TESARO, Inc.
Form 10-Q
November 04, 2016
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

OR

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

For the transition period from to

Commission file number 001-35587

TESARO, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation or Organization)	27-2249687 (I.R.S. Employer Identification No.)
1000 Winter Street, Suite 3300 Waltham, Massachusetts (Address of Principal Executive Offices)	02451 (Zip Code)

(339) 970-0900

(Registrant's Telephone Number, Including Area Code)

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

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

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

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

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

As of October 31, 2016, there were 51,662,407 shares of the registrant's Common Stock, par value $0.0001 per share, outstanding.

Table of Contents

TESARO, INC.

FORM 10-Q
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2016

TABLE OF CONTENTS

CERTIFICATIONS

Table of Contents

PART IFINANCIAL INFORMATION

Item 1. Financial Statements.

TESARO, INC.

Condensed Consolidated Balance Sheets

(all amounts in 000's, except share and per share data)

(Unaudited)

	December 31, 2015	September 30, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 230,146	$ 647,315
Accounts receivable	679	3,214
Inventories	1,106	12,163
Other current assets	4,560	7,409
Total current assets	236,491	670,101
Intangible assets, net	14,732	13,341
Property and equipment, net	2,779	3,781
Restricted cash	500	620
Other assets	779	1,751
Total assets	$ 255,281	$ 689,594
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 8,019	$ 3,264
Accrued expenses	36,628	53,135
Deferred revenue, current	500	772
Other current liabilities	1,534	670
Total current liabilities	46,681	57,841
Convertible notes, net	121,325	129,017
Deferred revenue, non-current	288	—
Other non-current liabilities	113	515
Total liabilities	168,407	187,373

Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at both December 31, 2015 and September 30, 2016; no shares issued or outstanding at both December 31, 2015 and September 30, 2016	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at both December 31, 2015 and September 30, 2016; 40,279,783 and 51,656,692 shares issued and outstanding at December 31, 2015 and September 30, 2016, respectively	4	5
Additional paid-in capital	688,788	1,356,040
Accumulated other comprehensive loss	—	(98)
Accumulated deficit	(601,918)	(853,726)
Total stockholders' equity	86,874	502,221
Total liabilities and stockholders' equity	$ 255,281	$ 689,594

See accompanying notes to condensed consolidated financial statements.

Table of Contents

TESARO, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(all amounts in 000's, except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2016	2015	2016
Revenues:				
Product revenue, net	$ —	$ 2,799	$ —	$ 4,408
License, collaboration, and other revenues	87	931	87	36,190
Total revenues	87	3,730	87	40,598
Expenses:				
Cost of sales – product	—	424	—	738
Cost of sales – intangible asset amortization	—	464	—	1,391
Research and development	40,063	60,783	112,538	163,630
Selling, general and administrative	22,766	37,685	50,791	104,052
Acquired in-process research and development	—	1,940	1,000	9,940
Total expenses	62,829	101,296	164,329	279,751
Loss from operations	(62,742)	(97,566)	(164,242)	(239,153)
Interest expense	(3,853)	(4,119)	(11,432)	(12,220)
Interest income	9	532	25	843
Net loss	$ (66,586)	$ (101,153)	$ (175,649)	$ (250,530)
Net loss per share applicable to common stockholders - basic and diluted	$ (1.66)	$ (1.98)	$ (4.49)	$ (5.45)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	40,038	51,151	39,129	45,994
Comprehensive loss:				
Net loss	$ (66,586)	$ (101,153)	$ (175,649)	$ (250,530)
Other comprehensive income/(loss):				
Unrealized gain/(loss) on pension obligation	—	—	—	(98)
Other comprehensive income/(loss)	—	—	—	(98)
Comprehensive loss	$ (66,586)	$ (101,153)	$ (175,649)	$ (250,628)

See accompanying notes to condensed consolidated financial statements.

Table of Contents

TESARO, INC.

Condensed Consolidated Statements of Cash Flows

(all amounts in 000's)

(Unaudited)

	Nine Months Ended September 30,	
	2015	2016
Operating activities		
Net loss	$ (175,649)	$ (250,530)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	1,000	9,940
Depreciation and amortization expense	437	2,254
Stock-based compensation expense	17,510	34,064
Non-cash interest expense	6,888	7,692
Changes in operating assets and liabilities:		
Accounts receivable	(1,105)	(2,535)
Inventories	(476)	(11,057)
Other assets	(2,683)	(4,512)
Accounts payable	(509)	(4,766)
Accrued expenses	16,642	15,698
Deferred revenues	913	(16)
Other liabilities	1,535	(728)
Net cash used in operating activities	(135,497)	(204,496)
Investing activities		
Acquisition of product candidate and technology licenses and milestone payments	(1,000)	(9,000)
Purchase of property and equipment	(1,869)	(1,820)
Change in restricted cash	—	(120)
Net cash used in investing activities	(2,869)	(10,940)
Financing activities		
Proceeds from sales of common stock, net of issuance costs	179,753	613,913
Proceeds from exercise of stock options	4,223	17,652
Proceeds from issuance of common stock under Employee Stock Purchase Plan	248	1,040
Payment of minimum tax withholdings on share-based awards	(201)	—
Net cash provided by financing activities	184,023	632,605
Increase in cash and cash equivalents	45,657	417,169

Cash and cash equivalents at beginning of period	256,861	230,146
Cash and cash equivalents at end of period	$ 302,518	$ 647,315
Non-cash investing and financing activities		
Purchase of property and equipment - cash not paid as of period end	$ 118	$ 115
Acquired in-process research and development - milestone not paid as of period end	$ —	$ 940
Supplemental cash flow information		
Interest paid	$ 3,052	$ 6,038

See accompanying notes to condensed consolidated financial statements.

Table of Contents

TESARO, INC.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Description of Business

TESARO, Inc., or the Company or TESARO, was incorporated in Delaware on March 26, 2010 and commenced operations in May 2010. Headquartered in Waltham, Massachusetts, TESARO is an oncology-focused biopharmaceutical company dedicated to improving the lives of cancer patients. TESARO acquires, in-licenses, develops, and commercializes oncology products and product candidates. Since incorporation, primary activities have consisted of acquiring product candidates, advancing development of these product candidates, developing intellectual property, recruiting personnel and raising capital. As part of its business strategy, the Company intends to continue to in-license or acquire additional product candidates across various stages of development. The Company operates in one segment. The Company is subject to a number of risks, including dependence on key individuals, regulatory and manufacturing risks, risk associated with competitors, the need to develop additional commercially viable products, competition from other companies, many of which are larger and better capitalized, and the need to obtain adequate additional financing to fund the development and potential commercialization of its product candidates and further its in-licensing and acquisition activities.

On September 1, 2015, the Company's first commercial product, VARUBI® (rolapitant), was approved by the United States Food and Drug Administration, or FDA, in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. The Company commenced sales of VARUBI during the fourth quarter of 2015. In March 2016, the Company submitted a new drug application, or NDA, for intravenous rolapitant to the FDA which was accepted for review in May 2016, with a target Prescription Drug User Fee Act, or PDUFA, date of January 11, 2017. The Company also submitted a Marketing Authorization Application, or MAA, for oral rolapitant to the European Medicines Agency, or EMA, in March 2016, which the EMA has accepted for review.

In October 2016, the Company submitted an NDA to the FDA, and an MAA to the EMA, for its product candidate niraparib, for the maintenance treatment of recurrent platinum-sensitive ovarian, fallopian tube, or primary peritoneal cancer. The EMA has accepted the MAA for review.

The Company has incurred significant operating losses since inception and has relied on its ability to fund its operations through private and public equity and debt financings. Management expects operating losses and negative

operating cash flows to continue for the foreseeable future. As the Company continues to incur losses, the transition to profitability is dependent upon the successful development, approval, and commercialization of its products and product candidates and the achievement of a level of revenues adequate to support its cost structure. The Company may never achieve profitability, and, unless and until it does, the Company will continue to need to raise additional capital. On March 18, 2016, the Company closed a private placement of its common stock with certain accredited investors, whereby an aggregate of 4,404,658 shares of common stock were issued at a price per share of $35.19 for aggregate gross proceeds of approximately $155.0 million. On April 5, 2016, the Company closed a private placement of 1,130,198 shares of its common stock with one accredited investor for gross proceeds of approximately $50.0 million. On July 7, 2016, the Company closed a follow-on public offering, whereby it issued an aggregate of 5,347,500 shares of its common stock at a price per share of $81.00, resulting in net proceeds of approximately $408.9 million. Management intends to fund future operations in part through the proceeds from these financings and additional public or private equity or debt offerings and may seek additional capital through arrangements with strategic partners or from other sources.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements are unaudited and have been prepared by TESARO in conformity with accounting principles generally accepted in the United States of America, or GAAP.

Table of Contents

The Company's condensed consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. The Company currently operates in one business segment, which is the identification, acquisition, development and commercialization of oncology therapeutics and supportive care product candidates, and has a single reporting and operating unit structure.

Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. These interim financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the Company's financial position and results of operations for the interim periods ended September 30, 2015 and 2016.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full fiscal year. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2015 and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, other comprehensive income and the related disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to sales of its approved product, accrued clinical trial and manufacturing development expenses, which form part of the Company's research and development expenses, and stock-based compensation expense. Significant estimates in these condensed consolidated financial statements include estimates made in connection with accrued research and development expenses, stock-based compensation expense, product revenue, license, collaboration, and other revenue, and valuation of convertible notes, inventory and intangible assets. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Cash and Cash Equivalents

The Company considers all highly-liquid investments with original or remaining maturity from the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include bank demand deposits and money market funds that invest primarily in certificates of deposit, commercial paper and U.S. government and U.S. government agency obligations. Cash equivalents are reported at fair value.

Fair Value of Financial Instruments

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. The fair value hierarchy prioritizes valuation inputs based on the observable nature of those inputs. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of investment credit quality. The hierarchy defines three levels of valuation inputs:

Level 1 inputsQuoted prices in active markets for identical assets or liabilities

Level 2 inputsObservable inputs other than Level 1 inputs, including quoted prices in active markets for similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active

Level 3 inputsUnobservable inputs that reflect the Company’s own assumptions about the assumptions market participants would use in pricing the asset or liability

Table of Contents

The following table presents information about the Company's financial assets and liabilities that have been measured at fair value as of December 31, 2015 and September 30, 2016 and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

		December 31, 2015			
Description	Balance Sheet Classification	Total	Level 1	Level 2	Level 3
Assets:					
Money market funds	Cash and cash equivalents	$ 224,885	$ 224,885	$ —	$ —
Total assets		$ 224,885	$ 224,885	$ —	$ —

		September 30, 2016			
Description	Balance Sheet Classification	Total	Level 1	Level 2	Level 3
Assets:					
Money market funds	Cash and cash equivalents	$ 635,007	$ 635,007	$ —	$ —
Total assets		$ 635,007	$ 635,007	$ —	$ —

The carrying amounts of accounts payable and accrued expenses approximate their fair values due to their short-term maturities.

In September 2014, the Company issued $201.3 million aggregate principal amount of 3.00% convertible senior notes due October 1, 2021, or the Convertible Notes. Interest is payable semi-annually in arrears on April 1 and October 1 of each year, beginning on April 1, 2015. As of September 30, 2016, the carrying value of the Convertible Notes, net of unamortized discount and debt issuance costs, was $129.0 million and the estimated fair value of the principal amount was $588.7 million. The Convertible Notes are discussed in more detail in Note 5, "Convertible Notes."

Revenue Recognition

Product Revenue

Revenues from product sales are recognized when persuasive evidence of an arrangement exists, delivery has occurred and title to the product and associated risk of loss has passed to the customer, the price is fixed or determinable,

collection from the customer has been reasonably assured, all performance obligations have been met, and returns and allowances can be reasonably estimated. Product revenues are recorded net of estimated rebates, chargebacks, discounts, co-pay assistance and other deductions as well as estimated product returns. Allowances are recorded as a reduction of revenue at the time product revenues are recognized.

VARUBI is currently distributed in the U.S. principally through a limited number of specialty distributors and to a lesser extent though the specialty pharmacy channel, or collectively, Customers. Customers subsequently resell VARUBI to health care providers and patients.

In addition to distribution agreements with Customers, the Company has entered into arrangements with many health care providers and payers that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of VARUBI.

The Company has determined that it does not yet meet the criteria for the recognition of revenue for shipments of VARUBI at the time of shipment to its specialty pharmacy and specialty distributor customers. For shipments of VARUBI from specialty distributors and from specialty pharmacies to providers and patients through September 30, 2016, allowances for rebates, chargebacks, discounts, co-pay assistance and other deductions are known or are estimable because they are based on the actual invoice information, claims data, or other market information and analyses. As a result, the Company has concluded that it can recognize revenue related to such shipments. For units that remained in distribution channel inventories as of September 30, 2016, the Company continues to conclude that it cannot yet reasonably make certain estimates necessary to recognize revenue on such shipments.

