

TESARO, Inc.
Form 10-Q
May 02, 2014
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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 March 31, 2014

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

(State or Other Jurisdiction of
Incorporation or Organization)

27-2249687

(IRS Employer
Identification No.)

1000 Winter Street, Suite 3300

Waltham, Massachusetts

(Address of Principal Executive Offices)

02451

(Zip Code)

(339) 970-0900

(Registrant's Telephone Number, Including Area Code)

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

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

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting company)

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

As of April 30, 2014, there were 35,995,685 shares of the registrant's Common Stock, par value \$0.0001 per share, outstanding.

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TESARO, INC.

(A Development Stage Company)

**FORM 10-Q
FOR THE THREE MONTHS ENDED MARCH 31, 2014**

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Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements.****TESARO, INC.****(A Development Stage Company)****Condensed Consolidated Balance Sheets***(all amounts in 000 \$, except share and per share data)***(Unaudited)**

	December 31, 2013	March 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 130,310	\$ 180,285
Other current assets	4,029	3,317
Total current assets	134,339	183,602
Property and equipment, net	440	1,241
Other assets	799	1,311
Total assets	\$ 135,578	\$ 186,154
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,869	\$ 2,416
Accrued expenses	10,541	13,130
Other current liabilities	13	
Total current liabilities	12,423	15,546
Other non-current liabilities	3	
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized at both December 31, 2013 and March 31, 2014; no shares issued or outstanding at both December 31, 2013 and March 31, 2014		
Common stock, \$0.0001 par value; 100,000,000 shares authorized at both December 31, 2013 and March 31, 2014; 32,739,008 and 35,981,019 shares issued and outstanding at December 31, 2013 and March 31, 2014, respectively	3	4

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Additional paid-in capital	302,647	399,902
Deficit accumulated during the development stage	(179,498)	(229,298)
Total stockholders' equity	123,152	170,608
Total liabilities and stockholders' equity	\$ 135,578	\$ 186,154

See accompanying notes to condensed consolidated financial statements.

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TESARO, INC.

(A Development Stage Company)

Condensed Consolidated Statements of Operations and

Comprehensive Loss

(all amounts in 000 \$, except per share data)

(Unaudited)

	Three Months Ended March 31,		The Period from
	2013	2014	March 26, 2010
			(Inception) to
			March 31, 2014
Expenses:			
Research and development	\$ 16,503	\$ 28,117	\$ 162,856
General and administrative	2,400	4,688	31,009
Acquired in-process research and development		17,000	34,070
Total expenses	18,903	49,805	227,935
Loss from operations	(18,903)	(49,805)	(227,935)
Interest income	34	5	298
Other income (expense), net			(1,661)
Net loss	\$ (18,869)	\$ (49,800)	\$ (229,298)
Net loss per share applicable to common stockholders - basic and diluted) \$ (0.66) \$ (1.43) \$ (16.86
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	28,798	34,856	13,600
Comprehensive loss	\$ (18,869)	\$ (49,800)	\$ (229,298)

See accompanying notes to condensed consolidated financial statements.

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TESARO, INC.

(A Development Stage Company)

Condensed Consolidated Statements of Cash Flows

(all amounts in 000 \$)

(Unaudited)

	Three Months Ended March 31,		The Period from
	2013	2014	March 26, 2010 (Inception) to March 31, 2014
Operating activities			
Net loss	\$ (18,869)	\$ (49,800)	\$ (229,298)
Adjustments to reconcile net loss to net cash used in operating activities:			
Acquired in-process research and development		17,000	34,070
Depreciation expense	37	63	348
Increase in fair value of investor rights obligation			1,661
Stock-based compensation expense	770	2,538	12,405
Loss on disposal of property and equipment		80	80
Changes in operating assets and liabilities:			
Other assets	294	200	(4,628)
Accounts payable	(1,065)	486	2,355
Accrued expenses	956	2,310	12,851
Other liabilities	23	(16)	
Net cash used in operating activities	(17,854)	(27,139)	(170,156)
Investing activities			
Acquisition of product candidate and technology licenses and milestone payments		(17,000)	(33,440)
Purchase of property and equipment	(308)	(604)	(1,329)
Net cash used in investing activities	(308)	(17,604)	(34,769)
Financing activities			
Proceeds from sale of common stock, net of issuance costs	91,312	94,199	263,471
Proceeds from exercise of stock options	49	519	1,186
Proceeds from issuance of common stock under Employee Stock Purchase Plan			147
Proceeds from sale of convertible preferred and common stock and related investor rights, net of issuance costs			120,406
Net cash provided by financing activities	91,361	94,718	385,210
Increase in cash and cash equivalents	73,199	49,975	180,285
Cash and cash equivalents at beginning of period	125,445	130,310	
Cash and cash equivalents at end of period	\$ 198,644	\$ 180,285	\$ 180,285

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Non-cash investing and financing activities

Issuance of Series O convertible preferred stock	\$	\$	\$	630
Settlement of investor rights obligation	\$	\$	\$	3,829
Purchase of property and equipment - cash not paid as of period end	\$	\$	340	\$ 340
Conversion of convertible preferred stock to common stock	\$	\$	\$	122,697

See accompanying notes to condensed consolidated financial statements.

