TESARO, Inc.
Form 10-Q
August 07, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2015

OR

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

For the transition period from to

Commission File #001-35587

TESARO, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**27-2249687**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
1000 Winter Street, Suite 3300 Waltham, Massachusetts	**02451**
(Address of Principal Executive Offices)	(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 x No o

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

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

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

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

As of July 30, 2015, there were 40,026,328 shares of the registrant s Common Stock, par value $0.0001 per share, outstanding.

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TESARO, INC.

FORM 10-Q
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2015

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PART I FINANCIAL 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, 2014	June 30, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 256,861	$ 354,369
Other current assets	1,735	2,871
Total current assets	258,596	357,240
Property and equipment, net	1,022	2,177
Other assets	4,284	3,960
Total assets	$ 263,902	$ 363,377
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 6,089	$ 9,623
Accrued expenses	16,750	24,791
Other current liabilities	1,526	1,559
Total current liabilities	24,365	35,973
Convertible notes, net	115,481	119,685
Total liabilities	139,846	155,658
Commitments and contingencies *(Note 8 and 9)*		
Stockholders equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at both December 31, 2014 and June 30, 2015; no shares issued or outstanding at both December 31, 2014 and June 30, 2015		
Common stock, $0.0001 par value; 100,000,000 shares authorized at both December 31, 2014 and June 30, 2015; 36,110,082 and 40,026,328 shares issued and outstanding at December 31, 2014 and June 30, 2015, respectively	4	4
Additional paid-in capital	474,562	667,288

Accumulated deficit	(350,510)	(459,573)
Total stockholders equity	124,056	207,719
Total liabilities and stockholders equity	$ 263,902	$ 363,377

See accompanying notes to condensed consolidated financial statements.

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TESARO, INC.

Condensed Consolidated Statements of Operations and

Comprehensive Loss

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

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	**2015**	**2014**	**2015**
Expenses:				
Research and development	$ 30,569	$ 38,930	$ 58,686	$ 72,475
General and administrative	5,587	16,783	10,275	28,025
Acquired in-process research and development	900	1,000	17,900	1,000
Total expenses	37,056	56,713	86,861	101,500
Loss from operations	(37,056)	(56,713)	(86,861)	(101,500)
Interest expense		(3,853)		(7,579)
Interest income	5	9	10	16
Net loss	$ (37,051)	$ (60,557)	$ (86,851)	$ (109,063)
Net loss per share applicable to common stockholders - basic and diluted	$ (1.03)	$ (1.51)	$ (2.45)	$ (2.82)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	35,982	40,008	35,422	38,667
Comprehensive loss	$ (37,051)	$ (60,557)	$ (86,851)	$ (109,063)

See accompanying notes to condensed consolidated financial statements.

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TESARO, INC.

Condensed Consolidated Statements of Cash Flows

(all amounts in 000 s)

(Unaudited)

	Six Months Ended June 30,	
	2014	**2015**
Operating activities		
Net loss	$ (86,851)	$ (109,063)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	17,900	1,000
Depreciation expense	158	227
Stock-based compensation expense	5,640	9,381
Non-cash interest expense		4,544
Loss on disposal of property and equipment	80	
Changes in operating assets and liabilities:		
Other assets	530	(1,136)
Accounts payable	980	2,303
Accrued expenses	6,015	7,806
Other liabilities	(16)	33
Net cash used in operating activities	(55,564)	(84,905)
Investing activities		
Acquisition of product candidate and technology licenses and milestone payments	(17,900)	
Purchase of property and equipment	(945)	(943)
Net cash used in investing activities	(18,845)	(943)
Financing activities		
Proceeds from sale of common stock, net of issuance costs	94,199	179,763
Proceeds from exercise of stock options	868	3,345
Proceeds from issuance of common stock under Employee Stock Purchase Plan	120	248
Net cash provided by financing activities	95,187	183,356
Increase in cash and cash equivalents	20,778	97,508
Cash and cash equivalents at beginning of period	130,310	256,861
Cash and cash equivalents at end of period	$ 151,088	$ 354,369
Non-cash investing and financing activities		
Purchase of property and equipment - cash not paid as of period end	$	$ 456
Acquired in-process research and development - milestone not paid as of period end	$	$ 1,000
Supplemental cash flow information		
Interest paid	$	$ 3,052

See accompanying notes to condensed consolidated financial statements.

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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 and develops oncology product candidates and, if approved for marketing, intends to commercialize these products. Since incorporation, primary activities have consisted of acquiring product candidates, advancing development of these product candidates, developing intellectual property, recruiting personnel and raising capital. The Company intends to in-license or acquire additional product candidates across various stages of development, operates in one segment and has never earned revenue from its activities. The Company is subject to a number of risks, including dependence on key individuals, the need to develop 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.

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, transition to profitability is dependent upon the successful development, approval, and commercialization of its 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. Management intends to fund future operations through 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.

The Company s condensed consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiaries: TESARO UK Limited, TESARO Securities Corporation and TESARO

Development, Ltd. 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 June 30, 2014 and 2015.

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, 2014 and the notes thereto, which are included in the Company s Annual Report on Form 10-K for the year ended December 31, 2014.

