 2015	$ 273

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.

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 six months ended June 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 six months ended June 30, 2016 and 2015 are shown in the chart below:

	Three and Six Months Ended June 30,	
(in thousands)	2016	2015
Outstanding options to purchase common stock	21,647	19,426
Common stock warrants	—	377
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 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 June 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 June 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.

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 of revenue during the three and six months ended June 30, 2016. 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.

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, 2021. The Company will periodically review and, if necessary, revise the estimated service period related to its collaboration with Baxalta. As of June 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 six months ended June 30, 2016 and 2015, the Company recognized revenue based on the following components of the Baxalta Agreement:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2016	2015	June 30, 2016	2015
Proportional performance revenue recognition model	$9,332	$16,558	$20,645	$31,399
Substantive milestones	10,000	20,000	10,000	20,000
Total	$19,332	$36,558	$30,645	$51,399

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

(in thousands)	June 30, 2016	December 31, 2015
Accounts receivable, billed	$642	$ 1,336
Accounts receivable, unbilled	233	626
Deferred revenues	80,064	97,365

Of the $80.1 million of deferred revenues related to the Baxalta Agreement as of June 30, 2016, $44.2 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.

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 June 30, 2016 and 2015, the Company recognized research and development expenses related to the PharmaEngine Agreement of $10.0 million and $11.1 million, respectively. During the six months ended June 30, 2016 and 2015, the Company recognized research and development expenses related to the PharmaEngine Agreement of $10.1 million and $11.3 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 recognized $0.3 million of revenue during the three and six months ended June 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 June 30, 2016. The Company will also receive a double digit 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.

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 June 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.

9

5. Product Revenue Reserves and Allowances

The following table summarizes activity in each of the product revenue reserve and allowance categories for the six months ended June 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	813	2,403	170	12	3,398
Adjustments related to sales in the prior year	—	(127)	—	—	(127)
Credits and payments made	(578)	(1,801)	(26)	(6)	(2,411)
Balance at June 30, 2016	$ 373	$ 837	$ 176	$ 14	$1,400

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 June 30, 2016 and December 31, 2015:

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

Money market funds	$8,476	$—	$ —
Corporate debt securities	—	2,503	—
Total cash equivalents	$8,476	$2,503	$ —
Marketable securities:			
Commercial paper	$—	$20,979	$ —
Corporate debt securities	—	21,200	—
U.S. government agency securities	—	18,997	—
Total marketable securities	$—	$61,176	$ —

	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 six months ended June 30, 2016 or during the year ended December 31, 2015. There were no liabilities measured at fair value on a recurring basis as of June 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 six months ended June 30, 2016 or 2015.

Other Fair Value Measurements

The estimated fair value of the Convertible Notes was $70.5 million as of June 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 is $45.0 million as of June 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 $168.3 million as of June 30, 2016. The carrying value of the 2022 Notes was $169.5 million as of June 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. 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 $1.0 million as of June 30, 2016. The carrying value of the Silver Creek Notes was also $1.0 million as of June 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 June 30, 2016 consisted of the following:

	June 30, 2016			
(in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:				

Money market funds	$8,476	$ —	$ —	$8,476
Corporate debt securities	2,504	—	(1)	2,503
Total cash equivalents	$10,980	$ —	$ (1)	$10,979
Marketable securities:				
Commercial paper	$20,980	$ 4	$ (5)	$20,979
Corporate debt securities	21,200	1	(1)	21,200
U.S. government agency securities	18,994	3	—	18,997
Total marketable securities	$61,174	$ 8	$ (6)	$61,176

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 six months ended June 30, 2016 or 2015. As of June 30, 2016, the Company held six individual cash equivalents or available-for-sale securities that had been in an unrealized loss position for less than twelve months, and the aggregate fair value of such securities was $22.6 million. As of June 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. The Company determined that there was no material change in the credit risk of the investments. As a result, the Company determined it did not hold any securities with an other-than-temporary-impairment as of June 30, 2016.

