TESARO, Inc.
Form 10-Q
November 06, 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 September 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 October 30, 2014, there were 36,061,589 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 NINE MONTHS ENDED SEPTEMBER 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 | September 30, 2014 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 130,310 | $ 295,912 |
| Other current assets | 4,029 | 1,753 |
| Total current assets | 134,339 | 297,665 |
| | | |
| Property and equipment, net | 440 | 1,075 |
| Other assets | 799 | 4,591 |
| Total assets | $ 135,578 | $ 303,331 |
| | | |
| **Liabilities and stockholders equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,869 | $ 4,138 |
| Accrued expenses | 10,541 | 17,629 |
| Other current liabilities | 13 | 17 |
| Total current liabilities | 12,423 | 21,784 |
| | | |
| Convertible notes, net | | 113,432 |
| Other non-current liabilities | 3 | |
| Total liabilities | 12,426 | 135,216 |
| | | |
| Commitments and contingencies *(Note 7)* | | |
| | | |
| Stockholders equity: | | |
| Preferred stock, $0.0001 par value; 10,000,000 shares authorized at both December 31, 2013 and September 30, 2014; no shares issued or outstanding at both December 31, 2013 and September 30, 2014 | | |
| Common stock, $0.0001 par value; 100,000,000 shares authorized at both December 31, 2013 and September 30, 2014; 32,739,008 and 36,055,339 shares issued and outstanding at December 31, 2013 and September 30, 2014, respectively | 3 | 4 |

| | | | | |
|---|---|---|---|---|
| Additional paid-in capital | | 302,647 | | 470,686 |
| Accumulated deficit | | (179,498) | | (302,575) |
| Total stockholders equity | | 123,152 | | 168,115 |
| Total liabilities and stockholders equity | $ | 135,578 | $ | 303,331 |

*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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2013** | **2014** | **2013** | **2014** |
| Expenses: | | | | |
| Research and development | $ 22,163 | $ 29,925 | $ 56,843 | $ 88,611 |
| General and administrative | 4,503 | 6,263 | 10,315 | 16,538 |
| Acquired in-process research and development | 1,940 | | 1,940 | 17,900 |
| Total expenses | 28,606 | 36,188 | 69,098 | 123,049 |
| Loss from operations | (28,606) | (36,188) | (69,098) | (123,049) |
| | | | | |
| Interest expense | | (42) | | (42) |
| Interest income | 17 | 4 | 76 | 14 |
| Net loss | $ (28,589) | $ (36,226) | $ (69,022) | $ (123,077) |
| | | | | |
| Net loss per share applicable to common stockholders - basic and diluted | $ (0.88) | $ (1.01) | $ (2.21) | $ (3.45) |
| | | | | |
| Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted | 32,453 | 36,029 | 31,209 | 35,627 |
| | | | | |
| Comprehensive loss | $ (28,589) | $ (36,226) | $ (69,022) | $ (123,077) |

*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)**

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2013** | **2014** |
| **Operating activities** | | |
| Net loss | $ (69,022) | $ (123,077) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Acquired in-process research and development | 1,940 | 17,900 |
| Depreciation expense | 130 | 254 |
| Stock-based compensation expense | 5,078 | 8,538 |
| Non-cash interest expense | | 26 |
| Loss on disposal of property and equipment | | 80 |
| Changes in operating assets and liabilities: | | |
| Other assets | (619) | 1,851 |
| Accounts payable | (1,181) | 2,246 |
| Accrued expenses | 4,966 | 7,009 |
| Other liabilities | 16 | 1 |
| Net cash used in operating activities | (58,692) | (85,172) |
| | | |
| **Investing activities** | | |
| Acquisition of product candidate and technology licenses and milestone payments | (1,940) | (17,900) |
| Purchase of property and equipment | (383) | (969) |
| Net cash used in investing activities | (2,323) | (18,869) |
| | | |
| **Financing activities** | | |
| Proceeds from issuance of convertible notes, net of issuance costs | | 195,193 |
| Purchase of capped call options | | (20,829) |
| Proceeds from sale of common stock, net of issuance costs | 91,312 | 94,199 |
| Proceeds from exercise of stock options | 633 | 960 |
| Proceeds from issuance of common stock under Employee Stock Purchase Plan | 65 | 120 |
| Net cash provided by financing activities | 92,010 | 269,643 |
| | | |
| Increase in cash and cash equivalents | 30,995 | 165,602 |
| Cash and cash equivalents at beginning of period | 125,445 | 130,310 |
| Cash and cash equivalents at end of period | $ 156,440 | $ 295,912 |
| | | |
| **Non-cash investing and financing activities** | | |
| Convertible note issuance costs unpaid as of period end | $ | $ 475 |

*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 and debt 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 its cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital. Management intends to fund future operations through additional public or private equity or debt offerings and may seek additional capital through arrangements with strategic partners or from other sources.

