TESARO, Inc.
Form 10-Q
July 25, 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 June 30, 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	**27-2249687**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
1000 Winter Street, Suite 3300 Waltham, Massachusetts	**02451**
(Address of Principal Executive Offices)	(Zip Code)

(339) 970-0900

(Registrant s Telephone Number, Including Area Code)

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

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

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

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

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

As of July 21, 2014, there were 36,043,167 shares of the registrant s Common Stock, par value $0.0001 per share, outstanding.

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TESARO, INC.

FORM 10-Q
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2014

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

TESARO, INC.

Condensed Consolidated Balance Sheets

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

(Unaudited)

	December 31, 2013	June 30, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 130,310	$ 151,088
Other current assets	4,029	2,997
Total current assets	134,339	154,085
Property and equipment, net	440	1,147
Other assets	799	908
Total assets	$ 135,578	$ 156,140
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 1,869	$ 2,849
Accrued expenses	10,541	16,163
Other current liabilities	13	
Total current liabilities	12,423	19,012
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 June 30, 2014; no shares issued or outstanding at both December 31, 2013 and June 30, 2014		
Common stock, $0.0001 par value; 100,000,000 shares authorized at both December 31, 2013 and June 30, 2014; 32,739,008 and 36,039,105 shares issued and outstanding at December 31, 2013 and June 30, 2014, respectively	3	4
Additional paid-in capital	302,647	403,473
Accumulated deficit	(179,498)	(266,349)

Total stockholders equity		123,152		137,128
Total liabilities and stockholders equity	$	135,578	$	156,140

See accompanying notes to condensed consolidated financial statements.

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TESARO, INC.

Condensed Consolidated Statements of Operations and

Comprehensive Loss

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

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	**2014**	**2013**	**2014**
Expenses:				
Research and development	$ 18,177	$ 30,569	$ 34,680	$ 58,686
General and administrative	3,412	5,587	5,812	10,275
Acquired in-process research and development		900		17,900
Total expenses	21,589	37,056	40,492	86,861
Loss from operations	(21,589)	(37,056)	(40,492)	(86,861)
Interest income	25	5	59	10
Net loss	$ (21,564)	$ (37,051)	$ (40,433)	$ (86,851)
Net loss per share applicable to common stockholders - basic and diluted	$ (0.67)	$ (1.03)	$ (1.32)	$ (2.45)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	32,336	35,982	30,577	35,422
Comprehensive loss	$ (21,564)	$ (37,051)	$ (40,433)	$ (86,851)

See accompanying notes to condensed consolidated financial statements.

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TESARO, INC.

Condensed Consolidated Statements of Cash Flows

(all amounts in 000 s)

(Unaudited)

	Six Months Ended June 30,	
	2013	**2014**
Operating activities		
Net loss	$ (40,433)	$ (86,851)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development		17,900
Depreciation expense	84	158
Stock-based compensation expense	2,354	5,640
Loss on disposal of property and equipment		80
Changes in operating assets and liabilities:		
Other assets	(711)	530
Accounts payable	(1,206)	980
Accrued expenses	1,432	6,015
Other liabilities	19	(16)
Net cash used in operating activities	(38,461)	(55,564)
Investing activities		
Acquisition of product candidate and technology licenses and milestone payments		(17,900)
Purchase of property and equipment	(369)	(945)
Net cash used in investing activities	(369)	(18,845)
Financing activities		
Proceeds from sale of common stock, net of issuance costs	91,312	94,199
Proceeds from exercise of stock options	99	868
Proceeds from issuance of common stock under Employee Stock Purchase Plan	65	120
Net cash provided by financing activities	91,476	95,187
Increase in cash and cash equivalents	52,646	20,778
Cash and cash equivalents at beginning of period	125,445	130,310
Cash and cash equivalents at end of period	$ 178,091	$ 151,088

See accompanying notes to condensed consolidated financial statements.

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TESARO, INC.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Description of Business

TESARO, Inc., or the Company or TESARO, was incorporated in Delaware on March 26, 2010 and commenced operations in May 2010. Headquartered in Waltham, Massachusetts, TESARO is an oncology-focused biopharmaceutical company dedicated to improving the lives of cancer patients. TESARO acquires, in-licenses and develops oncology product candidates and, if approved for marketing, intends to commercialize these products 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, operates in one segment and has never earned revenue from its activities. The Company is subject to a number of risks, including dependence on key individuals, the need to develop commercially viable products, competition from other companies, many of whom are larger and better capitalized, and the need to obtain adequate additional financing to fund the development and potential commercialization of its product candidates and further its in-licensing and acquisition activities.