8. Inventory

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

(in thousands)	June 30, 2016	December 31, 2015
Raw materials	$4,231	$ 900
Work in process	6,659	2,743
Finished goods	1,431	74
Total inventory	$12,321	$ 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 June 30, 2016 and December 31, 2015 consisted of the following:

(in thousands)	June 30, 2016	December 31, 2015
Accounts payable	$12,046	$ 5,049
Accrued goods and services	13,954	14,295
Accrued clinical trial costs	9,696	12,764
Accrued drug purchase costs	155	7,460
Accrued payroll and related benefits	6,381	9,009
Accrued interest	2,100	3,041
Accrued dividends payable	19	19
Deferred tax incentives	445	445
Total accounts payable, accrued expenses and other	$44,796	$ 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 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 six months ended June 30, 2016, interest expense related to the 2022 Notes was approximately $5.2 million and $10.4 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 June 30, 2016 and 2015, interest expense related to the Convertible Notes was $16.0 million and $3.4 million, respectively. For the six months ended June 30, 2016 and 2015, interest expense related to the Convertible Notes was $19.4 million and $6.8 million, respectively. As discussed above, interest expense for the three and six months ended June 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 that 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 June 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 June 30, 2016 are as follows:

(in thousands)	Convertible Notes	2022 Notes
Remainder of 2016	$ 1,368	$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	73,103	270,594
Less interest	(12,310)	(95,594)

Less unamortized discount	(15,798)	(5,476)
Less current portion	—	—
Long-term debt	$ 44,995	$ 169,524

11. 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 June 30, 2016, there were 3.3 million shares remaining available for grant under the 2011 Plan.

During the six months ended June 30, 2016 and 2015, the Company issued options to purchase 3.8 million and 2.7 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 six months ended June 30, 2016 and 2015 was estimated at the date of grant using the following assumptions:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Risk-free interest rate	1.1 – 1.5%	1.5 – 1.8%	1.1 – 1.5%	1.5 – 1.8%
Expected dividend yield	0%	0%	0%	0%
Expected term	5.0 – 5.8 years	5.0 – 5.9 years	5.0 – 5.8 years	5.0 – 5.9 years
Expected volatility	67 – 69%	66 – 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 six months ended June 30, 2016 and 2015 as follows:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
(in thousands)	2016	2015	2016	2015
Employee awards:				
Research and development expense	$1,804	$2,369	$3,672	$4,335
Selling, general and administrative expense	2,773	2,576	4,438	3,954
Stock-based compensation expense for employee awards	4,577	4,945	8,110	8,289
Stock-based compensation expense for non-employee awards	—	22	1	48
Less: stock-based compensation expense capitalized to inventory	(90)	—	(220)	—
Total stock-based compensation expense	$4,487	$4,967	$7,891	$8,337

The following table summarizes stock option activity during the six months ended June 30, 2016:

(in thousands, except per share amounts)	Shares	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	3,772	$ 5.61		
Exercised	(752)	$ 3.45		
Forfeited	(584)	$ 7.05		
Outstanding at June 30, 2016	21,647	$ 5.75	6.38	$ 16,475
Vested and expected to vest at June 30, 2016	21,260	$ 5.73	6.32	$ 16,470
Exercisable at June 30, 2016	15,797	$ 5.31	5.37	$ 16,224

The weighted-average grant date fair value per share of stock options granted during the three months ended June 30, 2016 and 2015 was $3.73 and $6.95, respectively. The weighted-average grant date fair value per share of stock options granted during the six months ended June 30, 2016 and 2015 was $3.35 and $5.75, 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 June 30, 2016

and 2015 was $0.6 million and $10.3 million, respectively. The aggregate intrinsic value of stock options exercised during the six months ended June 30, 2016 and 2015 was $2.7 million and $23.8 million, respectively.

As of June 30, 2016, there was $20.9 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 2.0 years.

12. 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:

- 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. 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 2016-03, “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.

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.

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, the European Medicines Agency, or EMA, has accepted for review a Marketing Authorization Application, or MAA, filed by 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 been previously treated with 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 and secured debt financings.

As of June 30, 2016, we had unrestricted cash and cash equivalents and marketable securities of $82.7 million. We believe that our existing financial resources, together with anticipated net product revenues and net royalty payments from sales of ONIVYDE and the net milestone payments and reimbursements we expect to receive under our Baxalta collaboration, will be sufficient to fund our operations into the second quarter of 2017. In addition, we have the ability to further manage spending as needed.

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.

We have never been profitable and, as of June 30, 2016, we had an accumulated deficit of $891.5 million. Our net loss was $51.0 million and $89.6 million for the three and six months ended June 30, 2016, respectively, and $22.9 million and $57.3 million for the three and six months ended June 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 substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. 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 June 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 June 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.