**2. Basis of Presentation and Significant Accounting Policies**

*Basis of Presentation*

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

The 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 September 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 Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or 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.

*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, or ASC, 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 potential future revenue streams and consolidated financial statements.

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

In August 2014, the FASB issued ASU No. 2014-15, which is intended to define management s responsibility to evaluate whether there is substantial doubt about an organization s ability to continue as a going concern and to provide related footnote disclosures. Substantial doubt about an entity s ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or are available to be issued). ASU No. 2014-15 provides guidance to an organization s management, with principles and definitions intended to reduce diversity in the timing and content of disclosures commonly provided by organizations in the footnotes of their financial statements. ASU No. 2014-15 is effective for annual reporting periods ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. The Company is currently in the process of evaluating the impact of adoption of this guidance on its consolidated financial statements and related disclosures.

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*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. Significant estimates in these condensed consolidated financial statements include estimates made in connection with accrued research and development expenses, stock-based compensation expense and valuation of convertible notes. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

*Cash and Cash Equivalents*

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

*Fair Value of Financial Instruments*

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. The fair value hierarchy prioritizes valuation inputs based on the observable nature of those inputs. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of 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 September 30, 2014 and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

| Description | Balance Sheet Classification | December 31, 2013 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 | $ | $ |

| Description | Balance Sheet Classification | September 30, 2014 Total | Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|---|
| **Assets:** | | | | | |
| Money market funds | Cash and cash equivalents | $ 292,837 | $ 292,837 | $ | $ |
| Total assets | | $ 292,837 | $ 292,837 | $ | $ |

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

In September 2014, the Company issued $201.3 million aggregate principal amount of 3.0% convertible senior notes due October 1, 2021, or the Convertible Notes. Interest is payable semi-annually in arrears on April 1 and October 1 of each year, beginning on April 1, 2015. As of September 30, 2014, the carrying value of the Convertible Notes was $113.4 million, net of unamortized discount, and the fair value of the principal amount approximated the issuance price of $201.3 million due to the recent issuance. The Convertible Notes are discussed in more detail in Note 9, Convertible Notes.

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*Research and Development Expenses*

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

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

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

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

- the cost of acquiring, developing and manufacturing active pharmaceutical ingredients, clinical trial materials and other research and development materials;

- fees and costs related to regulatory filings and operations;

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

- other costs associated with clinical and preclinical activities.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the condensed consolidated balance sheets as prepaid or accrued research and development expenses.

*Acquired In-Process Research and Development Expense*

The Company has acquired the rights to develop and commercialize new product candidates. Up-front payments that relate to the acquisition of a new drug compound, as well as milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the new drug compound did not also include processes or activities that would constitute a business , 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, unvested restricted stock, and shares issuable upon conversion of the Convertible Notes, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

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

| | Three and Nine Months Ended September 30, | |
|---|---|---|
| | 2013 | 2014 |
| Outstanding stock options | 2,819 | 3,663 |
| Unvested restricted stock | 164 | 13 |
| | 2,983 | 3,676 |

In September 2014, in conjunction with the issuance of the Convertible Notes, the Company entered into capped call option transactions, or Capped Calls, with certain counterparties. The Capped Calls are expected generally to reduce the potential dilution, and/or offset to an extent the cash payments the Company is required to make in excess of the principal amount, upon conversion of the Convertible Notes in the event that the market price of the Company s common stock is greater than the floor price of the Capped Calls. See Note 9, Convertible Notes , for additional information. As provided by the terms of the indenture underlying the Convertible Notes, the Company has a choice to settle the conversion obligation for the Convertible Notes in cash, shares or any combination of the two. The Company currently intends to settle the par value of the Convertible Notes in cash and any excess conversion premium in shares. Accordingly, the par value of the Convertible Notes will not be included in the calculation of diluted income per share, but the dilutive effect of the conversion premium will be considered in the calculation of diluted net income per share using the treasury stock method. During the period between issuance and September 30, 2014, the weighted average common stock price was below the conversion price of the Convertible Notes, and thus there would be no shares issuable under the conversion premium. As such, no shares have been presented in the table above.