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 and expenses, other comprehensive income and the related disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to 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 consolidated

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financial statements include estimates made in connection with accrued research and development expenses, stock-based compensation expense and valuation of convertible notes. 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 inputs	Quoted prices in active markets for identical assets or liabilities
Level 2 inputs	Observable 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 inputs	Unobservable inputs that reflect the Company s own assumptions about the assumptions market participants would use in pricing the asset or liability

The following table presents information about the Company s financial assets and liabilities that have been measured at fair value as of December 31, 2014 and June 30, 2015 and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

		December 31, 2014			
Description	**Balance Sheet Classification**	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets:					

Money market funds	Cash and cash equivalents	$ 254,840	$ 254,840	$	$
Total assets		$ 254,840	$ 254,840	$	$

		June 30, 2015			
Description	**Balance Sheet Classification**	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets:					
Money market funds	Cash and cash equivalents	$ 349,783	$ 349,783	$	$
Total assets		$ 349,783	$ 349,783	$	$

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 June 30, 2015, the carrying value of the Convertible Notes, net of unamortized discount, was $119.7 million and the estimated fair value of the principal amount was $365.9 million. The Convertible Notes are discussed in more detail in Note 4, Convertible Notes.

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Research and Development Expenses

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

- license fees and milestone payments related to the acquisition of in-licensed products, 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, 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 and preclinical 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 the pattern of costs incurred, and are reflected in the consolidated balance sheets as prepaid or accrued 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 milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the acquisition 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. Royalties owed on future sales of the products licensed pursuant to the agreements are expensed in the period the related revenues are recognized.

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 fair market value of its common stock. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period. The cumulative effect of any changes to the estimated forfeiture rates are accounted for as an adjustment to expense in the period of the change.

New Accounting Pronouncements - Recently Issued

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09, which amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in Accounting Standards Codification, or 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. On July 9, 2015, the FASB approved a deferral of the effective date by one year to December 15, 2017 for annual reporting periods beginning after that date. The FASB also approved permitting early adoption of the standard, but not before the original effective date of December 15, 2016. The Company has not yet determined which adoption method it will utilize or the effect that the adoption of this guidance will have on its potential future revenue streams and consolidated financial statements.

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In June 2014, the FASB issued 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 ASC 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 does not expect the adoption of this guidance to have a material impact on its consolidated financial statements.

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 is currently in the process of evaluating the impact of adoption of this guidance on its consolidated financial statements and related disclosures.

In April 2015, the FASB issued ASU No. 2015-03, which amends existing guidance to require the presentation of debt issuance costs in the balance sheet as a deduction from the carrying amount of the related debt liability instead of a deferred charge. ASU No. 2015-03 is effective for annual reporting periods beginning after December 15, 2015, and early adoption is permitted. The amendment must be applied retrospectively such that the balance sheet of each individual period presented is adjusted to reflect the period-specific impact of using the new guidance. Upon transition, a business must adhere to the appropriate disclosures for an adjustment in an accounting principle. Such disclosures include why the change in accounting principle is occurring, the transition method, an explanation of the prior period information that was retrospectively adjusted, and how the change impacts the financial statement line items (i.e., debt issuance cost asset and the debt liability). The Company is currently in the process of evaluating the timing of adoption. If the Company had adopted this guidance as of June 30, 2015, the impact would have been to decrease Other assets and Convertible notes, net by $3.2 million as of June 30, 2015.

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 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 does not expect the adoption of this guidance to have a material impact on its consolidated financial statements.

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, 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.

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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 Six Months Ended June 30,	
	2014	2015
Outstanding stock awards	3,612	5,448
Unvested restricted stock	22	
Shares issuable upon conversion of Convertible Notes		1,076
	3,634	6,524

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 4, 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 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 Convertible Notes first became convertible during the calendar quarter beginning on April 1, 2015. The share figure in the table above represents the estimated incremental shares that would be issued, after the consideration of the Capped Calls, assuming conversion of all of the outstanding Convertible Notes as of June 30, 2015.

4. 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 the 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, beginning from April 1, 2015, 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

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(3) upon the occurrence of specified corporate events.

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

	Three Months Ended June 30, 2015	Six Months Ended June 30, 2015
Contractual interest expense	$ 1,509	$ 3,035
Amortization of debt discount	2,178	4,204
Amortization of debt issuance costs	166	340
Total interest expense	$ 3,853	$ 7,579

During the three and six months ended June 30, 2015 the Company paid $3.1 million in interest related to the Convertible Notes.

5. Stock-Based Compensation

The Company maintains several equity compensation plans, including the 2012 Omnibus Incentive Plan, or the 2012 Incentive Plan, the 2010 Stock Incentive Plan, or the 2010 Incentive Plan, the 2015 Non-Employee Director Stock Incentive Plan, or the 2015 Director Plan, and the 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 allows 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 with 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. Accordingly, effective January 1, 2014 and 2015, the number of shares authorized for issuance under the 2012 Incentive Plan was increased by 1,309,560 shares and 1,444,403 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.

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 June 30,		Six Months Ended June 30,	
	2014	2015	2014	2015
Research and development	$ 1,454	$ 2,211	$ 2,364	$ 4,025
General and administrative	1,648	3,249	3,276	5,356
Total stock-based compensation expense	$ 3,102	$ 5,460	$ 5,640	$ 9,381

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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, 2014	3,726,329	$ 18.82
Granted	1,942,582	54.91
Exercised	(150,294)	22.26
Cancelled	(134,334)	37.81
Outstanding at June 30, 2015	5,384,283	$ 31.27
Vested at June 30, 2015	2,129,131	$ 14.18
Vested and expected to vest at June 30, 2015 (a)	5,042,367	$ 30.08

(a) This represents the number of vested options as of June 30, 2015, plus the number of unvested options expected to vest as of June 30, 2015, based on the unvested options at June 30, 2015, adjusted for the estimated forfeiture rate.

