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# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended September 30, 2018**

**OR**

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

**For the transition period from to**

**Commission file number 001-35587**

# TESARO, INC.

(Exact Name of Registrant as Specified in Its Charter)

| **Delaware** | **27-2249687** |
|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (I.R.S. Employer Identification No.) |
| **1000 Winter Street 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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

| | |
|---|---|
| Large accelerated filer ☒ | Accelerated filer ☐ |
| Non-accelerated filer ☐ | Smaller reporting company ☐ |
| | Emerging growth company ☐ |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of October 29, 2018, there were 55,046,956 shares of the registrant's Common Stock, par value $0.0001 per share, outstanding.

**TESARO, INC.**
**FORM 10-Q**
**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2018**

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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)**

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 476,812 | $ 643,095 |
| Accounts receivable | 31,362 | 53,416 |
| Inventories | 108,822 | 57,939 |
| Other current assets | 31,382 | 33,511 |
| Total current assets | 648,378 | 787,961 |
| | | |
| Intangible assets, net | 35,897 | 56,384 |
| Property and equipment, net | 9,923 | 9,652 |
| Restricted cash | 8,610 | 2,552 |
| Other assets | 8,032 | 5,636 |
| Total assets | $ 710,840 | $ 862,185 |
| | | |
| **Liabilities and stockholders' equity (deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 28,160 | $ 4,172 |
| Accrued expenses | 150,933 | 154,808 |
| Deferred revenue, current | 530 | 324 |
| Other current liabilities | 10,819 | 6,902 |
| Total current liabilities | 190,442 | 166,206 |
| | | |
| Convertible notes, net | 153,057 | 143,446 |
| Long-term debt, net | 490,525 | 293,659 |
| Deferred revenue, non-current | 141 | 211 |
| Other non-current liabilities | 7,467 | 9,577 |
| Total liabilities | 841,632 | 613,099 |
| | | |
| Commitments and contingencies *(Note 11)* | | |
| | | |
| Stockholders' equity (deficit): | | |
| Preferred stock, $0.0001 par value; 10,000,000 shares authorized at both September 30, 2018 and December 31, 2017; no shares issued or outstanding at both September 30, 2018 and December 31, 2017 | — | — |
| Common stock, $0.0001 par value; 100,000,000 shares authorized at both September 30, 2018 and December 31, 2017; 55,034,990 and 54,464,039 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively | 5 | 5 |
| Additional paid-in capital | 1,813,884 | 1,724,850 |
| Accumulated other comprehensive loss | (8,239) | (5,882) |
| Accumulated deficit | (1,936,442) | (1,469,887) |
| Total stockholders' equity (deficit) | (130,792) | 249,086 |
| Total liabilities and stockholders' equity (deficit) | $ 710,840 | $ 862,185 |

*See accompanying notes to condensed consolidated financial statements.*

**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, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Revenues: | | | | |
| Product revenue, net | $ 63,612 | $ 41,755 | $ 170,312 | $ 72,723 |
| License, collaboration and other revenues | 787 | 101,011 | 1,037 | 102,580 |
| Total revenues | 64,399 | 142,766 | 171,349 | 175,303 |
| Expenses: | | | | |
| Cost of sales – product | 14,225 | 6,216 | 37,735 | 10,280 |
| Cost of sales – intangible asset amortization | 728 | 1,254 | 3,663 | 4,723 |
| Research and development | 94,188 | 73,388 | 288,551 | 210,910 |
| Selling, general and administrative | 93,497 | 83,998 | 287,137 | 246,239 |
| Acquired in-process research and development | — | — | — | 7,000 |
| Total expenses | 202,638 | 164,856 | 617,086 | 479,152 |
| Loss from operations | (138,239) | (22,090) | (445,737) | (303,849) |
| Interest expense | (18,179) | (4,424) | (43,101) | (13,117) |
| Interest income | 1,944 | 1,133 | 5,143 | 2,933 |
| Gain on sale of business | 17,627 | — | 17,627 | — |
| Other income | 81 | 243 | 243 | 243 |
| Loss before income taxes | (136,766) | (25,138) | (465,825) | (313,790) |
| Provision for income taxes | 322 | 139 | 730 | 271 |
| Net loss | $ (137,088) | $ (25,277) | $ (466,555) | $ (314,061) |
| Net loss per share applicable to common stockholders - basic and diluted | $ (2.49) | $ (0.47) | $ (8.51) | $ (5.82) |
| Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted | 54,957 | 54,241 | 54,807 | 53,971 |
| Comprehensive income (loss): | | | | |
| Net loss | $ (137,088) | $ (25,277) | $ (466,555) | $ (314,061) |
| Other comprehensive income (loss): | | | | |
| Unrealized gain on pension obligation | 62 | 46 | 186 | 137 |
| Foreign currency translation adjustments | (406) | 131 | (2,543) | 421 |
| Other comprehensive income (loss) | (344) | 177 | (2,357) | 558 |
| Comprehensive income (loss) | $ (137,432) | $ (25,100) | $ (468,912) | $ (313,503) |

*See accompanying notes to condensed consolidated financial statements.*

**TESARO, INC.**
**Condensed Consolidated Statements of Cash Flows**
***(all amounts in 000's)***
**(Unaudited)**

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2018** | **2017** (as revised) |
| **Operating activities** | | |
| Net loss | $ (466,555) | $ (314,061) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Acquired in-process research and development | — | 7,000 |
| Depreciation and amortization expense | 7,139 | 7,092 |
| Stock-based compensation expense | 79,295 | 66,925 |
| Non-cash interest expense | 10,477 | 8,588 |
| Gain on sale of business | (17,627) | — |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 6,063 | (21,484) |
| Inventories | (54,647) | (35,827) |
| Other assets | 3,629 | (12,415) |
| Accounts payable | 23,921 | 692 |
| Accrued expenses | 12,178 | 49,375 |
| Deferred revenues | 146 | (70) |
| Other liabilities | 2,187 | 1,000 |
| Net cash used in operating activities | (393,794) | (243,185) |
| | | |
| **Investing activities** | | |
| Acquisition of product candidates, technology licenses and milestone payments | — | (42,000) |
| Proceeds from sale of business | 35,000 | — |
| Purchase of property and equipment | (3,757) | (4,926) |
| Net cash provided by (used in) investing activities | 31,243 | (46,926) |
| | | |
| **Financing activities** | | |
| Proceeds from term loan, net of issuance costs | 196,000 | — |
| Proceeds from sale of common stock, net of issuance costs | — | (8) |
| Proceeds from exercise of stock options and Employee Stock Purchase Plan | 8,734 | 25,849 |
| Net cash provided by financing activities | 204,734 | 25,841 |
| | | |
| Effect of exchange rate changes on cash, cash equivalents, and restricted cash | (2,409) | 498 |
| Decrease in cash, cash equivalents, and restricted cash | (160,226) | (263,772) |
| Cash, cash equivalents, and restricted cash at beginning of period | 645,954 | 787,866 |
| Cash, cash equivalents, and restricted cash at end of period | $ 485,728 | $ 524,094 |
| | | |
| **Non-cash investing and financing activities** | | |
| Stock option exercise proceeds receivable as of period end | $ — | $ 71 |
| Leasehold improvement assets funded by lessor | $ — | $ 585 |
| Purchase of property and equipment - cash not paid as of period end | $ — | $ 328 |
| | | |
| **Supplemental disclosure of cash flow information** | | |
| Cash paid for interest | $ 33,099 | $ 6,038 |
| Income taxes paid | $ 921 | $ 468 |

The following table presents the line items and amounts of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets:

| | **September 30, 2018** | **December 31, 2017** |
|---|---|---|
| Cash and cash equivalents | $ 476,812 | $ 643,095 |
| Restricted cash included in other current assets | 306 | 307 |
| Restricted cash, noncurrent | 8,610 | 2,552 |
| Total cash, cash equivalents and restricted cash | $ 485,728 | $ 645,954 |

*See accompanying notes to condensed consolidated financial statements.*

**TESARO, INC.**

**Notes to Condensed Consolidated Financial Statements**
**(Unaudited)**

## 1. Description of Business

TESARO, Inc., or the Company or TESARO, was incorporated in Delaware and commenced operations in 2010. Headquartered in Waltham, Massachusetts, TESARO is a commercial-stage biopharmaceutical company devoted to providing transformative therapies to people bravely facing cancer. TESARO's primary focus is to develop and commercialize treatments for solid tumors using various approaches, including small molecules and immuno-oncology antibodies, as monotherapies and in combinations. The Company has in-licensed and is developing several oncology-related product candidates, and has entered into several research collaborations with third parties for the discovery of new candidates. The Company operates in one segment. The Company is subject to a number of risks, including dependence on key individuals, regulatory and manufacturing risks, the need to develop additional commercially viable products, risks associated with competitors, many of which are larger and better capitalized, risks related to intellectual property, 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's product ZEJULA® is approved in both the U.S. and the European Union, or EU, as a maintenance treatment for adults with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. In June 2018, the Company entered into an agreement with TerSera Therapeutics LLC, or TerSera, pursuant to which the Company sold to TerSera its rights to VARUBI® (rolapitant) in the United States and Canada, and the transaction closed in July 2018. See Note 13, "VARUBI Transaction", for additional details. The Company is continuing to market and sell VARUBY in Europe.

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 to a lesser extent through product sales and license and collaboration arrangements. Management expects operating losses and negative operating cash flows to continue for the foreseeable future. As the Company continues to incur losses, the transition to profitability is dependent upon the successful development, approval, and commercialization of its products and product candidates and the achievement of a level of revenues adequate to support its cost structure. The Company believes that its currently available funds, in addition to cash generated from sales of its products, will be sufficient to fund the Company's operations through at least the next 12 months from the issuance of this Quarterly Report on Form 10-Q. Management's belief with respect to its ability to fund operations is based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, the Company may need to seek additional funding sooner than expected, or reduce or defer spending on future research and development.

## 2. Basis of Presentation and Significant Accounting Policies

*Basis of Presentation*

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

The Company's condensed consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. The Company currently operates in one business segment, which is the identification, acquisition, development and commercialization of oncology-related therapeutics, 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, 2018 and 2017.

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, 2017 and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017. The significant accounting policies used in preparation of these condensed consolidated financial statements for the three and nine months ended September 30, 2018 are consistent with those discussed in Note 2 to the consolidated financial statements in the Company's 2017 Annual Report on Form 10-K and are updated below as necessary.

*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, revenues and expenses, other comprehensive income (loss) 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, revenue, valuation of convertible notes, inventory, intangible assets and related amortization. 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.

*Fair Value of Financial Instruments*

The Company discloses 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 September 30, 2018 and December 31, 2017 and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

| | | September 30, 2018 | | | |
|---|---|---|---|---|---|
| **Description** | **Balance Sheet Classification** | **Total** | **Level 1** | **Level 2** | **Level 3** |
| **Assets:** | | | | | |
| Money market funds | Cash and cash equivalents | $ 345,237 | $ 345,237 | $ — | $ — |
| Total assets | | $ 345,237 | $ 345,237 | $ — | $ — |

| | | December 31, 2017 | | | |
|---|---|---|---|---|---|
| **Description** | **Balance Sheet Classification** | **Total** | **Level 1** | **Level 2** | **Level 3** |
| **Assets:** | | | | | |
| Money market funds | Cash and cash equivalents | $ 593,955 | $ 593,955 | $ — | $ — |
| Total assets | | $ 593,955 | $ 593,955 | $ — | $ — |

In September 2014, the Company issued $201.3 million aggregate principal amount of 3.00% convertible senior notes due October 1, 2021, or the Convertible Notes. Interest is payable semi-annually in arrears on April 1 and October 1 of each year. As of September 30, 2018, the carrying value of the Convertible Notes, net of unamortized discount and debt issuance costs, was $153.1 million and the estimated fair value of the principal amount was $266.9 million. As of

September 30, 2018, the carrying value of the Company's borrowing under its term loan agreement approximated its fair value. The Convertible Notes and the term loan agreement are discussed in more detail in Note 6, "Debt".