**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. 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2013 | 2014 | 2013 | 2014 |
| Research and development | $ 585 | $ 1,187 | $ 1,379 | $ 3,551 |
| General and administrative | 2,138 | 1,711 | 3,699 | 4,987 |
| Total stock-based compensation expense | $ 2,723 | $ 2,898 | $ 5,078 | $ 8,538 |

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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 | (80,225) | 0.20 |
| Forfeited | (8,929) | 0.53 |
| Unvested restricted stock at September 30, 2014 | 13,258 | $ 4.36 |

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 | 1,190,148 | 30.69 |
| Exercised | (109,477) | 9.39 |
| Cancelled | (270,528) | 16.95 |
| Outstanding at September 30, 2014 | 3,662,936 | $ 18.39 |
| | | |
| Vested at September 30, 2014 | 1,390,404 | $ 9.50 |
| Vested and expected to vest at September 30, 2014 | 3,582,082 | $ 18.12 |

At September 30, 2014, there was approximately $30.0 million of total unrecognized compensation cost related to unvested stock options, which the Company expects to recognize over a remaining weighted-average period of 2.59 years. At September 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 nine months ended September 30, 2014, the Company issued 5,372 shares under the 2012 ESPP, and recognized approximately $0.1 million in related stock-based compensation expense.

In August 2014, the Company issued 19,500 restricted stock units, or RSUs, to certain employees and 2,750 stock options to certain non-employee consultants. These stock awards have performance conditions, pursuant to which vesting of the award is contingent on the occurrence of certain milestone events. As a result, the related compensation cost is recognized as an expense when the probability of the milestone is met. At September 30, 2014, there was approximately $0.6 million of total unrecognized compensation cost related to unvested RSUs.

**5. Common Stock Transactions**

In March 2013, the Company sold 5,428,000 shares of common stock, 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, 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.

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**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 nine months ended September 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 September 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 September 30, 2014 were $0.4 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.

**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

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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 nine months ended September 30, 2014, the Company recorded approximately $1.7 million and $3.1 million of research and development expense, respectively, associated with amounts due to AnaptysBio under the collaboration. As of September 30, 2014, the Company has not made any additional milestone payments under this agreement.

**9. Convertible Notes**

On September 29, 2014, in a registered underwritten public offering, the Company completed the issuance of $201.3 million aggregate principal amount of the Convertible Notes, which includes $26.3 million principal amount of Convertible Notes issued pursuant to the full exercise of an over-allotment option granted to the underwriters in the offering. The Company received net proceeds of $194.7 million from the sale of the Convertible Notes, after deducting discounts, commissions and other expenses of $6.6 million. In conjunction with the sale of the Convertible Notes, the Company used $20.8 million of the net proceeds to enter into separate Capped Calls, as described below.

The Convertible Notes are governed by the terms of a Senior Debt Securities Indenture, or the Base Indenture, as supplemented by the First Supplemental Indenture relating to the Convertible Notes, or the Supplemental Indenture, and together with the Base Indenture, the Indenture, between the Company and U.S. Bank National Association, as trustee. The Convertible Notes bear interest at a rate of 3.00% per annum, payable semi-annually on April 1 and October 1, beginning from April 1, 2015, and will be convertible into cash, shares of the Company s common stock or a combination of cash and shares of the Company s common stock, at the Company s election. The Convertible Notes will mature on October 1, 2021, unless earlier converted or repurchased in accordance with their terms. Prior to the close of business on the business day immediately preceding April 1, 2021, the Convertible Notes will be convertible only upon the occurrence of certain events and during certain periods as discussed below, and thereafter, at any time until the close of business on the second scheduled trading day immediately preceding the maturity date. The initial conversion price of the Convertible Notes is approximately $35.13 per share of common stock at an initial conversion rate of 28.4627 shares of the Company s common stock per $1,000 principal amount of Convertible Notes, which represents a premium of approximately 35% over the last reported sale price of the Company s common stock on September 23, 2014.

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

(1) during any calendar quarter commencing after the calendar quarter ending on December 31, 2014 (and only during such calendar quarter), if the closing sale price of the Company s common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day

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of the immediately preceding calendar quarter in which the conversion occurs is greater than 130% of the conversion price on each applicable trading day;

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

(3) upon the occurrence of specified corporate events.

On or after April 1, 2021 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert all or any portion of their Convertible Notes, in multiples of $1,000 principal amount, at the option of the holder regardless of the foregoing circumstances.

If a make-whole adjustment event, as described in the Indenture, occurs and a holder elects to convert its Convertible Notes in connection with such make-whole adjustment event, such holder may be entitled to an increase in the conversion rate as described in the Indenture.

The Company may not redeem the Convertible Notes prior to the maturity date and no sinking fund is provided for the Convertible Notes, which means that the Company is not required to periodically redeem or retire the Convertible Notes. Upon the occurrence of certain fundamental changes involving the Company, holders of the Convertible Notes may require the Company to repurchase for cash all or part of their Convertible Notes at a repurchase price equal to 100% of the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest.