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TESARO, INC.

(A Development Stage Company)

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Description of Business

TESARO, Inc., or the Company or TESARO, is a development stage company that was incorporated in Delaware on March 26, 2010 and commenced operations in May 2010. TESARO is 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 globally. 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. The Company currently operates in one segment. The Company has never earned revenue from these activities, and, accordingly, the Company is considered to be in the development stage as of March 31, 2014. The Company is subject to a number of risks similar to those of other development stage companies, including dependence on key individuals, the need to develop commercially viable products, competition from other companies, many of whom are larger and better capitalized, and the need to obtain adequate additional financing to fund the development 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 financings, and 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 achieving a level of revenues adequate to support the Company's 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

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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 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 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 March 31, 2013 and 2014.

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, 2013 and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2013.

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New Accounting Pronouncements - Recently Adopted

In July 2013, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2013-11, which requires entities to present an unrecognized tax benefit, or a portion of an unrecognized tax benefit, as a reduction to a deferred tax asset for a net operating loss carryforward or a similar tax loss or a tax credit carryforward, unless certain conditions exist. This guidance is effective prospectively for fiscal years beginning after December 15, 2013. Early adoption and retrospective application are permitted. The Company adopted this guidance effective January 1, 2014 and this adoption did not have a material effect on its condensed consolidated financial statements.

New Accounting Pronouncements - Recently Issued

In April 2014, the FASB issued ASU No. 2014-08, which amends guidance for reporting discontinued operations and disposals of components of an entity. The amended guidance requires that a disposal representing a strategic shift that has (or will have) a major effect on an entity's operations and financial results or a business activity classified as held for sale should be reported as discontinued operations. The amendments also expand the disclosure requirements for discontinued operations and add new disclosures for individually significant dispositions that do not qualify as discontinued operations. This guidance is effective prospectively for fiscal years beginning after December 15, 2014 (early adoption is permitted only for disposals that have not been previously reported). The Company does not expect the adoption of this guidance to have a material effect on its consolidated financial statements.

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, expenses, other comprehensive income and the related disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to accrued research and development expenses and stock-based compensation expense. 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 certificate of deposits, commercial paper and U.S. government and U.S. government agency obligations. Cash equivalents are reported at fair value.

Fair Value of Financial Instruments

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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 indirectly	Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly
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, 2013 and March 31, 2014 and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

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Description	Balance Sheet Classification	Total	December 31, 2013		
			Level 1	Level 2	Level 3
Assets:					
Money market funds	Cash and cash equivalents	\$ 128,801	\$ 128,801	\$	\$
Total assets		\$ 128,801	\$ 128,801	\$	\$

Description	Balance Sheet Classification	Total	March 31, 2014		
			Level 1	Level 2	Level 3
Assets:					
Money market funds	Cash and cash equivalents	\$ 179,460	\$ 179,460	\$	\$
Total assets		\$ 179,460	\$ 179,460	\$	\$

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

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;
- expenses incurred under agreements with contract research organizations, investigative sites and research consortia in connection with the conduct of clinical trials and preclinical studies and related services, such as administrative, data management and biostatistics services;
- the cost of acquiring, developing and manufacturing active pharmaceutical ingredients, clinical trial materials and other research and development materials;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent, utilities, maintenance of facilities, insurance and other supplies; and

- costs associated with preclinical activities and regulatory operations.

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 the Company by its vendors on their actual costs incurred. 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 condensed 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 new drug compound did not also include processes or activities that would constitute a business, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use.

Stock-Based Compensation Expense

Stock-based compensation is recognized as expense for all stock-based awards based on estimated fair values. The Company determines the fair values of equity-based awards at the grant date using the Black-Scholes option pricing model. 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.

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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 convertible preferred stock (for the periods in which it was outstanding), outstanding stock options and unvested restricted stock, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

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

	Three Months Ended March 31,		The Period from
	2013	2014	March 26, 2010
			(Inception) to
			March 31, 2014
Outstanding stock options	2,783	3,364	3,364
Unvested restricted stock	287	31	31
	3,070	3,395	3,395

4. 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, 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 initially allowed the Company to grant awards for up to 1,428,571 shares of common stock plus the number of shares of common stock available for grant under the 2010 Incentive Plan as of the effectiveness of the 2012 Incentive Plan (which was an additional 6,857 shares) plus that 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. Each year starting with 2014, the number of shares available for grants of awards under the 2012 Incentive Plan will be 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, the number of shares authorized for issuance under the 2012 Incentive Plan was increased by 1,309,560 shares. 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.

Prior to the approval of the 2012 Incentive Plan, the Company granted equity awards under the 2010 Incentive Plan. As a result of the approval of the 2012 Incentive Plan, in April 2012 the Company ceased making awards under the 2010 Incentive Plan. Any shares subject to outstanding awards granted under the 2010 Incentive Plan that remained available at that time or that expire or terminate for any reason prior to exercise have been added to the total number of shares available for issuance under the 2012 Incentive Plan. Under the 2010 Incentive Plan, the

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Company was authorized to grant equity awards up to an aggregate of 1,981,130 shares of common stock. The exercise price of each stock option granted to date has been equal to the closing price of a share of the Company's common stock on the grant date or the fair value as determined by the board of directors on the grant date.