*Revenue Recognition*

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. For a further discussion of accounting for net product revenue and license, collaboration and other revenues, see Note 3, "Revenue Recognition".

*Intangible Assets*

The Company maintains definite-lived intangible assets related to milestone payments made to third parties subsequent to regulatory approval for acquired and in-licensed product candidates. These assets are amortized over their remaining useful lives, which are generally estimated to be the remaining patent life. If the Company's estimate of the product's useful life is shorter than the remaining patent life, then the shorter period is used. Intangible assets are amortized using the economic consumption method if anticipated future revenues can be reasonably estimated. The straight-line method is used when future revenues cannot be reasonably estimated, with a cumulative catch-up of amortization expense for milestone payments that do not result in additional intellectual property rights and/or incremental cash flows. Amortization expense is recorded as a component of cost of sales in the condensed consolidated statements of operations and comprehensive loss.

The Company assesses its intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding one of the Company's drug candidates or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate or new information regarding potential sales for the drug. If impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the condensed consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would determine the fair value of the intangible asset and recognize an impairment loss if the carrying value of the intangible asset exceeds its fair value.

*Comprehensive Loss*

Comprehensive loss represents the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss consists of net loss and other comprehensive loss. Other comprehensive loss includes foreign currency translation adjustments and unrealized gains and losses on pension obligations. The following table presents changes in the components of accumulated other comprehensive loss (in thousands):

| | Foreign currency translation adjustments | Unrealized loss on pension obligation | Total |
|---|---|---|---|
| **Balance at December 31, 2017** | $ 259 | $ (6,141) | $ (5,882) |
| Other comprehensive (loss) income | (2,543) | 186 | (2,357) |
| **Balance at September 30, 2018** | $ (2,284) | $ (5,955) | $ (8,239) |
| | | | |
| **Balance at December 31, 2016** | $ (142) | $ (2,782) | $ (2,924) |
| Other comprehensive (loss) income | 421 | 137 | 558 |
| **Balance at September 30, 2017** | $ 279 | $ (2,645) | $ (2,366) |

*New Accounting Pronouncements - Recently Adopted*

In August 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2016-15, which is intended to simplify and clarify how certain transactions are classified in the statement of cash flows, and to reduce diversity in practice for such transactions. This ASU addresses eight specific issues regarding classification of cash flows. The standard is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company adopted this ASU effective January 1, 2018, and the adoption did not have an impact on the Company's condensed consolidated financial statements and related disclosures.

In October 2016, the FASB issued ASU No. 2016-16, which removes the prohibition in ASC Topic 740 against the immediate recognition of the current and deferred income tax effects of intra-entity transfers of assets other than inventory. As a result, the income tax consequences from the intra-entity transfer of an asset, other than inventory, and associated changes to deferred taxes will be recognized when the transfer occurs. The Company adopted this new standard effective January 1, 2018 using the modified retrospective method. Upon adoption, the Company recorded a deferred tax asset and corresponding valuation allowance of $52.7 million. There was no cumulative effect adjustment to accumulated deficit as of the beginning of the period of adoption.

In November 2016, the FASB issued ASU No. 2016-18, which requires amounts generally described as restricted cash and restricted cash equivalents to be included with cash and cash equivalents when reconciling the total beginning and ending amounts for the periods shown on the statement of cash flows. ASU No. 2016-18 is effective for fiscal years beginning after December 15, 2017 (including interim periods within those periods) using a retrospective transition method to each period presented. The Company adopted this ASU effective January 1, 2018. The adoption of this guidance required the following changes and disclosures to the presentation of the condensed consolidated financial statements:

- Cash, cash equivalents and restricted cash and cash equivalents reported on the condensed consolidated statements of cash flows now includes restricted cash and cash equivalents and totals $485.7 million and $646.0 million as of September 30, 2018 and December 31, 2017, respectively.

- Restricted cash primarily consists of cash balances held as collateral for the Company's employee credit card programs.

In May 2017, the FASB issued ASU No. 2017-09, which clarifies when a change to the terms or conditions of a share-based payment award must be accounted for as a modification. The new guidance requires modification accounting if the fair value, vesting condition or classification of the award is not the same immediately before and after a change to the terms and conditions of the award. This ASU is effective on a prospective basis beginning on January 1, 2018, with early adoption permitted. The Company adopted this ASU effective January 1, 2018, and the adoption did not have an impact on the Company's condensed consolidated financial statements and related disclosures.

*New Accounting Pronouncements – Recently Issued*

In February 2016, the FASB issued ASU No. 2016-02, a comprehensive new lease accounting standard, which provides revised guidance on accounting for lease arrangements by both lessors and lessees and requires lessees to recognize a lease liability and a right-of-use asset for most leases. This ASU also requires additional disclosures. The new guidance is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with early adoption permitted. The new standard must be applied using a modified retrospective transition approach that requires application of the new guidance for all periods presented, with certain practical expedients available pursuant to ASU No. 2018-10, issued in July 2018. In July 2018, the FASB issued ASU No. 2018-11, which provides an additional transition method to adopt the new leasing standard. Under this new transition method, an entity initially applies the new leasing standard using a cumulative-effect adjustment to the opening balance of retained earnings but will continue to report comparative periods under existing guidance. Although its assessment is not complete, the Company currently expects the adoption of this guidance to result in the addition of material balances of leased assets and corresponding lease liabilities to its consolidated balance sheets, primarily relating to leases of office space. As part of its assessment, the Company is considering whether to utilize the practical expedients. The Company is also in the process of implementing appropriate changes to its controls to support lease accounting and related disclosures under the new standard.

In June 2018, the FASB issued ASU No. 2018-07, which simplifies the accounting for share-based payments granted to nonemployees by aligning the accounting with the requirements for employee share-based compensation. The new guidance is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with early adoption permitted. The Company is assessing the impact of the adoption of this guidance on its condensed consolidated financial statements.

**3. Revenue Recognition**

*Product Revenue, Net*

The Company sells its products principally to a limited number of specialty distributors and specialty pharmacy providers in the U.S., and directly to hospitals and clinics as well as to certain wholesale distributors in Europe, or collectively, its Customers. These Customers subsequently resell the Company's products to health care providers and patients. In addition to distribution agreements with Customers, the Company enters into arrangements with health care providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of the Company's products.

Revenues from product sales are recognized when the Customer obtains control of the Company's product, which occurs at a point in time, typically upon delivery to the Customer. When the Company performs shipping and handling activities after the transfer of control to the Customer (e.g., when control transfers prior to delivery), they are considered as fulfillment activities, and accordingly, the costs are accrued for when the related revenue is recognized. Taxes collected from Customers relating to product sales and remitted to governmental authorities are excluded from revenues.

*Product Revenue*. Net product revenue relates to sales of ZEJULA and VARUBI/VARUBY. The Company commenced sales of ZEJULA in the U.S. in April 2017 and in Europe in December 2017. For the nine months ended September 30, 2018, sales of ZEJULA in Europe accounted for over 25% of total net ZEJULA product revenues. The following tables present net product revenues by product for the three and nine months ended September 30, 2018 and 2017, respectively (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| ZEJULA | $ 63,226 | $ 39,375 | $ 165,989 | $ 65,321 |
| VARUBI/VARUBY | 386 | 2,380 | 4,323 | 7,402 |
| Product revenue, net | $ 63,612 | $ 41,755 | $ 170,312 | $ 72,723 |

The following tables summarize activity in each of the product revenue allowance and reserve categories for the nine months ended September 30, 2018 and 2017 (in thousands):

| | Chargebacks, discounts and fees | Government and other rebates | Returns | Total |
|---|---|---|---|---|
| Balance at December 31, 2017 | $ 2,088 | $ 6,450 | $ 16,350 | $ 24,888 |
| Provision related to current period sales | 13,052 | 14,778 | 428 | 28,258 |
| Adjustment related to prior period sales | (268) | (53) | (49) | (370) |
| Credit or payments made during the period | (13,639) | (12,667) | (15,671) | (41,977) |
| Balance at September 30, 2018 | $ 1,233 | $ 8,508 | $ 1,058 | $ 10,799 |
| | | | | |
| Balance at December 31, 2016 | $ 177 | $ 1,312 | $ 18 | $ 1,507 |
| Provision related to current period sales | 6,567 | 6,924 | 155 | 13,646 |
| Adjustment related to prior period sales | — | 62 | — | 62 |
| Credit or payments made during the period | (5,906) | (4,311) | — | (10,217) |
| Balance at September 30, 2017 | $ 838 | $ 3,987 | $ 173 | $ 4,998 |

*License, Collaboration and Other Revenues*

The Company enters into out-licensing agreements which are within the scope of Topic 606, under which it licenses certain rights to its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; payments for manufacturing supply services the Company provides through its contract manufacturers; and royalties on net sales of licensed products. Each of these payments results in license, collaboration and other revenues, except for revenues from royalties on net sales of licensed products, which are classified as royalty revenues.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The following tables present changes in the Company's contract assets and liabilities during the nine months ended September 30, 2018 and 2017 (in thousands):

| | Balance at Beginning of Period | Additions | Deductions | Balance at End of Period |
|---|---|---|---|---|
| **Nine Months Ended September 30, 2018** | | | | |
| Contract assets | $ 1,000 | $ — | $ (1,000) | $ — |
| Contract liabilities | $ 306 | $ — | $ (71) | $ 235 |
| | | | | |
| **Nine Months Ended September 30, 2017** | | | | |
| Contract assets | $ 1,000 | $ — | $ — | $ 1,000 |
| Contract liabilities | $ 400 | $ — | $ (70) | $ 330 |

During the three and nine months ended September 30, 2018 and 2017, the Company recognized the following revenues as a result of changes in the contract asset and the contract liability balances in the respective periods (in thousands):

| | Three Months Ended September 30, | |
|---|---|---|
| | 2018 | 2017 |
| **Revenue recognized in the period from:** | | |
| Amounts included in contract liabilities at the beginning of the period | $ 23 | $ 23 |
| Performance obligations satisfied in previous periods | $ — | $ — |

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2018 | 2017 |
| **Revenue recognized in the period from:** | | |
| Amounts included in contract liabilities at the beginning of the period | $ 71 | $ 70 |
| Performance obligations satisfied in previous periods | $ (1,000) | $ — |

The $(1.0) million noted above for the nine months ended September 30, 2018 was a reversal of license revenue based on a re-evaluation of the probability of a milestone being achieved, as more fully described in Note 12, "Collaboration Arrangements", under "*Jiangsu Hengrui Medicine Co., Ltd*".

**4. 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 outstanding stock options, Employee Stock Purchase Plan awards, unvested restricted stock units, or RSUs, 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.