During the three and nine months ended September 30, 2016, the Company recognized $2.8 million and $4.4 million in net product revenues, respectively, related to VARUBI sales. No net product revenue was recorded for the

Table of Contents

three and nine months ended September 30, 2015.

Payments received from Customers in advance of recognition of revenue are recorded as deferred revenue, net of payments made to Customers, providers and payers, on the condensed consolidated balance sheets. The related deferred revenue balance (current) as of September 30, 2016 was $0.4 million. No such amounts were recorded as of December 31, 2015.

License, Collaboration and Other Revenue

Revenues from license arrangements are recognized when persuasive evidence of an arrangement exists, delivery of goods or services has occurred including title to the product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer has been reasonably assured, all performance obligations have been met, and any associated reductions of revenue can be reasonably estimated. The Company licenses certain rights to its product candidates to third parties. Activities under licensing agreements are evaluated to determine if they represent a multiple element arrangement. The Company identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting. The Company accounts for those components as separate units of accounting if the following two criteria are met:

- the delivered item or items have stand-alone value to the customer; and

- delivery or performance of the undelivered item(s) is considered probable and substantially in the control of the Company, and the arrangement includes a general right of return relative to the delivered item(s).

Factors considered in this determination include, among other things, whether any other vendors sell the items separately and if the licensee could use the delivered item for its intended purpose without the receipt of the remaining deliverables. The consideration that is fixed or determinable is allocated to the separate units of accounting based on the relative selling prices of each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods and services are delivered. The amount allocable to the delivered units of accounting is limited to the amount that is not contingent upon the delivery of additional items or meeting other specified performance conditions.

The Company determines the selling price on the basis of vendor-specific objective evidence, or VSOE, third party evidence, or best estimate of selling price. VSOE is the price charged for a deliverable when it is sold separately. Third party evidence is the price that the Company or vendors charge for a similar deliverable when sold separately. Best estimate is the price at which the Company would sell the deliverable if the deliverable were sold by the Company regularly on a stand-alone basis.

When multiple deliverables are combined and accounted for as a single unit of accounting, the Company bases its revenue recognition on the last element to be delivered using the straight-line or proportional performance method depending on the Company's ability to estimate the timing of the delivery of the performance obligation. Amounts received or recorded as receivable prior to satisfying the associated revenue recognition criteria are recorded as deferred revenue in the condensed consolidated balance sheets. Amounts not expected to be recognized within one year following the balance sheet date are classified as non-current deferred revenue.

If a future milestone payment under a license agreement is contingent upon the achievement of a substantive milestone, license revenue is recognized in its entirety in the period in which the milestone is achieved. Nonsubstantive milestone payments that are paid based on the passage of time or as a result of the licensee's performance are allocated to the units of accounting within the arrangement and recognized as revenue when those deliverables are satisfied. A milestone is substantive if:

- it can only be achieved based in whole or in part on either the Company's performance or the occurrence of a specific outcome resulting from the Company's performance;

- there is substantive uncertainty at the date an arrangement is entered into that the event will be achieved; and

- it would result in additional payments being due to the Company.

Table of Contents

Commercial milestone and royalty payments received under license agreements will be recognized as license revenue when they are earned.

In July 2015, the Company entered into a license agreement with Jiangsu Hengrui Medicine Co., Ltd., or Hengrui, pursuant to which Hengrui has licensed rights to develop, manufacture and commercialize rolapitant in China, including Hong Kong and Macao. For this arrangement, the Company has determined that there is only one unit of accounting that includes the licensed patents and the licensed know-how, which will be delivered over a period of time. The Company recorded $0.1 and $0.4 million of license revenue related to a $1.0 million up-front payment under this arrangement during the three and nine months ended September 30, 2016, respectively, and recorded $0.4 million as deferred revenue as of September 30, 2016. This $1.0 million payment is being recognized as license revenue over the two-year period of performance relating to the Company's obligations to provide the licensed know-how to Hengrui. Under the terms of the agreement, the Company would be entitled to additional payments of up to $2.0 million contingent on the achievement of certain regulatory milestones, as well as royalties on product sales at percentage rates in the low teens.

In April 2016, the Company entered into a collaboration and license agreement with Janssen Biotech, Inc., or Janssen, under which the Company granted Janssen licenses under certain patent rights and know-how relating to niraparib, for prostate cancer worldwide. See Note 11, "License and Collaboration Arrangements", for further discussion.

In September 2016, the Company entered into a collaboration, development and license agreement with Zai Lab (Shanghai) Co., Ltd., or Zai Lab, under which the Company granted Zai Lab an exclusive license to develop and commercialize niraparib in China, including Hong Kong and Macao. In addition, the agreement provides the Company with certain negotiation rights with respect to two immuno-oncology assets being developed by Zai Lab, and in return for certain consideration, an option for the Company to co-market niraparib in greater China with Zai Lab. See Note 11, "License and Collaboration Arrangements", for further discussion.

Research and Development Expenses

Research and development costs are charged to expense as incurred and include:

- pre-commercial license fees and milestone payments related to the acquisition of in-licensed product candidates, which are reported on the statements of operations as acquired in-process research and development;

- employee-related expenses, including salaries, bonuses, benefits, travel and stock-based compensation expense;

- fees and expenses incurred under agreements with contract research organizations, investigative sites, research consortia and other entities in connection with the conduct of clinical trials and preclinical studies and related services, such as data management, laboratory and biostatistics services;

- the cost of acquiring, developing and manufacturing active pharmaceutical ingredients for product candidates that have not received regulatory approval, clinical trial materials and other research and development materials;

- fees and costs related to regulatory filings and activities;

- facilities, depreciation and other expenses, which include direct and allocated expenses for rent, utilities, maintenance of facilities, insurance and other supplies; and

- other costs associated with clinical, preclinical, discovery and other research activities.

Costs for certain development activities, such as clinical trials and manufacturing development activities, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors on their actual costs incurred or level of effort expended. Payments for these activities are based on the terms of the individual arrangements, which may differ from

Table of Contents

the pattern of costs incurred, and are reflected in the condensed consolidated balance sheets as prepaid or accrued research and development expenses. Certain clinical development costs incurred by the Company with respect to its niraparib program are reimbursed as part of a collaborative research agreement with Merck. Cost-sharing amounts received by the Company are recorded as a reduction to research and development expenses.

Acquired In-Process Research and Development Expense

The Company has acquired the rights to develop and commercialize new product candidates. Up-front payments that relate to the acquisition of a new drug compound, as well as pre-commercial milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the new drug compound did not also include processes or activities that would constitute a “business” as defined under GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use. Milestone payments made to third parties subsequent to regulatory approval are capitalized as intangible assets and amortized over the estimated remaining useful life of the related product. Royalties owed on sales of the products licensed pursuant to the agreements are expensed in the period the related revenues are recognized.

Intangible Assets

The Company maintains definite-lived intangible assets related to certain capitalized milestones. These assets are amortized on a straight-line basis over their remaining useful lives, which are estimated to be the remaining patent life. If the Company’s estimate of the product’s useful life is shorter than the remaining patent life, then the shorter period is used. Amortization expense is recorded as a component of cost of sales in the consolidated statements of operations.

The Company assesses its intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding one of the Company’s drug candidates or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate or new information regarding potential sales for the drug. If impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would determine the fair value of the intangible asset and recognize an impairment loss if the carrying value of the intangible asset exceeds its fair value.

Stock-Based Compensation Expense

Stock-based compensation is recognized as expense for each stock-based award based on its estimated fair value. The Company determines the fair value of each stock option award at its grant date using the Black-Scholes option pricing model. The Company determines the fair value of each restricted stock unit at its grant date based on the closing market price of the Company's common stock on that date. The value of the award is recognized as expense on a straight-line basis over the requisite service period and is adjusted for pre-vesting forfeitures in the period in which the forfeitures occur. For stock awards that have a performance condition, the Company recognizes compensation expense based on its assessment of the probability that the performance condition will be achieved, using an accelerated attribution model, over the explicit or implicit service period.

Inventory

Inventories are stated at the lower of cost or estimated net realizable value, on a first-in, first-out, or FIFO, basis.

Prior to the regulatory approval of its product candidates, the Company incurs expenses for the manufacture of drug product that could potentially be available to support the commercial launch of its products. Until the first reporting period when regulatory approval has been received or is otherwise considered probable, the Company records all such costs as research and development expense. The Company periodically analyzes its inventory levels, and writes down inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value and inventory in excess of expected sales requirements as cost of product sales. The determination of whether inventory

Table of Contents

costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required, which would be recorded as a cost of product sales in the consolidated statements of operations.

New Accounting Pronouncements - Recently Adopted

In June 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-12. The amendments in this ASU apply to reporting entities that grant their employees share-based payments in which the terms of the award provide that a performance target can be achieved after a requisite service period. The amendments require an entity to treat a performance target that affects vesting, and that could be achieved after the requisite service period, as a performance condition. A reporting entity should apply existing guidance in Accounting Standards Codification, or ASC, or Topic 718 relating to awards with performance conditions that affect vesting to account for such awards. The performance target should not be reflected in estimating the grant-date fair value of the award. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. The amendments in this ASU are effective for annual reporting periods and interim periods within those annual reporting periods beginning after December 15, 2015, and early adoption is permitted. The Company adopted this ASU on January 1, 2016, and the adoption of this guidance did not have an impact on the Company’s consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-05, which provides guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. The guidance will not change GAAP for a customer’s accounting for service contracts. ASU No. 2015-05 is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2015. Early adoption is permitted. An entity can elect to adopt the amendments either (1) prospectively to all arrangements entered into or materially modified after the effective date, or (2) retrospectively. For prospective transition, the only disclosure requirements at transition are the nature of and reason for the change in accounting principle, the transition method, and a qualitative description of the financial statement line items affected by the change. For retrospective transition, the disclosure requirements at transition include the requirements for prospective transition and quantitative information about the effects of the accounting change. The Company adopted this ASU prospectively on January 1, 2016 and the adoption of this guidance did not have a material impact on the Company’s consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, which simplifies various aspects of accounting for share-based payments to employees. Key provisions of the new standard include requiring excess tax benefits and shortfalls to be recorded as income tax benefit or expense in the income statement, rather than in equity, and permitting an election to record the impact of pre-vesting forfeitures as they occur. The new guidance is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years, with early adoption permitted. The Company elected to early adopt ASU No. 2016-09 during the quarter ended June 30, 2016, retroactive to January 1, 2016.

Impact of Adoption

As a result of adopting ASU No. 2016-09 during 2016, the Company adjusted retained earnings for the impact of its accounting policy election to recognize share-based award forfeitures only as they occur rather than by applying an estimated forfeiture rate as previously required. ASU No. 2016-09 requires that this change be applied using a modified-retrospective transition method by means of a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year in which the guidance is adopted. The following table summarizes the impact to the Company's condensed consolidated balance sheet, including the amount charged to retained earnings as of January 1, 2016 (in thousands):

	Balance Sheet Classification	Amount
Increase to additional paid-in capital resulting from the Company's election to recognize forfeitures as they occur rather than applying an estimated forfeiture rate	Additional paid-in capital	$ 1,278
Charge to accumulated deficit for cumulative-effect adjustment from adoption of ASU No. 2016-09	Accumulated deficit	$ 1,278

Table of Contents

In addition, the Company's stock-based compensation expense for the three months ended March 31, 2016 and additional-paid in capital as of March 31, 2016 have also been revised to reflect the adoption of ASU No. 2016-09, resulting in increases of approximately $0.2 million to both additional paid-in capital and accumulated deficit, compared to the amounts originally reported.

New Accounting Pronouncements - Recently Issued

In May 2014, the FASB issued ASU No. 2014-09, which amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in ASC Topic 605, Revenue Recognition, and creates a new Topic 606, Revenue from Contracts with Customers. Two adoption methods are permitted: retrospectively to all prior reporting periods presented, with certain practical expedients permitted; or retrospectively with the cumulative effect of initially adopting the ASU recognized at the date of initial application. In August 2015, the FASB issued ASU No. 2015-14, which defers the effective date by one year to December 15, 2017 for annual reporting periods beginning after that date, including interim periods within those periods. The FASB also approved permitting early adoption of the standard, but not before the original effective date of December 15, 2016. In 2016, the FASB has issued three additional ASUs related to Topic 606: ASU Nos. 2016-08, 2016-10, and 2016-12. These ASUs clarify various aspects of the new revenue guidance, including principal versus agent considerations, identifying performance obligations, and licensing, and include other improvements and practical expedients. The Company plans to early adopt the requirements of this new standard in the first quarter of 2017, using the full retrospective transition method. The Company has not yet completed its assessment of the impact of the adoption of this standard on its consolidated financial statements, but expects that the adoption will at least impact the amount and timing of certain revenues recognized through the periods prior to adoption, and the impact may be material to certain periods.