The Indenture does not contain any financial covenants or restrictions on the payments of dividends, the incurrence of indebtedness or the issuance or repurchase of securities by the Company or any of its subsidiaries. The Indenture contains customary terms and covenants and events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving the Company) occurs and is continuing, the Trustee by notice to the Company, or the holders of at least 25% in principal amount of the outstanding Convertible Notes by written notice to the Company and the Trustee, may declare 100% of the principal and accrued and unpaid interest, if any, on all of the Convertible Notes to be due and payable immediately. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving the Company, 100% of the principal and accrued and unpaid interest, if any, on all of the Convertible Notes will become due and payable automatically. Notwithstanding the foregoing, the Indenture provides that, to the extent the Company elects and for up to 180 days after the occurrence of an event of default relating to certain failures by the Company to comply with certain reporting covenants, the remedy for such an event of default consists exclusively of the right to receive additional interest on the Convertible Notes.

The terms of the Indenture provide the Company with the option to settle the Convertible Notes in cash, common stock, or a combination of cash and common stock. As a result, in accordance with accounting guidance for debt with conversion and other options that can be settled in cash, the Company separately accounts for the liability and equity components of the Convertible Notes by allocating the principal between the liability component and the embedded conversion option, or equity component. Based on market data available for publicly traded, senior, unsecured corporate bonds issued by companies in the same industry and with similar maturity, the Company estimated the implied interest rate, assuming no conversion option. Assumptions used in the estimate represent what market participants would use in pricing the liability

component, including market interest rates, credit standing, and yield curves, all of which are defined as Level 2 observable inputs. The estimated implied interest rate was applied to the Convertible Notes, which resulted in a fair value of the liability component of $113.4 million upon issuance, calculated as the present value of implied future payments based on the $201.3 million aggregate principal amount. The equity component of the Convertible Notes was recognized as a debt discount, recorded in additional paid-in capital, and represents the difference between the aggregate principal of the Convertible Notes and the fair value of the Convertible Notes without conversion option on their issuance date. The debt discount is amortized to interest expense using the effective interest method over seven years, or the life of the Convertible Notes. The equity component is not remeasured as long as it continues to meet the conditions for equity classification. In addition, third-party transaction costs are required to be allocated to the liability and equity components based on their relative values.

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The Company s outstanding convertible note balances as September 30, 2014 consisted of the following (in thousands):

| | | September 30, 2014 |
|---|---|---|
| Liability component: | | |
| Principal | $ | 201,250 |
| Less: debt discount, net | | (87,818) |
| Net carrying amount | $ | 113,432 |
| Equity component | $ | 87,843 |

In connection with the issuance of the Convertible Notes, the Company incurred approximately $6.6 million of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, which the Company allocated to the liability and equity components in a manner consistent with the allocation of the principal, as described above. Of the total $6.6 million of debt issuance costs, $2.9 million were allocated to the equity component and recorded as a reduction to additional paid-in capital and $3.7 million were allocated to the liability component and recorded as non-current assets on the balance sheet. The portion allocated to the liability component is amortized to interest expense over the expected life of the Convertible Notes using the effective interest method.

The Company determined the expected life of the debt was equal to the seven year contractual term of the Convertible Notes. As of September 30, 2014, the carrying value of the Convertible Notes was $113.4 million and the fair value of the principal approximated the issuance price of $201.3 million due to the recent issuance. The effective interest rate on the liability component was 12.9% for the period from the date of issuance through September 30, 2014. The following table sets forth total interest expense recognized related to the Convertible Notes during the three and nine months ended September 30, 2014 (in thousands):

| | | Three and Nine Months Ended September 30, 2014 |
|---|---|---|
| Contractual interest expense | $ | 17 |
| Amortization of debt discount | | 24 |
| Amortization of debt issuance costs | | 1 |
| Total interest expense | $ | 42 |

The Company has evaluated the Indenture for derivatives pursuant to ASC 815, *Derivatives and Hedging*, and identified an embedded derivative that requires bifurcation as the feature is not clearly and closely related to the host instrument. The embedded derivative is a default provision, which could require additional interest payments. The Company has determined that the fair value of this embedded derivative was nominal as of September 30, 2014.

In conjunction with the offering of the Convertible Notes, the Company entered into privately-negotiated Capped Calls with certain counterparties. Each Capped Call is an integrated instrument consisting of a call option on the Company s common stock purchased by the Company from the counterparties with an exercise price equal to the conversion price of $35.13 per share for the underlying number of shares and a cap component that incorporates a cap price of $45.54 per share. The cap component is economically equivalent to a call option sold by the Company to the counterparties for the underlying number of shares with an exercise price of $45.54 per share. As an integrated instrument, the settlement of the Capped Calls coincides with the maturity date of the Convertible Notes. The aggregate cost of the Capped Calls was $20.8 million and was recorded to stockholders equity and will not be remeasured.

**10. Subsequent Events**

On November 4, 2014 the Company s new drug application for oral rolapitant was accepted for review by the U.S. Food and Drug Administration. As a result, the Company is obligated to make a $5.0 million milestone payment in November 2014 to OPKO Health, or OPKO, consistent with the terms of the Company s license agreement with OPKO.