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, | |
|---|---|---|
| | 2018 | 2017 |
| Outstanding stock options and Employee Stock Purchase Plan | 7,797 | 7,033 |
| Unvested restricted stock units | 2,121 | 1,174 |
| Shares issuable upon conversion of Convertible Notes | — | 3,559 |
| | 9,918 | 11,766 |

In September 2014, the Company issued Convertible Notes, which provide in certain situations for the conversion of the outstanding principal amount of the Convertible Notes into shares of the Company's common stock at a predefined conversion rate. See Note 6, "Debt", for additional information. In conjunction with the issuance of the Convertible Notes, the Company entered into capped call option transactions, or Capped Calls, with certain counterparties. The Capped Calls are generally expected to reduce the potential dilution upon conversion of the Convertible Notes.

As provided by the terms of the indenture underlying the Convertible Notes, the Company has a choice to settle the conversion obligation for the Convertible Notes in cash, shares or any combination of the two. The share figures in the table above represent the estimated shares that would be issued, assuming settlement in shares of all of the outstanding Convertible Notes. The Convertible Notes were not eligible for conversion as of September 30, 2018, as per the terms noted below in Note 6, "Debt".

**5. Inventories**

The following table presents inventories as of September 30, 2018 and December 31, 2017 (in thousands):

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Raw materials | $ 14,809 | $ 17,876 |
| Work in process | 88,838 | 38,629 |
| Finished goods | 5,175 | 1,434 |
| Total inventories | $ 108,822 | $ 57,939 |

Inventories are related to the Company's approved products, primarily ZEJULA. If future sales of its approved products are less than expected, the Company may be required to write down the value of such inventories.

**6. Debt**

Our outstanding debt obligations consisted of the following (in thousands):

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Convertible notes, net | $ 153,057 | $ 143,446 |
| Term loan, net | 490,525 | 293,659 |
| Total long-term debt | $ 643,582 | $ 437,105 |

*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 Convertible Notes. In conjunction with the sale of the Convertible Notes, the Company used $20.8 million of the net proceeds to enter into separate Capped Calls.

The Convertible Notes bear interest at a rate of 3.00% per annum, payable semi-annually on April 1 and October 1, and will be convertible into cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election. The Convertible Notes will mature on October 1, 2021, unless earlier converted or repurchased in accordance with their terms. Prior to the close of business on the business day immediately preceding April 1, 2021, the Convertible Notes will be convertible only upon the occurrence of certain events and during certain periods as discussed below, and thereafter, at any time until the close of business on the second scheduled trading day immediately preceding the maturity date. The initial conversion price of the Convertible Notes is approximately $35.13 per share of common stock at an initial conversion rate of 28.4627 shares of the Company's common stock per $1,000 principal amount of Convertible Notes.

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

(1) during any calendar quarter commencing after the calendar quarter ending on December 31, 2014 (and only during such calendar quarter), if the closing sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter in which the conversion occurs is greater than 130% of the conversion price on each applicable trading day;

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

(3) upon the occurrence of specified corporate events.

As of September 30, 2018, the carrying value of the Convertible Notes, net of unamortized discount and debt issuance costs, was $153.1 million and the estimated fair value of the principal amount was $266.9 million. 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 following table presents total interest expense recognized related to the Convertible Notes during the three and nine months ended September 30, 2018 and 2017 (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Contractual interest expense | $ 1,509 | $ 1,509 | $ 4,528 | $ 4,528 |
| Amortization of debt discount | 3,139 | 2,779 | 9,231 | 8,172 |
| Amortization of debt issuance costs | 125 | 136 | 380 | 416 |
| Total interest expense | $ 4,773 | $ 4,424 | $ 14,139 | $ 13,116 |

*2017 Term Loan Agreement*

In November 2017, the Company entered into a loan agreement, or the Loan Agreement, with BioPharma Credit PLC and affiliates and certain assignees, or the Lenders. The Lenders agreed to provide up to an aggregate principal amount of $500.0 million in two tranches, with the first tranche equal to $300.0 million, or Tranche A, and the second in an amount between $50.0 million and $200.0 million at the Company's discretion, or Tranche B. The Company drew Tranche A on December 6, 2017 and $200.0 million in principal on Tranche B on June 29, 2018. Both tranches have a maturity date of December 6, 2024, with payments of principal commencing in the fourth quarter of 2019 for Tranche A and the second quarter of 2020 for Tranche B. Borrowings under the Tranche A and Tranche B loans bear interest at rates equal to the three-month London Interbank Offered Rate, or LIBOR, plus an applicable margin of 8% per annum and 7.5% per annum, respectively (with the LIBOR rate subject to a floor of 1% and cap equal to the LIBOR rate as of the Tranche A closing date, which was 1.69%, plus 1.5%). The loans have an up-front fee of 2% on the funded amount of each tranche, payable at the applicable closing date.

Both Tranche A and Tranche B of the Loan Agreement were recorded on the condensed consolidated balance sheets, net of debt discounts of $6.0 million and $4.0 million, respectively, in up-front fees assessed by the Lenders at the time of the borrowings. The debt discounts and deferred financing costs of $0.4 million are being amortized to interest expense using the effective interest method over the same term. The effective annual interest rate of the outstanding debt under both Tranche A and Tranche B is approximately 10%.

For the three and nine months ended September 30, 2018, respectively, the Company recognized $13.4 million and $29.0 million of interest expense related to the Loan Agreement, including $0.4 million and $0.9 million related to the accretion of debt discounts and deferred financing costs.

**7. Accrued Expenses**

The following table presents the components of accrued expenses (in thousands):

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Research and development | $ 46,449 | $ 55,949 |
| Salaries, bonuses and other compensation | 32,787 | 33,717 |
| Product revenue allowances | 9,567 | 22,847 |
| Inventory | 35,468 | 16,469 |
| Sales and marketing | 7,098 | 6,701 |
| Royalties | 7,675 | 6,552 |
| Professional services | 4,655 | 3,944 |
| Other | 7,234 | 8,629 |
| Total accrued expenses | $ 150,933 | $ 154,808 |

**8. Stock-Based Compensation**

The Company maintains several equity compensation plans, including the TESARO, Inc. 2012 Omnibus Incentive Plan, or the 2012 Incentive Plan, the TESARO, Inc. 2010 Stock Incentive Plan, or the 2010 Incentive Plan, the TESARO, Inc. 2015 Non-Employee Director Stock Incentive Plan, or the 2015 Director Plan, and the TESARO, Inc. 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 (an additional 6,857 shares) plus the number of shares of common stock related to awards outstanding under the 2010 Incentive Plan that terminate by expiration, forfeiture, cancellation, cash settlement or otherwise. The number of shares available for grants of awards under the 2012 Incentive Plan is increased automatically each January 1 by a number of shares of common stock equal to the lesser of 4% of the shares of common stock then outstanding or the number of shares determined by the Company's board of directors. Most recently, on January 1, 2018 and 2017, the number of shares authorized for issuance under the 2012 Incentive Plan was increased by 2,178,561 shares and 2,144,867 shares, respectively. 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; RSUs; dividend equivalent rights; performance shares; performance units; cash-based awards; other stock-based awards, including unrestricted shares; or any combination of the foregoing. The exercise price of stock options granted under the 2012 Incentive Plan is equal to the closing price of a share of the Company's common stock on the grant date.

The 2015 Director Plan allows the Company to grant awards for up to 500,000 shares of common stock. Awards under the 2015 Director Plan may include the following award types: stock options; stock appreciation rights; restricted stock; RSUs; unrestricted stock; or any combination of the foregoing. The exercise price of stock options granted under the 2015 Director Plan is equal to the closing price of a share of the Company's common stock on the grant date.

The following table presents stock-based compensation expense as reflected in the Company's condensed consolidated statements of operations and comprehensive loss (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Research and development | $ 7,392 | $ 8,545 | $ 23,635 | $ 23,532 |
| Selling, general and administrative | 17,740 | 16,471 | 56,662 | 43,393 |
| Subtotal | 25,132 | 25,016 | 80,297 | 66,925 |
| Capitalized stock-based compensation costs | (374) | — | (1,002) | — |
| Stock-based compensation expense included in total expenses | $ 24,758 | $ 25,016 | $ 79,295 | $ 66,925 |

*Stock Options*

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

| | Shares | Weighted-average exercise price per share |
|---|---|---|
| Outstanding at December 31, 2017 | 6,908,313 | $ 52.00 |
| Granted | 1,663,879 | 53.56 |
| Exercised | (193,895) | 34.71 |
| Cancelled | (668,765) | 78.27 |
| Outstanding at September 30, 2018 | 7,709,532 | $ 50.49 |
| | | |
| Vested at September 30, 2018 | 5,115,380 | $ 41.81 |

At September 30, 2018, there was approximately $95.0 million of unrecognized compensation cost related to unvested stock options, which the Company expects to recognize over a remaining weighted-average period of 2.51 years.

*Restricted Stock Units*

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

| | Shares | Weighted-average grant date fair value per share |
|---|---|---|
| Unvested restricted stock units at December 31, 2017 | 1,159,118 | $ 115.01 |
| Granted | 1,580,825 | 56.56 |
| Vested | (297,389) | 106.19 |
| Forfeited | (321,668) | 93.27 |
| Unvested restricted stock units at September 30, 2018 | 2,120,886 | $ 75.98 |

At September 30, 2018, there was approximately $127.9 million of unrecognized compensation cost related to unvested RSUs, which the Company expects to recognize over a remaining weighted-average period of 2.80 years.

*ESPP*

Under the Company's 2012 ESPP, as amended, an aggregate of 550,000 shares of common stock have been reserved for issuance pursuant to purchase rights granted to the Company's employees or to employees of the Company's designated subsidiaries. As of September 30, 2018, 354,238 shares remained available for issuance. During the nine months ended September 30, 2018 and 2017, the Company issued 72,621 and 17,684 shares under the 2012 ESPP and recognized approximately $1.2 million and $1.4 million in related stock-based compensation expense, respectively.

**9. 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.

The Company does not recognize a tax benefit for uncertain tax positions unless it is more likely than not that the position will be sustained upon examination by tax authorities, including resolution of any related appeals or litigation processes, based on the technical merits of the position. The tax benefit that is recorded for these positions is measured at the largest amount of cumulative benefit that has greater than a 50 percent likelihood of being realized upon ultimate settlement. Deferred tax assets that do not meet these recognition criteria are not recorded and the Company recognizes a liability for uncertain tax positions that may result in tax payments. If such unrecognized tax benefits were realized and not subject to valuation allowances, the entire amount would impact the tax provision. As of September 30, 2018, the Company's uncertain tax positions were subject to valuation allowances.

As of September 30, 2018, the Company continues to consider interpretations of the application of SEC Staff Accounting Bulletin No. 118, and has not finalized incremental accounting adjustments related to the Tax Cuts and Jobs Act of 2017, or the Tax Act. However, the Company currently does not expect any material incremental accounting adjustments related to the Tax Act.

The Company recorded $0.3 million and $0.1 million provisions for income taxes for the three months ended September 30, 2018 and 2017, and $0.7 million and $0.3 million in provisions for the nine months ended September 30, 2018 and 2017, respectively. The provisions for income taxes consist of current tax expense, which relates primarily to the Company's subsidiary operations in non-U.S. tax jurisdictions.

