TESARO, Inc.
Form 10-Q
April 26, 2013
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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, 2013

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 o
Non-accelerated filer x (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 April 25, 2013 there were 32,579,200 shares of the registrant s Common Stock, par value $.0001 per share, outstanding.

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TESARO, INC.

(A Development Stage Company)

FORM 10-Q
FOR THE THREE MONTHS ENDED MARCH 31, 2013

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

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TESARO, INC.

(A Development Stage Company)

Condensed Consolidated Balance Sheets

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

(Unaudited)

	December 31, 2012	March 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 125,445	$ 198,644
Other current assets	1,175	889
Total current assets	126,620	199,533
Property and equipment, net	219	490
Other assets	541	533
Total assets	$ 127,380	$ 200,556
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 3,170	$ 2,105
Accrued expenses	8,545	9,501
Other current liabilities	3	13
Total current liabilities	11,718	11,619
Other non-current liabilities		13
Commitments and contingencies *(Note 7)*		
Stockholders equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at both December 31, 2012 and March 31, 2013; no shares issued and outstanding at both December 31, 2012 and March 31, 2012		
Common stock, $0.0001 par value; 100,000,000 shares authorized at both December 31, 2012 and March 31, 2013; 27,136,329 and 32,578,753 shares issued and outstanding at December 31, 2012 and March 31, 2013, respectively	3	3
Additional paid-in capital	202,795	294,926
Deficit accumulated during the development stage	(87,136)	(106,005)
Total stockholders equity	115,662	188,924
Total liabilities and stockholders equity	$ 127,380	$ 200,556

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 s, except per share data*)

(Unaudited)

	Three Months Ended March 31,		The Period from March 26, 2010 (Inception) to March 31,
	2012	2013	2013
Expenses:			
Research and development	$ 8,150	$ 16,503	$ 75,517
General and administrative	1,199	2,400	13,941
Acquired in-process research and development			15,130
Total expenses	9,349	18,903	104,588
Loss from operations	(9,349)	(18,903)	(104,588)
Interest income	20	34	244
Other expense			(1,661)
Net loss	$ (9,329)	$ (18,869)	$ (106,005)
Net loss per share applicable to common stockholders - basic and diluted	$ (13.59)	$ (0.66)	$ (14.80)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	687	28,798	7,163
Comprehensive Loss	$ (9,329)	$ (18,869)	$ (106,005)

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 s)

(Unaudited)

	Three Months Ended March 31,		The Period from March 26, 2010 (Inception) to March 31,
	2012	**2013**	**2013**
Operating activities			
Net loss	$ (9,329)	$ (18,869)	$ (106,005)
Adjustments to reconcile net loss to net cash used in operating activities:			
Acquired in-process research and development			15,130
Depreciation	12	37	143
Increase in fair value of investor rights obligation			1,661
Share based compensation expense	206	770	2,878
Changes in operating assets and liabilities:			
Other assets	(215)	294	(1,422)
Accounts payable	221	(1,065)	2,105
Accrued expenses	655	956	9,501
Other liabilities	(3)	23	26
Net cash used in operating activities	(8,453)	(17,854)	(75,983)
Investing activities			
Acquisition of product candidate licenses and milestone payments			(14,500)
Purchase of property and equipment	(30)	(308)	(633)
Net cash used in investing activities	(30)	(308)	(15,133)
Financing activities			
Accumulated issuance costs of planned initial public offering	(1,054)		
Proceeds from sale of common stock, net of issuance costs		91,312	169,272
Proceeds from exercise of stock options		49	82
Proceeds from sale of convertible preferred stock and related investor rights, net of issuance costs	58,356		120,406
Net cash provided by financing activities	57,302	91,361	289,760
Increase in cash and cash equivalents	48,819	73,199	198,644
Cash and cash equivalents at beginning of period	39,825	125,445	
Cash and cash equivalents at end of period	$ 88,644	$ 198,644	$ 198,644
Non-cash investing and financing activities			

Issuance of Series O convertible preferred stock	$	630
Settlement of investor rights obligation	$	3,829
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. (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 by identifying, acquiring, developing and commercializing cancer therapeutics and oncology supportive care products in the United States, Europe and other international markets. Since incorporation, primary activities have consisted of acquiring product candidates, advancing development of its 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 has never earned revenue from these activities, and, accordingly, the Company is considered to be in the development stage as of March 31, 2013. 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 public and private equity financings, and management expects operating losses and negative 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 private or public debt or equity 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 accordance with accounting principles generally accepted in the United States of America (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 significant intercompany balances and transactions have been eliminated. 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 a single reporting and operating unit structure.