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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 March 31,		The Period from March 26, 2010 (Inception) to March 31, 2014	
	2013	2014		
Research and development	\$ 332	\$ 910	\$	3,534
General and administrative	438	1,628		8,871
Total stock-based compensation expense	\$ 770	\$ 2,538	\$	12,405

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

	Shares	Weighted-average grant date fair value per share
Unvested restricted stock at December 31, 2013	102,412	\$ 0.76
Granted		
Vested	(62,011)	0.10
Forfeited	(8,929)	0.53
Unvested restricted stock at March 31, 2014	31,472	\$ 2.14

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, 2013	2,852,793	\$ 12.77
Granted	737,898	33.11
Exercised	(50,940)	10.19
Cancelled	(175,551)	11.36
Outstanding at March 31, 2014	3,364,200	\$ 17.35
Vested at March 31, 2014	1,103,977	\$ 7.43
Vested and expected to vest at March 31, 2014	3,364,200	\$ 17.35

At March 31, 2014, there was approximately \$30.6 million of total unrecognized compensation cost related to unvested stock options, which the Company expects to recognize over a remaining weighted-average period of 2.8 years. At March 31, 2014, total unrecognized compensation cost related to unvested restricted stock was insignificant.

On June 6, 2012, the board of directors adopted the 2012 ESPP, and the stockholders approved it on June 18, 2012, to be effective in connection with the closing of the Company's initial public offering. An aggregate of 275,000 shares of common stock have been reserved for issuance under the 2012 ESPP pursuant to purchase rights granted to the Company's employees or to employees of the Company's designated subsidiaries.

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As of March 31, 2014, the Company had issued an aggregate of 7,831 shares under the 2012 ESPP. As of March 31, 2014, the Company has recognized approximately \$0.1 million in related stock-based compensation expense.

During 2013, the Company's former Executive Vice President, Chief Financial Officer, Treasurer and Secretary, or the former CFO, resigned from his employment with the Company effective August 31, 2013 and transitioned to serving the Company as a non-employee consultant. In accordance with the terms of the 2012 Incentive Plan and the 2010 Incentive Plan, stock awards previously granted to the former CFO under these plans continued to vest through March 31, 2014 (the end of the term of the Company's consulting agreement with the former CFO). As a result, beginning in September 2013 and ending March 31, 2014, the Company has accounted for unvested stock awards previously granted to the former CFO as non-employee awards. The Company has recorded stock-based compensation expense based on the fair values of awards as measured on their vesting dates, and the fair values of any unvested awards are remeasured at each financial reporting date until they vest, with any increases or decreases in fair value recorded as stock-based compensation expense. Fair values of

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stock options are determined on each measurement date using the Black-Scholes option pricing model, and fair values of restricted stock awards are equal to the fair market value of the Company's common stock on the measurement date. During the three months ended March 31, 2014, the Company recorded incremental stock-based compensation expense of \$0.4 million associated with these awards.

5. Common Stock Transactions

In March 2013, the Company sold 5,428,000 shares of common stock, \$0.0001 par value per share, in an underwritten public offering at a price to the public of \$18.00 per share, resulting in gross proceeds of approximately \$97.7 million. Net proceeds to the Company after deducting fees, commissions and other expenses related to the offering were approximately \$91.3 million. The shares were issued pursuant to a registration statement on Form S-1.

In February 2014, the Company sold 3,200,000 shares of common stock, \$0.0001 par value per share, 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.

6. 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 months ended March 31, 2013 and 2014, the Company did not record any current or deferred income tax provisions or benefits. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded full valuation allowances against its otherwise recognizable net deferred tax assets at both December 31, 2013 and March 31, 2014.

7. Commitments and Contingencies

In January 2014, the Company entered into an amendment of its existing office lease agreement whereby beginning in March 2014 it expanded the total leased space in the facility to approximately 53,200 square feet and extended the term of the lease through June 30, 2017. The amended lease provides for additional rent expense of approximately \$0.9 million on an annualized basis. In addition, the amended lease increased the security deposit to approximately \$0.7 million and continues to require the Company to pay a proportionate share of certain of the landlord's annual operating costs. The Company recognizes rental expense on a straight-line basis over the respective lease term.

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Future minimum rental commitments under the amended lease as of March 31, 2014 were \$1.3 million, \$1.7 million, \$1.7 million and \$0.8 million for the remainder of the year ending December 31, 2014, and the years ending December 31, 2015, 2016 and 2017, respectively.

The Company has entered into agreements with certain vendors for the provision of services, including services related to data management and clinical operation support services, 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.

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Legal Proceedings

The Company may periodically become subject to legal proceedings and claims arising in connection with on-going 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 does not have contingency reserves established for any litigation liabilities.