**10. Intangible Assets**

The following table presents intangible assets as of September 30, 2018 and December 31, 2017 (in thousands):

| | September 30, 2018 | December 31, 2017 | Estimated useful life |
|---|---|---|---|
| Acquired and in-licensed rights | $ 39,665 | $ 64,665 | 13-15 Years |
| Less accumulated amortization | (3,768) | (8,281) | |
| Total intangible assets, net | $ 35,897 | $ 56,384 | |

The Company recorded $0.7 million and $1.3 million in amortization expense related to intangible assets during the three months ended September 30, 2018 and 2017, respectively, and $3.7 million and $4.7 million during the nine months ended September 30, 2018 and 2017, respectively. Estimated future amortization expense for intangible assets as of September 30, 2018 is $0.7 million for the remainder of 2018, $2.9 million per year for 2019, 2020, 2021, and 2022, and $23.5 million thereafter. During the three months ended September 30, 2018, $16.8 million of intangible assets (net book value) were derecognized from the condensed consolidated balance sheet in connection with the VARUBI divestiture transaction further described in Note 13, "VARUBI Transaction".

**11. Commitments and Contingencies**

The Company leases approximately 275,000 square feet of office space in Waltham, Massachusetts under a non-cancelable operating lease agreement. The Company also leases office space in several locations throughout Europe. The Company recognizes rental expense on a straight-line basis over the respective lease term including any free rent periods and tenant allowances.

Future minimum rental commitments under the Company's leased properties as of September 30, 2018 were $3.0 million for the remainder of 2018 and $12.1 million, $7.9 million, $3.8 million, $3.6 million and $2.3 million for the years ending December 31, 2019, 2020, 2021, 2022 and thereafter, respectively.

The Company has entered into agreements with certain vendors for the provision of services, including services related to commercial manufacturing, data management and clinical operation support, that the Company is not able to terminate for convenience under its contracts, and thus 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 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.

*Litigation and Other Proceedings*

The Company may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities, including claims or disputes related to patents that have been issued or that are pending in the field of research on which the Company is focused.

A putative class action complaint was filed on January 17, 2018 in the United States District Court for the District of Massachusetts, captioned *Roger Bowers v. TESARO Incorporated* (sic)*, et. al.,* Case No. 18-10086. The complaint alleged that the Company and its Chief Executive Officer and Chief Financial Officer violated certain federal securities laws, specifically under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 thereunder. The plaintiff sought unspecified damages on behalf of a purported class of purchasers of the Company's common stock between March 14, 2016 and January 12, 2018. On March 19, 2018, six separate applicants filed motions seeking appointment as lead plaintiff. Four of these applicants subsequently withdrew their motions or indicated that they did not oppose a competing motion filed by another applicant. On May 4, 2018, the Court entered an order appointing one of the two remaining applicants – Zev Crawley – as the lead plaintiff and approving his selection of

lead counsel for the class. On October 12, 2018, lead counsel informed the Court that its investigation had not revealed facts adequate to state a claim. Accordingly, the lead plaintiff has filed a Notice of Voluntary Dismissal Without Prejudice, ending the lawsuit.

On May 19, 2018, a putative stockholder derivative action was filed, purportedly for the Company's benefit, in the United States District Court for the District of Delaware against eleven of the Company's directors and/or officers. The action is styled *Dai v. Moulder, et, al.*, Case no.: 1:18-cv-00773 (D. Del.) and contains substantive disclosure allegations similar to those alleged in the *Bowers* action. Additionally, the complaint in the *Dai* action alleges that the defendants breached their fiduciary duties by failing to maintain proper internal controls, wasting corporate assets through a write-down, awarding themselves excessive compensation, and by engaging in insider trading. The Complaint contains counts for: (1) alleged violations of Section 14(a) of the Securities Exchange Act of 1934; (2) breach of fiduciary duty for failure to maintain proper internal controls, making false and misleading statements and corporate waste; (3) breach of fiduciary duty for excessive compensation; (4) unjust enrichment; and (5) waste of corporate assets. The Complaint seeks, among other things, an award of an unspecified amount of damages to the Company, a series of supposed governance reforms, restitution and costs and expenses (including attorneys' fees). On June 25, 2018, the Court entered a joint stipulation by the parties staying the *Dai* action. The Company intends to vigorously defend the *Dai* action.

On June 29, 2018, a putative stockholder derivative action was filed, purportedly for the Company's benefit, in the United States District Court for the District of Massachusetts against eleven of the Company's directors and/or officers. The action is styled *Friedt v. Moulder, et al.*, Case No. 1-18-cv-11374 (D. Mass.) and contains substantive disclosure allegations similar to those alleged in the *Bowers* action and substantive derivative allegations similar to those alleged in the *Dai* action. The complaint in the *Friedt* action contains counts for: (1) alleged violations of Section 14(a) of the Securities Exchange Act of 1934; (2) breach of fiduciary duty for failure to maintain proper internal controls, making false and misleading statements and corporate waste; (3) waste of corporate assets; and (4) unjust enrichment. The Complaint seeks, among other things, an award of an unspecified amount of damages to the Company, a series of supposed governance reforms, restitution and costs and expenses (including attorneys' fees). No defendant has yet responded to the Complaint. On August 2, 2018, the Court entered a joint stipulation by the parties staying the *Friedt* action. The Company intends to vigorously defend the *Friedt* action.

The Company has not recorded any estimated liabilities associated with these legal proceedings as it does not believe that such liabilities are probable.

**12. Collaboration Arrangements**

***Merck Collaboration***

In May 2015, the Company entered into a research agreement with Merck Sharp & Dohme B.V., a subsidiary of Merck, to perform a trial to evaluate the preliminary safety and efficacy of niraparib plus KEYTRUDA® in patients with triple negative breast cancer and patients with ovarian cancer. Under the terms of this agreement, the Company is responsible for providing niraparib study materials and for carrying out clinical research activities. The Company and Merck share in the external costs of the study equally, with certain exceptions. The Company records cost-sharing payments due from Merck as reductions of research and development expense. During the three and nine months ended September 30, 2018, the Company incurred $1.3 million and $4.5 million in external costs related to this study, of which $0.6 million and $2.2 million is reimbursable by Merck, respectively. At September 30, 2018, $1.0 million of cost-sharing receivable from Merck has been recorded in other current assets on the condensed consolidated balance sheets.

***Out-Licenses***

*Takeda Pharmaceutical Co., Ltd.*

On July 27, 2017, the Company entered into an exclusive license agreement, or the Takeda Agreement, with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, or Takeda. Pursuant to the Takeda Agreement, the Company granted Takeda licenses under certain patent rights and know-how relating to niraparib to develop and commercialize niraparib for the treatment of all tumor types in Japan, and all tumor types excluding prostate cancer in South Korea, Taiwan, Russia and Australia. In July 2018, the Company

expanded its license grant to Takeda for all tumor types in the countries of Armenia, Belarus, Kazakhastan and Kyrgyzstan, but limited solely for Takeda's non-commercial use.

In connection with the Takeda Agreement, the Company received a $100.0 million up-front payment and is eligible to receive additional payments of up to $140.0 million related to the achievement of certain clinical development and regulatory milestones as well as up to $100.0 million related to the achievement of additional sales milestones. The Company will also be eligible to receive tiered royalties from Takeda based on percentages of net product sales ranging from the high teens to low thirties. Takeda is responsible for conducting and funding all development and commercialization of niraparib in the licensed territories, including research, development, regulatory and commercialization activities. Unless earlier terminated, the Takeda Agreement will continue in effect until the date on which the royalty term and all payment obligations with respect to all products in all countries have expired.

The Company identified the following performance obligations at the inception of the Takeda Agreement: (1) exclusive license with rights to develop and commercialize niraparib to Takeda in the licensed territories for the associated tumor types, and (2) initial supply to Takeda of certain materials for the manufacture of niraparib. In addition, the Company may also become responsible for manufacturing certain niraparib products for clinical and commercial supply and providing technical assistance related to the transfer of know-how, at Takeda's option, for the manufacture of niraparib for which the Company will receive reimbursement that approximates stand-alone selling prices.

Revenue associated with the transfer of the license was fully recognized during the third quarter of 2017, the performance obligation is fully satisfied, and no changes have occurred in the transaction price during the three and nine months ended September 30, 2018.

Revenue associated with the initial supply of niraparib materials will be recognized when delivered to Takeda. During the three and nine months ended September 30, 2018, the Company recognized no revenue and $0.1 million, respectively, as other revenues within license, collaboration and other revenues in the Company's condensed consolidated statements of operations and comprehensive loss related to materials delivered to Takeda. No revenues were recognized during the three and nine months ended September 30, 2017. No changes have occurred in the transaction price of previously delivered goods during the three and nine months ended September 30, 2018.

*Janssen Biotech, Inc.*

Under the terms of the Company's collaboration agreement with Janssen Biotech, Inc., or Janssen, the Company granted Janssen licenses under certain patent rights and know-how relating to niraparib for prostate cancer worldwide, except for Japan. Janssen will conduct all development and commercialization of niraparib in the field of prostate cancer worldwide (excluding Japan).

Pursuant to the collaboration agreement, within 30 days after the date of the collaboration agreement, the Company provided Janssen with electronic copies of certain know-how relating to development of niraparib. In addition, at Janssen's request and in return for certain reimbursement, the Company is also responsible for manufacturing and supplying to Janssen all of Janssen's requirements of active pharmaceutical ingredient, or API, and finished drug product, for niraparib and niraparib products to be used by Janssen for its development activities in prostate cancer indications. Also at Janssen's request, the Company is responsible for manufacturing of certain niraparib products and API for commercial sale in the field of prostate cancer. In both cases, if Janssen exercises its right to receive the manufacturing services, the Company will receive reimbursement that will at least cover its cost of providing such services.

The Company received a $35.0 million up-front, non-refundable license fee from Janssen. Assuming successful development and commercialization of niraparib products for prostate cancer, the Company could receive up to an additional $43.0 million in clinical milestones and $372.0 million in regulatory and sales milestones as well as tiered, double-digit royalties on aggregate net sales of products in the field of prostate cancer. Subsequent to September 30, 2018, the Company received notification that certain development milestones were met in October 2018. As a result, the Company is entitled to receive $18.0 million in cash milestones, and expects to recognize this amount in license, collaboration and other revenues in its consolidated statement of operations and comprehensive loss during the three months ending December 31, 2018.

Janssen is responsible for funding all development and commercialization of niraparib in prostate cancer worldwide (excluding Japan), including research, development, manufacturing, regulatory and commercialization activities. Janssen may terminate the collaboration agreement at any time upon 90 days' written notice, upon termination of the Company's license agreement with Merck or in the event of certain safety concerns. Either party may terminate the collaboration agreement for uncured material breach or bankruptcy. Unless earlier terminated, the collaboration agreement will continue in effect until the date on which the royalty term and all payment obligations with respect to all products in all countries have expired.

The Company assessed this arrangement in accordance with Topic 606 and concluded that the contract counterparty, Janssen, is a customer. The Company identified the following material promises under the contract: (1) the licenses under certain patent rights relating to niraparib for prostate cancer worldwide, except for Japan, and transfer of certain development and regulatory information; and (2) the obligation to participate in Joint Committees. In addition, the Company identified the following customer options that will create manufacturing obligations for the Company upon exercise by Janssen: (1) the supply of API and niraparib products for Janssen's development and commercial needs; and (2) the supply of niraparib for Janssen's clinical trial needs. The Company considered the manufacturing capabilities of Janssen, Janssen's right to sublicense and manufacture API, and the fact that the manufacturing services are not proprietary and can be provided by other vendors, to conclude that the license has stand-alone functionality and is distinct. The Company's obligation to participate in the Joint Committees and provide development, regulatory and commercialization information to Janssen does not significantly impact or modify the licenses' granted functionality. Further, the customer options for manufacturing services were evaluated as a material right, but were concluded to be immaterial to the Company's financial statements. Based on these assessments, the Company identified the license and the participation in Joint Committees as the only performance obligations at the inception the arrangement, which were both deemed to be distinct.