In August 2014, the FASB issued ASU No. 2014-15, which is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or are available to be issued). ASU No. 2014-15 provides guidance to an organization's management, with principles and definitions intended to reduce diversity in the timing and content of disclosures commonly provided by organizations in the footnotes of their financial statements. ASU No. 2014-15 is effective for annual reporting periods ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. The Company has not yet adopted this standard; however, if this standard had been adopted as of September 30, 2016, the Company believes that it would have concluded there was not substantial doubt about its ability to continue as a going concern.

In July 2015, the FASB issued ASU No. 2015-11, which amends existing guidance for measurement of inventory. Current inventory guidance requires an entity to measure inventory at the lower of cost or market. Market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. The amendments do not apply to inventory that is measured using last-in, first-out (LIFO) or the retail

inventory method. The amendments apply to all other inventory, which includes inventory that is measured using first-in, first-out or average cost. An entity should measure all inventory to which the amendments apply at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. The amendments in this ASU more closely align the measurement of inventory in GAAP with the measurement of inventory in International Financial Reporting Standards. The amendments are effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017. The amendments should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company is currently in the process of evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, a comprehensive new lease accounting standard, which provides revised guidance on accounting for lease arrangements by both lessors and lessees and requires lessees to recognize a lease liability and a right-of-use asset for most leases. The new guidance is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with early adoption permitted. The new standard must be applied using a modified retrospective transition method which requires application of the new guidance for all periods presented. The Company is currently in the process of evaluating the impact that the adoption of

Table of Contents

this guidance will have on its consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, which is intended to simplify and clarify how certain transactions are classified in the statement of cash flows, and to reduce diversity in practice for such transactions. This ASU addresses eight specific issues regarding classification of cash flows. The standard is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, provided that all of the amendments are adopted in the same period. The guidance requires application using a retrospective transition method. The Company believes that the adoption of this guidance will not have a significant impact on its consolidated financial statements and related disclosures.

3. Net Loss per Share

Basic and diluted net loss per common share is calculated by dividing net loss applicable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. The Company's potentially dilutive shares, which include outstanding stock options, unvested restricted stock units, and shares issuable upon conversion of the Convertible Notes, 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.

The following table presents amounts that were excluded from the calculation of diluted net loss per share, due to their anti-dilutive effect (in thousands):

	Three and Nine Months Ended September 30,	
	2015	2016
Outstanding stock options	6,044	7,045
Unvested restricted stock units	—	666
Shares issuable upon conversion of Convertible Notes	663	—
	6,707	7,711

In September 2014, the Company issued Convertible Notes, which provide in certain situations for the conversion of the outstanding principal amount of the Convertible Notes into shares of the Company's common stock at a predefined conversion rate. See Note 5, "Convertible Notes", for additional information. In conjunction with the issuance of the Convertible Notes, the Company entered into capped call option transactions, or Capped Calls, with certain

counterparties. The Capped Calls are expected generally to reduce the potential dilution, and/or offset, to an extent, the cash payments the Company may choose to make in excess of the principal amount, upon conversion of the Convertible Notes.

As provided by the terms of the indenture underlying the Convertible Notes, the Company has a choice to settle the conversion obligation for the Convertible Notes in cash, shares or any combination of the two. The Company currently intends to settle the par value of the Convertible Notes in cash and any excess conversion premium in shares. Accordingly, the par value of the Convertible Notes will not be included in the calculation of diluted net income per share, but the dilutive effect of the conversion premium will be considered in the calculation of diluted net income per share using the treasury stock method. The share figures in the table above represent the estimated incremental shares that would be issued, after consideration of the Capped Calls, assuming conversion of all of the outstanding Convertible Notes as of September 30, 2015 and 2016. The Convertible Notes were not convertible as of September 30, 2016.

4. Inventories

The following table presents inventories as of December 31, 2015 and September 30, 2016 (in thousands):

	December 31, 2015	September 30, 2016
Raw materials	$ 364	$ 10,602
Work in process	83	560
Finished goods	659	1,001
Total inventories	$ 1,106	$ 12,163

Table of Contents

5. Convertible Notes

On September 29, 2014, in a registered underwritten public offering, the Company completed the issuance of $201.3 million aggregate principal amount of Convertible Notes. In conjunction with the sale of the Convertible Notes, the Company used $20.8 million of the net proceeds to enter into separate Capped Calls.

The Convertible Notes bear interest at a rate of 3.00% per annum, payable semi-annually on April 1 and October 1, and will be convertible into cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election. The Convertible Notes will mature on October 1, 2021, unless earlier converted or repurchased in accordance with their terms. Prior to the close of business on the business day immediately preceding April 1, 2021, the Convertible Notes will be convertible only upon the occurrence of certain events and during certain periods as discussed below, and thereafter, at any time until the close of business on the second scheduled trading day immediately preceding the maturity date. The initial conversion price of the Convertible Notes is approximately $35.13 per share of common stock at an initial conversion rate of 28.4627 shares of the Company's common stock per $1,000 principal amount of Convertible Notes.

The conversion rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the issuance of stock dividends and payment of cash dividends. At any time prior to the close of business on the business day immediately preceding April 1, 2021, holders may convert their Convertible Notes at their option only under the following circumstances:

(1) during any calendar quarter commencing after the calendar quarter ending on December 31, 2014 (and only during such calendar quarter), if the closing 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 in which the conversion occurs is greater than 130% of the conversion price on each applicable trading day;

(2) during the five business day period after any ten consecutive trading day period, or the measurement period, in which the trading price per $1,000 principal amount of the Convertible Notes for each trading day of the measurement period was less than 98% of the product of the closing sale price of the Company's common stock and the conversion rate on each such trading day; or

(3) upon the occurrence of specified corporate events.

As of September 30, 2016, the carrying value of the Convertible Notes, net of unamortized discount and debt issuance costs, was $129.0 million and the estimated fair value of the principal amount was $588.7 million. As provided by

the terms of the indenture underlying the Convertible Notes, the Company has a choice to settle the conversion obligation for the Convertible Notes in cash, shares or any combination of the two. The Company currently intends to settle the par value of the Convertible Notes in cash and any excess conversion premium in shares.

The following table sets forth total interest expense recognized related to the Convertible Notes during the three and nine months ended September 30, 2015 and 2016 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2016	2015	2016
Contractual interest expense	$ 1,509	$ 1,509	$ 4,544	$ 4,528
Amortization of debt discount	2,178	2,460	6,383	7,236
Amortization of debt issuance costs	166	150	505	456
Total interest expense	$ 3,853	$ 4,119	$ 11,432	$ 12,220

Table of Contents

6. Stock-Based Compensation

The Company maintains several equity compensation plans, including the TESARO, Inc. 2012 Omnibus Incentive Plan, or the 2012 Incentive Plan, the TESARO, Inc. 2010 Stock Incentive Plan, or the 2010 Incentive Plan, the TESARO, Inc. 2015 Non-Employee Director Stock Incentive Plan, or the 2015 Director Plan, and the TESARO, Inc. 2012 Employee Stock Purchase Plan, or the 2012 ESPP.

On April 27, 2012, the stockholders of the Company approved the 2012 Incentive Plan, which had been previously adopted by the board of directors. Upon effectiveness of the 2012 Incentive Plan, the Company ceased making awards under the 2010 Incentive Plan. The 2012 Incentive Plan initially allowed the Company to grant awards for up to 1,428,571 shares of common stock plus the number of shares of common stock available for grant under the 2010 Incentive Plan as of the effectiveness of the 2012 Incentive Plan (an additional 6,857 shares) plus the number of shares of common stock related to awards outstanding under the 2010 Incentive Plan that terminate by expiration, forfeiture, cancellation, cash settlement or otherwise. In addition, each year starting in 2014, the number of shares available for grants of awards under the 2012 Incentive Plan is increased automatically on January 1 by a number of shares of common stock equal to the lesser of 4% of the shares of common stock outstanding at such time or the number of shares determined by the Company's board of directors. Most recently, on January 1, 2015 and 2016, the number of shares authorized for issuance under the 2012 Incentive Plan was increased by 1,444,403 shares and 1,611,191 shares, respectively. On May 14, 2015, the stockholders of the Company approved an increase of 2,000,000 shares of common stock available for grant under the 2012 Incentive Plan. Awards under the 2012 Incentive Plan may include the following award types: stock options, which may be either incentive stock options or nonqualified stock options; stock appreciation rights; restricted stock; restricted stock units; dividend equivalent rights; performance shares; performance units; cash-based awards; other stock-based awards, including unrestricted shares; or any combination of the foregoing. The exercise price of stock options granted under the 2012 Incentive Plan is equal to the closing price of a share of the Company's common stock on the grant date.

On May 14, 2015, the stockholders of the Company approved the 2015 Director Plan, which had been previously adopted by the board of directors in order to have a plan in addition to the 2012 Incentive Plan for purposes of granting awards to non-employee directors. The 2015 Director Plan allows the Company to grant awards for up to 500,000 shares of common stock. Awards under the 2015 Director Plan may include the following award types: stock options; stock appreciation rights; restricted stock; restricted stock units; unrestricted stock; or any combination of the foregoing. The exercise price of stock options granted under the 2015 Director Plan is equal to the closing price of a share of the Company's common stock on the grant date. On May 11, 2016, the Company's stockholders approved an amendment to the 2015 Director Plan that limits the maximum number of shares of stock subject to awards granted in any calendar year to any non-employee director of the Company to 50,000 shares and affirms that 500,000 shares are reserved for issuance under the 2015 Director Plan.

Effective January 1, 2016, the Company adopted ASU No. 2016-09. Upon adoption of ASU No. 2016-09, the Company made an accounting policy election to account for the impact of pre-vesting forfeitures as they occur rather than by applying an estimated forfeiture rate, as previously required. See Note 2, "Basis of Presentation and Significant Accounting Policies", for more details regarding the adoption of ASU No. 2016-09.

Stock-based compensation expense as reflected in the Company's condensed consolidated statements of operations and comprehensive loss was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2016	2015	2016
Research and development	$ 3,783	$ 5,605	$ 7,808	$ 13,826
Selling, general and administrative	4,346	7,314	9,702	20,238
Total stock-based compensation expense	$ 8,129	$ 12,919	$ 17,510	$ 34,064

Table of Contents

Stock Options

The following table presents a summary of the Company's stock option activity and related information:

	Shares	Weighted-average exercise price per share
Outstanding at December 31, 2015	5,878,352	$ 35.00
Granted	1,845,551	52.89
Exercised	(448,301)	37.83
Cancelled	(230,233)	51.54
Outstanding at September 30, 2016	7,045,369	$ 38.96
Vested at September 30, 2016	3,164,911	$ 24.38

At September 30, 2016, there was approximately $108.7 million of total unrecognized compensation cost related to unvested stock options, which the Company expects to recognize over a remaining weighted-average period of 2.8 years.

Restricted Stock Units

The following table presents a summary of the Company's restricted stock unit, or RSU, activity and related information:

	Shares	Weighted-average grant date fair value per share
Unvested restricted stock units at December 31, 2015	60,000	$ 56.00
Granted	638,673	49.64
Vested	(15,000)	56.00
Forfeited	(17,600)	43.39
Unvested restricted stock units at September 30, 2016	666,073	$ 50.23

At September 30, 2016, there was approximately $28.6 million of unrecognized compensation cost related to unvested RSUs, which the Company expects to recognize over a remaining weighted-average period of 3.4 years.

In July 2016, the Company issued 15,000 restricted stock units with service and performance conditions to certain employees, none of which vested during the three and nine months ended September 30, 2016. Vesting of these awards is contingent on the occurrence of certain milestone events and fulfillment of any remaining service condition. As a result, the related compensation cost is recognized as an expense when achievement of the milestone is considered probable. The Company recognized $0.2 million of related expense during the three and nine months ended September 30, 2016.

ESPP

Under the Company's 2012 ESPP, an aggregate of 275,000 shares of common stock have been reserved for issuance pursuant to purchase rights granted to the Company's employees or to employees of the Company's designated subsidiaries. As of September 30, 2016, 211,498 shares remained available for issuance. During the nine months ended September 30, 2015 and 2016, the Company issued 7,523 and 25,225 shares under the 2012 ESPP, and recognized approximately $0.2 million and $0.7 million in related stock-based compensation expense, respectively.

7. Common Stock Transactions

In March 2015, the Company sold 3,755,000 shares of common stock in an underwritten public offering at a price to the public of $51.00 per share, resulting in gross proceeds of approximately $191.5 million. Net proceeds to the Company after deducting fees, commissions and other expenses related to the offering were approximately $179.8 million. The shares were issued pursuant to an automatic shelf registration statement on Form S-3.