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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. In September 2014, we submitted to the U.S. Food and Drug Administration, or FDA, a new drug application, or NDA, for oral rolapitant, which was accepted for review by the FDA in November 2014. We are currently preparing to be able to launch oral rolapitant as soon as the third quarter of 2015, assuming the NDA is approved without significant delay. The intravenous, or IV, formulation of rolapitant is currently in Phase 1 clinical trials. As part of a registration program for rolapitant IV we have initiated a

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clinical study comparing the exposure of rolapitant IV and oral formulations and we plan to initiate clinical studies to evaluate the safety of IV rolapitant.

- *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 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, private placements of our preferred stock and the issuance of convertible notes.

As of September 30, 2014, we had an accumulated deficit of $302.6 million. Our net losses were $123.1 million, $92.4 million, $61.8 million, and $16.4 million for the nine months ended September 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 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, our NDA submission for oral rolapitant was accepted for review by the FDA in November 2014; therefore 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 and we will incur substantial interest expense going forward as a result of the issuance of convertible debt in September 2014. Accordingly, we will seek to fund our operations through additional public or private equity or debt offerings and may seek additional capital

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through arrangements with strategic partners or from other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

*Rolapitant.* In December 2010, we entered into a license agreement with OPKO to obtain exclusive worldwide rights to research, develop, manufacture, market and sell rolapitant. The license agreement also extended to an additional, backup compound, SCH900978, to which we have similar rights and obligations as rolapitant, but which we are not currently advancing. 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. 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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In September 2014, we presented data from two of the three Phase 3 trials at the annual meeting of the European Society of Medical Oncology, including a retrospective subset analysis on outcomes by geographic regions and an analysis of the impact of CINV on daily life in the two trials that enrolled patients receiving HEC. In the regional subset analysis, patients treated with rolapitant achieved a higher complete response rate in the delayed, acute and overall phases across all geographic regions. Patients treated with rolapitant also achieved higher mean scores compared to the control group on the Functional Living Index-Emesis questionnaire, a patient reported outcome measure used to assess quality of life.

*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 have initiated a clinical study comparing the exposure of rolapitant IV and oral formulations and we plan to initiate clinical studies 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 trial, 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 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

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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.

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 nine month period ended September 30, 2014.

*Public Offerings of Common Stock, Private Placements of Securities and Issuance of Convertible Notes.* As of September 30, 2014, our principal source of liquidity was cash and cash equivalents, which totaled $295.9 million. Since our inception on March 26, 2010, we have funded our operations primarily through public offerings of our common stock, the private placement of our equity securities and issuance of convertible notes. 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. On September 29, 2014, we issued $201.3 million

aggregate principal amount of Convertible Notes, with estimated net proceeds of $194.7 million, and we used $20.8 million of the proceeds from this transaction for the purchase of Capped Calls. See Note 9, Convertible Notes , for additional information.

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**Financial Operations Overview**

***Research and Development Expenses***

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

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

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

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

- the cost of acquiring, developing and manufacturing active pharmaceutical ingredients, clinical trial materials and other research and development materials;

- fees and costs related to regulatory filings and operations;

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

- other costs associated with clinical and preclinical activities.

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 from current levels, 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. More specifically, we expect costs to increase as we continue our currently ongoing phase 3 trials for, and initiate additional investigative studies related to, niraparib; continue clinical and other development activities for both the oral and IV formulations of rolapitant as well as TSR-011; incur potential research and development related milestones; incur increased discovery, development and manufacturing related expenses associated with our immuno-oncology platform; and hire additional development and scientific personnel.

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

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

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| | Nine Months Ended September 30, | |
|---|---|---|
| | 2013 | 2014 |
| ***Rolapitant Expenses*** | | |
| Acquired in-process research and development | $ | $ |
| Research and development | 34,853 | 24,940 |
| Rolapitant total | 34,853 | 24,940 |
| | | |
| ***Niraparib Expenses*** | | |
| Acquired in-process research and development | 1,940 | 900 |
| Research and development | 10,134 | 35,590 |
| Niraparib total | 12,074 | 36,490 |
| | | |
| ***TSR-011 Expenses*** | | |
| Acquired in-process research and development | | |
| Research and development | 1,970 | 4,760 |
| TSR-011 total | 1,970 | 4,760 |
| | | |
| ***Immuno-Oncology Platform Expenses*** | | |
| Acquired in-process research and development | | 17,000 |
| Research and development | | 3,500 |
| Immuno-Oncology Platform total | | 20,500 |
| | | |
| ***Personnel and Other Expenses*** | 9,886 | 19,821 |
| | | |
| **Total** | **$ 58,783** | **$ 106,511** |

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 certain facility-related costs, communication expenses, pre-commercialization activities and professional fees for legal, patent review, consulting and accounting services.