At June 30, 2015, there was approximately $81.0 million of total unrecognized compensation cost related to unvested stock options, which the Company expects to recognize over a remaining weighted-average period of 3.0 years.

Restricted Stock Units

During the three months ended June 30, 2015, the Company issued 50,000 restricted stock units, or RSUs, to certain employees. These RSUs are subject to time-based vesting. At June 30, 2015, there was approximately $2.8 million of unrecognized compensation cost related to the time-based RSUs, which the Company expects to recognize over a remaining weighted-average period of 4.0 years. All 50,000 RSUs remain outstanding at June 30, 2015.

In August 2014, the Company issued 19,500 RSUs to certain employees, of which 3,900 vested during 2014 and no additional units have vested. During the six months ended June 30, 2015, 3,600 of these RSUs were cancelled. These stock awards have performance conditions, pursuant to which vesting of the award is contingent on the occurrence of certain milestone events. As a result, the related compensation cost is recognized as an expense when the probability of the milestone is deemed probable. At June 30, 2015, there was approximately $0.3 million of unrecognized compensation cost related to the RSU grants.

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 June 30, 2015, 249,801 shares remained available for issuance. During the six months ended June 30, 2014 and 2015, the Company issued 5,372 and 7,523 shares, respectively, under the 2012 ESPP, and recognized approximately $0.1 million and $0.1 million in related stock-based compensation expense, respectively.

6. Common Stock Transactions

In February 2014, the Company sold 3,200,000 shares of common stock, in an underwritten public offering at a price to the public of $31.50 per share, resulting in gross proceeds of approximately $100.8 million. Net proceeds to the Company after deducting fees, commissions and other expenses related to the offering were approximately $94.2 million. The shares were issued pursuant to an automatic shelf registration statement on Form S-3.

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.

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7. 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 six months ended June 30, 2014 and 2015, 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, 2014 and June 30, 2015.

8. Commitments and Contingencies

The Company leases office space in Waltham, Massachusetts under a non-cancelable operating lease agreement. In April 2015, the Company amended its lease to add an additional 17,700 square feet to its existing leased office space of 53,200 square feet, increasing the total to approximately 70,900 square feet. The term of the lease commenced April 1, 2013 and continues through June 30, 2017. The lease agreement provides for one month of free rent with respect to a portion of the leased premises and a tenant improvement allowance of $0.1 million. 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 June 30, 2015 were $1.2 million, $2.3 million and $1.2 million for the remainder of the year ending December 31, 2015, and the years ending December 31, 2016 and 2017, respectively.

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 companion diagnostic development, that the Company is not contractually able to terminate for convenience and 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 litigation and does not have contingency reserves established for any litigation liabilities.

9. Collaboration Arrangements

In May 2015, the Company entered into a research agreement with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., or Merck, 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 will share in the costs of the study equally, with certain exceptions. The Company records cost-sharing payments received from Merck as reductions of research and development expense.

The Company and Merck have the right to terminate the agreement, prior to the study completion date, in the event of the other party s uncured breach or insolvency, and in certain other circumstances agreed to by the parties. Costs incurred by the Company related to this study were insignificant during the three months ended June 30, 2015.

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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, 2014.

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 commercialization plans for rolapitant, including the potential timing of commercial launch of both the oral and IV formulations; our intent to in-license or acquire additional product candidates; our expectation that research and development and general and administrative expenses will increase in the future; our expectations regarding the timing and design of our development plans, the timing of regulatory filings, and the timing of data from clinical trials, with respect to each of our rolapitant, niraparib, TSR-011 and TSR-042 programs; our expectations regarding our discovery and development plans, including the expected timing, for immunotherapy antibodies; our anticipated royalty payments; our expectation that we will continue to incur significant expenses, including increases in our general and administrative expenses, and 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 execution and completion of clinical trials, uncertainties surrounding the timing of availability of data from our clinical trials, ongoing discussions with and actions by regulatory authorities, patient accrual rates for clinical trials, and other matters that could affect the timing of data, the potential regulatory approval, or the commercial availability of the Company s product candidates. 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, and in light of factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2014, including under the heading Risk Factors.

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 were founded in March 2010 by former executives of MGI PHARMA, Inc., an oncology and acute-care focused biopharmaceutical company. We have in-licensed and are currently developing three oncology-related product candidates, rolapitant, niraparib and TSR-011. We submitted a new drug application, or NDA, for oral rolapitant to the United States Food and Drug Administration, or FDA, in September 2014. If the NDA is approved by the FDA, oral rolapitant will become our first marketed product. In March 2014, we added immuno-oncology programs to our portfolio of product

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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 expect to file an investigational new drug application for our first immuno-oncology antibody, TSR-042, which targets PD-1, by the end of 2015.

- *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. We are developing both oral and intravenous formulations of rolapitant. In December 2013, we announced top-line results for two Phase 3 trials of oral rolapitant and in May 2014, we announced top-line results for a third Phase 3 trial of oral rolapitant. The primary endpoint was successfully achieved in each of these three trials. Our NDA for oral rolapitant was accepted for review by the FDA in November 2014. We are currently preparing to begin marketing oral rolapitant in the fourth quarter of 2015, assuming the NDA is approved on or about the Prescription Drug User Fee Act date of September 5, 2015. The intravenous, or IV, formulation of rolapitant is currently in various Phase 1 clinical trials. As part of a registration program for IV rolapitant, we have successfully completed a clinical study comparing the exposure of IV rolapitant and oral rolapitant. In addition, in the first quarter of 2015, we initiated a clinical study to evaluate the safety of IV rolapitant to support an NDA submission, which we expect to submit following the commercial launch of oral rolapitant, assuming the oral rolapitant NDA is approved.