Revenue associated with the transfer of the license was fully recognized during the second quarter of 2016, the performance obligation is fully satisfied, and no changes have occurred in the transaction price during the three and nine months ended September 30, 2018.

Revenue associated with the Joint Committees performance obligation, $0.5 million, is being recognized on a straight-line basis over a period of five years, which, in management's judgment is the best measure of progress toward satisfying the performance obligation and represents the Company's best estimate of the period of the obligation to participate in the Joint Committees. The remaining transaction price of $0.2 million is recorded in deferred revenue as of September 30, 2018 on the condensed consolidated balance sheets and will be recognized as revenue over the remaining period of 30 months.

Revenue associated with providing materials supply is recognized when the material is delivered to Janssen. During the three and nine months ended September 30, 2018 and 2017, the Company recognized $0.8 million and $1.5 million, and $0.9 million and $2.5 million, respectively, as other revenues within license, collaboration and other revenues in the Company's condensed consolidated statements of operations and comprehensive loss related to materials delivered to Janssen. No changes have occurred in the transaction price of previously delivered goods during the three months ended September 30, 2018.

*Zai Lab (Shanghai) Co., Ltd.*

On September 28, 2016, the Company entered into a Collaboration, Development and License Agreement, or the Zai Agreement, with Zai Lab. Under the terms of the Zai Agreement, the Company exclusively licensed the rights to develop and commercialize niraparib to Zai Lab for China, Hong Kong and Macao, or the China Territories. Zai Lab will conduct all development, manufacturing and commercialization of niraparib in the China Territories, except for prostate cancer.

Under the terms of the Zai Agreement, the Company received a $15.0 million up-front, non-refundable license fee from Zai Lab in the fourth quarter of 2016. Assuming successful development and commercialization of niraparib products in the China Territories, the Company could receive additional regulatory and sales milestones as well as tiered, double-digit royalties on aggregate net sales of products in the China Territories. Zai Lab is responsible for funding all development and commercialization of niraparib in the China Territories, including research, development, manufacturing, regulatory and commercialization activities. The term of the Zai Agreement continues, on a country-by-country basis, until the later of expiration of the last patent in the China Territories covering the niraparib product, or ten

years from the first commercial sale in such country. The Zai Agreement may also be terminated by Zai Lab at any time upon prior written notice, or by either party for material breach or insolvency.

The Company identified three performance obligations under the contract. Revenue associated with all three performance obligations was fully recognized during 2016, the performance obligations are fully satisfied, and no changes have occurred in the transaction price during the three months ended September 30, 2018.

In August 2018, the Company and Zai Lab entered into a three-year supply agreement under which the Company agreed to supply a limited amount of niraparib finished drug product initially for Zai Lab's expanded patient access programs in Hong Kong and China, while Zai Lab qualifies its local manufacturing in its territory.

*Jiangsu Hengrui Medicine Co., Ltd.*

In July 2015, the Company entered into a license agreement with Jiangsu Hengrui Medicine Co., Ltd., or Hengrui, pursuant to which Hengrui licensed the rights to develop, manufacture and commercialize rolapitant in the China Territories. The Company received a $1.0 million up-front, non-refundable license fee from Hengrui in the fourth quarter of 2015. The Company evaluated the terms of this arrangement under Topic 606 and determined that there were two performance obligations: (1) exclusive license with rights to develop, manufacture and commercialize rolapitant in the China Territories; and (2) provision of technical assistance related to the know-how transfer for the development of the rolapitant formulations. The Company further determined that the transaction price for this arrangement included the $1.0 million up-front consideration received and a future regulatory development milestone of $1.0 million. This future milestone payment related to the submission of the clinical trial application with the China Food and Drug Administration. The Company re-evaluates the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

All performance obligations were recognized in 2015 and 2016, including a $1.0 million future regulatory development milestone that the Company assessed as probable. During the first quarter of 2018, Hengrui ceased development activities related to the licensed product. Accordingly, the Company re-evaluated the probability of the milestone, including its impact on the transaction price, and recognized a $1.0 million reversal of license revenue during the three months ended March 31, 2018. In August 2018, the Company and Hengrui terminated the license agreement. No revenue was recognized during the three months ended September 30, 2018 or the three and nine months ended September 30, 2017.

**13. VARUBI Transaction**

On June 28, 2018, the Company entered into an Asset Purchase Agreement, or the APA, with TerSera, pursuant to which the Company sold to TerSera its rights to rolapitant in the U.S. and Canada, or the Territory, for an initial purchase price of $40.0 million in cash, with $35.0 million paid at closing and an additional $5.0 million to be paid by January 12, 2020. This transaction, or the Sale, closed on July 12, 2018. The Sale includes both the oral formulation of rolapitant distributed and sold under the brand name VARUBI®, or the Oral Product, and the intravenous formulation of rolapitant sold under the brand name VARUBI® IV, or the IV Product and, together with the Oral Product, the Products.

Pursuant to the APA, the Company will also be eligible to receive certain post-closing royalties and milestone payments. For a period of twelve years after consummation of the Sale, or the Royalty Term, TerSera will pay to the Company a percentage of any consideration for (i) the transfer of intellectual property rights relating to future sales of rolapitant, and (ii) the license or sublicense of any intellectual property rights related to rolapitant, in each case, to the extent allocable to non-oncology indications. TerSera will also pay to the Company milestone payments of (a) $10.0 million each time the marketing approval for a new indication of rolapitant in the U.S. is first granted, and (b) $10.0 million the first time aggregate net sales of a reformulated version of the IV Product during a calendar year reach or exceed $50.0 million. In addition, during the Royalty Term, TerSera will pay to the Company a royalty at the rate of 20% of the aggregate net sales of the IV Product in the Territory for any calendar year in which such sales reach or exceed $100.0 million, on the net sales that exceed such threshold.

In connection with the Sale, the Company assigned to TerSera its rights and obligations under a number of commercial contracts, including (i) the Company's contracts with commercial manufacturing organizations for the global supply of rolapitant, except for certain contracts that are specific to packaging outside of the Territory, and (ii) the Company's exclusive license agreement with OPKO Health, Inc. dated December 10, 2010, as previously amended, for certain patent rights and know-how related to rolapitant. Simultaneously with the closing of the Sale, the Company and TerSera entered into a license agreement pursuant to which TerSera granted the Company an exclusive sublicense under

such patent rights and to such know-how for the development and commercialization of the Products outside of the Territory.

For the three and nine months ended September 30, 2018, the Company recorded a $17.6 million pre-tax gain on the Sale in its condensed consolidated statements of operations and comprehensive loss. The Company determined that the Sale does not qualify for reporting as discontinued operations, as the Sale does not constitute on its own a strategic shift that will have a major effect on the Company's operations and its financial results.

**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, 2017.*

*Except for the historical information contained herein, the matters discussed in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In this Quarterly Report on Form 10-Q, words such as "may," "will," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.*

*Examples of forward-looking statements contained in this report include statements regarding the following: our commercialization plans for niraparib and rolapitant, including the progress of the commercial launches of ZEJULA® (niraparib) in the U.S. and Europe; our intent to in-license or acquire additional product candidates; our expectations regarding product revenues and license, collaboration and other revenues; our expectation that research and development and selling, general and administrative expenses will increase in the future; our expectations regarding the timing and design of our development plans, the timing of regulatory filings, and the timing of data from clinical trials, including with respect to each of our niraparib, TSR-042, TSR-022 and TSR-033 programs; our expectations regarding new clinical trials of our product candidates, including the commencement and timing thereof; our expectations regarding our discovery and development plans for immunotherapy antibodies, including the timing thereof; our anticipated milestone and royalty payment obligations; our expectations that our operating losses and negative operating cash flows will continue, and possibly increase, for the foreseeable future; our intent to settle the par value of the Convertible Notes in cash and any excess conversion premium in shares of common stock; the expected impact of new accounting pronouncements on our financial results; and our needs for additional capital and the forecast of the period of time through which our financial resources will be adequate to support our operations.*

*Forward-looking statements are not guarantees of future performance. Actual future results, performance, achievements or the timing of certain events may differ significantly from those expressed or implied by the forward-looking statements. Risks and uncertainties involved in the forward-looking statements include, among others: uncertainties inherent in the development or commercialization of any new pharmaceutical product and the execution and completion of clinical trials; risks related to competition; the timing and availability of data from clinical trials; uncertainties regarding ongoing discussions with and actions by regulatory authorities; patient accrual rates for clinical trials; manufacturing and supply risks; risks related to intellectual property; and other matters that could affect the timing of data or the potential regulatory approval or commercial availability or success of our products. Forward-looking statements contained in this Quarterly Report on Form 10-Q should be considered in light of these factors and the factors discussed elsewhere in this Quarterly Report on Form 10-Q, and in light of factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2017, including under the heading "Risk Factors". You should read carefully the factors described in the "Risk Factors" section to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. You are also advised to consult any further disclosures we make on related subjects in our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and our website.*

*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 U.S. Securities and Exchange Commission, or 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.*

*TESARO, the TESARO logo, and ZEJULA are trademarks of TESARO, Inc. in the United States and in other selected countries. All other brand names or trademarks appearing in this report are the property of their respective holders. Unless the context requires otherwise, references in this report to "TESARO", the "Company," "we," "us," and "our" refer to TESARO, Inc.*

**Overview**

We are a commercial-stage biopharmaceutical company devoted to providing transformative therapies to people bravely facing cancer. Our primary focus is to develop and commercialize treatments for solid tumors using various approaches, including small molecules and immuno-oncology antibodies, as monotherapies and in combinations. We have in-licensed and are developing several oncology-related product candidates, and we have entered into several research collaborations with third parties for the discovery of new candidates. We have also entered into arrangements with other companies for the development and commercialization of certain of our product candidates in specific indications and/or geographies.

To date, we have received regulatory approvals for the following products, which are currently marketed and sold in the U.S. and in certain countries in Europe:

- The U.S. Food and Drug Administration, or FDA, approved ZEJULA® (niraparib) in March 2017 for the maintenance treatment of women with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. The European Commission, or EC, approved ZEJULA in November 2017 as a monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy.

- VARUBI® (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. The FDA approved the oral formulation of VARUBI in September 2015 for use in combination with other antiemetic agents in adults for the prevention of delayed (24 to 120 hours after chemotherapy administration) nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. The EC approved VARUBY®, the brand name of oral rolapitant in Europe, in April 2017 for the prevention of delayed nausea and vomiting associated with highly and moderately emetogenic chemotherapy in adults. The FDA approved the intravenous, or IV, formulation of VARUBI in October 2017.

  In January 2018, after post-marketing reports of side effects experienced following the commercial introduction of VARUBI IV, we updated the VARUBI IV package insert, including modifications to the contraindications, warnings and precautions, and adverse reactions sections, and issued a "Dear Healthcare Professional Letter" to healthcare providers to highlight the updates. In February 2018, we determined that we would cease marketing and distribution of VARUBI IV and pursue strategic alternatives for the VARUBI brand. In June 2018, we entered into an agreement with TerSera Therapeutics LLC, or TerSera, pursuant to which we sold to TerSera our rights to VARUBI in the United States and Canada, and the transaction closed in July 2018. We are continuing to market and sell VARUBY in Europe. For additional details, see Note 13, "VARUBI Transaction", in the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1, "*Financial Statements (unaudited)*", of this Quarterly Report on Form 10-Q.