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

***Other Income and Expense***

Other income and expense consists primarily of interest expense related to the Convertible Notes, and interest income earned on cash and cash equivalents.

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**Results of Operations**

**Comparison of the Three Months Ended September 30, 2013 and 2014**

| | Three Months Ended September 30, | | Increase/ |
|---|---|---|---|
| | 2013 | 2014 | (Decrease) |
| | (in thousands) | | |
| Expenses: | | | |
| Research and development | $ 22,163 | $ 29,925 | $ 7,762 |
| General and administrative | 4,503 | 6,263 | 1,760 |
| Acquired in-process research and development | 1,940 | | (1,940) |
| Total expenses | 28,606 | 36,188 | 7,582 |
| | | | |
| Loss from operations | (28,606) | (36,188) | (7,582) |
| Other income (expense), net | 17 | (38) | (55) |
| | | | |
| Net loss | $ (28,589) | $ (36,226) | $ (7,637) |

*Research and Development Expenses.* Research and development expenses were $29.9 million for the three months ended September 30, 2014, compared to $22.2 million for the three months ended September 30, 2013, an increase of $7.7 million. The increase was primarily due to higher expenses related to the development of our in-licensed product candidate niraparib 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 $8.9 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 $2.5 million in personnel and other costs (excluding stock-based compensation) primarily related to increased research and development headcount supporting the growth of our development activities;

- an increase of $2.0 million in costs associated with our immuno-oncology platform strategy; and

- a decrease of $6.3 million in costs associated with rolapitant development activities, primarily due to lower costs related to the recently completed Phase 3 clinical trials, partially offset by increases in costs associated with regulatory filing fees and activities.

In addition, stock-based compensation expense included in research and development expenses increased $0.6 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 $6.3 million for the three months ended September 30, 2014, compared to $4.5 million for the three months ended September 30, 2013, an increase of $1.8 million. The increase was primarily due to increases of $1.2 million in salaries, benefits and other personnel-related costs and $1.0 million in professional and consulting fees and other expenses to support corporate operational and pre-commercialization activities, offset by a decrease of $0.4 million in stock-based compensation expense. The decrease in stock-based compensation expense was due to $0.9 million of expense recorded in the three months ended September 30, 2013 related to variable accounting for awards held by a non-employee consultant.

*Acquired In-Process Research and Development Expenses.* There were no acquired in-process research and development expenses for the three months ended September 30, 2014. We recorded $1.9 million in acquired in-process research and development expenses for the three months ended September 30, 2013, representing a milestone payment made as the result of the first patient dosing in the Phase 3 clinical trial of niraparib in patients with high grade serous, platinum sensitive, relapsed ovarian cancer, which occurred in July 2013.

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*Other Income (Expense), Net*. Other income (expense) is primarily comprised of interest expense related to our Convertible Notes, and interest income earned on cash and cash equivalents. Interest expense increased by $42,000 in the three months ended September 30, 2014, as there was no interest expense in the prior year period. Interest income decreased from $17,000 in the three months ended September 30, 2013 to $4,000 in the three months ended September 30, 2014.

**Comparison of the Nine Months Ended September 30, 2013 and 2014**

| | Nine Months Ended September 30, | | Increase/ (Decrease) |
|---|---|---|---|
| | 2013 | 2014 | |
| | (in thousands) | | |
| Expenses: | | | |
| Research and development | $ 56,843 | $ 88,611 | $ 31,768 |
| General and administrative | 10,315 | 16,538 | 6,223 |
| Acquired in-process research and development | 1,940 | 17,900 | 15,960 |
| Total expenses | 69,098 | 123,049 | 53,951 |
| | | | |
| Loss from operations | (69,098) | (123,049) | (53,951) |
| Other income (expense), net | 76 | (28) | (104) |
| | | | |
| Net loss | $ (69,022) | $ (123,077) | $ (54,055) |

*Research and Development Expenses.* Research and development expenses were $88.6 million for the nine months ended September 30, 2014, compared to $56.8 million for the nine months ended September 30, 2013, an increase of $31.8 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 $25.5 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 $7.7 million in personnel and other costs (excluding stock-based compensation) primarily related to increased research and development headcount supporting the growth of our development activities;

- an increase of $6.3 million in costs associated with TSR-011 development activities and our immuno-oncology platform strategy; and

- a decrease of $9.9 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 regulatory filing fees and activities as well as Phase 1 bioequivalence and intravenous formulation studies.

In addition, stock-based compensation expense included in research and development expenses increased $2.2 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 $16.5 million for the nine months ended September 30, 2014, compared to $10.3 million for the nine months ended September 30, 2013, an increase of $6.2 million. The increase was due primarily to increases of $2.8 million in salaries, benefits and other personnel-related costs; $2.1 million in professional and consulting fees and other expenses to support corporate operational and pre-commercialization activities; and $1.3 million in stock-based compensation expense, related to increased awards of employee stock options and higher grant-date fair values of those awards.