Table of Contents

In March 2016, the Company sold 4,404,658 shares of common stock in a private placement offering at a price of $35.19 per share, to certain accredited investors, including funds affiliated with three of its directors and current investors, resulting in gross proceeds of approximately $155.0 million. The price per share was equal to the volume weighted average price for the ten-day period ending on March 17, 2016. There were no placement agents used for this financing. The sale and issuance of the shares of common stock in the private placement was made in reliance on the exemption afforded by Section 4(a)(2) under the Securities Act of 1933 and Regulation D promulgated under the Securities Act.

In April 2016, the Company sold 1,130,198 shares of common stock to Johnson & Johnson Innovation – JJDC, Inc., or JJDC, at a price per share of $44.24, for an aggregate purchase price of approximately $50.0 million. The price per share was equal to the volume weighted average price for the five-day period ending on April 4, 2016. There were no placement agents used, or any underwriting discounts or commissions paid in connection with the transaction. The sale and issuance of the shares of common stock was made in reliance on the exemption afforded by Section 4(a)(2) under the Securities Act of 1933 and Regulation D promulgated under the Securities Act.

In July 2016, the Company sold 5,347,500 shares of common stock, which included 697,500 shares pursuant to the full exercise of the underwriters' option, in an underwritten public offering at a price to the public of $81.00 per share, resulting in gross proceeds of approximately $433.1 million. Net proceeds to the Company after deducting fees, commissions and other expenses related to the offering were approximately $408.9 million. The shares were issued pursuant to an automatic shelf registration statement on Form S-3.

8. Income Taxes

Deferred tax assets and deferred tax liabilities are determined based on temporary differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some portion or all of the deferred tax assets will not be realized.

For the three and nine months ended September 30, 2015 and 2016, the Company did not record any current or deferred income tax provisions or benefits. Due to the uncertainty surrounding the future realization of the favorable tax attributes, the Company has recorded full valuation allowances against its otherwise recognizable net deferred tax assets at both December 31, 2015 and September 30, 2016.

9. Intangible Assets

The following table presents intangible assets as of December 31, 2015 and September 30, 2016 (in thousands):

	December 31, 2015	September 30, 2016	Estimated useful life
Intangible asset - OPKO milestone	$ 15,000	$ 15,000	8 Years
Less accumulated amortization	(268)	(1,659)	
Total intangible asset, net	$ 14,732	$ 13,341	

For the three and nine months ended September 30, 2016, the Company recorded $0.5 million and $1.4 million in amortization expense related to this intangible asset, respectively. Estimated future amortization expense for intangible assets as of September 30, 2016 is $0.5 million for the remainder of 2016, $1.9 million per year for 2017, 2018, 2019, and 2020, and $5.5 million thereafter.

10. Commitments and Contingencies

The Company leases approximately 116,000 square feet of office space in Waltham, Massachusetts under a non-cancelable operating lease agreement. The term of the lease commenced on April 1, 2013. In August 2016, the lease was amended to extend the term through June 30, 2020 and to add 45,000 square feet to the Company’s existing space in the same building. The Company recognizes rental expense on a straight-line basis over the respective lease term including any free rent periods and tenant allowances.

Future minimum rental commitments under the lease as of September 30, 2016 were $0.8 million for the

Table of Contents

remainder of the year ending December 31, 2016 and $4.6 million, $5.0 million, $5.0 million, and $2.5 million for the years ending December 31, 2017, 2018, 2019 and 2020, respectively. No amounts are due thereafter.

The Company has entered into agreements with certain vendors for the provision of services, including services related to data management, clinical and commercial operation support and diagnostic test development, that the Company is not able to terminate for convenience under its contracts, and thus avoid any and all future obligations to the vendors. Under such agreements, the Company is contractually obligated to make certain minimum payments to the vendors, with the exact amounts in the event of termination to be based on the timing of the termination and the exact terms of the agreement.

The Company has certain obligations under licensing agreements with third parties that are contingent upon achieving various development, regulatory and commercial milestones. Pursuant to these license agreements, the Company is required to make milestone payments if certain development, regulatory and commercial sales milestones are achieved, and may have certain additional research funding obligations. Also, pursuant to the terms of each of these license agreements, when and if commercial sales of a product commence, the Company will pay royalties to its licensors on net sales of the respective products.

Legal Proceedings

The Company may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities, including claims or disputes related to patents that have been issued or that are pending in the field of research on which the Company is focused. The Company is not a party to any material litigation and does not have contingency reserves established for any litigation liabilities.

11. License and Collaboration Arrangements

Merck Sharp & Dohme Corp

In May 2015, the Company entered into a research agreement with Merck Sharp & Dohme Corp., or Merck, a subsidiary of Merck & Co., Inc., to perform a trial to evaluate the preliminary safety and efficacy of niraparib plus KEYTRUDA® in patients with triple negative breast cancer and patients with ovarian cancer. Under the terms of this agreement, the Company is responsible for providing niraparib study materials and for carrying out clinical research activities. The Company and Merck share in the external costs of the study equally, with certain exceptions. The Company records cost-sharing payments due from Merck as reductions of research and development expense. During the three and nine months ended September 30, 2016, the Company incurred $1.1 million and $2.9 million in external

costs related to this study, of which $0.6 million and $1.4 million is reimbursable by Merck, respectively. At September 30, 2016, $0.6 million of cost-sharing receivable from Merck has been recorded in accounts receivable on the condensed consolidated balance sheets.

Janssen Biotech, Inc.

On April 5, 2016, the Company entered into separate transactions with Janssen Biotech, Inc., or Janssen, and its affiliate, Johnson & Johnson Innovation — JJDC, Inc., or JJDC, consisting of a collaboration and license agreement with Janssen, or the Collaboration Agreement, and a stock purchase agreement and investor agreement, each with JJDC (the "Stock Purchase Agreement" and the "Investor Agreement," respectively, and collectively with the Collaboration Agreement, the "Agreements").

Under the terms of the Collaboration Agreement, the Company granted Janssen licenses under certain patent rights and know-how relating to niraparib for prostate cancer worldwide, except for Japan. Janssen will conduct all development and commercialization of niraparib in the field of prostate cancer worldwide (excluding Japan). With the exception of China, the Company retains all rights worldwide to develop and commercialize niraparib outside of prostate cancer.

Pursuant to the Collaboration Agreement, within 30 days after the date of the Collaboration Agreement, the Company agreed to provide Janssen with electronic copies of certain know-how relating to development of niraparib. In addition, and in return for certain reimbursement, the Company is also responsible for manufacturing and supplying to Janssen all of Janssen's requirements of active pharmaceutical ingredient, or API, for niraparib and niraparib products to

Table of Contents

be used by Janssen for its development activities in prostate cancer indications. The Company is also responsible for manufacturing of certain niraparib products and API for commercial sale in the field of prostate cancer. In both cases, the Company will receive reimbursement from Janssen that will at least cover the cost of providing such manufacturing services.

The Company received a $35 million up-front, nonrefundable license fee from Janssen. Assuming successful development and commercialization of niraparib products for prostate cancer, the Company could receive up to an additional $415 million in clinical, regulatory and sales milestones as well as tiered, double-digit royalties on aggregate net sales of products in the field of prostate cancer. Janssen is responsible for funding all development and commercialization of niraparib in prostate cancer worldwide (excluding Japan), including research, development, manufacturing, regulatory and commercialization activities. Janssen may terminate the Collaboration Agreement at any time after April 5, 2017 upon 90 days' written notice, upon termination of the Merck License Agreement or in the event of certain safety concerns. Either party may terminate the Collaboration Agreement for uncured material breach or bankruptcy.

The Company evaluated the Collaboration Agreement under ASC Subtopic 605-25, "Multiple Element Arrangements". The Company identified four deliverables including: (1) the licenses under certain patent rights relating to niraparib for prostate cancer worldwide, except for Japan, and transfer of certain development and regulatory information within 30 days after the Effective Date; (2) the participation in Joint Committees; (3) the Company's obligation to supply API for Janssen's development needs; and (4) the Company's obligation to manufacture clinical supply of niraparib product. Each deliverable was determined to have a stand-alone value and to meet the criteria to be accounted for as a separate unit of accounting. For the license and manufacturing deliverables, the Company considered the manufacturing capabilities of Janssen, Janssen's right to sublicense and manufacture API, and the fact that the manufacturing services are not proprietary and can be provided by other vendors. The Company is obligated to participate in the Joint Committees and provide development, regulatory and commercialization information to Janssen and, therefore, the Company identified the participation in the Joint Committees as a separate deliverable.

The consideration allocable to the delivered unit or units of accounting is limited to the amount that is not contingent upon the delivery of additional items or meeting other specified performance conditions. Therefore, the Company will exclude from the allocable consideration the milestone payments and royalties, regardless of the probability that such milestone and royalty payments will be made, until the events that give rise to such payments actually occur. Consideration for manufacturing services was not allocated because the amount is not fixed and determinable and it is not being provided at a significant and incremental discount.

The Company allocated consideration to each unit of accounting using the relative selling price method based on the Company's best estimate of selling price for the license and other deliverables. The best estimate of selling price for the license was calculated using an income approach model and using the following key assumptions: the development timeline, revenue forecast, discount rate and probabilities of technical and regulatory success. The Company believes that a change in the assumptions used to determine its best estimate of selling price for the license most likely would not have a significant effect on the allocation of consideration transferred.

The amount that the Company recognized concurrent with the transfer of license and certain development and regulatory know-how was limited to the lesser of the amount otherwise allocable using the relative selling price method, which was $45.1 million, or the non-contingent amount, which was the $35.0 million up-front fee. As the remaining deliverables are provided, any consideration received would be first allocated to license revenue until such time as the full $45.1 million has been recognized as license revenue. Thereafter, any consideration received will be allocated to all deliverables based on their relative percentages. Through September 30, 2016, the Company recognized $35.8 million as license and collaboration revenue under the Collaboration Agreement.

Revenue allocated to the manufacturing unit of accounting is recognized when general revenue recognition criteria are met, under the proportional performance method. Revenue allocated to the participation in Joint Committees unit of accounting is recognized on a straight-line basis over the Company's estimate of the period of the obligation to participate in Joint Committees through the completion of any non-contingent deliverables.

The Company determined that the milestone payments under the Collaboration Agreement are not subject to ASC Subtopic 605-28, "Milestone Method", because the achievement of the milestone events depends solely on Janssen's performance. The milestone payments will instead be allocated to license revenue and the other units of

Table of Contents

accounting based on the relative selling price percentages and the revenue associated with the milestone payment will then be recognized in accordance with the pattern of recognition for each unit of accounting to which it was allocated. The Company will recognize royalty revenue and commercial milestones when the specified net sales threshold is achieved. For income statement presentation, sales-based royalties are recognized as earned.

Additionally, the Company considered whether the Stock Purchase Agreement and the Investor Agreement with JJDC would be subject to combination with the Collaboration Agreement. The Company determined that they should not be combined because the deliverables and terms in these arrangements are not closely interrelated or interdependent in terms of payment or functionality, the arrangements were negotiated separately, and the common stock was sold at approximately its fair value.

In connection with entry into the Agreements with Janssen discussed above, the Company also entered into Amendment No. 1 to the License Agreement dated as of May 22, 2012 by and between the Company and Merck. This amendment was executed in April 2016 to make certain conforming changes to the Agreements with Janssen.

Zai Lab (Shanghai) Co., Ltd.

On September 28, 2016, or the Effective Date, the Company entered into a Collaboration, Development and License Agreement, or the Zai Agreement, with Zai Lab (Shanghai) Co., Ltd., or Zai Lab. Under the terms of the Zai Agreement, the Company exclusively licensed the rights to develop and commercialize niraparib to Zai Lab for the territories of China, Hong Kong and Macau, or the China Territories. Zai will conduct all development and commercialization of niraparib in the China Territories, except for prostate cancer. The Company retains all rights outside of the China Territories, to develop and commercialize niraparib with the exception of prostate cancer.

Under the terms of the Zai Agreement, the Company will receive a $15.0 million upfront, nonrefundable license fee from Zai Lab in the fourth quarter of 2016. Assuming successful development and commercialization of niraparib products in the China Territories, the Company could receive additional clinical, regulatory and sales milestones as well as tiered, double-digit royalties on aggregate net sales of products in the China Territories. Zai Lab is responsible for funding all development and commercialization of niraparib in the China Territories, including research, development, manufacturing, regulatory and commercialization activities. The term of the Zai Agreement continues, on a country-by-country basis, until the later of expiration of the last patent in the China Territories covering the niraparib product, or ten years from the first commercial sale in such country. The Zai Agreement may also be terminated by Zai Lab at any time upon prior written notice, or by either party for material breach or insolvency.