Recently, we have also reported data from various ongoing clinical trials of niraparib and TSR-042 (our anti-PD-1 antibody), as summarized below:

- In March 2018, we announced the presentation of preliminary data from the TOPACIO trial of niraparib in combination with an anti-PD-1 monoclonal antibody, KEYTRUDA®, at the 2018 Society for Gynecologic Oncology Annual Meeting on Women's Cancer. Preliminary results suggest the combination of niraparib and an anti-PD-1 antibody could provide meaningful clinical benefit to patients with platinum-resistant or platinum-refractory ovarian cancer, regardless of biomarker status.

- In April 2018, we presented summary initial data from the Phase 1 GARNET trial of TSR-042 in patients with microsatellite instability high, or MSI-H, endometrial cancer and non-small cell lung cancer, or NSCLC, during the American Association for Cancer Research Annual Meeting. At the European Society for Medical Oncology 2018 Congress in October, we summarized updated safety and efficacy data from the GARNET cohort of patients with MSI-H endometrial cancer, which showed robust clinical activity of TSR-042. We expect to complete enrollment in the MSI-H endometrial cohort of the GARNET trial by the end of 2018. The GARNET trial is intended to support a biologics license application submission to the FDA in 2019.

- In April 2018, we announced positive top-line results from the QUADRA trial, which was designed to assess clinical benefit of ZEJULA treatment in heavily pre-treated patients with ovarian cancer. Results successfully achieved the pre-specified primary endpoint and demonstrated ZEJULA monotherapy activity in a biomarker selected patient population.

- In June 2018, we summarized the results of the TOPACIO trial during the 2018 Annual Meeting of the American Society of Clinical Oncology. TOPACIO data for niraparib in combination with an anti-PD-1 antibody demonstrated encouraging activity in platinum-resistant/refractory ovarian cancer and triple-negative breast cancer beyond patients with BRCA mutations.

- In September 2018, we announced the initiation of a second stage of the JASPER study that is designed to assess clinical benefit of ZEJULA in combination with an anti-PD-1 antibody in first-line NSCLC patients. Preliminary results suggest that the combination of ZEJULA and an anti-PD-1 antibody could be active as a first-line treatment for patients with NSCLC and high levels of PD-L1 expression.

As of September 30, 2018, we had an accumulated deficit of $1.9 billion. Our net losses were $466.6 million, $496.1 million, $374.2 million, and $247.7 million for the nine months ended September 30, 2018 and the years ended December 31, 2017, 2016, and 2015, respectively. We expect to incur significant expenses and operating losses for the foreseeable future. Overall, we expect operating expenses to increase over current levels as we continue to incur costs related to: (i) our ongoing U.S. and international commercialization and pre-commercial activities including executing related marketing and promotional programs for the launches and commercialization of ZEJULA; (ii) the advancement of clinical trial and other development and regulatory activities under our current development programs for niraparib, TSR-042, TSR-022 and TSR-033, and our collaborations; (iii) expanding our international operations; and (iv) other research and development activities and potential future collaborative or in-licensed development programs. Operating expenses (research and development and selling, general and administrative expenses) could fluctuate up or down from quarter to quarter, based on the timing and magnitude of activities taking place in a given quarter. In addition, future license payments or milestone payments could cause our total operating expenses and cash usage to fluctuate. If we obtain regulatory approval for any of our other product candidates, or if we anticipate the near-term possibility of obtaining regulatory approval, we expect that we will incur significant additional commercialization expenses related to product sales, marketing, manufacturing and distribution. We will also continue to incur interest expense related to our outstanding convertible debt and term loan. The actual amount of many of the expenditures described above will depend on numerous factors, including the timing of expenses and the timing, progress and results of our clinical trials and other development and regulatory activities, and commercialization efforts for ZEJULA. Accordingly, until we can generate a sufficient amount of revenue from our products, if ever, we expect to finance our operations in part through additional public or private equity or debt offerings, and we may seek additional capital through arrangements with strategic partners or from other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

**Financial Operations Overview**

***Revenues***

Product revenue is derived from sales of ZEJULA and VARUBI in the United States, and ZEJULA and VARUBY in Europe. In June 2018, we entered into an agreement with TerSera pursuant to which we sold to TerSera our rights to VARUBI in the United States and Canada, and the transaction closed in July 2018. We are continuing to market and sell VARUBY in Europe.

License, collaboration and other revenues relate to our license agreements with Takeda, Janssen, Zai Lab and Hengrui. Takeda has licensed the rights to develop and commercialize niraparib for the treatment of all tumor types in Japan, and all tumor types excluding prostate cancer in certain other specified countries. Janssen has licensed the rights to develop, manufacture and commercialize niraparib worldwide (except for Japan) for the treatment of prostate cancer. Zai Lab has licensed the rights to develop and commercialize niraparib for China, Hong Kong and Macao, or the China Territories, except for prostate cancer. In October 2018, Zai Lab announced that the Hong Kong Department of Health had approved ZEJULA for adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian cancer

who are in a complete response or partial response to platinum-based chemotherapy, and that Zai Lab expects to commence sales of ZEJULA in Hong Kong in late 2018.

Hengrui previously licensed the rights to develop, manufacture and commercialize rolapitant in the China Territories. During the first quarter of 2018, Hengrui ceased development activities related to rolapitant, and in August 2018, the Company and Hengrui terminated the license agreement.

***Cost of Sales – Product***

Product cost of sales consists primarily of materials used in commercial product manufacturing, third-party contract manufacturing costs, and royalties related to our licensing agreements.

***Cost of Sales – Intangible Asset Amortization***

Intangible asset amortization classified as cost of sales consists of amortization of capitalized milestone payments made to third parties subsequent to regulatory approval for acquired and in-licensed product candidates.

***Research and Development Expenses***

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

- 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 biologic drug substance for product candidates that have not received regulatory approval, clinical trial materials and other research and development materials;
- pre-commercial license fees and milestone payments related to the acquisition of in-licensed product candidates, which are reported on our statements of operations as acquired in-process research and development;
- fees and costs related to regulatory filings and activities;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent, utilities, maintenance of facilities, insurance and other supplies; and
- other costs associated with clinical, preclinical, discovery and other research activities.

Research and development costs are expensed as incurred. License fees and development milestone payments related to in-licensed products and technology are expensed as acquired in-process research and development if it is determined at that point that they have no established 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 and information provided to us by our vendors.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials and manufacturing costs. We expect that our total future research and development costs will continue to increase over current levels, depending on the progress of our clinical development programs. We also anticipate increasing costs associated with our collaborations, manufacturing activities, and potential development milestone payments. More specifically, we expect costs to increase, including as we: continue our currently ongoing clinical trials, continue our manufacturing development and validation, and initiate additional investigative and collaborative studies related to niraparib; incur research and development related milestones; incur increased discovery, development and manufacturing related expenses associated with our immuno-

oncology platform and related collaborations; lease additional facility space; 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 currently unapproved 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 based upon an assessment of each product candidate's commercial potential. If we experience delays in the completion of, or the termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our future ability to generate product revenues from any of these product candidates will be delayed or jeopardized. These occurrences would harm our business, financial condition and prospects, perhaps significantly, which would require us to alter our current operating plan and potentially delay, scale back, or discontinue the development or commercialization of one or more programs and/or other areas of the business in order to reduce our future expenses and continue to fund our remaining operations.

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 products and product candidates for the nine months ended September 30, 2018 and 2017 (in thousands):

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2018** | **2017** |
| ***Niraparib Expenses*** | | |
| Acquired in-process research and development | $ — | $ — |
| Research and development | 89,666 | 63,629 |
| Niraparib total | 89,666 | 63,629 |
| | | |
| ***Immuno-Oncology Expenses*** | | |
| Acquired in-process research and development | — | 7,000 |
| Research and development: | | |
| TSR-042 | 42,112 | 17,489 |
| TSR-022 | 19,228 | 8,911 |
| TSR-033 | 6,092 | 4,760 |
| Combinations and other | 8,049 | 10,765 |
| Immuno-Oncology total | 75,481 | 48,925 |
| | | |
| ***Rolapitant Expenses*** | | |
| Acquired in-process research and development | — | — |
| Research and development | 2,287 | 7,825 |
| Rolapitant total | 2,287 | 7,825 |
| | | |
| ***Personnel and Other Expenses*** | 121,117 | 97,531 |
| | | |
| **Total** | **$ 288,551** | **$ 217,910** |

For further discussion of the changes in our research and development expenses with respect to the nine months ended September 30, 2018 and the corresponding period of 2017, see "Results of Operations — Comparison of the Three and Nine Months Ended September 30, 2018 and 2017 — Research and Development Expenses" below.

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

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses consist principally of salaries and related costs, including stock-based compensation, for our commercial personnel, including our field sales force, certain medical education professionals and other commercial support personnel, as well as personnel in executive and other administrative or non-research and development functions. Other selling, general and administrative expenses include certain facility-related costs, information technology costs, pre-commercial and commercial consulting, advertising, market research and other activities necessary to prepare for and support product launches, and professional fees for legal, patent review, consulting and accounting services.

We anticipate that our selling, general and administrative expenses will continue to increase in the future in support of our commercial and pre-commercial activities related to ZEJULA and potential other products, continued research and development activities, and the continued costs of operating as a public multinational company. These increases will likely include increased costs related to the hiring of additional personnel, executing marketing and promotional programs, hiring consultants, leasing of additional facility space, enhancing information technology systems, and legal and other professional fees, among other expenses.

***Other Income and Expense***

Other income and expense consists primarily of interest expense related to our debt instruments and interest income earned on cash and cash equivalents. A portion of the interest expense is non-cash expense relating to accretion of debt discounts and issuance costs.

**Results of Operations**

***Comparison of the Three and Nine Months Ended September 30, 2018 and 2017***

| *(data in thousands)* | Three Months Ended September 30, | | Change | | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|---|---|---|---|
| | 2018 | 2017 | Amount | Percentage | 2018 | 2017 | Amount | Percentage |
| Revenues: | | | | | | | | |
| Product revenue, net | $ 63,612 | $ 41,755 | $ 21,857 | 52% | $ 170,312 | $ 72,723 | $ 97,589 | 134% |
| License, collaboration and other revenues | 787 | 101,011 | (100,224) | (99%) | 1,037 | 102,580 | (101,543) | (99%) |
| Total revenues | 64,399 | 142,766 | (78,367) | (55%) | 171,349 | 175,303 | (3,954) | (2%) |
| Expenses: | | | | | | | | |
| Cost of sales – product | 14,225 | 6,216 | 8,009 | 129% | 37,735 | 10,280 | 27,455 | 267% |
| Cost of sales – intangible asset amortization | 728 | 1,254 | (526) | (42%) | 3,663 | 4,723 | (1,060) | (22%) |
| Research and development | 94,188 | 73,388 | 20,800 | 28% | 288,551 | 210,910 | 77,641 | 37% |
| Selling, general and administrative | 93,497 | 83,998 | 9,499 | 11% | 287,137 | 246,239 | 40,898 | 17% |
| Acquired in-process research and development | — | — | — | 0% | — | 7,000 | (7,000) | (100%) |
| Total expenses | 202,638 | 164,856 | 37,782 | 23% | 617,086 | 479,152 | 137,934 | 29% |
| Loss from operations | (138,239) | (22,090) | (116,149) | 526% | (445,737) | (303,849) | (141,888) | 47% |
| Gain on sale of business | 17,627 | — | 17,627 | n/m | 17,627 | — | 17,627 | n/m |
| Other income (expense), net | (16,154) | (3,048) | (13,106) | 430% | (37,715) | (9,941) | (27,774) | 279% |
| Loss before income taxes | (136,766) | (25,138) | (111,628) | 444% | (465,825) | (313,790) | (152,035) | 48% |
| Provision for income taxes | 322 | 139 | 183 | 132% | 730 | 271 | 459 | 169% |
| Net loss | $ (137,088) | $ (25,277) | $ (111,811) | 442% | $ (466,555) | $ (314,061) | $ (152,494) | 49% |

n/m = not meaningful

*Product Revenue.* Net product revenue relates to sales of ZEJULA and VARUBI/VARUBY in the U.S. and Europe. For the nine months ended September 30, 2018, sales of ZEJULA in Europe accounted for over 25% of total net ZEJULA product revenues. The following table presents net product revenues by product for the three and nine months ended September 30, 2018 and 2017, respectively (in thousands):

| | Three Months Ended September 30, | | Change | | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|---|---|---|---|
| | 2018 | 2017 | Amount | Percentage | 2018 | 2017 | Amount | Percentage |
| ZEJULA | $ 63,226 | $ 39,375 | $ 23,851 | 61% | $ 165,989 | $ 65,321 | $ 100,668 | 154% |
| VARUBI/VARUBY | 386 | 2,380 | (1,994) | (84%) | 4,323 | 7,402 | (3,079) | (42%) |
| Product revenue, net | $ 63,612 | $ 41,755 | $ 21,857 | 52% | $ 170,312 | $ 72,723 | $ 97,589 | 134% |