*Acquired In-Process Research and Development Expenses.* We recorded $17.9 million in acquired in-process research and development expenses for the nine months ended September 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

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BRCA mutations in April 2014. We recorded $1.9 million in acquired in-process research and development expenses during the nine months ended September 30, 2013, representing a milestone payment made as the result of the first patient dosing in the Phase 3 clinical trial of niraparib in patients with high grade serous, platinum sensitive, relapsed ovarian cancer, which occurred in July 2013.

*Other Income (Expense), Net*. Other income (expense) is primarily comprised of interest expense related to our Convertible Notes, and interest income earned on cash and cash equivalents. Interest expense increased by $42,000 in the nine months ended September 30, 2014, as there was no interest expense in the prior period. Interest income decreased from $76,000 in the nine months ended September 30, 2013 to $14,000 in the nine months ended September 30, 2014.

**Liquidity and Capital Resources**

*Sources of Liquidity*

To date, we have not generated any revenue. As of September 30, 2014, our principal source of liquidity was cash and cash equivalents, which totaled $295.9 million. Since our inception on March 26, 2010, we have funded our operations primarily through public offerings of our common stock, the private placement of our equity securities and the issuance of convertible notes. On September 29, 2014, we completed the issuance of $201.3 million aggregate principal amount of senior convertible notes, generating proceeds, net of underwriting discounts, commissions and offering expenses, of $194.7 million. In conjunction with the sale of the Convertible Notes, we used approximately $20.8 million of the net proceeds to enter into separate Capped Calls with certain counterparties. The Capped Calls transactions are expected generally to reduce the potential dilution, and/or offset to an extent the cash payments we are required to make in excess of the principal amount, upon conversion of the Convertible Notes. 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):

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2013 | 2014 |
| Net cash provided by (used in): | | |
| Operating activities | $ (58,692) | $ (85,172) |
| Investing activities | (2,323) | (18,869) |
| Financing activities | 92,010 | 269,643 |

| | | | | |
|---|---|---|---|---|
| Increase in cash and cash equivalents | $ | 30,995 | $ | 165,602 |

*Cash Flows from Operating Activities*

The use of cash in operating activities during both the nine months ended September 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 $26.5 million for the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013, primarily due to an increase in external research and development expenses as we continued to progress the niraparib and TSR-011 development programs and initiated the immuno-oncology platform. Higher costs associated with increased employee headcount also contributed to the increase in cash used in operating activities. These factors were partially offset by lower external costs associated with our oral rolapitant program.

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*Cash Flows from Investing Activities*

The increase of $16.6 million in net cash used in investing activities for the nine months ended September 30, 2014 compared to the nine months ended September 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 recorded $1.9 million in acquired in-process research and development expenses during the nine months ended September 30, 2013, representing a milestone payment made as the result of the first patient dosing in the Phase 3 clinical trial of niraparib in patients with high grade serous, platinum sensitive, relapsed ovarian cancer, which occurred in July 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.

*Cash Flows from Financing Activities*

The increase of $177.6 million in net cash provided by financing activities for the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013 was due primarily to issuance of the Convertible Notes with net cash proceeds of $195.2 million, partly offset by the use of $20.8 million in cash associated with the Capped Calls. We also completed public offerings of our common stock 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 $0.4 million.

*Operating Capital Requirements*

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, required costs relating to our March 2014 collaboration and exclusive license agreement with AnaptysBio and cash interest obligations related to our Convertible Notes, through at least the 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 and to meet our obligation to repay the Convertible Notes at maturity or, at our election, upon conversion.

Until we can generate a sufficient amount of revenue from our products, if ever, we expect to finance future cash needs through public or private equity or debt offerings and may seek additional capital through arrangements with strategic partners or from other sources. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us,

we 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 Convertible Notes and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

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

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

- 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 September 30, 2014 were $0.4 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.

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During the third quarter of 2014, we issued $201.3 million aggregate principal amount of 3.00% convertible senior notes due 2021. Contractual interest obligations related to the convertible senior notes will total $6.0 million due in each year from 2015 through 2021.