The Company has incurred significant operating losses since inception and has relied on its ability to fund its operations through private and public equity 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 the achievement of 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

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 June 30, 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 June 2014, the FASB issued ASU No. 2014-10, which eliminates the concept of a development stage entity, or DSE, in its entirety from GAAP. Under existing guidance, DSEs are required to report incremental information, including inception-to-date financial information, in their financial statements. A DSE is an entity devoting substantially all of its efforts to establishing a new business and for which either planned principal operations have not yet commenced or have commenced but there has been no significant revenues generated from that business. Entities classified as DSEs will no longer be subject to these incremental reporting requirements after adopting ASU No. 2014-10. ASU No. 2014-10 is effective for fiscal years beginning after December 15, 2014, with early adoption permitted. Retrospective application is required for the elimination of incremental DSE disclosures. Prior to the issuance of ASU No. 2014-10, the Company had met the definition of a DSE since its inception. The Company elected to adopt this ASU early, and therefore it has eliminated the incremental disclosures previously required of DSEs, starting with this Quarterly Report on Form 10-Q.

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 disclosure requirements 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.

In May 2014, the FASB issued ASU No. 2014-09, which amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in Accounting Standards Codification Topic 605, *Revenue Recognition*, and creates a new Topic 606, *Revenue from Contracts with Customers*. This guidance is effective for fiscal years beginning after December 15, 2016, with early adoption not permitted. Two adoption methods are permitted: retrospectively to all prior reporting periods presented, with certain practical expedients permitted; or retrospectively with the cumulative effect of initially adopting the ASU recognized at the date of initial application. The Company has not yet determined which adoption method it will utilize or the effect that the adoption of this guidance will have on its 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.

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Fair Value of Financial Instruments

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

Level 1 inputs Quoted prices in active markets for identical assets or liabilities

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

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

The following table presents information about the Company s financial assets and liabilities that have been measured at fair value as of December 31, 2013 and June 30, 2014 and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

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

		June 30, 2014			
Description	**Balance Sheet Classification**	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets:					
Money market funds	Cash and cash equivalents	$ 149,390	$ 149,390	$	$
Total assets		$ 149,390	$ 149,390	$	$

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

- other costs associated with clinical and 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

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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 , as defined under GAAP, 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 each stock-based award based on its estimated fair value. The Company determines the fair value of each equity-based award at its 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.

3. Net Loss per Share

Basic and diluted net loss per common share is calculated by dividing net loss applicable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. The Company s potentially dilutive shares, which include outstanding stock options 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, due to their anti-dilutive effect (in thousands):

	Three and Six Months Ended June 30,	
	2013	2014
Outstanding stock options	2,845	3,612
Unvested restricted stock	226	22
	3,071	3,634

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.

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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. The exercise price of each stock option granted 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2014	2013	2014
Research and development	$ 462	$ 1,454	$ 794	$ 2,364
General and administrative	1,122	1,648	1,560	3,276
Total stock-based compensation expense	$ 1,584	$ 3,102	$ 2,354	$ 5,640

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	(71,118)	0.15
Forfeited	(8,929)	0.53
Unvested restricted stock at June 30, 2014	22,365	$ 2.80

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	1,051,123	30.92
Exercised	(93,243)	9.30
Cancelled	(199,103)	13.16
Outstanding at June 30, 2014	3,611,570	$ 18.12
Vested at June 30, 2014	1,264,144	$ 9.37
Vested and expected to vest at June 30, 2014	3,526,361	$ 17.84

At June 30, 2014, there was approximately $30.9 million of total unrecognized compensation cost related to unvested stock options, which the Company expects to recognize over a remaining weighted-average period of 2.7 years. At June 30, 2014, total unrecognized compensation cost

related to unvested restricted stock was insignificant.

Under the Company s 2012 ESPP, an aggregate of 275,000 shares of common stock have been reserved for issuance pursuant to purchase rights granted to the Company s employees or to employees of the Company s designated subsidiaries. During the six months ended June 30, 2014, the Company issued 5,372 shares under the 2012 ESPP, and recognized approximately $0.1 million in related stock-based compensation expense.