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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, 2012 and 2013.

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, 2012 and the notes thereto, which are included in the Company s Annual Report on Form 10-K for the year ended December 31, 2012.

Recent Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board (FASB) issued new accounting guidance to update the presentation of reclassifications from comprehensive income to net income in consolidated financial statements. Under this new guidance, an entity is required to provide information about the amounts reclassified out of accumulated other comprehensive income either by the respective line items of net income or by cross-reference to other required disclosures. The new guidance does not change the requirements for reporting net income or other comprehensive income in financial statements. This guidance is effective for fiscal years beginning after December 15, 2012. The Company adopted this guidance effective January 1, 2013, and it did not have any effect on the Company s condensed consolidated financial statements.

Use of Estimates and Assumptions

The preparation of condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make certain estimates and assumptions that affect the reported amounts of assets, liabilities, expenses, other comprehensive income and related disclosures. The most significant estimates and assumptions are used in, among other things, estimating research and development expense accruals and stock-based compensation expense. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions 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

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 the 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	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 at December 31, 2012 and March 31, 2013 and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

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Description	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
December 31, 2012				
Money market funds	$ 123,888	$ 123,888	$	$
	$ 123,888	$ 123,888	$	$
March 31, 2013				
Money market funds	$ 197,262	$ 197,262	$	$
	$ 197,262	$ 197,262	$	$

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, but are not limited to:

- license fees 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, benefits, travel and stock-based compensation expense;
- expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies;
- the cost of acquiring, developing and manufacturing clinical trial and other research and development materials;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and 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 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 financial statements as prepaid or accrued research and development.

Acquired In-Process Research and Development Expense

The Company has acquired the rights to develop and commercialize new product candidates. The up-front payments to acquire a new drug compound, as well as future milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred provided that no processes or activities have been obtained along with the license, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use.

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Stock-Based Compensation

Stock-based compensation is recognized as expense for all stock-based awards based on estimated fair values. The Company determines equity-based compensation 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 would be recognized as a true-up in compensation cost in the period of the change.

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 the Preferred Stock, 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 share amounts in the table below were excluded from the calculation of diluted net loss per share for the relevant periods during 2012 and 2013, prior to the use of the treasury stock method, due to their anti-dilutive effect (in thousands):

	As of March 31,	
	2012	**2013**
Preferred stock	19,410	
Outstanding stock options	1,786	2,783
Unvested restricted stock	535	287
	21,731	3,070

4. Stock-Based Compensation

The Company maintains several equity compensation plans, including the 2012 Omnibus Incentive Plan (the 2012 Incentive Plan), the 2010 Stock Incentive Plan (the 2010 Incentive Plan), and the 2012 Employee Stock Purchase Plan (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 (which was an additional 6,857 shares) plus that number of shares of common stock related to awards outstanding under the 2010 Incentive Plan which 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. 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. As of March 31, 2013, the Company has granted stock options covering a total of 1,044,004 shares of common stock under the 2012 Incentive Plan and the exercise price of each option 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. In

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addition, as of March 31, 2013, no options have been exercised and 7,856 options have been cancelled under the 2012 Incentive Plan.

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 Company was authorized to grant equity awards up to an aggregate of 1,981,130 shares of common stock. As of March 31, 2013, a total of 1,785,703 options and 188,570 restricted stock awards have been granted under the 2010 Incentive Plan. In addition, as of March 31, 2013, 33,440 options have been exercised and 5,000 options have been cancelled under the 2010 Incentive Plan.

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, 2013
	2012	2013	
Research and development	$ 56	$ 332	$ 922
General and administrative	150	438	1,956
Total stock-based compensation expense	$ 206	$ 770	$ 2,878

A summary of the Company s restricted stock activity and related information is as follows:

	Shares	Weighted-average fair value per share
Unvested at December 31, 2012	349,334	$ 0.15
Granted		
Vested	(62,010)	0.10
Forfeited		
Unvested at March 31, 2013	287,324	$ 0.16

A summary of the Company s stock option activity and related information is as follows:

	Shares	Weighted-average exercise price per share
Outstanding at December 31, 2012	2,134,185	$ 5.52

Granted	668,650		24.15
Exercised	(14,424)		3.41
Cancelled	(5,000)		1.33
Outstanding at March 31, 2013	2,783,411	$	10.02

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At March 31, 2013, there was less than $0.1 million and $16.9 million of total unrecognized compensation cost related to unvested restricted stock and unvested stock options, respectively. As of March 31, 2013, the Company expects to recognize these costs over remaining weighted-average periods of 1.8 years and 3.1 years, respectively.