Pursuant to the Zai Agreement, over the six-month period commencing on the Effective Date, the Company agreed to provide Zai Lab with electronic copies of certain know-how relating to the development of niraparib, as well as

technical assistance. In addition, and in return for certain reimbursement, the Company is also responsible for manufacturing and supplying to Zai Lab an initial supply of certain materials for niraparib. The Company may also become responsible for manufacturing of certain niraparib products and materials for commercial sale in certain instances based on regulatory requirements in the China Territories. In both cases, the Company will receive reimbursement from Zai Lab that will at least cover the cost of providing such manufacturing services.

The Zai Agreement also provides the Company with an option to co-market niraparib in the China Territories with Zai Lab, in return for certain consideration. This co-marketing right must be exercised by the Company prior to the first anniversary of the launch of niraparib in the China Territories.

In addition, the Zai Agreement provides the Company with the right of first refusal with respect to licenses for two novel, discovery-stage immuno-oncology programs from Zai Lab.

The Company evaluated the Zai Agreement under ASC Subtopic 605-25, “Multiple Element Arrangements”. As a result of the inclusion of the co-marketing option and its associated potential future payment, the contract price was determined not to be reasonably estimable. Therefore, the Company has concluded that it has not met certain of the above revenue recognition criteria, and no revenue has been recognized associated with the Zai Agreement.

Table of Contents

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

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2015.

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

Examples of forward looking statements contained in this report include statements regarding the following: our intent to in-license or acquire additional product candidates; our expectation that research and development and selling, general and administrative expenses will increase in the future; our expectations regarding the timing and design of our clinical development plans, the timing of regulatory filings, and the timing of data from clinical trials, with respect to each of our IV rolapitant, niraparib, TSR-042, and TSR-022 programs; our expected gross-to-net adjustment range for VARUBI®; our expectation that we will continue to incur significant expenses, and our expectation that our operating losses and negative cash flows will continue to increase for the foreseeable future; the expected impact of recent accounting pronouncements and guidance on our financial statements; and our needs for additional capital and the forecast of the period of time through which our financial resources will be adequate to support our operations.

Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report on Form 10-Q. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report on Form 10-Q, they may not be predictive of results or developments in future periods.

These forward-looking statements involve substantial risks and uncertainties that could cause actual future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the development or launch of any new pharmaceutical product and the execution and completion of clinical trials, uncertainties surrounding the timing of availability of data from our clinical trials, uncertainties regarding ongoing discussions with and actions by regulatory authorities, patient accrual rates for clinical trials, manufacturing and supply risks, and other matters that could affect the timing of data, the potential regulatory approval, or the commercial availability of our product candidates or the success of any product. The following information and any forward-looking statements

should be considered in light of these factors and the factors discussed elsewhere in this Quarterly Report on Form 10-Q, including under the heading “Risk Factors,” and in light of factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2015.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are an oncology-focused biopharmaceutical company dedicated to improving the lives of cancer patients. We have in-licensed and are currently developing several oncology-related product candidates, including rolapitant, niraparib, and the product candidates under our immuno-oncology platform.

On September 1, 2015, our first commercial product, VARUBI, which is the oral formulation of rolapitant, was approved by the United States Food and Drug Administration, or FDA, for use in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. We commenced shipments of VARUBI to distributors in November 2015.

Table of Contents

A summary description of our current products and product candidates is as follows:

- Rolapitant is a potent and long-acting neurokinin-1, or NK-1, receptor antagonist for the prevention of chemotherapy induced nausea and vomiting, or CINV. The oral form of rolapitant, VARUBI, has been approved for commercialization in the United States, and we are also developing an intravenous, or IV, formulation of rolapitant. In March 2016, we submitted a new drug application, or NDA, for IV rolapitant to the FDA which was accepted for review in May 2016, with a target Prescription Drug User Fee Act, or PDUFA, date of January 11, 2017. We also submitted a Marketing Authorization Application, or MAA, for oral rolapitant to the European Medicines Agency, or EMA, in March 2016, which the EMA has accepted for review.

- Niraparib is an orally active and potent poly (ADP-ribose) polymerase, or PARP, inhibitor. We currently have several ongoing clinical trials evaluating niraparib for the treatment of ovarian or breast cancers, and we expect to initiate activities in support of further clinical trials of niraparib during 2016. We are also collaborating with various other organizations to evaluate niraparib in combination with other therapeutics for the treatment of various cancers. Based on research related to PARP inhibitors generally, we believe that niraparib may also be active in the treatment of several other tumor types. In June 2016, we announced that the Phase 3 NOVA trial of niraparib successfully achieved its primary endpoint, demonstrating that niraparib significantly prolonged progression-free survival, or PFS, compared to control among patients with platinum-sensitive, recurrent ovarian cancer. We submitted an NDA and an MAA for niraparib in October 2016. The EMA has accepted the MAA for review.

- Immuno-Oncology Platform: In March 2014, we added immuno-oncology programs to our portfolio of product candidates by entering into a collaboration and exclusive license agreement with AnaptysBio, Inc., or AnaptysBio, for the discovery and development of antibodies for several immuno-oncology targets. We submitted an investigational new drug application, or IND, for our first immuno-oncology antibody, TSR-042, which targets PD-1, to the FDA in December 2015, and we initiated a Phase 1, dose escalation study in March 2016. In April 2016, we submitted an IND to the FDA, for our second immuno-oncology antibody, TSR-022, which targets TIM-3, and in July 2016, we commenced the dosing of the first patient in a Phase 1, dose escalation study. We have commenced pre-clinical research for our antibody candidate targeting LAG-3, TSR-033, and expect to initiate a Phase 1 study in 2017. As part of our collaboration with AnaptysBio, we received exclusive rights to monospecific antibody product candidates targeting PD-1, TIM-3, and LAG-3 and bi-specific antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an additional bi-specific combination. In addition, we plan to evaluate our immuno-oncology anti-tumor agents, such as TSR-042, in combination preclinical pharmacology studies with niraparib and other anti-tumor agents.

In February 2016, we entered into an exclusive collaboration with the Institute for Applied Cancer Science at The University of Texas MD Anderson Cancer Center, or MDACC, to discover and develop small molecule product candidates against undisclosed immuno-oncology targets. This collaboration is intended to leverage MDACC's expertise in drug discovery and translational medicine and our oncology drug development and commercialization capabilities. Under terms of the agreement, we will receive exclusive worldwide rights to develop and commercialize any small molecule product candidates that result from this collaboration. MDACC will be responsible for conducting research activities aimed at identifying clinical candidates with defined characteristics targeting certain immuno-oncology targets. We will fund research, development, and commercialization expenses for this

collaboration.

In April 2016, we entered into a global prostate cancer collaboration and license agreement, or the Collaboration Agreement, with Janssen Biotech, Inc., or Janssen, under which we granted Janssen licenses under certain patent rights and know-how relating to niraparib, for prostate cancer worldwide, except for Japan. We retain all rights worldwide (except China) to develop and commercialize niraparib outside of prostate cancer. In connection with the execution of the Collaboration Agreement, we received a $35.0 million up-front license fee from Janssen, and assuming successful development and commercialization of niraparib products for prostate cancer, we could receive up to an additional $415 million in clinical, regulatory and sales milestones as well as tiered, double-digit royalties on aggregate net sales of products in the field of prostate cancer. Janssen is responsible for conducting and funding all development and commercialization of niraparib in prostate cancer worldwide (excluding Japan), including research, development, manufacturing, regulatory and commercialization activities. We also entered into separate stock purchase and investor agreements with an affiliate of Janssen, Johnson & Johnson Innovation — JJDC, Inc., or JJDC, whereby we sold and issued 1,130,198 shares of our common stock to JJDC on April 5, 2016 at a price per share of $44.24, for an aggregate purchase price of approximately $50.0 million.

Table of Contents

In September 2016, we entered into a collaboration, development and license agreement with Zai Lab (Shanghai) Co., Ltd., or Zai Lab. Under the terms of the agreement, we granted to Zai Lab an exclusive license to develop and commercialize niraparib for the territories of China, Hong Kong and Macao, or the China Territories. In partial consideration for the license grant to Zai Lab for the China Territories, Zai Lab will pay us a non-refundable, up-front license fee of $15.0 million in the fourth quarter of 2016. We will be eligible to receive milestone payments contingent on Zai Lab achieving certain specified development and commercial goals. In return for certain consideration, we also have an option to co-market niraparib in the China Territories with Zai Lab; if we elect not to exercise this option, we will be eligible to receive tiered royalties based on percentages of net sales of niraparib in the China Territories ranging from the mid- to high-teens. This agreement also provides the Company with the right of first refusal with respect to licenses for two novel, discovery-stage immuno-oncology programs from Zai Lab.

As of September 30, 2016, we had an accumulated deficit of $853.7 million. Our net losses were $250.5 million, $251.4 million, $171.0 million, and $92.4 million for the nine months ended September 30, 2016 and the years ended December 31, 2015, 2014 and 2013, respectively. We expect to incur significant expenses and operating losses for the foreseeable future. Overall, we expect operating expenses to continue to increase over current levels as we incur increased costs related to: (i) our ongoing U.S. and ex-U.S. commercialization and pre-commercial activities including executing related marketing and promotional programs for the commercialization of VARUBI and our other product candidates; (ii) the advancement of clinical trial and other development and regulatory activities under our current development programs such as IV rolapitant, niraparib, TSR-042 and TSR-022; (iii) the immuno-oncology development activities under our collaborations, costs related to expanding our international operations; and (iv) other research and development activities and potential future collaborative or in-licensed development programs. In addition, future license payments or milestone payments could cause our total operating expenses and cash usage to fluctuate. If we obtain regulatory approval for any of our additional product candidates, or in anticipation of obtaining regulatory approval, we expect that we will incur significant additional commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, we expect to incur increasing selling, general and administrative costs associated with our anticipated growth and continuing operation as a public company, and we will continue to incur substantial interest expense related to our outstanding convertible debt. The actual amount of many of the expenditures described above will depend on numerous factors, including the timing of expenses and the timing, progress, and results of our clinical trial and other development and regulatory activities, and commercialization efforts for VARUBI and our other product candidates. Accordingly, until we can generate a sufficient amount of revenue from our products, if ever, we expect to finance our operations in part through additional public or private equity or debt offerings, and we may seek additional capital through arrangements with strategic partners or from other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

Public Offerings of Common Stock, Private Placements of Securities and Issuance of Convertible Notes. As of September 30, 2016, our principal source of liquidity was cash and cash equivalents, which totaled $647.3 million. Since our inception on March 26, 2010, we have funded our operations primarily through public offerings of our common stock, the private placement of our equity securities and issuance of convertible notes. From inception through December 31, 2015, we received $758.3 million in proceeds, net of underwriting discounts and commissions and offering expenses, from private placements of convertible preferred stock, and public offerings of common stock and convertible notes. On March 18, 2016, we completed a private placement whereby we sold 4,404,658 shares of our common stock at a price of $35.19 per share and received approximately $155.0 million in proceeds. On April 5,

2016, we completed a private placement whereby we sold 1,130,198 shares of our common stock at a price of $44.24 per share and received approximately $50.0 million in proceeds. On July 7, 2016, we closed the sale of 5,347,500 shares of common stock in an underwritten public offering at a price to the public of $81.00 per share, resulting in net proceeds to us after deducting fees, commissions and other expenses related to the offering of approximately $408.9 million.

Financial Operations Overview

Revenues

Product revenue is derived from sales of our product, VARUBI, in the United States.

License, collaboration and other revenues relate to our license agreements with Janssen and Jiangsu Hengrui Medicine Co., Ltd. or Hengrui. Janssen has licensed the rights to develop, manufacture and commercialize niraparib worldwide (except for Japan) for the treatment of prostate cancer. Hengrui has licensed the rights to develop, manufacture and commercialize rolapitant in the China Territories.

Table of Contents

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- pre-commercial license fees and milestone payments related to the acquisition of in-licensed product candidates, which are reported on our statements of operations as acquired in-process research and development;
- employee-related expenses, including salaries, bonuses, benefits, travel and stock-based compensation expense;
- fees and expenses incurred under agreements with contract research organizations, investigative sites, research consortia and other entities in connection with the conduct of clinical trials and preclinical studies and related services, such as administrative, data management, laboratory and biostatistics services;
- the cost of acquiring, developing and manufacturing active pharmaceutical ingredients for product candidates that have not received regulatory approval, clinical trial materials and other research and development materials;
- fees and costs related to regulatory filings and operations;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent, utilities, maintenance of facilities, insurance and other supplies; and
- other costs associated with clinical, preclinical, discovery and other research activities.

Research and development costs are expensed as incurred. License fees and development milestone payments related to in-licensed products and technology are expensed as acquired in-process research and development if it is determined at that point that they have no established alternative future use. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors.