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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 and six months ended June 30, 2013 and 2014, the Company did not record any current or deferred income tax provisions or benefits. Due to the uncertainty surrounding the future realization of the favorable tax attributes, the Company has recorded full valuation allowances against its otherwise recognizable net deferred tax assets at both December 31, 2013 and June 30, 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.

Future minimum rental commitments under the amended lease as of June 30, 2014 were $0.8 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, clinical operation support services, and certain contract manufacturing 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.

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.

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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 worldwide annual net sales, 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. For the three and six months ended June 30, 2014, the Company recorded approximately $1.3 million and $1.5 million of research and development expense, respectively, associated with amounts due to AnaptysBio under the collaboration. As of June 30, 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

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 for the prevention of chemotherapy induced nausea and vomiting, or CINV. We are developing both oral and intravenous formulations of rolapitant. In December 2013, we announced top-line results for two Phase 3 trials of oral rolapitant. The primary endpoint was successfully achieved in both trials. In May 2014, we announced top-line results for the third Phase 3 trial of oral rolapitant. The primary and secondary endpoints were successfully achieved in this trial. Preparations in support of our anticipated submission to the U.S. Food and Drug Administration, or FDA, of a new drug application, or NDA, for oral rolapitant are ongoing. We expect to file our NDA for oral rolapitant with the FDA in approximately six weeks. The intravenous, or IV, formulation of rolapitant is currently in Phase 1 clinical trials. As part of a registration program for rolapitant IV we plan to initiate clinical studies comparing the exposure of rolapitant IV and oral formulations and to evaluate the safety of IV rolapitant.

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- *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 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 also intend to evaluate niraparib as a first-line maintenance therapy in both ovarian cancer patients and in advanced metastatic small cell lung cancer, or SCLC, patients. 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 and 120 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 both monospecific and dual-reactive immunotherapy antibodies developed using AnaptysBio s proprietary technology and targeting TIM-3, LAG-3 and PD-1 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 submitting an investigational new drug application, or IND, to the U.S. FDA for TSR-042, the lead anti-PD-1 antibody that we have in-licensed as part of the agreement, in late 2015. With respect to the TIM-3 target, we have identified lead and backup compounds for clinical development. We are also working toward the identification of a LAG-3 clinical candidate.

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

As of June 30, 2014, we had an accumulated deficit of $266.3 million. Our net losses were $86.9 million, $92.4 million, $61.8 million, and $16.4 million for the six months ended June 30, 2014 and the years ended December 31, 2013, 2012 and 2011, 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, TSR-011, costs related to the immuno-oncology development activities occurring under our collaboration with AnaptysBio, potential future in-licensed development programs, costs associated with pre-commercialization activities, 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 the FDA accepts our NDA filing for oral rolapitant, we are obligated to make a $5.0 million milestone payment to OPKO Health, or OPKO. 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

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raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

Rolapitant. In December 2010, we entered into a license agreement with OPKO to obtain exclusive worldwide rights to research, develop, manufacture, market and sell rolapitant. The license agreement also extended to an additional, backup compound, SCH900978, to which we have similar rights and obligations as rolapitant, but which we are not currently advancing. 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 commercial sales milestones are achieved in the U.S. and Europe. Preparations in support of our anticipated submission to the FDA in approximately six weeks 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 milestone payments to OPKO of up to an aggregate of $85.0 million if specified levels of annual net sales of rolapitant are achieved. If commercial sales of rolapitant commence, we are required to pay OPKO tiered royalties on the amount of annual net sales achieved in the United States and Europe at percentage rates that range from the low teens to the low twenties, which we expect will result in an effective royalty rate in the low teens. The royalty rate on annual net sales outside of the United States and Europe is slightly above the single digits. We will pay royalties on rolapitant until the later of: (i) the date that all of the patent rights licensed from OPKO and covering rolapitant expire, are invalidated or are not enforceable, and (ii) 12 years from the first commercial sale of the product, in each case, on a country-by-country and product-by-product basis. If we elect to develop and commercialize rolapitant in Japan through a third-party licensee, we will share equally with OPKO all amounts received by us in connection with such activities under our agreement with such third party, subject to certain exceptions and deductions. OPKO also retains an option to become the exclusive distributor of such products in Latin America, provided that OPKO exercises that option within a defined period following specified regulatory approvals in the United States.

We are responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize rolapitant. 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.