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. A total of 275,000 shares of common stock have been reserved for future issuance under the 2012 ESPP pursuant to purchase rights granted to the Company s employees or to employees of the Company s designated subsidiaries. The first offering period under the 2012 ESPP began on January 1, 2013, and the Company has recognized approximately $13,000 in related stock compensation expense through March 31, 2013.

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 registration statements on Form S-1.

6. Income Taxes

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized.

There were no significant income tax provisions or benefits for the three months ended March 31, 2012 and 2013. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company s otherwise recognizable net deferred tax assets.

7. Commitments and Contingencies

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 is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.

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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, 2012.

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 plans not to develop backup compounds to which we currently have rights; our estimate of the earliest date at which we might commercialize any of our products; 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. 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, 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 the Prospectus that forms a part of our Registration Statement on Form S-1 (File No. 333-186753), which Prospectus was filed with the SEC pursuant to Rule 424 on February 27, 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

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PHARMA, Inc., or MGI PHARMA, 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:

- *Rolapitant* a potent and long-acting neurokinin-1, or NK-1, receptor antagonist currently in Phase 3 clinical trials for the prevention of chemotherapy induced nausea and vomiting, or CINV.

- *Niraparib* formerly known as MK-4827, an orally active and potent poly (ADP-ribose) polymerase, or PARP, inhibitor that has undergone a Phase 1 clinical trial in cancer patients as a monotherapy. We intend to evaluate niraparib for the treatment of patients with platinum sensitive ovarian cancer in a Phase 3 clinical study, which we expect to commence during 2013. Additionally, we intend to initiate a Phase 3 clinical study using niraparib to treat breast cancer during the second half of 2013. Further, we may also evaluate niraparib for the treatment of gastric, lung, sarcoma and prostate cancer.

- *TSR-011* an orally available anaplastic lymphoma kinase, or ALK, inhibitor (targeted anti-cancer agent) currently in a Phase 1/2 dose escalation clinical trial in cancer patients.

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, 2013, we had a deficit accumulated during the development stage of $106.0 million. Our net losses were $18.9 million, $61.8 million, $16.4 million and $9.0 million for the three months ended March 31, 2013, the years ended December 31, 2012 and 2011 and for the period from March 26, 2010 (inception) to December 31, 2010, respectively. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the development and clinical trials of, and seek regulatory approval for, our product candidates. 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 additional costs associated with operating as a public company. Accordingly, we will seek to fund our operations through additional private or public 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 expect that research and development expenses will increase as we continue the development of our product candidates and general and administrative costs will increase as we grow and operate as a public company. 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 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

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for this license, we paid OPKO $6.0 million upon signing the agreement and issued 1,500,000 shares of our Series O preferred stock. At the time of this transaction, the fair value of our Series O preferred stock was determined to be approximately $0.6 million. We are also required to make milestone payments to OPKO of up to an aggregate of $30.0 million if specified regulatory and initial commercial sales milestones are achieved. 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 twelve 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.

Niraparib. In May 2012, we entered into a license agreement with Merck Sharp & Dohme Corp., a subsidiary of 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 are also required to make 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 intend to evaluate niraparib for the treatment of patients with platinum sensitive ovarian cancer in a Phase 3 clinical study, which we expect to commence during 2013. Additionally, we intend to initiate a Phase 3 clinical study using niraparib to treat breast cancer during the second half of 2013. Further, we may also evaluate niraparib for the treatment of gastric, lung, sarcoma 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 have accounted for this transaction as an asset acquisition because we did not acquire any processes or activities in addition to the license. Accordingly, we recorded the entire purchase price of $7.0 million to acquired in-process research and

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development expense.