Research and development activities are central to our business model. Product candidates in later 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 later-stage clinical trials and manufacturing costs. We expect that our total future research and development costs will continue to increase over current levels, depending on the progress of our

clinical development programs. We also anticipate increasing costs associated with our collaborations with AnaptysBio, Merck, MDACC, and other potential collaborators, manufacturing related costs, and potential development milestone payments. More specifically, we expect costs to increase, including as we: continue our currently ongoing Phase 2 and 3 trials, continue our manufacturing development and validation, and initiate additional investigative and collaborative studies related to niraparib; continue clinical, manufacturing and regulatory development activities for the IV formulation of rolapitant; incur potential research and development related milestones; incur increased discovery, development and manufacturing related expenses associated with our immuno-oncology platform and related collaborations; lease additional facility space; and hire additional development and scientific personnel.

We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our product candidates or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our currently unapproved product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rates and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as based upon an assessment of each product candidate’s commercial potential. If we experience delays in the completion of, or the termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our future ability to generate product revenues from any of these product candidates will be delayed or

Table of Contents

jeopardized. These occurrences would harm our business, financial condition and prospects, perhaps significantly, which would require us to alter our current operation plan and potentially delay, scale back, or discontinue the development or commercialization of one or more programs and/or other areas of the business in order to reduce our future expenses and continue to fund our remaining operations.

The following table presents research and development expenses and acquired in-process research and development expenses on a program-specific basis for our in-licensed products and product candidates for the nine months ended September 30, 2015 and 2016 (in thousands):

	Nine Months Ended September 30,	
	2015	2016
Rolapitant Expenses		
Acquired in-process research and development	$ —	$ —
Research and development	20,114	13,018
Rolapitant total	20,114	13,018
Niraparib Expenses		
Acquired in-process research and development	—	940
Research and development	42,805	72,758
Niraparib total	42,805	73,698
TSR-011 Expenses		
Acquired in-process research and development	—	—
Research and development	3,623	1,312
TSR-011 total	3,623	1,312
Immuno-Oncology Platform Expenses		
Acquired in-process research and development	1,000	9,000
Research and development	14,960	23,034
Immuno-Oncology Platform total	15,960	32,034
Personnel and Other Expenses	31,036	53,508
Total	$ 113,538	$ 173,570

For further discussion of the changes in our research and development expenses with respect to the nine months ended September 30, 2016 and the corresponding period of 2015, see “Results of Operations — Comparison of the Nine Months Ended September 30, 2015 and 2016 — Research and Development Expenses” below.

Personnel-related costs, depreciation and stock-based compensation are not allocated to any programs, as they are deployed across multiple projects under development and, as such, are separately classified as personnel and other expenses in the table above.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist principally of salaries and related costs, including stock-based compensation, for our commercial personnel, including our field sales force, certain medical education professionals and other commercial support personnel, as well as personnel in executive and other administrative or non-research and development functions. Other selling, general and administrative expenses include certain facility-related costs, communication expenses, pre-commercial and commercial consulting, advertising, market research and other activities necessary to prepare for and support the launches of VARUBI and any other potential products, and professional fees for legal, patent review, consulting and accounting services.

We anticipate that our selling, general and administrative expenses will continue to increase in the future in support of our commercial and pre-commercial activities related to VARUBI and niraparib and continued research and development activities, as well as the continued costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel, executing marketing and promotional programs, hiring consultants, leasing of additional facility space, enhancing information technology systems, and legal and other professional fees, among other expenses.

Table of Contents

Other Income and Expense

Other income and expense consists primarily of interest expense related to the Convertible Notes and interest income earned on cash and cash equivalents. A portion of the interest expense on the Convertible Notes is non-cash expense relating to accretion of the debt discount and amortization of issuance costs.

Results of Operations

Comparison of the Three Months Ended September 30, 2015 and 2016

	Three Months Ended September 30,		Increase/ (Decrease)
	2015	2016	
	(in thousands)		
Revenues:			
Product revenue, net	$ —	$ 2,799	$ 2,799
License, collaboration and other revenues	87	931	844
Total revenues	87	3,730	3,643
Expenses:			
Cost of sales - product	—	424	424
Cost of sales - intangible asset amortization	—	464	464
Research and development	40,063	60,783	20,720
Selling, general and administrative	22,766	37,685	14,919
Acquired in-process research and development	—	1,940	1,940
Total expenses	62,829	101,296	38,467
Loss from operations	(62,742)	(97,566)	(34,824)
Other income (expense), net	(3,844)	(3,587)	257
Net loss	$ (66,586)	$ (101,153)	$ (34,567)

Product Revenue. No product revenue was recorded for the three months ended September 30, 2015. We recorded $2.8 million of net product revenue for the three months ended September 30, 2016. This amount relates to sales of VARUBI, our first commercial product, which we began shipping in November of 2015. We distribute our product in the U.S. principally through a limited number of specialty distributors and to a lesser extent though the specialty pharmacy channel. During the three months ended September 30, 2016, we have recorded product revenue related to VARUBI shipped by the specialty pharmacy to patients during the period, and that was shipped by the specialty distributors to providers from April 1, 2016 through September 30, 2016. For units shipped by specialty distributors to providers during the quarter ended June 30, 2016, we did not recognize product revenue as we did not meet the

criteria for revenue recognition at that time. As a result, net product revenue for the three months ended September 30, 2016 includes approximately $1.2 million relating to units shipped to providers during the previous quarter. We have not recorded any product revenue from VARUBI that has been shipped by distributors to providers or patients after September 30, 2016, or units that remained in distributors' inventories as of September 30, 2016. For such shipments, we have concluded that we did not yet meet the revenue recognition criteria under current accounting guidance. We expect specialty distributors to comprise a majority of our ultimate product sales. We anticipate recognizing revenue on any deferred product sales when the net sales price can be reasonably estimated. For further discussion regarding our revenue recognition policy, see the "Critical Accounting Policies" section below and Note 2, "Basis of Presentation and Significant Accounting Policies", in the Notes to Condensed Consolidated Financial Statements. The corresponding costs of product sales for which we have not recognized product revenue have similarly not yet been reflected in the condensed consolidated statement of operations.

Since the launch of VARUBI through September 30, 2016, we have shipped approximately 15,200 units both for stocking and to satisfy reorders from distributors. Of these units, approximately 13,600 units were subsequently shipped from our distributors to providers and patients through September 30, 2016. The Wholesale Acquisition Cost, or WAC, which is the gross list price at which our direct customers purchase each unit of VARUBI, is $530 per unit. For product sales recognized to date which, as described above, are comprised of units shipped by distributors to providers or patients through September 30, 2016, the average net sales price per unit to us (after accounting for fees,

Table of Contents

rebates, chargebacks, and other discounts or reserves, or, the gross-to-net adjustment) was $324 or approximately 61% of WAC. We expect that our gross-to-net adjustment to VARUBI revenues will be higher in the future (and net revenue per unit will be lower) as a result of changes to our customer and payer mix. Overall, we expect that our gross-to-net adjustments will increase through the remainder of 2016 such that our average net sales price will represent around 60% of WAC per unit.

License, Collaboration and Other Revenues. License, collaboration and other revenues of $0.9 million for the three months ended September 30, 2016 relates to our license agreements with Janssen and Hengrui, and includes amortization of up-front license payments and shipments of materials to our collaborators.

Cost of Sales - Product. Cost of sales of $0.4 million for the three months ended September 30, 2016 consists of costs associated with the manufacturing of VARUBI and royalties owed to our licensor for such sales, as well as costs of product provided under our sampling and other commercial programs and certain period costs. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, certain of the costs of VARUBI units recognized as revenue during the three months ended September 30, 2016 were expensed prior to the September 2015 FDA approval, and therefore are not included in cost of sales during the current period. We expect cost of sales to increase in relation to product revenues as we deplete these inventories. No product cost of sales was recorded for the three months ended September 30, 2015.

Cost of Sales - Intangible Asset Amortization. Cost of sales of $0.5 million for the three months ended September 30, 2016 consists of amortization of the intangible asset recorded as a result of the $15.0 million milestone paid to OPKO Health, Inc., or OPKO, upon the first commercial sale of VARUBI. No similar amortization was recorded for the three months ended September 30, 2015.

Research and Development Expenses. Research and development expenses were $60.8 million for the three months ended September 30, 2016, compared to $40.1 million for the three months ended September 30, 2015, an increase of $20.7 million. The increase was primarily due to higher external costs associated with our niraparib development efforts, development of TSR-042 and TSR-022 and our other immuno-oncology product candidates, as well as higher personnel and related costs. Significant changes resulting in this increase included:

- an increase of $8.5 million in external costs associated with our niraparib program, primarily comprised of increased costs related to ongoing or new clinical trials and manufacturing development activities; and

- an increase of $6.5 million in personnel and other costs (excluding stock-based compensation), primarily related to increased research and development headcount supporting the growth of our development activities.

In addition, stock-based compensation expense included in research and development expenses increased by $1.8 million, primarily due to increased awards of employee stock options and restricted stock units.

The above increases were offset by a decrease of $0.5 million in external costs related to rolapitant and the completion of related clinical studies.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $37.7 million for the three months ended September 30, 2016, compared to $22.8 million for the three months ended September 30, 2015, an increase of $14.9 million. The increase was primarily due to increases of: $6.6 million in salaries, benefits and other personnel-related costs (excluding stock-based compensation), primarily due to the hiring of sales, marketing, medical affairs and other support personnel associated with the commercialization of VARUBI, plus hiring to support our international operations; $5.4 million in professional and consulting fees and other expenses to support corporate operational and commercialization activities; and $3.0 million in stock-based compensation expense.

Acquired In-Process Research and Development. Acquired in-process research and development expenses were $1.9 million for the three months ended September 30, 2016, comprised of a $1.0 million milestone to AnaptysBio and a $0.9 million milestone to Merck. Our obligation to pay the milestone to AnaptysBio was triggered by the initiation of the first good laboratory practice, or GLP, toxicology study for TSR-033, which occurred in September 2016. Our obligation to pay the milestone to Merck was triggered by the first dosing of a patient in a Phase 2 clinical trial for niraparib in subjects with prostate cancer by our licensee, Janssen.

Table of Contents

Other Income (Expense), Net. Other income (expense) is primarily comprised of interest expense related to our Convertible Notes and interest income earned on cash and cash equivalents. Interest income increased by $0.5 million during the three months ended September 30, 2016, primarily due to higher balances of interest-bearing cash equivalents. Interest expense increased by $0.3 million, due to the accretion of the debt discount, which is a component of interest expense, and the use of the effective interest method.

Comparison of the Nine Months Ended September 30, 2015 and 2016

	Nine Months Ended September 30,		Increase/ (Decrease)
	2015	2016	
	(in thousands)		
Revenues:			
Product revenue, net	$ —	$ 4,408	$ 4,408
License, collaboration and other revenues	87	36,190	36,103
Total revenues	87	40,598	40,511
Expenses:			
Cost of sales - product	—	738	738
Cost of sales - intangible asset amortization	—	1,391	1,391
Research and development	112,538	163,630	51,092
Selling, general and administrative	50,791	104,052	53,261
Acquired in-process research and development	1,000	9,940	8,940
Total expenses	164,329	279,751	115,422
Loss from operations	(164,242)	(239,153)	(74,911)
Other income (expense), net	(11,407)	(11,377)	30
Net loss	$ (175,649)	$ (250,530)	$ (74,881)

Product Revenue. No product revenue was recorded for the nine months ended September 30, 2015. We recorded $4.4 million of net product revenue for the nine months ended September 30, 2016. This amount relates to sales of VARUBI, our first commercial product, which we began shipping in November of 2015. During the nine months ended September 30, 2016 we have recorded product revenue related to VARUBI shipped by distributors to providers and patients through September 30, 2016. We have not recorded any product revenue from VARUBI for units that remained in distributors' inventories as of September 30, 2016. For such shipments, we have concluded that we did not yet meet the revenue recognition criteria under current accounting guidance. We expect specialty distributors to comprise a majority of our ultimate product sales. We anticipate recognizing revenue on any deferred product sales when the net sales price can be reasonably estimated. For further discussion regarding our revenue recognition policy, see the "Critical Accounting Policies" section below and Note 2, "Basis of Presentation and Significant Accounting Policies", in the Notes to Condensed Consolidated Financial Statements. The corresponding costs of product sales for which we have not recognized product revenue have similarly not yet been reflected in the condensed consolidated statement of operations.

License, Collaboration and Other Revenues. License, collaboration and other revenues of $36.2 million for the nine months ended September 30, 2016 relates to our license agreements with Janssen and Hengrui, and includes amortization of up-front license payments and shipments of materials to our collaborators. This total consists of $35.8 million related to Janssen and $0.4 million related to Hengrui.

Cost of Sales - Product. Cost of sales of $0.7 million for the nine months ended September 30, 2016 consists of costs associated with the manufacturing of VARUBI and royalties owed to our licensor for such sales, as well as costs of product provided under our sampling and other commercial programs and certain period costs. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, certain of the costs of VARUBI units recognized as revenue during the three months ended September 30, 2016 were expensed prior to the September 2015 FDA approval, and therefore, are not included in cost of sales during the current period. We expect cost of sales to increase in relation to product revenues as we deplete these inventories. No product cost of sales was recorded for the nine months ended September 30, 2015.