- *Niraparib* is an orally active and potent poly (ADP-ribose) polymerase, or PARP, inhibitor. In July 2013, we dosed the first patient in a Phase 3 clinical trial evaluating niraparib for the treatment of patients with high grade serous, platinum sensitive, relapsed ovarian cancer. We refer to this Phase 3 trial as our NOVA trial. In April 2015, enrollment was completed for the NOVA trial. In April 2014, we dosed the first patient in a Phase 3 clinical trial evaluating niraparib in breast cancer patients with germline BRCA mutations. We refer to this Phase 3 trial as our BRAVO trial. In the first quarter of 2015, we initiated a Phase 2 clinical trial evaluating niraparib as a therapy for patients with ovarian cancer who have previously been treated with three or more regimens of therapy. We dosed the first patient in this trial, which we refer to as our QUADRA trial, in April 2015. In May 2015, we entered into a research agreement with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., or Merck, 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. We also are collaborating with the Sarcoma Alliance for Research through Collaboration, or SARC, to evaluate niraparib in combination with chemotherapy for the treatment of Ewing s sarcoma, as well as the Nordic Society of Gynecologic Oncology (in collaboration with the European Network for Gynaecological Oncological Trial groups) in their trial evaluating niraparib plus bevacizumab in ovarian cancer patients in a Phase 1/2 trial referred to as the AVANOVA trial. Additionally, we intend to evaluate niraparib in the first-line setting in ovarian cancer patients. Based on research related to PARP inhibitors generally, we believe that niraparib may also be active in the treatment of several other tumor types.

- *TSR-011* is an orally available targeted anti-cancer agent that is a potent inhibitor of both anaplastic lymphoma kinase, or ALK, and tropomyosin-related kinase, or TRK, currently in a Phase 1/2a dose escalation clinical trial in cancer patients. We have identified the maximum tolerated dose of TSR-011 and are now evaluating a fractionated 120mg dose of TSR-011 in patients with ALK or TRK expression, including those with ALK-positive, or ALK+, non-small cell lung cancer, or NSCLC, who have not been previously treated with ALK inhibitors, those with ALK+ NSCLC who have progressed during treatment with other ALK inhibitors, and in those patients with other

tumor types driven by ALK or TRK. A controlled release formulation is now available and is being evaluated in the ongoing Phase 1/2a study.

- *Immuno-Oncology Platform*: PD-1, or programmed cell death protein 1, is a key immune checkpoint molecule that can limit T-cell-mediated immune responses. The presence of the PD-1 ligand, or PD-L1, has been identified on many tumor types, and expression of PD-L1 has been linked to poor clinical outcomes in a variety of cancers. Anti-PD-1 antibodies have demonstrated in vivo efficacy in tumor models and have shown promising results in several clinical studies. In September 2014, the FDA approved KEYTRUDA®, and in December 2014, the FDA approved OPDIVO®, the first two approved anti-PD-1 antibodies, for the treatment of certain melanomas. In March 2015, the FDA also approved OPDIVO® for the treatment of a type of NSCLC. As part of our collaboration with AnaptysBio, we received exclusive rights to monospecific antibody product candidates targeting TIM-3, LAG-3 and PD-1 and bi-specific antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an additional bi-specific combination. We anticipate beginning clinical trials using TSR-042, the lead anti-PD-1 antibody product candidate that we have in-licensed as part of the agreement with AnaptysBio, in early 2016. With respect to the TIM-3 and LAG-3 targets, we have either identified or are

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working toward identifying lead and backup compounds. We intend to select lead and backup compounds for the bi-specific PD-1/TIM-3 and PD-1/LAG-3 targets during the second half of 2015. In addition, we are evaluating our immuno-oncology anti-tumor agents, such as TSR-042, in combination preclinical pharmacology studies with niraparib, TSR-011 and other anti-tumor agents.

We commenced business operations in May 2010. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing product candidates, identifying potential product candidates and undertaking preclinical studies, clinical trials and manufacturing activities related to our product candidates. To date, we have not generated any revenues and have financed our operations with net proceeds from public offerings of our common stock, private placements of our preferred stock and the issuance of convertible notes.

As of June 30, 2015, we had an accumulated deficit of $459.6 million. Our net losses were $109.1 million, $171.0 million, $92.4 million, and $61.8 million for the six months ended June 30, 2015 and the years ended December 31, 2014, 2013 and 2012, respectively. We expect to incur significant expenses and operating losses for the foreseeable future. Overall, we expect 2015 operating expenses to continue to increase over current levels as we incur increased costs related to the advancement of our ongoing commercialization activities, including hiring our own sales force, developing our marketing infrastructure, executing related marketing and promotional programs, hiring consultants and establishing systems in preparation for the potential commercialization of oral rolapitant, costs related to the advancement of clinical trial and other development activities under our current development programs, such as IV rolapitant, niraparib and TSR-011, costs related to the immuno-oncology development activities under our collaboration with AnaptysBio, and costs related to 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. For example, if our NDA submission for oral rolapitant is approved by the FDA, upon our first commercial sale we would be obligated to make a $15.0 million milestone payment to OPKO Health, or OPKO. If we obtain regulatory approval for any of our product candidates, or in anticipation of obtaining regulatory approval, such as with respect to oral rolapitant, we expect that we will continue to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, we expect to incur increasing 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 and progress of the regulatory approval of oral rolapitant and our development, sales and marketing efforts. Accordingly, we will seek to fund our operations through additional public or private equity or debt offerings and 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.