8. AnaptysBio Collaboration and Exclusive License Agreement

Immuno-Oncology Platform License

In March 2014, the Company entered into a collaboration and exclusive license agreement with AnaptysBio, Inc., or AnaptysBio, a privately-held therapeutic antibody company. Under the terms of this agreement, the Company obtained an exclusive, royalty-bearing, sublicenseable worldwide license to research, develop, manufacture, market and sell products based on AnaptysBio's proprietary technology for the discovery, generation and optimization of certain specified immunotherapy antibodies. Specifically, the Company received exclusive rights to monospecific antibody product candidates targeting TIM-3, LAG-3 and PD-1 (TSR-042) and dual-reactive antibody product candidates targeting PD-1/TIM-3 and PD-1/LAG-3. Under the agreement, AnaptysBio is responsible for performing initial discovery and development of therapeutic antibodies, with the goal of generating immunotherapy antibodies for use in the treatment of cancer. The Company is responsible for the performance and costs of all subsequent preclinical, clinical, regulatory, manufacturing and other activities necessary to develop and commercialize antibodies selected under each of three development programs and is obligated to use commercially reasonable efforts to research, develop or commercialize at least one product under each development program.

Under the terms of the agreement, the Company made an up-front, non-creditable and non-refundable cash payment of \$17.0 million to AnaptysBio in March 2014. The Company is also required to reimburse AnaptysBio, on a quarterly basis for up to two years from the effective date of the agreement, for specified costs incurred by AnaptysBio in its initial discovery and development activities covered by the agreement. Programs may be extended by mutual agreement of the parties, and the Company can terminate on a program-by-program basis by providing 90 days' prior written notice, subject to a wind-down period during which the Company's obligation to reimburse AnaptysBio for specified costs would continue. For each of the three development programs, the Company will be required to make milestone payments to AnaptysBio of up to \$18.0 million if certain research and development milestone events are achieved, 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. The Company will be required to pay AnaptysBio tiered single-digit royalties, on a product-by-product basis, on the amount of worldwide annual net sales achieved, and additional commercial milestone payments if specified levels of annual net sales of a product are attained.

As of the date of the license transaction, none of the assets acquired had alternative future uses, nor had they reached a stage of technological feasibility. As the processes or activities that were acquired along with the license do not constitute a business, the transaction has been accounted for as an asset acquisition. In addition, the Company has concluded that it is reimbursing AnaptysBio at fair value for the research services called for under the agreement. As a result of these factors, the entire up-front payment of \$17.0 million has been recorded as acquired in-process research and development expense, and no portion of the payment has been ascribed to the future services to be provided to the Company by AnaptysBio. The Company has recorded approximately \$0.2 million of research and development expense associated with amounts due to AnaptysBio under the collaboration through March 31, 2014. As of March 31, 2014, the Company has not made any additional milestone payments under this agreement.

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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, 2013.

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 expectation that research and development and general and administrative expenses will increase in the future; our expectations regarding our development plans for rolapitant, niraparib and TSR-011; our expectations regarding our discovery and development plans for immunotherapy antibodies; our plans not to develop backup compounds to which we currently have rights; our anticipated royalty payments; 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.

The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in this Quarterly Report on Form 10-Q, including those risks identified in our Annual Report on Form 10-K for the year ended December 31, 2013.

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

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currently developing three oncology-related product candidates, rolapitant, niraparib and TSR-011, and, in March 2014 we initiated our immuno-oncology platform strategy by entering into a collaboration and exclusive license agreement with AnaptysBio, Inc., or AnaptysBio, for the discovery and development of antibodies for immuno-oncology targets.

- *Rolapitant* is a potent and long-acting neurokinin-1, or NK-1, receptor antagonist currently in Phase 3 (oral formulation) and Phase 1 (intravenous formulation) clinical trials for the prevention of chemotherapy induced nausea and vomiting, or CINV. In December 2013, we announced top-line results for two Phase 3 trials of rolapitant. The primary endpoint was successfully achieved in each trial, and preparations in support of our anticipated submission to the U.S. Food and Drug Administration, or FDA, in mid-2014 of a new drug application, or NDA, for oral rolapitant are ongoing.
- *Niraparib*, formerly known as MK-4827, 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. In April 2014, we dosed the first patient in a Phase 3 clinical trial evaluating niraparib in breast cancer patients with germline

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BRCA mutations. We also are collaborating with the Sarcoma Alliance for Research through Collaboration, or SARC, to evaluate niraparib in combination with temozolomide for the treatment of Ewing's sarcoma. We may also evaluate niraparib for the treatment of gastric, lung and prostate cancer.

- *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 fractionated 60 milligram (mg) doses of TSR-011 in patients with ALK or TRK expression, including those with ALK-positive, or ALK+, and TRK-positive, or TRK+, 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.

- *Immuno-Oncology Platform:* Under the terms of our collaboration and exclusive license agreement with AnaptysBio, we obtained an exclusive, royalty-bearing, sublicenseable worldwide license to research, develop, manufacture, market and sell products incorporating certain specified immunotherapy antibodies developed using AnaptysBio's proprietary technology for the discovery, generation and optimization of antibodies. We believe that these therapeutic antibodies will form the basis of a strategic platform that will potentially enable us to initiate clinical development in new tumor indications not addressed with our current product candidates and to study combination approaches in the clinic, both with our existing product candidates and with new candidates we either in-license or access through collaborative transactions with others. We believe that antibody candidates from this platform may potentially enter clinical trials over the next 18 to 24 months. For example, we anticipate beginning clinical trials using TSR-042, the lead anti-PD-1 antibody that we have in-licensed as part of the agreement, in mid-2015.