Rolapitant Clinical Development Update

Rolapitant Oral Formulation. In May 2014, we announced top-line results of the third and final completed Phase 3 trial of oral rolapitant. This Phase 3 trial was an international, multicenter, randomized, double-blind, active-controlled study that enrolled 532 cancer patients receiving highly emetogenic chemotherapy, or HEC, defined as cisplatin-based regimens at a dose equal to or greater than 60 mg/m2. Patients were randomized to receive either control, which consisted of a 5-HT3 receptor antagonist plus dexamethasone, or 200mg of oral rolapitant plus control. The rolapitant arm in this study successfully achieved statistical significance over the control arm for the primary endpoint of complete response (CR) in the delayed phase of CINV. In addition, the rolapitant arm also successfully achieved statistical significance over the control arm for the key secondary endpoints of CR in the acute (0 to 24 hour) and overall (0 to 120 hour) phases of CINV, and for the secondary endpoints of no significant nausea (overall phase), and time to first event. In addition, tertiary endpoints of no significant nausea (acute and delayed phases), no nausea (delayed and overall phases) and complete protection, meaning no emesis, no use of rescue medication and no significant nausea (acute, delayed and overall phases) were achieved. Treatment emergent adverse events were similar between the rolapitant and control arms, and were consistent with earlier clinical studies. The most frequently observed adverse events in this trial were balanced across treatment arms, commonly associated with chemotherapy, and included fatigue, constipation and asthenia.

During June 2014, we presented data from all three of our Phase 3 trials of rolapitant for the prevention of CINV at the annual meeting of the American Society of Clinical Oncology in Chicago, and at the MASCC/ISOO International Symposium on Supportive Care in Cancer annual meeting in Miami. These data included a retrospective subset analysis on U.S. patients in our trial of rolapitant in patients receiving moderately emetogenic chemotherapy, or MEC. This subset represented approximately 33% of the evaluable subjects in the MEC trial. In the U.S. subset analysis, patients treated with rolapitant achieved a higher complete response rate in the delayed, acute and overall phases and experienced higher rates of no emesis, no significant nausea, and complete protection in the overall phase, compared to the control arm.

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Rolapitant Intravenous Formulation. We have selected a single intravenous dose of 185mg for further development. We have also completed a multiple ascending dose study of intravenous rolapitant which confirmed the safety and tolerability profiles and linear pharmacokinetics of repeat daily doses. As part of a registration program for rolapitant IV we plan to initiate clinical studies comparing the exposure of rolapitant IV and oral formulations and to evaluate the safety of IV rolapitant.

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 U.S. and European development and regulatory milestones for the first indication, up to $29.5 million in development and regulatory milestones for each successive indication, and up to $87.5 million in one-time sales milestones based on the achievement of annual sales objectives. If commercial sales of niraparib commence, we will pay Merck tiered royalties at percentage rates in the low teens based on worldwide annual net sales, until the later of the expiration of the last patent licensed from Merck covering or claiming niraparib, or the tenth anniversary of the first commercial sale of niraparib, in either case, on a country-by-country basis.

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.

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. Based on our analysis of third-party market research, we believe there will be approximately 10,000 eligible ovarian cancer patients in both the U.S. and in Europe, and approximately 10,000 eligible breast cancer patients in both the U.S. and in Europe at the time of potential launch.

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.

We also intend to evaluate niraparib as a first-line, maintenance therapy in both ovarian cancer patients and in advanced metastatic SCLC patients. The first-line ovarian cancer study will include patients who have completed first-line platinum chemotherapy or surgery if indicated, with no evidence of progression. Patients will likely be randomized 2:1 to receive niraparib or placebo. The endpoints for this study include progression free survival, PFS2, overall survival and safety. The SCLC study is currently planned to enroll patients with advanced metastatic SCLC who have received platinum-based chemotherapy with a partial or complete response. Patients will receive niraparib or placebo based on biomarker analysis and identification for selection or stratification. Endpoints will include progression free survival, overall survival, safety and quality of life. Based on our analysis of third-party market research, we believe there are approximately 30,000 new cases of SCLC diagnosed in the U.S. annually, representing 13% of all lung cancers. We plan to begin enrollment of patients in these two trials in 2015.

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 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.

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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 immunotherapy 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 in the six month period ended June 30, 2014.