Rolapitant. In December 2010, we entered into a license agreement with OPKO to obtain exclusive worldwide rights to research, develop, manufacture, market and sell rolapitant. The license agreement also extended to an additional, backup compound, SCH900978, to which we have similar rights and obligations as rolapitant, but which we are not currently advancing. We are required to make development milestone payments to OPKO of up to an aggregate of $30.0 million, of which we have paid $5.0 million to date, if specified regulatory and initial commercial sales milestones are achieved in the U.S. and Europe. In addition, we are required to make milestone payments to OPKO of up to an aggregate of $85.0 million if specified levels of annual net sales of rolapitant are achieved. If commercial sales of rolapitant commence, we are required to pay OPKO tiered royalties on the amount of annual net sales achieved in the United States and Europe at percentage rates that range from the low teens to the low twenties, which we expect will result in an effective royalty rate in the low teens. The royalty rate on annual net sales outside of the United States and Europe is slightly above the single digits. We will pay royalties on rolapitant until the later of (i) the date that all of the patent rights licensed from OPKO and covering rolapitant expire, are invalidated or are not enforceable, and (ii) 12 years from the first commercial sale of the product, in each case, on a country-by-country and product-by-product basis. If we elect to develop and commercialize rolapitant in Japan through a third-party licensee,

we will share equally with OPKO all amounts received by us in connection with such activities under our agreement with such third party, subject to certain exceptions and deductions. OPKO also retains an option to become the exclusive distributor of such products in Latin America, provided that OPKO exercises that option within a defined period following specified regulatory approvals in the United States. We are responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize rolapitant.

Rolapitant Intravenous Formulation. We are also developing a single dose intravenous rolapitant formulation with respect to which we have selected a single intravenous dose of 185mg for further development. We have also completed a multiple ascending dose study of intravenous rolapitant that confirmed the safety and tolerability profiles and linear

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pharmacokinetics of repeat daily doses. As part of a registration program for IV rolapitant, we have successfully completed a clinical study comparing the exposure of the IV and oral formulations of rolapitant and we initiated a clinical study in the first quarter of 2015 to evaluate the safety of IV rolapitant to support an NDA submission, which we expect to submit following the commercial launch of oral rolapitant.

Niraparib. In May 2012, we entered into a license agreement with Merck, under which we obtained exclusive, worldwide rights to certain patents and non-exclusive rights to certain Merck know-how, to research, develop, manufacture, market and sell niraparib and a backup compound, MK-2512, for all therapeutic and prophylactic uses in humans. We are not currently advancing MK-2512. Under the terms of the license agreement, we have made two milestone payments to Merck, one in the amount of $1.9 million upon dosing of the first patient in our NOVA trial in July 2013 and one in the amount of $0.9 million upon dosing of the first patient in our BRAVO trial in April 2014. We are required to make total milestone payments to Merck of up to $57.0 million in U.S. and European development and regulatory milestones for the first indication, up to $29.5 million in development and regulatory milestones for each successive indication, and up to $87.5 million in one-time sales milestones based on the achievement of annual sales objectives. If commercial sales of niraparib commence, we will pay Merck tiered royalties at percentage rates in the low teens based on worldwide annual net sales, until the later of the expiration of the last patent licensed from Merck covering or claiming niraparib, or the tenth anniversary of the first commercial sale of niraparib, in either case, on a country-by-country basis.

We are responsible for all clinical, regulatory and other activities necessary to develop and commercialize niraparib. At the time of the license transaction, niraparib had completed a Phase 1 clinical trial in cancer patients as a monotherapy. We are evaluating niraparib for the treatment of patients with high grade serous, platinum sensitive, relapsed ovarian cancer in our NOVA trial, which we initiated in July 2013. In April 2015, enrollment was completed for the NOVA trial. We also initiated our QUADRA trial during the first quarter of 2015. QUADRA is a Phase 2 clinical trial of niraparib for the treatment of patients with ovarian cancer who have previously been treated with three or more regimens of therapy. This trial is a single arm, open label study, targeted to enroll 225 patients who have previously received three or more lines of chemotherapy. Endpoints include objective response rate and duration of response across platinum sensitive, platinum resistant, $gBRCA_{mut}$ and HRD patient subsets. We further intend to initiate a clinical trial of niraparib in the first-line ovarian cancer setting, which we refer to as our PRIMA trial, during the second half of 2015. The PRIMA trial will include patients who have responded to first-line platinum chemotherapy. Patients will likely be randomized 2:1 to receive niraparib or placebo. The endpoints for this study will include progression free survival, PFS2, overall survival and safety. We are also evaluating niraparib in breast cancer patients with germline BRCA mutations in our BRAVO trial, which we initiated in April 2014. We also sponsor certain investigator sponsored trials investigating the use of niraparib in various other tumor types.

In May 2015, we entered into a research agreement with Merck 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.

TSR-011. In March 2011, we entered into a license agreement with Amgen, Inc., or Amgen, to obtain exclusive worldwide rights to research, develop, manufacture, market and sell certain licensed ALK inhibitor compounds,

including TSR-011. Under the terms of the license agreement, we have made a milestone payment of $1.0 million. We are required to make total milestone payments to Amgen of up to an aggregate of $138.0 million if specified clinical development, regulatory, initial commercialization and annual net product sales milestones are achieved. If commercial sales of a product commence, we will pay Amgen tiered royalties at percentage rates ranging from the mid-single digits to slightly above the single digits based on cumulative worldwide net sales until the later of the last patent licensed from Amgen covering the product, the loss of regulatory exclusivity for the product, or the tenth anniversary of the first commercial sale of the product, in all cases, on a country-by-country and product-by-product basis. We are responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize the licensed product candidates. We are currently conducting a Phase 1/2a dose escalation clinical trial in cancer patients.