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.

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, 2021. We will periodically review and, if necessary, revise the estimated service period related to our collaboration with Baxalta. As of June 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 EMA accepted for review an 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 six months ended June 30, 2016 and 2015, we recognized revenue based on the following components of the Baxalta agreement:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
(in thousands)	2016	2015	2016	2015
Proportional performance revenue recognition model	$9,332	$16,558	$20,645	$31,399
Substantive milestones	10,000	20,000	10,000	20,000
Total	$19,332	$36,558	$30,645	$51,399

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

	June 30,	December 31,
(in thousands)	2016	2015
Accounts receivable, billed	$642	$ 1,336
Accounts receivable, unbilled	233	626
Deferred revenues	80,064	97,365

Of the $80.1 million of deferred revenues related to the Baxalta agreement as of June 30, 2016, $44.2 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.

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 June 30, 2016. We will also receive a double digit 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.

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 June 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 June 30, 2016 and 2015, we recognized research and development expenses related to the PharmaEngine agreement of $10.0 million and $11.1 million, respectively. During the six months ended June 30, 2016 and 2015, we recognized research and development expenses related to the PharmaEngine agreement of $10.1 million and $11.3 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 six months ended June 30, 2016, we recognized net product revenues of $12.9 million and $22.8 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 six months ended June 30, 2016, we recognized revenue of $1.2 million and $0.3 million related to ONIVYDE bulk drug substance provided to Baxalta and PharmaEngine, 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 increase throughout the remainder of 2016 as we expect to achieve additional substantive regulatory milestones in 2016.

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 to some extent at least 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 six months ended June 30, 2016 and 2015:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2016	2015	June 30, 2016	2015
ONIVYDE	$13,300	$15,543	$18,168	$24,527
MM-302	5,148	3,736	10,407	8,675
MM-121	5,561	1,432	10,039	3,626
MM-141	1,882	3,276	4,226	6,909
MM-151	1,094	1,246	1,823	2,434
Companion therapeutics program	1,402	564	2,591	778
Preclinical, general research and discovery	10,806	14,640	22,952	27,198
Stock-based compensation	1,803	2,369	3,672	4,338
Total research and development expenses	$40,996	$42,806	$73,878	$78,485

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

ONIVYDE

We have received FDA and TFDA approvals of 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 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 $10.0 million and $11.1 million during the three months ended June 30, 2016 and 2015, respectively, and $10.1 million and $11.3 million for the six months ended June 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 September 2009, we entered into a license and collaboration agreement with Sanofi related to the development and commercialization of MM-121. On June 17, 2014, we agreed with Sanofi that such agreement would terminate effective December 17, 2014. Under the terms of the agreement, we were responsible for executing clinical trials through the development period that ended December 17, 2014. We separately recorded revenue and expenses on a gross basis under this arrangement. Sanofi remained responsible for all development and manufacturing costs of MM-121 through December 17, 2014, subsequent to which we became fully responsible for development and manufacturing costs of MM-121.

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

In May 2016, we announced the initiation of a biomarker-directed, multi-arm Phase 1 clinical trial in patients with metastatic colorectal, non-small cell lung, and head and neck cancers. The trial will evaluate the safety and tolerability of MM-151 in combination with MM-121 in patients with heregulin positive tumors, MM-151 in combination with MM-141 in patients with IGF-1-positive tumors, and MM-151 in combination with a MEK inhibitor (trametinib) in patients with 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 or increase selling, general and administrative expense in future periods as a result of increased payroll, expanded infrastructure, increased consulting, legal, accounting and investor relations expenses and costs incurred to develop and commercialize our clinical products.

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. This loss on extinguishment was recorded as a component of interest expense for the three and six months ended June 30, 2016. 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. We expect that interest expense will decrease in subsequent periods 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 June 30, 2016 and 2015

	Three Months Ended June 30,	
(in thousands)	2016	2015
Product revenues, net	$12,851	$—
License and collaboration revenues	19,332	36,558
Other revenues	1,498	—
Cost of revenues	(1,872)	—
Research and development expenses	(40,996)	(42,806)
Selling, general and administrative expenses	(20,680)	(12,315)
Loss from operations	(29,867)	