Cost of Sales - Intangible Asset Amortization. Cost of sales of $1.4 million for the nine months ended September 30, 2016 consists of amortization of the intangible asset recorded as a result of the $15.0 million milestone

Table of Contents

paid to OPKO upon the first commercial sale of VARUBI. No similar amortization was recorded for the nine months ended September 30, 2015.

Research and Development Expenses. Research and development expenses were $163.6 million for the nine months ended September 30, 2016, compared to $112.5 million for the nine months ended September 30, 2015, an increase of $51.1 million. The increase was primarily due to higher external costs associated with our niraparib development efforts, development of TSR-042, TSR-022 and our other immuno-oncology product candidates, as well as higher personnel and related costs. Significant changes resulting in this increase included:

- an increase of $30.0 million in external costs associated with our niraparib program, primarily comprised of increased costs related to ongoing or new clinical trials and manufacturing development activities;

- an increase of $8.1 million in costs associated with our immuno-oncology platform due to increased costs related to the TSR-042 Phase 1 clinical trial, biologics manufacturing as well as non-clinical and other immuno-oncology program research activities; and

- an increase of $16.4 million in personnel and other costs (excluding stock-based compensation), primarily related to increased research and development headcount supporting the growth of our development activities.

In addition, stock-based compensation expense included in research and development expenses increased by $6.0 million, primarily due to increased awards of employee stock options and restricted stock units.

The above increases were offset by a decrease of $7.1 million in external costs related to rolapitant and the completion of related clinical studies.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $104.0 million for the nine months ended September 30, 2016, compared to $50.8 million for the nine months ended September 30, 2015, an increase of $53.2 million. The increase was primarily due to increases of: $26.2 million in salaries, benefits and other personnel-related costs, primarily due to the hiring of sales, marketing, medical affairs and other support personnel associated with the commercialization of VARUBI, and hiring to support our international operations; $16.5 million in professional and consulting fees and other expenses to support corporate operational and commercialization activities; and $10.5 million in stock-based compensation expense.

Acquired In-Process Research and Development. Acquired in-process research and development expenses were $9.9 million for the nine months ended September 30, 2016. This amount is comprised of three milestones to AnaptysBio totaling $9.0 million, plus a $0.9 million milestone to Merck. Our obligations to pay the milestones to AnaptysBio

were triggered by the clearances of our INDs for TSR-042 and TSR-022 ($4.0 million each), and the start of the first GLP toxicology study for TSR-033 ($1.0 million). Our obligation to pay the milestone to Merck was triggered by the first dosing of a patient in a Phase 2 clinical trial for niraparib in subjects with prostate cancer by our licensee, Janssen. There was $1.0 million recorded in acquired in-process research and development expenses for the nine months ended September 30, 2015, consisting solely of a milestone to AnaptysBio for the initiation of the first GLP toxicology study under our immuno-oncology platform.

Other Income (Expense), Net. Other income (expense) is primarily comprised of interest expense related to our Convertible Notes and interest income earned on cash and cash equivalents. Interest income increased by $0.8 million during the nine months ended September 30, 2016, primarily due to higher balances of interest-bearing cash equivalents. Interest expense increased by $0.8 million due to the accretion of the debt discount, which is a component of interest expense, and the use of the effective interest method.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2016, our principal source of liquidity was cash and cash equivalents, which totaled $647.3 million. Since our inception on March 26, 2010, we have funded our operations primarily through public offerings of our common stock, the private placement of our equity securities and the issuance of convertible notes. From inception through December 31, 2015, including our 2012 initial public offering, we raised a total of $758.3 million in net cash proceeds from private placements of convertible preferred stock and public offerings of common stock, and convertible notes. On March 18, 2016, we issued an aggregate of 4,404,658 shares of our common stock in a

Table of Contents

private placement at a price of $35.19 per share and received approximately $155.0 million in proceeds. On April 5, 2016, we completed a private placement whereby we sold 1,130,198 shares of our common stock at a price of $44.24 per share and received approximately $50.0 million in proceeds. On July 7, 2016, we issued an aggregate of 5,347,500 shares of our common stock at an offering price to the public of $81.00 per share and received approximately $408.9 in net cash proceeds. We have also received an up-front license fee of $35.0 million from Janssen, and we expect to receive an up-front license fee of $15.0 million from Zai Lab in the fourth quarter of 2016, both payments relating to niraparib license agreements.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods noted (in thousands):

	Nine Months Ended September 30,	
	2015	2016
Net cash provided by (used in):		
Operating activities	$ (135,497)	$ (204,496)
Investing activities	(2,869)	(10,940)
Financing activities	184,023	632,605
Increase in cash and cash equivalents	$ 45,657	$ 417,169

Cash Flows from Operating Activities

The use of cash in operating activities during both the nine months ended September 30, 2015 and 2016 resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. Net cash used in operating activities increased by $69.0 million for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015, primarily due to increased external expenses related to commercialization activities and increased external research and development expenses as we continued to progress the niraparib development program and the immuno-oncology platform. Higher costs associated with increased employee headcount related to both research and development and commercial activities also contributed to the increase in cash used in operating activities. These factors were partially offset by lower external costs associated with our oral rolapitant development program.

Cash Flows from Investing Activities

The increase of $8.1 million in net cash used in investing activities for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 was due primarily to $9.0 million in milestones paid to AnaptysBio during the current year period, compared to a $1.0 million milestone paid to AnaptysBio during the prior year period.

Cash Flows from Financing Activities

The increase of $448.6 million in net cash provided by financing activities for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 was primarily due to cash proceeds of $155.0 million from the closing of our March 2016 private placement of common stock, cash proceeds of $50.0 million from the closing of our sale of common stock to JJDC in April 2016 and cash proceeds of $408.9 million from the closing of our July 2016 public offering of common stock, compared to cash proceeds of $179.8 million in the prior year period from the closing of our March 2015 public offering of common stock (all amounts net of underwriting discounts and commissions and offering expenses, if any). Cash provided by stock option exercises and ESPP purchases also increased by $14.2 million.

Operating Capital Requirements

We expect to incur significant expenses and operating losses for the foreseeable future. Overall, we expect operating expenses for the remainder of 2016 to increase over current levels as we incur increased costs related to: (i) the continued development of niraparib, and IV rolapitant; (ii) the advancement of our clinical trials, manufacturing and other development activities, as well as milestone payments under our current development programs, such as niraparib and the immuno-oncology activities under our collaboration with AnaptysBio; (iii) ongoing commercial activities, including our commercial sales force, executing marketing and promotional programs and other commercialization costs associated with VARUBI; (iv) expanding our international operations; and (v) potential future in-licensed development programs. We are subject to the risks incident in the development of new biopharmaceutical

Table of Contents

products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business and cause increased uses of cash.

We will require additional capital for the continuing commercialization of VARUBI, further development and potential commercialization of our other product candidates, including any license payments or milestone obligations that may arise, required costs relating to our research collaborations, and cash interest obligations related to our Convertible Notes. We may also need additional funds to pursue our strategy of in-licensing or acquiring additional product candidates and to meet our obligation to repay the Convertible Notes at maturity or, at our election, upon conversion. Our balance of cash and cash equivalents as of September 30, 2016, and the cash we expect to generate from sales of VARUBI, are expected to be sufficient to meet our existing cash flow requirements and fund our existing operations at their currently planned levels through at least the twelve months following the filing of this Quarterly Report on Form 10-Q.

Unless and until we can generate a sufficient amount of revenue from our products, we expect to finance future cash needs through public or private equity or debt offerings, and we may seek additional capital through arrangements with strategic partners or from other sources. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we would have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates and/or other areas of our business. Raising additional funds through the issuance of equity or debt securities could result in dilution to our existing stockholders, increased fixed payment obligations, or both. Furthermore, these securities may have rights senior to those of our common stock and Convertible Notes and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both short and long-term, will depend on many factors, including:

- our ability to generate revenues from sales of VARUBI and future products;
- the cost of establishing U.S. and ex-U.S. sales, marketing and distribution capabilities for VARUBI or any product candidates for which we may receive regulatory approval;
- the outcome, timing and cost of regulatory approvals by the FDA and comparable non-U.S. regulatory authorities, including the potential that the FDA or comparable non-U.S. regulatory authorities may require that we perform

more studies than those that we currently expect;

- the initiation, progress, timing, costs and results of clinical trials for our product candidates and any future product candidates we may in-license, including our current and potential future Phase 2 and 3 clinical trials for niraparib;

- the cost and timing of completion of commercial-scale outsourced manufacturing activities;

- the discovery, preclinical and clinical development plans that are or will be established for potential product candidates under our collaboration with AnaptysBio;

- the attainment of milestones and our obligations to make milestone payments, royalty payments, or both to OPKO, Merck, or AnaptysBio or to any other current or future product candidate licensor, if any, under our in-licensing agreements;

- the number and characteristics of product candidates that we in-license and develop;

- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

Table of Contents

- the amount and timing of potential conversion requests, if any, and interest expense associated with our Convertible Notes; and

- the effect of competing technological and market developments.

If we lack sufficient capital to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected.

Contractual Obligations and Commitments

Other than the amendment to our lease of office space described in Note 10, “Commitments and Contingencies,” in the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, there have been no material changes to our contractual obligations and commitments included in our Annual Report on Form 10-K for the year ended December 31, 2015.

Off-Balance Sheet Arrangements

As of September 30, 2016, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K.

Critical Accounting Policies

Our management’s discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to net product revenue, accrued research and development expenses and stock-based compensation expense. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. In making estimates and judgments, management employs critical accounting policies.

Product Revenue

In September 2015, our product VARUBI, which is the oral formulation of rolapitant, was approved for sale by the FDA, and in November 2015 we began shipping VARUBI to our U.S. customers. We distribute our product in the U.S. principally through a limited number of specialty distributors and to a lesser extent though the specialty pharmacy channel, or collectively, our Customers. Our Customers subsequently resell our products to health care providers and patients.

Revenues from product sales are recognized when persuasive evidence of an arrangement exists, delivery has occurred and title of the product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer has been reasonably assured and all performance obligations have been met and returns and allowances can be reasonably estimated. Product revenues are recorded net of estimated rebates, chargebacks, discounts, co-pay assistance and other deductions as well as estimated product returns. Allowances are recorded as a reduction of revenue at the time product revenues are recognized.

In addition to distribution agreements with our Customers, we have entered into direct and indirect arrangements with many health care providers and payers that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of VARUBI. We have determined that we do not yet meet the criteria for revenue recognition for shipments of VARUBI at the time of shipment to our specialty pharmacy and specialty distributor customers. For shipments of VARUBI from specialty distributors and specialty pharmacies to providers and patients through September 30, 2016, allowances for rebates, chargebacks, discounts, co-pay assistance and other deductions are known or are estimable because they are based on the actual invoice information, claims data, or other market information and analyses. As a result, we have concluded that we can recognize revenue related to such shipments. For units that remained in distribution channel inventories as of September 30, 2016, we continue to conclude that we cannot yet reasonably make certain estimates necessary to recognize revenue on such shipments.

Table of Contents

During the three and nine months ended September 30, 2016, we recognized $2.8 million and $4.4 million, respectively, in net product revenues related to VARUBI sales through the specialty pharmacy and specialty distributor channels.

Payments received from Customers in advance of recognition of revenue are recorded as deferred revenue by the Company net of payments made to Customers, providers and payers.

For those quantities shipped to Customers for which revenue has not been recognized, the cost of the related units has been accounted for within “Other current assets” in the condensed consolidated balance sheets, and will be recorded to cost of sales upon recognition of the related product revenue. We will assess the recoverability of these costs on a quarterly basis. We will continue to evaluate the criteria for revenue recognition in future periods to determine if and when we have met these criteria with respect to any previously deferred product revenues.