We began to recognize revenues on sales of ZEJULA in the U.S. starting in the second quarter of 2017, and in Europe late in the fourth quarter of 2017. For the three and nine months ended September 30, 2018 as compared to the same periods in 2017, net ZEJULA product revenues increased primarily due to the launch in Europe in late 2017, and higher average revenue per unit in the U.S., due to the introduction of a more convenient packaging format this quarter. For the three month year-over-year comparative periods, these increases were partially offset by lower U.S. ex-factory volumes associated with the bolus of patients added in the third quarter of 2017, our second quarter of launch. With respect to ZEJULA net product revenues for the three months ended September 30, 2018, the average net sales price per unit to us was approximately 85% of the Wholesale Acquisition Cost, or WAC, which is the gross list price at which our direct customers purchase each unit, as compared to 89% of WAC for the same period in 2017.

In June 2018, we entered into an agreement with TerSera, pursuant to which we sold to TerSera our rights to VARUBI in the United States and Canada, and the transaction closed in July 2018. We are continuing to market and sell VARUBY in Europe.

*License, Collaboration and Other Revenues.* License, collaboration and other revenues were $0.8 million and $101.0 million, respectively, for the three months ended September 30, 2018 and 2017 and $1.0 million and $102.6 million, respectively, for the nine months ended September 30, 2018 and 2017. The decreases primarily relate to the $100.0 million up-front payment we received under our license agreement with Takeda during the three months ended September 30, 2017.

*Cost of Sales - Product.* Cost of sales were $14.2 million and $6.2 million for the three months ended September 30, 2018 and 2017 and $37.7 million and $10.3 million for the nine months ended September 30, 2018 and 2017, respectively. These amounts consist of costs associated with the manufacturing of ZEJULA and VARUBI and royalties owed to our licensors for such sales, as well as costs of product provided under our sampling and other commercial programs and certain period costs. The increases were primarily related to the increases in ZEJULA net revenues, as well as higher supplier set-up and transition expenses. Also, cost of product sales for the nine months ended September 30, 2018 includes a charge of $3.4 million relating to the write-off of prepayments we made to a contract manufacturer for ZEJULA. We had expected to recover this amount in future periods, but during the nine months ended September 30, 2018, we concluded that this amount is now unlikely to be recovered due to expected changes in our future purchasing volume from this manufacturer. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, certain of the costs of units recognized as revenue during the nine months ended September 30, 2018 and 2017 were expensed prior to the respective initial regulatory approval dates, and therefore are not included in cost of sales during these periods. We expect cost of sales to increase in relation to net product revenues as we deplete these inventories, which is expected by the second half of 2019 for ZEJULA.

*Cost of Sales - Intangible Asset Amortization.* The amounts of $0.7 million and $1.3 million for the three months ended September 30, 2018 and 2017, and $3.7 million and $4.7 million for the nine months ended September 30, 2018 and 2017, respectively, consist of amortization of intangible assets recorded as a result of post-approval milestones paid to licensors. During the three months ended September 30, 2018, $16.8 million of intangible assets (net book value) were derecognized from the condensed consolidated balance sheet in connection with the VARUBI divestiture transaction, resulting in the lower amortization expense. The decrease for the nine months ended September 30, 2018 was primarily related to the VARUBI divestiture transaction and a one-time cumulative catch-up related to a capitalized milestone recorded upon the first commercial sale of VARUBY in Europe during the three months ended June 30, 2017.

*Research and Development Expenses.* Research and development expenses were $94.2 million for the three months ended September 30, 2018, compared to $73.4 million for the three months ended September 30, 2017, an increase of $20.8 million.

Significant increases for the three months ended September 30, 2018 compared to the same period in 2017 included:

- an increase of $10.2 million in costs associated with our immuno-oncology platform related to the TSR-042 and TSR-022 clinical trials, biologics manufacturing and non-clinical and other immuno-oncology program research activities; and
- an increase of $9.2 million in costs associated with our niraparib program, primarily related to increased clinical trial activities.

Research and development expenses were $288.6 million for the nine months ended September 30, 2018, compared to $210.9 million for the nine months ended September 30, 2017, an increase of $77.7 million.

Significant increases for the nine months ended September 30, 2018 compared to the same period in 2017 included:

- an increase of $26.6 million in costs associated with our immuno-oncology platform related to the TSR-042 and TSR-022 clinical trials, biologics manufacturing and non-clinical and other immuno-oncology program research activities;
- an increase of $26.0 million in costs associated with our niraparib program, primarily related to increased clinical trial activities; and
- an increase of $24.0 million in personnel and other costs (excluding stock-based compensation), primarily related to increased research and development headcount supporting the growth of our development activities, and costs related to research collaborations.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses were $93.5 million for the three months ended September 30, 2018, compared to $84.0 million for the three months ended September 30, 2017, an increase of $9.5 million. The increase was primarily due to increases of: $5.3 million in salaries, benefits and other personnel-related costs (excluding stock-based compensation), primarily due to the hiring of sales, marketing, medical affairs and other support personnel associated with the commercialization of ZEJULA, and hiring to support our international operations; $1.0 million of facility-related costs, and $1.1 million in stock-based compensation expense. Selling, general and administrative expenses were $287.1 million for the nine months ended September 30, 2018, compared to $246.2 million for the nine months ended September 30, 2017, an increase of $40.9 million. The increase was primarily due to increases of: $19.7 million in salaries, benefits and other personnel-related costs (excluding stock-based compensation), primarily due to the hiring of sales, marketing, medical affairs and other support personnel associated with the commercialization of ZEJULA, and hiring to support our international operations; $3.9 million of facility-related costs, and $12.8 million in stock-based compensation expense.

*Acquired In-Process Research and Development*. There were no acquired in-process research and development expenses for the three months ended September 30, 2018 or 2017. Acquired in-process research and development expenses for the nine months ended September 30, 2017 were $7.0 million, comprised of two milestones paid to AnaptysBio related to TSR-033 and TSR-042.

*Other Income (Expense), Net*. Other income (expense) is primarily comprised of interest expense related to our Convertible Notes and our term loan, and interest income earned on cash and cash equivalents. Interest expense for the three and nine months ended September 30, 2018 as compared to the same periods in 2017, increased primarily due to interest on the term loan. Other income (expense) for three and nine months ended September 30, 2018 also included a $17.6 million gain on the sale of our rights to VARUBI in the United States and Canada to TerSera.

**Liquidity and Capital Resources**

*Sources of Liquidity*

As of September 30, 2018, our principal source of liquidity was cash and cash equivalents, which totaled $476.8 million. Since our inception in 2010, we have funded our operations primarily through public offerings of our common stock, the private placement of our equity securities, the issuance of convertible notes and a term loan financing. From inception through September 30, 2018, we received $2.1 billion in total net cash proceeds from these sources.

*Cash Flows*

The following table presents the primary sources and uses of cash for each of the periods noted (in thousands):

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2018 | 2017 |
| Net cash provided by (used in): | | (as revised) |
| Operating activities | $ (393,794) | $ (243,185) |
| Investing activities | 31,243 | (46,926) |
| Financing activities | 204,734 | 25,841 |
| Effect of exchange rate changes on cash, cash equivalents and restricted cash | (2,409) | 498 |
| Decrease in cash, cash equivalents and restricted cash | $ (160,226) | $ (263,772) |

*Cash Flows from Operating Activities*

The use of cash in operating activities during both the nine months ended September 30, 2018 and 2017 resulted primarily from our net losses adjusted for non-cash charges. Net cash used in operating activities increased by $150.6 million for the nine months ended September 30, 2018 as compared to the same period in 2017, primarily due to the inclusion of the $100.0 million up-front payment received from Takeda in cash used in operating activities during the nine months ended September 30, 2017. Increases in headcount in research and development and selling, general and administrative functions, as well as increased external research and development expenses for niraparib and our immuno-oncology portfolio, also contributed to the increase in cash used in operating activities. Higher purchases of ZEJULA inventories during the nine months ended September 30, 2018 also contributed to the increase.

*Cash Flows from Investing Activities*

Net cash provided by investing activities of $31.2 million for the nine months ended September 30, 2018 consisted of the $35.0 million payment received from TerSera for the sale of VARUBI rights for the U.S. and Canada, net of $3.8 million used for purchases of property and equipment. Net cash used in investing activities of $46.9 million for the nine months ended September 30, 2017 consisted of $42.0 million of milestones paid and $4.9 million used for purchases of property and equipment.

*Cash Flows from Financing Activities*

The increase of $178.9 million in net cash provided by financing activities for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 was primarily due to cash proceeds of $196.0 million from the draw of Tranche B of our Term Loan in June 2018. There were no similar financing transactions in the nine months ended September 30, 2017. In addition, cash proceeds from exercises of stock options and employee stock purchase plan purchases decreased from $25.8 million for the nine months ended September 30, 2017 to $8.7 million for the nine months ended September 30, 2018.

*Operating Capital Requirements*

We expect to incur significant expenses and operating losses for the foreseeable future. Overall, we expect operating expenses to continue to increase over current levels as we incur increased costs related to: (i) our ongoing U.S. and international commercialization and pre-commercial activities including executing related marketing and promotional programs for the commercialization of ZEJULA; (ii) the advancement of clinical trial and other development and regulatory activities under our current development programs including niraparib, TSR-042, TSR-022 and TSR-033; (iii) activities under our research collaborations; (iv) expanding our international operations; and (v) other

research and development activities and potential future collaborative or in-licensed development programs. If we obtain regulatory approval for any of our product candidates in addition to our current product approvals, or in anticipation of obtaining regulatory approval, we expect that we will incur significant additional commercialization expenses related to product sales, marketing, manufacturing and distribution. We also expect to incur increasing selling, general and administrative costs associated with our anticipated growth and continuing operation as a multinational public company, and we will continue to incur substantial interest expense related to our outstanding debt. The actual amount of many of these expenditures will depend on numerous factors, including the timing of expenses and the timing and progress of our clinical trial activity and commercialization efforts for our products and product candidates.