ALK Program. 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. To date, under the terms of the license agreement, we have made up-front and milestone payments to Amgen of $1.5 million. We are also required to make additional milestone payments to Amgen of up to an aggregate of $137.0 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 ALK product candidates. At the time of the license transaction, ALK was a preclinical compound. We accounted for this transaction as an asset acquisition because we did not acquire any processes or activities in addition to the license. We recorded the entire purchase price of $0.5 million to acquired in-process research and development expense. During the fourth quarter of 2012, we announced that our IND application for TSR-011 had become effective and that we had dosed the first patient in a Phase 1/2 dose escalation clinical study in cancer patients. We have currently dosed patients at the fifth dose level in this trial.

Private Placements of Securities and Public Offerings of Common Stock. As of March 31, 2013, our principal source of liquidity was cash and cash equivalents, which totaled $198.6 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. 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 consist primarily of costs incurred for the development of our product candidates, which include:

- license fees 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;
- expenses incurred under agreements with contract research organizations, or CROs, and investigative sites that conduct our clinical trials and preclinical studies;
- the cost of acquiring, developing and manufacturing active pharmaceutical ingredients and

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clinical trial materials;

- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and 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 plan to increase our research and development expenses for the foreseeable future. Our costs associated with rolapitant will increase as we continue to enroll our Phase 3 clinical trials and continue the development of both the oral and intravenous formulations. We also expect that we will incur increasing costs and expenses associated with the niraparib development program as we continue to progress toward, and initiate, phase 3 clinical trials. We expect costs associated with TSR-011 to increase as we continue clinical development activities for this program.

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 rate 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 identifies research and development expenses and acquired in-process research and development expenses on a program-specific basis for our product candidates in-licensed through March 31, 2013. Personnel-related costs, depreciation and stock-based compensation are not allocated to a program, as they are deployed across multiple projects under development and, as such, are separately classified as personnel and other expenses in the table below (in thousands):

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	Three Months Ended March 31,		(Inception) to March 31,
	2012	2013	2013
Rolapitant Expenses			
Acquired in-process research and development	$	$	$ 6,630
Research and development	5,926	11,314	56,893
Rolapitant total	5,926	11,314	63,523
Niraparib Expenses			
Acquired in-process research and development			7,000
Research and development		1,732	2,411
Niraparib total		1,732	9,411
TSR-011 Expenses			
Acquired in-process research and development			1,500
Research and development	958	471	4,225
TSR-011 total	958	471	5,725
Personnel and Other Expenses	1,266	2,986	11,988
Total	**$ 8,150**	**$ 16,503**	**$ 90,647**

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.

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Results of Operations

Comparison of the Three Months Ended March 31, 2012 and 2013

	Three Months Ended March 31,		Increase/ (Decrease)
	2012	2013	
	(in thousands)		
Expenses:			
Research and development	$ 8,150	$ 16,503	$ 8,353
General and administrative	1,199	2,400	1,201
Acquired in-process research and development			
Total expenses	9,349	18,903	9,554
Loss from operations	(9,349)	(18,903)	(9,554)
Other income (expense), net	20	34	14
Net loss	$ (9,329)	$ (18,869)	$ (9,540)

Research and Development Expenses. Research and development expenses were $16.5 million for the three months ended March 31, 2013, compared to $8.2 million for the three months ended March 31, 2012, an increase of $8.3 million. The increase was primarily due to higher expenses related to the development of our in-licensed product candidates, rolapitant and niraparib, partially offset by lower expenses associated with the development of our in-licensed product candidate, TSR-011. Significant 2013 activities causing the increase in expense included:

- an increase of $5.4 million in costs associated with the rolapitant development program, including the Phase 3 and other ongoing clinical trials, drug substance and drug product development, clinical supply manufacturing and distribution;

- an increase of $1.7 million associated with niraparib product development activities, offset by a decrease of $0.5 million associated with TSR-011 product development activities, and;

- an increase of $1.7 million for salaries, benefits and other personnel costs to support the growth of our development activities.

Expenses related to the TSR-011 program decreased in the three months ended March 31, 2013 versus the same period in the prior year primarily as a result of lower drug substance development and non-clinical activities offset by higher clinical costs associated with the ongoing Phase 1/2 study which began in the fourth quarter of 2012.

General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2013 were $2.4 million compared to $1.2 million for the three months ended March 31, 2012, an increase of $1.2 million. The increase was due primarily to an increase of $0.8 million in salaries, benefits and other personnel related costs and $0.4 million in professional and

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consulting fees and other expenses to support corporate operational activities including certain additional costs associated with public company operations.