Immuno-Oncology Platform. In March 2014, we entered into a collaboration and exclusive license agreement with AnaptysBio, a privately-held therapeutic antibody company, which we expanded by amending the agreement in November

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2014. Under the terms of this agreement, we obtained an exclusive, royalty-bearing, sublicensable worldwide license to research, develop, manufacture, market and sell products based on AnaptysBio s proprietary technology for the discovery, generation and optimization of immunotherapy antibody product candidates targeting TIM-3, LAG-3 and PD-1 (TSR-042) and bi-specific antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an additional bi-specific combination. Under this amended agreement, AnaptysBio is responsible for performing initial discovery and development of therapeutic antibodies against immune checkpoint proteins, with the goal of generating immunotherapy antibodies for use in the treatment of cancer. We are responsible for all subsequent preclinical, clinical, regulatory, manufacturing and other activities necessary to develop and commercialize antibodies selected under each of four development programs, and we are obligated to use commercially reasonable efforts to research, develop or commercialize at least one product under each development program.

Under the terms of the amended agreement, we are required to reimburse AnaptysBio on a quarterly basis for specified costs incurred by AnaptysBio in its initial discovery and development activities covered by the agreement. For each of the four development programs, we will be required to make milestone payments to AnaptysBio of up to $18.0 million if certain research and development milestone events are achieved, of which we have incurred $1.0 million to date, and up to an additional $90.0 million of milestone payments if certain U.S. and non-U.S. regulatory submissions and approvals occur in initial and subsequent indications. We will also be required to pay AnaptysBio tiered single-digit royalties, on a product-by-product basis, on worldwide annual net sales, and additional commercial milestone payments if specified levels of annual net sales of a product are attained.

Public Offerings of Common Stock, Private Placements of Securities and Issuance of Convertible Notes. As of June 30, 2015, our principal source of liquidity was cash and cash equivalents, which totaled $354.4 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, 2014, we received $383.9 million in proceeds, net of underwriting discounts and commissions and offering expenses, from public offerings of common stock and private placements of convertible preferred stock. In March 2015, we completed a public offering of our common stock whereby we sold an additional 3,755,000 shares of our common stock at a price to the public of $51.00 per share and received approximately $179.8 million in proceeds, net of underwriting discounts and commissions and offering expenses. On September 29, 2014, we issued $201.3 million aggregate principal amount of Convertible Notes, with net proceeds of $194.7 million, and we used $20.8 million of the proceeds from this transaction to enter into capped call option transactions, or Capped Calls, associated with the Convertible Notes.

Financial Operations Overview

Research and Development Expenses

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

- license fees and milestone payments related to the acquisition of in-licensed products, 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, 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 and preclinical activities.

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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 that they have no 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 as well as expected increasing costs associated with our collaboration with AnaptysBio, manufacturing related costs, and potential development milestone payments. More specifically, we expect costs to increase as we: continue our currently ongoing Phase 2 and 3 trials for, and initiate additional investigative and collaborative studies related to, niraparib; continue clinical and other development activities for the IV formulation of rolapitant as well as TSR-011; incur potential research and development related milestones; incur increased discovery, development and manufacturing related expenses associated with our immuno-oncology platform; 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 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 an assessment of each product candidate s commercial potential.

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 product candidates for the six months ended June 30, 2014 and 2015 (in thousands):

	Six Months Ended June 30,	
	2014	**2015**
Rolapitant Expenses		
Acquired in-process research and development	$	$
Research and development	18,366	15,571
Rolapitant total	18,366	15,571
Niraparib Expenses		
Acquired in-process research and development	900	
Research and development	22,012	26,378
Niraparib total	22,912	26,378
TSR-011 Expenses		
Acquired in-process research and development		
Research and development	3,723	2,823
TSR-011 total	3,723	2,823

Immuno-Oncology Platform Expenses				
Acquired in-process research and development		17,000		1,000
Research and development		1,547		8,787
Immuno-Oncology Platform total		18,547		9,787
Personnel and Other Expenses		13,038		18,916
Total	**$**	**76,586**	**$**	**73,475**

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For further discussion of the changes in our research and development expenses with respect to the six months ended June 30, 2015 and the corresponding period of 2014, see Results of Operations Comparison of the Six Months Ended June 30, 2014 and 2015 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.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs, including stock-based compensation, for personnel in executive and other administrative or non-research and development functions. Other general and administrative expenses include certain facility-related costs, communication expenses, pre-commercialization activities and professional fees for legal, patent review, consulting and accounting services.

We anticipate that our general and administrative expenses will continue to increase in the future in support of both our preparation for the potential commercialization of our product candidates 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, including the hiring of our own sales force, continuing the development of our marketing infrastructure, executing related marketing and promotional programs, hiring consultants, establishing information technology systems, and legal and other professional fees, among other expenses. Additionally, if we obtain regulatory approval of a product candidate, we anticipate that we will continue to incur significant increases in payroll and other expenses relating to the sales and marketing of our products.

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.