Development Stage Operations. 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 and clinical trials of 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 and private placements of our preferred stock.

As of March 31, 2014, we had a deficit accumulated during the development stage of \$229.3 million. Our net losses were \$49.8 million, \$92.4 million, \$61.8 million, \$16.4 million and \$9.0 million for the three months ended March 31, 2014, the years ended December 31, 2013, 2012 and 2011 and for the period from March 26, 2010 (inception) to December 31, 2010, respectively. We expect to incur significant expenses and operating losses for the foreseeable future. Overall, we expect operating expenses to increase over time, primarily dependent on the timing and magnitude of clinical trial and other development activities under our current development programs, such as niraparib and TSR-011, costs incurred related to the immuno-oncology discovery and development activities occurring under our collaboration with AnaptysBio and potential future in-licensed development programs, and expected decreases in clinical trial and other development activities under our rolapitant program. In addition, future up-front license payments or milestone payments, which we expense as acquired in-process research and development as incurred, could cause our total operating expenses to fluctuate. For example, during the three months ended March 31, 2014, we recorded \$17.0 million in acquired in-process research and development expense resulting from the up-front payment relative to our collaboration and exclusive license agreement with AnaptysBio. If we obtain regulatory approval for any of our product candidates, we expect 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. 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.

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Rolapitant. In December 2010, we entered into a license agreement with OPKO Health, Inc., or 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 the same rights and obligations as rolapitant, but which we are not currently advancing. In consideration for this license, we paid OPKO \$6.0 million upon signing the agreement and issued 1,500,000 shares of our Series O convertible preferred stock. At the time of this transaction, the fair value of the Series O convertible preferred stock was determined to be \$0.6 million. We are also required to make development milestone payments to OPKO of up to an aggregate of \$30.0 million if specified regulatory and initial

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commercial sales milestones are achieved. Preparations in support of our anticipated submission to the FDA in mid-2014 of an NDA for oral rolapitant are currently ongoing; upon acceptance of this NDA by the FDA, we would owe OPKO a milestone payment of \$5.0 million. In addition, we are required to make additional 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 the date that all of the patent rights licensed from OPKO and covering rolapitant expire, are invalidated or are not enforceable and 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. There were no ongoing clinical trials for rolapitant or SCH900978 at the time of our acquisition of these rights. As of the date of acquisition, none of the assets acquired had alternative future uses, nor had they reached a stage of technological feasibility. We accounted for this transaction as an asset acquisition because we did not acquire any processes or activities that would constitute a business in addition to the license. Accordingly, we recorded the entire purchase price of \$6.6 million as acquired in-process research and development expense in 2010.

Niraparib. In May 2012, we entered into a license agreement with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., or 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 made an up-front payment to Merck of \$7.0 million in June 2012. We have made two milestone payments to Merck, one in the amount of \$1.9 million upon dosing of the first patient in our Phase 3 ovarian cancer clinical trial in July 2013 and one in the amount of \$0.9 million upon dosing of the first patient in our Phase 3 breast cancer clinical trial in April 2014. We are required to make total milestone payments to Merck of up to \$57.0 million in 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 a Phase 3 clinical study, which we initiated in July 2013. We are also evaluating niraparib in breast cancer patients with germline BRCA mutations in a Phase 3 clinical trial, which we initiated in April 2014. We also are collaborating with SARC to evaluate niraparib in combination with temozolomide for the treatment of Ewing's sarcoma. We may also evaluate niraparib for the treatment of gastric, lung and prostate cancer. None of the assets to which we acquired rights have alternative future uses, nor have they reached a stage of technological feasibility. We accounted for this transaction as an asset acquisition because we did not acquire any processes or activities that would constitute a business in addition to the license. Accordingly, we recorded the entire purchase price of \$7.0 million as acquired in-process research and development expense in 2012.

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 made an up-front payment to Amgen of \$0.5 million, and upon dosing of the first patient in our Phase 1/2a clinical trial of TSR-011 in October 2012, we 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

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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. At the time of the license transaction, TSR-011 was a preclinical compound. We are currently conducting a Phase 1/2a dose escalation clinical trial in cancer patients. We accounted for this transaction as an asset acquisition because we did not acquire any processes or activities that would constitute a business in addition to the license. Accordingly, we recorded the entire purchase price of \$0.5 million as acquired in-process research and development expense in 2011.