**Off-Balance Sheet Arrangements**

As of September 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 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 September 30, 2014 and December 31, 2013, we had cash and cash equivalents of $295.9 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 September 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. In addition, you should also consider the risk factors set forth below, which amend and supplement the risks set forth in the Risk Factors section of our Annual Report.*

**Risks Related to Our Indebtedness**

***Servicing our debt will require significant amounts of cash, and we may not have sufficient cash flow from our business to pay our debt.***

Our ability to make scheduled payments of the principal of, to pay interest on, to pay any cash due upon conversion of, or to refinance, our indebtedness, including our 3.0% convertible senior notes due October 1, 2021, or the Convertible Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

***Despite our current debt levels, we may still incur additional debt; if we incur substantial additional debt, these higher levels of debt may affect our ability to pay the principal of and interest on the Convertible Notes.***

We and our subsidiaries may be able to incur substantial additional debt in the future, some of which may be secured debt. The indenture governing the Convertible Notes does not restrict our ability to incur additional indebtedness or require us to maintain financial ratios or specified levels of net worth or liquidity. If we incur substantial additional indebtedness in the future, these higher levels of indebtedness may affect our ability to pay the principal of and interest on the Convertible Notes, or any fundamental change in purchase price or any cash due upon conversion, and our creditworthiness generally.

***The conditional conversion feature of the Convertible Notes, if triggered, may adversely affect our financial condition and operating results.***

In the event the conditional conversion feature of the Convertible Notes is triggered, holders of notes will be entitled to convert their notes at any time during specified periods at their option. If one or more holders elect to convert their notes, unless we satisfy our conversion obligation by delivering solely shares of our common stock (other than cash in lieu of any fractional share), we would be required to settle all or a portion of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

***The accounting method for convertible debt securities that may be settled in cash, such as the Convertible Notes, could have a material effect on our reported financial results.***

Pursuant to Accounting Standards Codification Subtopic 470-20, *Debt with Conversion and Other Options*, which we refer to as ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the Convertible Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer s economic interest cost. The effect of ASC 470-20 on the accounting for the Convertible Notes is that the equity component is required to be included in the additional paid-in capital caption of stockholders equity on our consolidated balance sheet and the value of the equity component would be treated as original issue discount for purposes of

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accounting for the debt component of the Convertible Notes. As a result, we will be required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the Convertible Notes to their face amount over the term of the Convertible Notes. We will report greater losses in our financial statements because ASC 470-20 will require interest to include both the current period s amortization of the debt discount and the instrument s coupon interest, which could adversely affect our reported or future financial results, the market price of our common stock and the trading price of the Convertible Notes.

In addition, under certain circumstances, convertible debt instruments (such as the Convertible Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the Convertible Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the Convertible Notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable to use the treasury stock method in accounting for the shares issuable upon conversion of the Convertible Notes, then our diluted earnings per share would be adversely affected.

***To the extent we issue shares of our common stock to satisfy all or a portion of our conversion obligation, conversions of the Convertible Notes may dilute the ownership interest of our existing stockholders.***

Upon conversion of the Convertible Notes, we have the option to pay or deliver, as the case may be, either cash, shares of our common stock, or a combination of cash and shares of our common stock. To the extent we issue shares of our common stock to satisfy all or a portion of our conversion obligation, the conversion of some or all of the Convertible Notes will dilute the ownership interests of our existing stockholders. Any sales in the public market of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Convertible Notes may encourage short selling by market participants because the conversion of the Convertible Notes could depress the price of our common stock.

***The fundamental change purchase feature of the Convertible Notes may delay or prevent an otherwise beneficial attempt to take over our Company.***

The terms of the Convertible Notes require us to offer to purchase the Convertible Notes for cash in the event of a fundamental change. A non-stock takeover of our Company may trigger the requirement that we purchase the Convertible Notes. This feature may have the effect of delaying or preventing a takeover of our Company that would otherwise be beneficial to investors.

**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: November 6, 2014

By: /s/ Timothy R. Pearson
Timothy R. Pearson
*Executive Vice President and Chief Financial Officer*

*(principal financial officer)*

Date: November 6, 2014

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**EXHIBIT INDEX**

| Exhibit Number | Exhibit Description |
|---|---|
| 4.1(A) | Senior Debt Securities Indenture, dated September 29, 2014, between the Company and U.S. Bank National Association, as trustee |
| 4.2(A) | First Supplemental Indenture, dated September 29, 2014, between the Company and U.S. Bank National Association, as trustee |
| 10.1(A) | Base Capped Call Confirmation, dated September 23, 2014, between the Company and Citibank, N.A. |
| 10.2(A) | Base Capped Call Confirmation, dated September 23, 2014, among the Company, Deutsche Bank AG, London Branch, and Deutsche Bank Securities Inc., acting solely as agent |
| 10.3(A) | Additional Capped Call Confirmation, dated September 25, 2014, between the Company and Citibank, N.A. |
| 10.4(A) | Additional Capped Call Confirmation, dated September 25, 2014, among the Company, Deutsche Bank AG, London Branch, and Deutsche Bank Securities Inc., acting solely as agent |
| 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 |

(A) Filed as an exhibit to the Registrant s Current Report on Form 8-K filed on September 29, 2014 (File No. 001-35587).