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Results of Operations

Comparison of the Three Months Ended June 30, 2014 and 2015

	Three Months Ended June 30,		Increase/ (Decrease)
	2014	2015	
	(in thousands)		
Expenses:			
Research and development	$ 30,569	$ 38,930	$ 8,361
General and administrative	5,587	16,783	11,196
Acquired in-process research and development	900	1,000	100
Total expenses	37,056	56,713	19,657
Loss from operations	(37,056)	(56,713)	(19,657)
Other income (expense), net	5	(3,844)	(3,849)
Net loss	$ (37,051)	$ (60,557)	$ (23,506)

Research and Development Expenses. Research and development expenses were $38.9 million for the three months ended June 30, 2015, compared to $30.6 million for the three months ended June 30, 2014, an increase of $8.4 million. The increase was primarily due to higher expenses related to the development of our immuno-oncology platform, niraparib and rolapitant. Significant changes resulting in this increase included:

- an increase of $4.4 million in costs associated with our immuno-oncology platform strategy due to increased costs related to biologics manufacturing as well as non-clinical and other immuno-oncology program research activities;

- an increase of $1.2 million in costs associated with niraparib and rolapitant development activities, primarily related to the progression of niraparib and intravenous rolapitant clinical trials, partially offset by lower oral rolapitant clinical costs; and

- an increase of $2.0 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 $0.8 million, primarily related to increased awards of employee stock options and higher grant-date fair values of those awards.

General and Administrative Expenses. General and administrative expenses were $16.8 million for the three months ended June 30, 2015, compared to $5.6 million for the three months ended June 30, 2014, an increase of $11.2 million. The increase was primarily due to increases of: $6.4 million in salaries, benefits and other personnel-related costs, primarily due to the hiring of personnel associated with the potential commercialization of rolapitant; $3.2 million in professional and consulting fees and other expenses to support corporate operational and pre-commercialization activities; and $1.6 million in stock-based compensation expense.

Acquired In-Process Research and Development Expenses. We recorded $1.0 million in acquired in-process research and development expenses for the three months ended June 30, 2015, due to a milestone related to the initiation of the first good laboratory practice, or GLP, toxicology study under our immuno-oncology platform. We paid this amount subsequent to June 30, 2015. We recorded $0.9 million in acquired in-process research and development expenses for the three months ended June 30, 2014, consisting of a milestone payment related to the initiation of the Phase 3 clinical trial of niraparib in breast cancer patients with germline BRCA mutations in April 2014.

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 expense increased by $3.9 million in the three months ended June 30, 2015, as there was no interest expense in the prior year period. Interest income increased from $5,000 in the three months ended June 30, 2014 to $9,000 in the three months ended June 30, 2015.

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Comparison of the Six Months Ended June 30, 2014 and 2015

	Six Months Ended June 30, 2014	2015	Increase/ (Decrease)
		(in thousands)	
Expenses:			
Research and development	$ 58,686	$ 72,475	$ 13,789
General and administrative	10,275	28,025	17,750
Acquired in-process research and development	17,900	1,000	(16,900)
Total expenses	86,861	101,500	14,639
Loss from operations	(86,861)	(101,500)	(14,639)
Other income (expense), net	10	(7,563)	(7,573)
Net loss	$ (86,851)	$ (109,063)	$ (22,212)

Research and Development Expenses. Research and development expenses were $72.5 million for the six months ended June 30, 2015, compared to $58.7 million for the six months ended June 30, 2014, an increase of $13.8 million. The increase was primarily due to higher expenses related to the development of our immuno-oncology platform and niraparib, partially offset by lower expenses associated with the development of rolapitant and TSR-011. Significant changes resulting in this increase included:

- an increase of $7.2 million in costs associated with our immuno-oncology platform strategy due to increased costs related to biologics manufacturing and non-clinical research activities. In addition, the current year expense represented six months of effort on all of the current antibody candidates; the expense for the prior year period reflected effort on only those candidates identified in the initial collaboration and exclusive license agreement with AnaptysBio, which was executed during March 2014;

- an increase of $4.4 million in costs associated with niraparib development activities primarily related to increased costs of our various ovarian cancer clinical trials, partially offset by lower costs relating to drug process development and manufacturing;

- an increase of $4.2 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; and

- a decrease of $2.8 million in costs associated with rolapitant development activities, primarily due to lower costs related to the oral rolapitant Phase 3 clinical trials, which were completed in 2014, partially offset by increased costs relating to drug process development and manufacturing and costs relating to IV rolapitant Phase 1 bioequivalence, safety and other studies.

In addition, stock-based compensation expense included in research and development expenses increased by $1.7 million, primarily related to increased awards of employee stock options and higher grant-date fair values of those awards.

General and Administrative Expenses. General and administrative expenses were $28.0 million for the six months ended June 30, 2015, compared to $10.3 million for the six months ended June 30, 2014, an increase of $17.8 million. The increase was primarily due to increases of: $9.8 million in salaries, benefits and other personnel-related costs, primarily due to the hiring of personnel associated with the potential commercialization of rolapitant; $5.9 million in professional and consulting fees and other expenses to support corporate operational and pre-commercialization activities; and $2.1 million in stock-based compensation expense.

Acquired In-Process Research and Development Expenses. We recorded $1.0 million in acquired in-process research and development expenses for the six months ended June 30, 2015, due to a milestone related to the initiation of the first GLP toxicology study under our immuno-oncology platform. We recorded $17.9 million in acquired in-process research and development expenses for the six months ended June 30, 2014. This amount consisted of the $17.0 million up-front payment related to the collaboration and exclusive license agreement with AnaptysBio, and a $0.9 million milestone payment related to the initiation of the Phase 3 clinical trial of niraparib in breast cancer patients with germline BRCA mutations in April 2014.