Immuno-Oncology Platform. In March 2014, we entered into a collaboration and exclusive license agreement with AnaptysBio, a privately-held therapeutic antibody company. Under the terms of this agreement, we obtained an exclusive, royalty-bearing, sublicenseable worldwide license to research, develop, manufacture, market and sell products based on AnaptysBio's proprietary technology for the discovery, generation and optimization of certain specified immunotherapy antibodies. Specifically, we received exclusive rights to monospecific antibody product candidates targeting TIM-3, LAG-3 and PD-1 (TSR-042) and dual-reactive antibody product candidates targeting PD-1/TIM-3 and PD-1/LAG-3. Under the 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 three 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 this agreement, we made an up-front, non-creditable and non-refundable cash payment of \$17.0 million to AnaptysBio. We are also 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 three development programs, we will also be required to make milestone payments to AnaptysBio of up to \$18.0 million if certain research and development milestone events are achieved, 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 the amount of worldwide annual net sales achieved, and additional commercial milestone payments if specified levels of annual net sales of a product are attained. At the time of the license transaction, the specified antibodies were in preclinical development. We accounted for this transaction as an asset acquisition because the processes or activities that were acquired along with the license do not constitute a business. We recorded the entire up-front payment of \$17.0 million as acquired in-process research and development expense.

Public Offerings of Common Stock and Private Placements of Securities. As of March 31, 2014, our principal source of liquidity was cash and cash equivalents, which totaled \$180.3 million. Since our inception on March 26, 2010, we have funded our operations primarily through public offerings of our common stock and the private placement of our equity securities. In July 2012, we completed an initial public offering of our common stock whereby we sold 6,430,183 shares of our common stock at a price to the public of \$13.50 per share and received approximately \$78.0 million in proceeds, net of underwriting discounts and commissions and offering expenses. In March 2013, we completed a public offering of our common stock whereby we sold an additional 5,428,000 shares of our common stock at a price to the public of \$18.00 per share and received approximately \$91.3 million in proceeds, net of underwriting discounts and commissions and offering expenses. In February 2014, we completed a public offering of our common stock whereby we sold an additional 3,200,000 shares of our common stock at a price to the public of \$31.50 per share and received approximately \$94.2 million in proceeds, net of underwriting discounts and commissions and offering expenses. Prior to our initial public offering, we had received \$120.4 million in net proceeds from the issuance of preferred stock.

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;

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- employee-related expenses, including salaries, bonuses, benefits, travel and stock-based compensation expense;
- expenses incurred under agreements with contract research organizations, investigative sites and research consortia in connection with the conduct of clinical trials and preclinical studies and related services, such as administrative, data management and biostatistics services;
- the cost of acquiring, developing and manufacturing active pharmaceutical ingredients, clinical trial materials and other research and development materials;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent, utilities, maintenance of facilities, insurance and other supplies; and
- costs associated with other preclinical activities and regulatory operations.

Research and development costs are expensed as incurred. License fees and milestone payments related to in-licensed products and technology are expensed 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. We expect that our total research and development costs will increase in fiscal year 2014 versus the prior year, depending on the progress of our clinical development programs as well as costs associated with our collaboration with AnaptysBio and potential milestone payments. We expect overall costs associated with our rolapitant development program to decrease going forward, principally due to the reduction of activities as we finalize our Phase 3 clinical trials of oral rolapitant. However, this decrease will be offset to an extent by increased development activities with respect to our intravenous formulation of rolapitant. In addition, we expect an increase in costs associated with our niraparib development program, for which we enrolled the first patient in our Phase 3 clinical trial in patients with ovarian cancer in July 2013 and enrolled the first patient in our Phase 3 clinical trial in breast cancer patients with germline BRCA mutations in April 2014. We expect costs associated with our TSR-011 development program to increase as we continue to progress through clinical testing. Finally, we expect to incur milestone and other discovery and development related expenses under our March 2014 collaboration and exclusive license agreement with AnaptysBio, which will further contribute to higher research and development expenses in 2014.

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

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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.

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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 through March 31, 2014 (in thousands):

	Three Months Ended March 31,		The Period From
	2013	2014	March 26, 2010 (Inception) to March 31, 2014
<i>Rolapitant Expenses</i>			
Acquired in-process research and development	\$	\$	\$ 6,630
Research and development	11,314	10,370	98,634
Rolapitant total	11,314	10,370	105,264
<i>Niraparib Expenses</i>			
Acquired in-process research and development			8,940
Research and development	1,732	9,183	25,604
Niraparib total	1,732	9,183	34,544
<i>TSR-011 Expenses</i>			
Acquired in-process research and development			1,500
Research and development	471	2,210	9,488
TSR-011 total	471	2,210	10,988
<i>Immuno-Oncology Platform Expenses</i>			
Acquired in-process research and development		17,000	17,000
Research and development		244	244
Immuno-Oncology Platform total		17,244	17,244
<i>Personnel and Other Expenses</i>			
	2,986	6,110	28,886
Total	\$ 16,503	\$ 45,117	\$ 196,926

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 for personnel, including stock-based compensation and travel expenses, in executive and other administrative functions. Other general and administrative expenses include facility related costs, communication expenses and professional fees for legal, patent review, consulting and accounting services.

We anticipate that our general and administrative expenses will increase in the future in support of continued research and development activities, potential commercialization of our product candidates and continued costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and payments to outside consultants, lawyers and accountants, among other expenses. Additionally, if and when we believe a regulatory approval of the first product candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

Other Income and Expense

Other income and expense consists primarily of interest income earned on cash and cash equivalents.