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

Liquidity and Capital Resources

Sources of Liquidity

To date, we have not generated any revenue. As of March 31, 2013, our principal source of liquidity was cash and cash equivalents, which totaled $198.6 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 February 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.

Prior to July 2012, we had received $120.4 million in net proceeds from the private placement of our preferred stock. This amount includes net proceeds of approximately $58.3 million that we received in March 2012 upon the issuance of 26,884,442 shares of our Series B preferred stock to certain existing investors in connection with the Series B Purchase Agreement.

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,	
	2012	**2013**
Net cash provided by (used in):		
Operating activities	$ (8,453)	$ (17,854)
Investing activities	(30)	(308)
Financing activities	57,302	91,361
Net increase in cash and cash equivalents	48,819	73,199

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Cash Flows from Operating Activities.

The use of cash in both the three months ended March 31, 2012 and 2013 resulted primarily from our net losses adjusted for non-cash charges and favorable changes in components of working capital. The increase of $9.4 million in cash used in operating activities for the three months ended March 31, 2013 compared to the three months ended March 31, 2012 is primarily due to an increase in research and development expenses as we continued to progress the rolapitant, niraparib and TSR-011 development programs. This increase included increased spending on external research and development costs, in particular higher costs associated with our rolapitant clinical program coupled with increased costs associated with development personnel, partially offset by a decrease in the balance of accrued expenses.

Cash Flows from Investing Activities

The increase of $0.3 million in cash used in investing activities for the three months ended March 31, 2013 compared to the three months ended March 31, 2012 was due primarily to purchases of furniture and other fixed assets related to the build-out of additional leased office space at our headquarters in Waltham, Massachusetts which we occupied during the first quarter of 2013.

Cash Flows from Financing Activities

The increase of $34.1 million in cash provided by financing activities for the three months ended March 31, 2013 compared to the three months ended March 31, 2012 was due primarily to the aggregate net proceeds of $91.3 million, which is net of underwriting discounts and commissions, from the closing of our March 2013 public offering. The cash provided by financing activities for the three months ended March 31, 2012 was the result of the sale and issuance of 26,884,442 shares of our Series B Preferred Stock for net proceeds of $58.3 million in March 2012.

Operating Capital Requirements

We do not anticipate commercializing any of our product candidates for several years. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to 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.

We believe that our existing cash and cash equivalents and interest thereon will be sufficient to fund our projected operating requirements through at least the next twelve 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, or from other sources, such as arrangements with strategic partners. 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. If we raise additional funds through the issuance of debt or equity securities it could result in dilution to our existing stockholders, increased fixed payment obligations and these securities may have rights senior to those of our common stock and could contain covenants that would restrict our

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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 near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of clinical trials for our product candidates and future product candidates we may in-license, including our Phase 3 clinical trials for rolapitant and niraparib and the further development of TSR-011;

- the attainment of milestones and our need to make milestone and royalty payments to OPKO, Merck or Amgen, 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 for the FDA or comparable foreign regulatory authorities to 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

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

If a lack of available capital results in an inability 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 from those described in our Annual Report on Form 10-K for the year ended December 31, 2012.

Off-Balance Sheet Arrangements

As of March 31, 2013, we did not have any off-balance sheet arrangements as defined in Regulation S-K, Item 303(a)(4)(ii).

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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. 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, 2012. There have not been any material changes to our critical accounting policies since December 31, 2012.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of December 31, 2012 and March 31, 2013, we had cash and cash equivalents of $125.4 million and $198.6 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.

Item 4. Controls and Procedures.

Managements 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.

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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.

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, 2012.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 33-180309) that was declared effective by the Securities and Exchange Commission on June 27, 2012.

As of March 31, 2013, we had used approximately $41.2 million of the net proceeds from our initial public offering to fund operations, capital expenditures, working capital and other general corporate purposes. The remainder of the proceeds are held by the Company as cash and cash equivalents.

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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

Date: April 26, 2013

TESARO, INC.

By: /s/ Richard J. Rodgers
Richard J. Rodgers
Executive Vice President, Chief Financial Officer, Secretary and Treasurer

Date: April 26, 2013

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EXHIBIT INDEX

Exhibit Number	Exhibit Description
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