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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 expense increased by $7.6 million in the six months ended June 30, 2015, as there was no interest expense in the prior year period. Interest income increased from $10,000 in the six months ended June 30, 2014 to $16,000 in the six months ended June 30, 2015.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have not generated any revenue. As of June 30, 2015, our principal source of liquidity was cash and cash equivalents, which totaled $354.4 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, 2014, including our 2012 initial public offering, we raised a total of $383.9 million in net cash proceeds from private placements of convertible preferred stock and public offerings of common stock. In March 2015, we completed a public offering of our common stock whereby we sold an additional 3,755,000 shares of our common stock at a price to the public of $51.00 per share and received approximately $179.8 million in proceeds, net of underwriting discounts and commissions and offering expenses.

On September 29, 2014, we completed the issuance of $201.3 million aggregate principal amount of senior convertible notes, generating proceeds, net of underwriting discounts, commissions and offering expenses, of $194.7 million. In conjunction with the sale of the Convertible Notes, we used approximately $20.8 million of the net proceeds to enter into 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 we may choose to make in excess of the principal amount, upon conversion of the Convertible Notes.

Cash Flows

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

	Six Months Ended June 30,	
	2014	**2015**
Net cash provided by (used in):		
Operating activities	$ (55,564)	$ (84,905)
Investing activities	(18,845)	(943)
Financing activities	95,187	183,356
Increase in cash and cash equivalents	$ 20,778	$ 97,508

Cash Flows from Operating Activities

The use of cash in operating activities during both the six months ended June 30, 2014 and 2015 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 $29.3 million for the six months ended June 30, 2015 compared to the six months ended June 30, 2014, primarily due to increased expenses related to pre-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 pre-launch commercial preparation 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 and TSR-011 programs.

Cash Flows from Investing Activities

The decrease of $17.9 million in net cash used in investing activities for the six months ended June 30, 2015 compared to the six months ended June 30, 2014 was due primarily to the $17.0 million up-front payment made in the six months ended June 30, 2014 in connection with the collaboration and exclusive license agreement with AnaptysBio for our immuno-oncology platform. We also made a $0.9 million milestone payment in the second quarter of 2014 related to the initiation of the Phase 3 clinical trial of niraparib in breast cancer patients with germline BRCA mutations. In June 2015 we incurred a $1.0 million milestone payment under the agreement with AnaptysBio, which we paid in July 2015.

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Cash Flows from Financing Activities

The increase of $88.2 million in net cash provided by financing activities for the six months ended June 30, 2015 compared to the six months ended June 30, 2014 was due primarily to completed public offerings of our common stock in each period. The current year period included cash proceeds of $179.8 million from the closing of our March 2015 public offering of common stock, compared to cash proceeds of $94.2 million in the prior year period from the closing of our February 2014 public offering of common stock (both amounts net of underwriting discounts and commissions and offering expenses). Also, cash proceeds from exercises of employee stock options and ESPP purchases increased by $2.6 million during the current year period.

Operating Capital Requirements

We expect to incur significant expenses and operating losses for the foreseeable future. Overall, we expect 2015 operating expenses to continue to increase for the remainder of 2015 as we incur increased costs related to the advancement of our ongoing commercialization activities, including hiring our own sales force, developing our marketing infrastructure, executing related marketing and promotional programs, hiring consultants and establishing systems in preparation for the potential commercialization of oral rolapitant, costs related to the advancement of clinical trial and other development activities under our current development programs, such as IV rolapitant, niraparib and TSR-011, costs related to the immuno-oncology development activities under our collaboration with AnaptysBio, and costs related to potential future in-licensed development programs. We are subject to the risks incident in the development of new biopharmaceutical 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 believe that our existing cash and cash equivalents will be sufficient to fund our cash flow requirements, including any license payments or milestone obligations that may arise, required costs relating to our March 2014 collaboration and exclusive license agreement with AnaptysBio and cash interest obligations related to our Convertible Notes, through at least the 12 months following the filing of this Quarterly Report on Form 10-Q. However, we expect to require additional capital for the further development and potential commercialization of our product candidates and may also need to raise 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.

Until we can generate a sufficient amount of revenue from our products, if ever, we expect to finance future cash needs through public or private equity or debt offerings and 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. 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:

- the cost of establishing sales, marketing and distribution capabilities for rolapitant 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;

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- 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 clinical development plans we establish for TSR-011;

- 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, Amgen or AnaptysBio or to any other 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;

- 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

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, 2014.

Off-Balance Sheet Arrangements

As of June 30, 2015, 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 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 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.

For a description of our 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, 2014. There have not been any material changes to our critical accounting policies since December 31, 2014.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of June 30, 2015 and December 31, 2014, we had cash and cash equivalents of $354.4 million and $256.9 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 six months ended June 30, 2015.

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.

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PART II **OTHER 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 risks set forth in the Risk Factors section of our Annual Report on Form 10-K for the year ended December 31, 2014.

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.

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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:	August 7, 2015
By:	/s/ Timothy R. Pearson Timothy R. Pearson *Executive Vice President and Chief Financial Officer* *(principal financial officer)*
Date:	August 7, 2015

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EXHIBIT INDEX

Exhibit Number	Exhibit Description
10.1+	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors
10.2+	Form of Restricted Stock Unit Agreement
10.3+	2015 Non-Employee Director Stock Incentive Plan
10.4+	Non-Qualified Stock Option Inducement Award Agreement, dated March 30, 2015, by and between the Company and Joseph L. Farmer
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

+ Indicates management contract or compensatory plan.