Table of Contents**Results of Operations****Comparison of the Three Months Ended March 31, 2013 and 2014**

	Three Months Ended March 31,		Increase/ (Decrease)
	2013	2014	
	(in thousands)		
Expenses:			
Research and development	\$ 16,503	\$ 28,117	\$ 11,614
General and administrative	2,400	4,688	2,288
Acquired in-process research and development		17,000	17,000
Total expenses	18,903	49,805	30,902
Loss from operations	(18,903)	(49,805)	(30,902)
Other income (expense), net	34	5	(29)
Net loss	\$ (18,869)	\$ (49,800)	\$ (30,931)

Research and Development Expenses. Research and development expenses were \$28.1 million for the three months ended March 31, 2014, compared to \$16.5 million for the three months ended March 31, 2013, an increase of \$11.6 million. The increase was primarily due to higher expenses related to the development of our in-licensed product candidates niraparib and TSR-011, partially offset by lower expenses associated with the development of our in-licensed product candidate rolapitant. Significant changes resulting in this increase included:

- an increase of \$7.5 million in costs associated with niraparib development activities, primarily related to the Phase 3 clinical trial of niraparib in subjects with ovarian cancer, which was initiated in July 2013, start-up activities for the Phase 3 clinical trial in breast cancer patients with germline BRCA mutations, and costs relating to drug substance and drug product development, clinical supply manufacturing and distribution;
- an increase of \$2.5 million in salaries, benefits and other personnel costs (excluding stock-based compensation) related to increased research and development headcount supporting the growth of our development activities;
- an increase of \$1.7 million in costs associated with TSR-011 development activities, which primarily resulted from higher clinical costs associated with the ongoing Phase 1/2a clinical study and costs relating to drug substance and drug product development;
- an increase of \$0.6 million in stock-based compensation expense, related to increased awards of employee stock options and higher grant-date fair values of those awards; and

- a decrease of \$0.9 million in costs associated with rolapitant development activities, primarily the Phase 3 and other ongoing clinical trials, and costs related to nonclinical toxicology studies.

Research and development expenses related to our immuno-oncology platform strategy, which was initiated in March 2014, totaled \$0.2 million for the three months ended March 31, 2014.

General and Administrative Expenses. General and administrative expenses were \$4.7 million for the three months ended March 31, 2014, compared to \$2.4 million for the three months ended March 31, 2013, an increase of \$2.3 million. The increase was due primarily to increases of \$1.2 million in stock-based compensation expense, of which \$0.4 million was related to variable accounting for awards held by a non-employee consultant, with the remainder related to increased awards of employee stock options and higher grant-date fair values of those awards, \$0.5 million in salaries, benefits and other personnel related costs, and \$0.6 million in professional and consulting fees and other expenses to support corporate operational activities.

Acquired In-Process Research and Development Expenses. We recorded \$17.0 million in acquired in-process research and development expenses for the three months ended March 31, 2014, consisting of the up-front payment related to the collaboration and exclusive license agreement with AnaptysBio. There were no acquired in-process research and development expenses for the three months ended March 31, 2013.

Other Income (Expense), Net. Other income is primarily comprised of interest income earned on cash and cash equivalents.

Table of Contents**Liquidity and Capital Resources***Sources of Liquidity*

To date, we have not generated any revenue. As of March 31, 2014, our principal source of liquidity was cash and cash equivalents, which totaled \$180.3 million. Since our inception on March 26, 2010, we have funded our operations primarily through public offerings of our common stock and the private placement of our equity securities. In July 2012, we completed an initial public offering of our common stock whereby we sold 6,430,183 shares of our common stock at a price to the public of \$13.50 per share and received approximately \$78.0 million in proceeds, net of underwriting discounts and commissions and offering expenses. In March 2013, we completed a public offering of our common stock whereby we sold an additional 5,428,000 shares of our common stock at a price to the public of \$18.00 per share and received approximately \$91.3 million in proceeds, net of underwriting discounts and commissions and offering expenses. In February 2014, we completed a public offering of our common stock whereby we sold an additional 3,200,000 shares of our common stock at a price to the public of \$31.50 per share and received approximately \$94.2 million in proceeds, net of underwriting discounts and commissions and offering expenses. Prior to July 2012, we had received \$120.4 million in net proceeds from the private placement of our preferred stock.

Cash Flows

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

	Three Months Ended March 31,	
	2013	2014
Net cash provided by (used in):		
Operating activities	\$ (17,854)	\$ (27,139)
Investing activities	(308)	(17,604)
Financing activities	91,361	94,718
Increase in cash and cash equivalents	\$ 73,199	\$ 49,975

Cash Flows from Operating Activities

The use of cash in operating activities during both the three months ended March 31, 2013 and 2014 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 \$9.3 million for the three months ended March 31, 2014 compared to the three months ended March 31, 2013, primarily due to an increase in research and development expenses as we continued to progress the rolapitant, niraparib and TSR-011 development programs and initiated the immuno-oncology platform. This increase included higher external research and development costs, primarily associated with our niraparib and TSR-011 programs, coupled with higher costs associated with increased employee headcount, partially offset by lower costs associated with our rolapitant program.