Public Offerings of Common Stock and Private Placements of Securities. As of June 30, 2014, our principal source of liquidity was cash and cash equivalents, which totaled $151.1 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 private placement of our 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;

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

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- 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

- other costs associated with clinical and 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 and manufacturing costs. 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, manufacturing related costs, 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 related to our recently completed 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 also intend to evaluate niraparib as a first-line maintenance therapy in both ovarian cancer patients and in advanced metastatic SCLC patients, further contributing to increased niraparib costs. 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 determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate s commercial potential.

The following table presents research and development expenses and acquired in-process research and development expenses on a program-specific basis for our in-licensed product candidates for the six months ended June 30, 2013 and 2014 (in thousands):

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	Six Months Ended June 30,	
	2013	2014
Rolapitant Expenses		
Acquired in-process research and development	$	$
Research and development	21,967	18,366
Rolapitant total	21,967	18,366
Niraparib Expenses		
Acquired in-process research and development		900
Research and development	5,491	22,012
Niraparib total	5,491	22,912
TSR-011 Expenses		
Acquired in-process research and development		
Research and development	1,025	3,723
TSR-011 total	1,025	3,723
Immuno-Oncology Platform Expenses		
Acquired in-process research and development		17,000
Research and development		1,547
Immuno-Oncology Platform total		18,547
Personnel and Other Expenses	6,197	13,038
Total	**$ 34,680**	**$ 76,586**

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

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs, including stock-based compensation and travel expenses for personnel, in executive and other administrative functions. Other general and administrative expenses include facility-related costs, communication expenses, certain pre-commercialization activities 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 June 30, 2013 and 2014

	Three Months Ended June 30, 2013	2014	Increase/ (Decrease)
		(in thousands)	
Expenses:			
Research and development	$ 18,177	$ 30,569	$ 12,392
General and administrative	3,412	5,587	2,175
Acquired in-process research and development		900	900
Total expenses	21,589	37,056	15,467
Loss from operations	(21,589)	(37,056)	(15,467)
Other income (expense), net	25	5	(20)
Net loss	$ (21,564)	$ (37,051)	$ (15,487)

Research and Development Expenses. Research and development expenses were $30.6 million for the three months ended June 30, 2014, compared to $18.2 million for the three months ended June 30, 2013, an increase of $12.4 million. The increase was primarily due to higher expenses related to the development of our in-licensed product candidates niraparib and TSR-011, and our immuno-oncology platform, 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 $9.1 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, the Phase 3 clinical trial in breast cancer patients with germline BRCA mutations, which was initiated in April 2014, and costs relating to drug substance and drug product development and manufacturing as well as clinical supply distribution;

- an increase of $2.7 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 $2.3 million in costs associated with TSR-011 development activities and our immuno-oncology platform strategy; and

- a decrease of $2.7 million in costs associated with rolapitant development activities, primarily lower costs related to the recently completed Phase 3 clinical trials, partially offset by increases in costs relating to Phase 1 bioequivalence and intravenous formulation studies.

In addition, stock-based compensation expense included in research and development expenses increased $1.0 million, related to increased awards of employee stock options and higher grant-date fair values of those awards.

General and Administrative Expenses. General and administrative expenses were $5.6 million for the three months ended June 30, 2014, compared to $3.4 million for the three months ended June 30, 2013, an increase of $2.2 million. The increase was primarily due to increases of $0.5 million in stock-based compensation expense related to increased awards of employee stock options and higher grant-date fair values of those awards, $1.1 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 $0.9 million in acquired in-process research and development expenses for the three months ended June 30, 2014, consisting of a milestone payment related to the initiation of the Phase 3 clinical trial of niraparib in breast cancer patients with germline BRCA mutations in April 2014. There were no acquired in-process research and development expenses for the three months ended June 30, 2013.

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

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Comparison of the Six Months Ended June 30, 2013 and 2014

	Six Months Ended June 30, 2013	2014	Increase/ (Decrease)
		(in thousands)	
Expenses:			
Research and development	$ 34,680	$ 58,686	$ 24,006
General and administrative	5,812	10,275	4,463
Acquired in-process research and development		17,900	17,900
Total expenses	40,492	86,861	46,369
Loss from operations	(40,492)	(86,861)	(46,369)
Other income (expense), net	59	10	(49)
Net loss	$ (40,433)	$ (86,851)	$ (46,418)

Research and Development Expenses. Research and development expenses were $58.7 million for the six months ended June 30, 2014, compared to $34.7 million for the six months ended June 30, 2013, an increase of $24.0 million. The increase was primarily due to higher expenses related to the development of our in-licensed product candidates niraparib and TSR-011, and our immuno-oncology platform, 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 $16.5 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, the Phase 3 clinical trial in breast cancer patients with germline BRCA mutations, which was initiated in April 2014, and costs relating to drug substance and drug product development and manufacturing as well as clinical supply distribution;

- an increase of $5.3 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 $4.2 million in costs associated with TSR-011 development activities and our immuno-oncology platform strategy; and

- a decrease of $3.6 million in costs associated with rolapitant development activities, primarily lower costs related to the recently completed Phase 3 clinical trials, partially offset by increases in costs relating to Phase 1 bioequivalence and intravenous formulation studies.