The following table presents an analysis of product sales allowances and accruals for the nine months ended September 30, 2016 (in thousands):

	Chargebacks, Discounts and Fees	Governmental and Other Rebates and Fees	Returns	Total
Balance at December 31, 2015	$ -	$ -	$ -	$ -
Provision related to current period sales	2,121	687	12	2,820
Adjustment related to prior period sales	-	-	-	-
Credits or payments made	(1,773)	(396)	-	(2,169)
Balance at September 30, 2016	$ 348	$ 291	$ 12	$ 651
Total gross product sales				$ 7,228
Total provision for product sales allowances and accruals as a percentage of total gross product sales				39%

Allowances and accruals are comprised of direct and indirect fees, discounts and rebates. Direct fees, certain discounts and rebates are contractual fees and price adjustments payable to specialty distributors and specialty pharmacies that purchase products directly from us. Indirect fees, discounts and rebates are contractual price adjustments payable to healthcare providers and organizations, such as physicians, clinics, hospitals, and group purchasing organizations that purchase products from specialty distributors and specialty pharmacies. Indirect rebates

also include amounts owed to health insurance providers and pharmacy benefit managers. Both types of allowances are based on definitive contractual agreements or legal requirements (such as Medicaid) related to the purchase and/or utilization of the product by these entities. In accordance with guidance related to accounting for fees and consideration given by a vendor to a customer (including a reseller of a vendor's products), these fees, discounts and rebates are presumed to be a reduction of the selling price of our product. Allowances are recorded in the same period that the related product revenue is recognized and are estimated using either historical, actual and/or other data, including estimated patient usage, customer buying patterns, applicable contractual rebate rates, and contract performance by the benefit providers. Reserve estimates are evaluated quarterly and may require adjustments to better align estimates with actual results. As part of this evaluation, we review changes to federal legislation, changes to rebate contracts, changes in the level of discounts, and changes in product sales trends. Although allowances are accrued at the time of product sale, certain rebates are typically paid out, on average, up to nine months or longer after the related sale.

Chargebacks, Discounts and Fees: Chargeback and discount reserves represent our estimated obligations resulting from the difference (which is charged to us by specialty distributors and specialty pharmacies) between the specialty distributor and specialty pharmacy price and the lower pricing as mandated by statute to eligible federally funded healthcare providers or lower contractual pricing to certain private organizations. Fees under our arrangements with specialty distributors and specialty pharmacies are based upon units of VARUBI purchased.

Table of Contents

Governmental and Other Rebates and Fees: Governmental and other rebate and fee reserves relate to our reimbursement arrangements with state Medicaid programs, the Medicare program, or volume or performance rebate agreements with certain other private organizations, such as health insurance providers and pharmacy benefit managers.

Returns: Consistent with industry practice, we generally offer Customers a limited right to return units of VARUBI that have been purchased directly from us based on the product's expiration date, which generally lapses upon shipment to the patient. To date, there have been no returns.

For a description of our other critical accounting policies, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2015. Other than as described above, there have not been any material changes to our critical accounting policies since December 31, 2015.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of September 30, 2016 and December 31, 2015, we had cash and cash equivalents of $647.3 million and $230.1 million, respectively, consisting primarily of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates, particularly because our investments are in short-term securities. Our securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio. There has been no material change to our interest rate sensitivity during the three months ended September 30, 2016.

Item 4. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

Our principal executive officer and our principal financial officer, after evaluating the effectiveness of our "disclosure controls and procedures" (as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act, Rule 13a-15(e) or Rule 15d-15(e)), with the participation of our management, has concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures are effective and are designed to ensure that information we are required to disclose in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our principal executive officer and

principal financial officer, as appropriate, to allow timely decisions regarding required disclosure, and is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. It should be noted that any system of controls is designed to provide reasonable, but not absolute, assurances that the system will achieve its stated goals under all reasonably foreseeable circumstances. Our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures are effective at a level that provides such reasonable assurances.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fiscal quarter covered by this report that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART IIOTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently a party to any material legal proceedings.

Item 1A. Risk Factors.

An investment in our stock involves a high degree of risk. You should carefully consider the following discussion of risk factors, in its entirety, in addition to the other information contained in this Quarterly Report on Form 10-Q, our Annual Report on Form 10-K for the year ended December 31, 2015 and the other filings we make with the Securities and Exchange Commission, as well the information in our financial statements and the related notes. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks, or other events that we do not currently anticipate or that we currently deem immaterial, may have a material adverse effect on our business, prospects, financial condition and results of operations.

We have no manufacturing facility, and we are dependent on a limited number of third-party manufacturers for the manufacture of VARUBI® and our product candidates, as well as on a number of third parties for our supply chain. If we experience problems with any of these third parties, the manufacturing of VARUBI or our product candidates could be delayed, which could harm our ability to generate revenues from our approved products, our ability to obtain regulatory approval for our product candidates, and our results of operations.

We do not own or operate facilities for the manufacture of VARUBI or our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We currently work with one contract manufacturing organization, or CMO, Hovione, for the production of rolapitant drug substance used for VARUBI and IV rolapitant, and one other CMO, Patheon, for commercial production of VARUBI. We also work with two CMOs for the production of IV rolapitant drug product for our expected clinical and commercial needs.

As our drug development pipeline matures and we continue to commercialize VARUBI and, if approved, our other product candidates, including niraparib and IV rolapitant, we will have a greater need for clinical study and commercial manufacturing capacity. We have limited experience manufacturing pharmaceutical products on a commercial scale, and some of our suppliers will need to increase their scale of production to meet our projected needs for commercial manufacturing. For example, to meet our projected needs for commercial manufacturing of VARUBI, Patheon will need to increase scale of production. The development of commercial-scale manufacturing capabilities may require our third-party manufacturers to invest substantial additional funds and hire and retain the

technical personnel who have the necessary manufacturing experience. Our third-party manufacturers may not successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all. Because of the complex nature of our compounds, our manufacturers may not be able to manufacture our compounds at an acceptable cost or in sufficient quantities or in a timely manner necessary to make commercially successful products, or may require us to pay significant costs, including for capital improvements to their facilities. Therefore, successful commercialization of VARUBI or any of our product candidates, including niraparib and IV rolapitant, may require us to establish large-scale commercial manufacturing capabilities. If our contract manufacturers or other third parties fail to deliver VARUBI and our potential future products, including niraparib and IV rolapitant, for commercial sale on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be required to delay or suspend commercialization of VARUBI or our other potential future products.

Existing inventory for niraparib drug substance and drug product from Merck provided the initial clinical trial material needed for our niraparib clinical program. We have agreements in place with CMOs for the further production of niraparib to meet our clinical supply needs. For preclinical development of our immuno-oncology antibody product candidates, we currently work with one CMO for the production of biologics. For each of our product candidates, we may elect to pursue arrangements with other CMOs for manufacturing clinical supplies for later-stage trials and for commercialization. We have not yet qualified alternate suppliers in the event the current CMOs we utilize are unable to scale production, or if we otherwise experience any problems with them. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them.

Table of Contents

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications) and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and similar foreign authorities require that our product candidates and approved products, such as VARUBI, be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. Specifically, following regulatory inspections of the facilities of one of our contract manufacturers of rolapitant IV, the FDA issued the manufacturer a Form 483 containing a number of inspection observations regarding such facilities, and the U.K. Medicines and Healthcare Products Regulatory Agency, or MHRA, withdrew the manufacturer's cGMP certificate for one of its facilities and recommended a recall of products made at two of its facilities. If the contract manufacturer fails or is unable to address and remediate these observations in a manner satisfactory to the FDA, then this failure could result in a delay in the expected timing of regulatory approval of rolapitant IV in the United States. In addition, such failure could be the basis for the FDA or an equivalent foreign regulatory authority to issue a warning or untitled letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction, or imposition of civil and criminal penalties.

Any significant disruption in our supplier relationships could harm our business. We source key materials from third parties, either directly through agreements with suppliers or indirectly through our manufacturers who have agreements with suppliers. There are a small number of suppliers for certain capital equipment and key materials that are used to manufacture our drug products and product candidates. Such suppliers may not sell these key materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these key materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these key materials. Any significant delay in the supply of a product candidate or its key materials for an ongoing clinical study could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these key materials for VARUBI or for our product candidates after regulatory approval, the commercial launch of our product candidates could be delayed or there could be a shortage in supply, which would impair our ability to generate revenues from the sale of VARUBI or our product candidates.

The results of the United Kingdom's referendum on withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.

In June 2016, a majority of voters in the United Kingdom elected to withdraw from the European Union in a national referendum. The referendum was advisory, and the terms of any withdrawal are subject to a negotiation period that could last at least two years after the government of the United Kingdom formally initiates a withdrawal process. Nevertheless, the referendum has created significant uncertainty about the future relationship between the United Kingdom and the European Union, including with respect to the laws and regulations that will apply as the United Kingdom determines which European Union laws to replace or replicate in the event of a withdrawal. The referendum has also given rise to calls for the governments of other European Union member states to consider withdrawal. These developments, or the perception that any of them could occur, have had and may continue to have

a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict our access to capital, which could have a material adverse effect on our business, financial condition and results of operations and reduce the price of our securities.

Table of Contents

If we are unable to protect our intellectual property rights, our competitive position could be harmed, and we could be required to incur significant expenses to enforce our rights.

We depend on our ability to protect our proprietary technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. Patents may cover the composition of matter of products, pharmaceutical formulations, processes for or intermediates useful in the manufacture of products or the uses of products. Protection for individual products extends for varying periods in accordance with the legal life of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent and its scope of coverage. Where we have the right to do so under our license agreements, we seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain.

The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the United States. The rights already granted under any of our currently issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected. Further, under our agreement with Merck for niraparib, Merck is responsible, subject to certain exceptions, for prosecuting the licensed patents, and we are reliant on them to do so in a diligent fashion, subject to our right to review and approve their prosecution activities. If Merck fails to conduct such activities diligently, does not take approved actions, or otherwise fails to adequately protect our licensed patent rights, we may not obtain or maintain broad proprietary protection for niraparib. Similarly, under our agreement with AnaptysBio, during preclinical development of our antibody product candidates, AnaptysBio has primary responsibility for prosecuting certain licensed patents at our expense, subject in certain circumstances to our right to prior approval of expenses. If AnaptysBio fails to conduct such activities diligently, does not take approved actions, or otherwise fails to adequately protect our licensed patent rights, we may not obtain or maintain broad proprietary protection for antibody product candidates targeting PD-1, TIM-3 and LAG-3.

With respect to patent rights, we do not know whether any of the pending patent applications for any of our licensed compounds will result in the issuance of patents that protect our technology or products, or whether they will effectively prevent others from commercializing competitive technologies and products. Although we have a number of issued patents under our licensing agreements covering our technology, our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Further, the examination process may require us or, in the case of niraparib and our antibody product candidates during preclinical development, our licensor, to narrow the claims, which may limit the scope of patent protection that may be obtained. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents, or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our

patented technology, trademarks and other intellectual property rights is expensive, difficult and, may in some cases not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

The patent prosecution process is expensive and time-consuming, and we, or in the case of niraparib and our antibody product candidates during preclinical development, our licensor, may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them. Further, given the amount of time

Table of Contents

required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms where they are available in any countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent. However the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions typically are not published until 18 months after filing, or in some cases not at all. Therefore we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Previously, in the United States, assuming the other requirements for patentability are met, the first to make the claimed invention was entitled to the patent. Outside the United States, the first to file a patent application is entitled to the patent. In March 2013, the United States transitioned to a ‘first to file’ system in which the first inventor to file a patent application will be entitled to the patent. Under either the previous or current system, third parties will be allowed to submit prior art prior to the issuance of a patent by the United States Patent and Trademark Office, and may become involved in opposition, derivation, reexamination, inter-partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position with respect to third parties.

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

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In the U.S., the Hatch-Waxman Act provides generic companies valuable incentives to seek to invalidate patents for human pharmaceutical products approved under an NDA. As a result, it is likely that our U.S. patents covering approved drugs such as rolapitant and niraparib, if approved, will be challenged in Hatch-Waxman litigation and administrative proceedings, and may not be upheld. We may face generic manufacturer challenges to our patents outside the U.S. as well. The entry of generic

competitors typically results in a rapid decline in sales.

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

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates, and to use our proprietary technologies without infringing the proprietary rights

Table of Contents

of third parties. And, because patent applications in the United States and many other jurisdictions are maintained in secrecy for at least 18 months, the patent landscape is continuously evolving. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference proceedings before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. For example, we are aware of third party patents that contain broad claims potentially relevant to certain therapeutic uses of immune checkpoint receptors, and we are also aware of ongoing patent litigation involving third parties in the area. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and commercializing our products and technology, which could impact the profitability of our products. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

Item 6. Exhibits.

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

Table of Contents

SIGNATURES

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

TESARO, INC.

By: /s/ Leon O. Moulder, Jr.
Leon O. Moulder, Jr.
Chief Executive Officer
(principal executive officer)

Date: November 4, 2016

By: /s/ Timothy R. Pearson
Timothy R. Pearson
Executive Vice President and Chief Financial Officer
(principal financial officer)

Date: November 4, 2016

Table of Contents

EXHIBIT INDEX

Exhibit Number	Exhibit Description
10.1*	Collaboration, Development and License Agreement, dated September 28, 2016, by and between the Company and Zai Lab (Shanghai) Co., Ltd.
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
EX-101.INS	XBRL Instance Document
EX-101.SCH	XBRL Taxonomy Extension Schema Document
EX-101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
EX-101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
EX-101.LAB	XBRL Taxonomy Extension Label Linkbase Document
EX-101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Confidential Treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.