Cash Flows from Investing Activities

The increase of \$17.3 million in net cash used in investing activities for the three months ended March 31, 2014 compared to the three months ended March 31, 2013 was due primarily to the \$17.0 million up-front payment made in the first quarter of 2014 in connection with the collaboration and exclusive license agreement with AnaptysBio for our immuno-oncology platform. We did not make any comparable product candidate license or milestone payments in the first quarter of 2013. Cash used for capital expenditures increased by \$0.3 million, primarily due to purchases of furniture and other fixed assets for the additional office space we occupied at our headquarters in Waltham, Massachusetts during the first quarter of 2014.

Cash Flows from Financing Activities

The increase of \$3.4 million in net cash provided by financing activities for the three months ended March 31, 2014 compared to the three months ended March 31, 2013 was due primarily to the public offerings of our common stock that occurred in each period. The current year period included cash proceeds of \$94.2 million from the closing of our February 2014 public offering of common stock, compared to cash proceeds of \$91.3 million in the prior year period from the closing of our March 2013 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 increased by \$0.5 million.

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Operating Capital Requirements

We do not anticipate commercializing any of our product candidates within the next 12 months. Further, we anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to primarily increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. We are subject to all of 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 projected operating requirements, including any milestone obligations that may arise, and costs relating to our March 2014 collaboration and exclusive license agreement with AnaptysBio, through at least the next 12 months. However, we expect to require additional capital for the further development and 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.

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 may 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 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 initiation, progress, timing, costs and results of clinical trials for our product candidates and any future product candidates we may in-license, including our Phase 3 clinical trials for rolapitant and niraparib;
- the clinical development plans we establish for TSR-011;
- the discovery, preclinical and clinical development plans that are or will be established for potential product candidates under our collaboration with AnaptysBio;

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- 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 outcome, timing and cost of regulatory approvals by the FDA and comparable foreign regulatory authorities, including the potential that the FDA or comparable foreign regulatory authorities may require that we perform more studies than those that we currently expect;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities; and

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- the cost of establishing sales, marketing and distribution capabilities for rolapitant or any product candidates for which we may receive regulatory approval.

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

Except as described below, 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, 2013.

In January 2014, we entered into an amendment of our office facility lease agreement whereby beginning in March 2014, we expanded the total leased space in the facility to 53,200 square feet and extended the term of the lease through June 30, 2017. The amended lease provides for additional rent expense of approximately \$0.9 million on an annualized basis. In addition, the amended lease increased the security deposit to approximately \$0.7 million and continues to require us to pay a proportionate share of certain of the landlord's annual operating costs. Future minimum rental commitments under the amended lease as of March 31, 2014 were \$1.3 million, \$1.7 million, \$1.7 million and \$0.8 million for the remainder of the year ending December 31, 2014, and the years ending December 31, 2015, 2016 and 2017, respectively.

Pursuant to our March 2014 collaboration and exclusive license agreement with AnaptysBio, we have made an up-front, non-creditable and non-refundable cash payment of \$17.0 million to AnaptysBio. We are also required to reimburse AnaptysBio, on a quarterly basis for up to two years from the effective date of the agreement, for specified costs incurred by AnaptysBio in its initial discovery and development activities covered by the agreement. Programs may be extended by mutual agreement of the parties, and the Company can terminate on a program-by-program basis by providing 90 days prior written notice, subject to a wind-down period during which the Company's obligation to reimburse AnaptysBio for specified costs would continue. For each of our three development programs, we will also be required to make milestone payments to AnaptysBio of up to \$18.0 million if certain research and development milestone events are achieved, 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, and additional commercial milestone payments if specified levels of annual net sales of a product are attained. Finally, when and if commercial sales of a product developed under this agreement commence, we will pay royalties on net sales of the product.

Off-Balance Sheet Arrangements

As of March 31, 2014, we did not have any off-balance sheet arrangements as defined in Regulation S-K, Item 303(a)(4)(ii).

Critical Accounting Policies

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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, 2013. There have not been any material changes to our critical accounting policies since December 31, 2013.

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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 March 31, 2014 and December 31, 2013, we had cash and cash equivalents of \$180.3 million and \$130.3 million, respectively, consisting primarily of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates, particularly because our investments are in short-term securities. Our securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio. There has been no material change to our interest rate sensitivity during the three months ending March 31, 2014.

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, 2013. There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013.

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: May 2, 2014

By: /s/ Edward C. English
Edward C. English
*Vice President of Finance and Administration
(principal financial and accounting officer)*

Date: May 2, 2014

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EXHIBIT INDEX

Exhibit Number	Exhibit Description
10.1*	Collaboration and Exclusive License Agreement by and among TESARO, Inc., TESARO Development, Ltd. and AnaptysBio, Inc., dated as of March 10, 2014.
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
EX-101.INS	XBRL Instance Document
EX-101.SCH	XBRL Taxonomy Extension Schema Document
EX-101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
EX-101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
EX-101.LAB	XBRL Taxonomy Extension Label Linkbase Document
EX-101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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