In addition, stock-based compensation expense included in research and development expenses increased $1.6 million, related to increased awards of employee stock options and higher grant-date fair values of those awards.

General and Administrative Expenses. General and administrative expenses were $10.3 million for the six months ended June 30, 2014, compared to $5.8 million for the six months ended June 30, 2013, an increase of $4.5 million. The increase was due primarily to increases of $1.7 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; $1.6 million in salaries, benefits and other personnel-related costs; and $1.2 million in professional and consulting fees and other expenses to support corporate operational activities.

Acquired In-Process Research and Development Expenses. We recorded $17.9 million in acquired in-process research and development expenses for the six months ended June 30, 2014. This amount consisted of the $17.0 million up-front payment related to the collaboration and exclusive license agreement with AnaptysBio, and a $0.9 million milestone payment related to the initiation of the Phase 3 clinical trial of niraparib in breast cancer patients with germline BRCA mutations in April 2014. There were no acquired in-process research and development expenses for the six months ended June 30, 2013.

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

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Liquidity and Capital Resources

Sources of Liquidity

To date, we have not generated any revenue. As of June 30, 2014, our principal source of liquidity was cash and cash equivalents, which totaled $151.1 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):

	Six Months Ended June 30,	
	2013	2014
Net cash provided by (used in):		
Operating activities	$ (38,461)	$ (55,564)
Investing activities	(369)	(18,845)
Financing activities	91,476	95,187
Increase in cash and cash equivalents	$ 52,646	$ 20,778

Cash Flows from Operating Activities

The use of cash in operating activities during both the six months ended June 30, 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 $17.1 million for the six months ended June 30, 2014 compared to the six months ended June 30, 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 $18.5 million in net cash used in investing activities for the six months ended June 30, 2014 compared to the six months ended June 30, 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 also made a $0.9 million milestone payment in the second quarter of 2014 related to the initiation of the Phase 3 clinical trial of niraparib in breast cancer patients with germline BRCA mutations. We did not make any comparable product candidate license or milestone payments in the six months ended June 30, 2013. Cash used for capital expenditures increased by $0.6 million, primarily due to purchases of furniture and other fixed assets for the additional office space we leased at our headquarters in Waltham, Massachusetts beginning in the first quarter of 2014.

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Cash Flows from Financing Activities

The increase of $3.7 million in net cash provided by financing activities for the six months ended June 30, 2014 compared to the six months ended June 30, 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 and purchases under the Employee Stock Purchase Plan increased by $0.8 million.

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 cash flow requirements, including any milestone obligations that may arise, and required 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 potential commercialization of our product candidates and may also need to raise additional funds to pursue our strategy of in-licensing or acquiring additional product candidates.

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;

- 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;

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- the outcome, timing and cost of regulatory approvals by the FDA and comparable non-U.S. regulatory authorities, including the potential that the FDA or comparable non-U.S. regulatory authorities may require that we perform more studies than those that we currently expect;

- the 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 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 June 30, 2014 were $0.8 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 June 30, 2014, we did not have any off-balance sheet arrangements as defined in Regulation S-K, Item 303(a)(4)(ii).

Critical Accounting Policies

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

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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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of June 30, 2014 and December 31, 2013, we had cash and cash equivalents of $151.1 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 June 30, 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.

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:	July 25, 2014
By:	/s/ Timothy R. Pearson Timothy R. Pearson *Executive Vice President and Chief Financial Officer* *(principal financial officer)*
Date:	July 25, 2014

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EXHIBIT INDEX

Exhibit Number	Exhibit Description
10.1	Offer Letter Agreement by and between TESARO, Inc. and Timothy R. Pearson, dated May 27, 2014 (Incorporated by reference from the Registrant s Current Report on Form 8-K filed on May 27, 2014 (File No. 001-35587))
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