We may require additional capital for the continuing commercialization of our products, further development and potential commercialization of our product candidates, and cash interest obligations related to our outstanding debt. In addition, future license payments or milestone payments could cause our total operating expenses and cash usage to fluctuate. We may also need additional funds to pursue our strategy of in-licensing or acquiring additional product candidates and to meet our obligation to repay the principal of our term loan when due and to repay the Convertible Notes at maturity or, at our election, upon conversion. We are subject to the risks incident to the development of new biopharmaceutical products, and to global expansion, 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 will need to generate significant revenues to achieve profitability, and we may never do so. 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 facilities, and we may seek additional capital through arrangements with strategic partners or from other sources. Additional capital may not be available to us on reasonable terms, if at all. If we are unable to raise additional needed capital in sufficient amounts or on terms acceptable to us, we would have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates and/or other areas of our business. Raising additional funds through the issuance of equity or debt securities could result in dilution to our existing stockholders, increased fixed payment obligations, or both. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

We believe our currently available funds and the cash we expect to generate from product sales will be sufficient to fund our existing cash flow requirements and our operations at their currently planned levels through at least the 12 months following the filing of this Quarterly Report on Form 10-Q. 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:

- our ability to generate sufficient revenues from sales of ZEJULA and, if approved, our other product candidates;
- the cost of continuing to expand our development and commercial capabilities for our products and our product candidates, both in the U.S. and in certain foreign markets, including Europe;
- the outcome, timing and cost of regulatory approvals by the FDA and comparable non-U.S. regulatory authorities and 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 initiation, progress, timing, costs and results of clinical trials for our current product candidates and any future product candidates we may in-license;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities for niraparib and our immuno-oncology antibody product candidates;
- the cost and timing of clinical development activities for niraparib;

- the cost and timing of preclinical and clinical development and manufacturing activities associated with our immuno-oncology antibody product candidates;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights that we own or control;
- the cost of acquiring or in-licensing global rights for additional product candidates;
- the amount and timing of milestone payments and royalties we may potentially receive from our licensees pursuant to our out-license arrangements;
- the amount and timing of potential conversion requests, if any, and interest expense associated with our Convertible Notes; and
- our need to repay amounts due under our loan agreement.

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*

Other than the Tranche B Term Loan draw during the nine months ended September 30, 2018, as described in Note 6, "Debt", in the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1, "*Financial Statements (unaudited)",* of this Quarterly Report on Form 10-Q*,* 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, 2017.

**Off-Balance Sheet Arrangements**

As of September 30, 2018, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K.

**Critical Accounting Policies**

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues 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, net product revenue, stock-based compensation expense and intangible assets. 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 other 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, 2017. There have not been any material changes to our critical accounting policies since December 31, 2017.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

There have been no material changes with respect to the information appearing in Part II, Item 7A, "Quantitative and Qualitative Disclosures About Market Risk," in our Annual Report on Form 10-K for the year ended December 31, 2017.

**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.

## PART II OTHER INFORMATION

### Item 1. Legal Proceedings.

The information set forth under the heading "Litigation and Other Proceedings" in Note 11, "Commitments and Contingencies", in the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1, "*Financial Statements (unaudited)*", of this Quarterly Report on Form 10-Q is incorporated herein by reference.

### Item 1A. Risk Factors.

*An investment in our stock involves a high degree of risk. You should carefully consider the following discussion of risk factors, in its entirety, in addition to the other information contained in this Quarterly Report on Form 10-Q, our Annual Report on Form 10-K for the year ended December 31, 2017 and the other filings we make with the SEC. We cannot assure you that any of the events discussed in the risk factors below or in our other filings will not occur. These risks, or other events that we do not currently anticipate or that we currently deem immaterial, may have a material adverse effect on our business, prospects, financial condition and results of operations.*

**Risks Related to Our Business and Industry**

***We face substantial competition for our marketed product ZEJULA and our product candidates, which could limit our ability to generate significant product sales.***

The development and commercialization of new drug products is highly competitive. Many of our competitors are more established companies and may therefore have competitive advantages due to their size, cash flows, and institutional experience. We may be unable to compete successfully against these more established companies.

There are a number of large pharmaceutical and biotechnology companies that market and sell products or are pursuing the development of products that compete or we expect will compete with ZEJULA. There are currently two commercially available PARP inhibitors for ovarian cancer other than ZEJULA. AstraZeneca Plc's LYNPARZA® (olaparib) was initially approved by the U.S. Food and Drug Administration, or FDA, for use by ovarian cancer patients with a germline BRCA mutation, and was granted a new approval in August 2017 by the FDA for use as a maintenance treatment for recurrent, epithelial ovarian, fallopian tube or primary peritoneal adult cancer who are in response to platinum-based chemotherapy, regardless of BRCA status. In May 2018, the European Commission, or EC, approved LYNPARZA for a new tablet formulation and a broad maintenance label. In October 2018, AstraZeneca announced results from its Phase 3 SOLO-1 trial, testing olaparib tablets as a maintenance treatment for patients with newly-diagnosed, advanced BRCA-mutated ovarian cancer who were in complete or partial response following first-line standard platinum-based chemotherapy. Results demonstrated improvement in progression-free survival for olaparib compared to placebo, reducing the risk of disease progression or death by 70%. In addition, Clovis Oncology, Inc.'s RUBRACA® (rucaparib) was approved in December 2016 by the FDA for use as a monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. In April 2018, the FDA granted an expanded approval of RUBRACA for the maintenance treatment of adult women with recurrent ovarian cancer who have responded to their latest treatment with platinum chemotherapy, regardless of BRCA status, and in May 2018, the EC authorized RUBRACA as a third line treatment of adult women with platinum sensitive, relapsed or progressive ovarian cancer with a BRCA-mutation and who are unable to tolerate further platinum chemotherapy. Clovis is expecting an expanded EC approval for maintenance treatment by the first quarter of 2019.

In January 2018, the FDA approved LYNPARZA for patients with deleterious or suspected deleterious BRCA-mutated HER2-negative metastatic breast cancer who have been previously treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. AstraZeneca is also awaiting a decision from the EMA's Committee for Medicinal Products for Human Use for LYNPARZA for the same indication by the end of 2018. Additionally, in October 2018, Pfizer's talazoparib became the second PARP inhibitor to gain FDA approval for metastatic breast cancer in patients with an inherited BRCA mutation.

Recent PARP inhibitor developments have been made in additional tumor types. In October 2018, the FDA granted LYNPARZA orphan drug designation for the treatment of pancreatic cancer, and granted RUBRACA breakthrough therapy designation as a monotherapy for treatment of adult patients with BRCA1/2 mutated metastatic castrate-resistant prostate cancer who have received at least one prior androgen receptor directed therapy and taxane-

based chemotherapy. Each of LYNPARZA and RUBRACA would be the first PARP inhibitor approved for these respective indications.

We believe there are also several additional products in clinical development targeting the PARP pathway, as detailed in Part I, Item 1, "Business – Competition" of our Annual Report on Form 10-K for the year ended December 31, 2017. Both LYNPARZA and rucaparib have received "orphan drug designation" from the EC, which provides certain benefits including market exclusivity for up to ten years in the approved indication post-approval. In addition to other PARP inhibitors, ZEJULA also competes with AVASTIN® (bevacizumab), Roche's angiogenesis inhibitor. AVASTIN is FDA- and EC-approved in combination with chemotherapy for the treatment of recurrent ovarian cancer following platinum-containing chemotherapy (platinum-sensitive and platinum-resistant) as well as front-line treatment in combination with chemotherapy.

We are aware of several companies that have antibody-based products on the market or in clinical development that are directed at the same biological targets as some of our immuno-oncology programs. There are currently three anti-PD-1 antibody products and three anti-PD-L1 antibody products being marketed. OPDIVO® (nivolumab, marketed by Bristol-Myers Squibb) is approved in a number of indications as a monotherapy or in combination with other products; KEYTRUDA® (pembrolizumab, marketed by Merck) is approved in a number of indications as a monotherapy or in combination with other products; TECENTRIQ® (atezolizumab, marketed by Roche) is approved in patients with various forms of locally advanced or metastatic urothelial carcinoma or metastatic non-small cell lung cancer, or NSCLC; IMFINZI® (durvalumab, marketed by AstraZeneca) was approved in 2017 for patients with various forms of locally advanced or metastatic urothelial carcinoma, and for patients with unresectable Stage III NSCLC whose disease has not progressed following chemoradiation; and BAVENCIO® (avelumab, co-marketed by Merck KGaA and Pfizer) was approved in 2017 for adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma and for patients with various forms of locally advanced or metastatic urothelial carcinoma. In September 2018, the FDA approved LIBTAYO® (cemiplimab-rwlc) (co-marketed by Regeneron Pharmaceuticals and Sanofi) for the treatment of metastatic cutaneous squamous cell carcinoma, or CSCC. Although there are currently no anti-TIM-3 antibody products or anti-LAG-3 antibody products being marketed, we are aware that five companies, Novartis, Eli Lilly, Bristol-Myers Squibb, or BMS, Incyte and Symphogen have anti-TIM-3 modulator antibodies in Phase 1 or 1/2 clinical development for various indications. We are also aware of several companies that have anti-LAG-3 modulators in development for various indications, including BMS, which has an anti-LAG-3 antibody in Phase 3 clinical development; Novartis, which has an anti-LAG-3 antibody in Phase 2 clinical development; and Merck, Boehringer Ingelheim, Regeneron Pharmaceuticals, Symphogen and Incyte, each of which has an anti-LAG-3 antibody in Phase 1 clinical development.

For further detail on the specific competition that ZEJULA and our immuno-oncology antibody product candidates face, see Part I, Item 1, "Business – Competition" of our Annual Report on Form 10-K for the year ended December 31, 2017.

Many of the approved drugs with which our products or product candidates may compete are well-established therapies or products and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. Any of our product candidates that are approved may be priced at a significant premium over competitive generic products.

Our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more widely used and less costly than ours, and may also be more successful than us in manufacturing and marketing their products.

***Our ability to successfully commercialize our products and generate revenues outside of the U.S. depends heavily on our ability to secure adequate pricing and reimbursement from government and other third-party payors for ZEJULA and our other product candidates in each country in which we market and sell our products.***

Outside the U.S., certain countries, including a number of EU Member States and other European countries, set prices and reimbursement for pharmaceutical products, or medicinal products as they are commonly referred to in the EU, with limited participation from the marketing authorization holders. We cannot be sure that the prices and reimbursement ultimately offered for our products, including ZEJULA, will be acceptable to us or our collaborators. If the pricing and reimbursement authorities in these foreign jurisdictions set prices or reimbursement levels that are not commercially attractive to us or our collaborators, our revenues from sales by us or our collaborators, and the potential

profitability and commercial viability of our drug products, in those countries would be negatively affected. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world, but have been very comprehensive in the EU.

Some countries require approval of the sale price of a product before it can be marketed, such as Spain, Italy and others. In many countries, the pricing review period begins after marketing or product licensing approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. Additionally, in certain large European countries, such as Germany, we were allowed to set the launch price for ZEJULA for the initial launch period without approval of the competent government authorities. However, within the initial launch period, we have to negotiate the price for ZEJULA with the authorities, which will likely result in a decrease in the price for ZEJULA for future periods. Such price decreases could be meaningful and may have an adverse impact on our revenues from such countries going forward.

***Significant changes in U.S. and international trade policies that restrict imports or increase tariffs could have a material adverse effect on our results of operations.***

We depend on third-party manufacturers and suppliers outside of the United States, including China, in connection with the manufacture of certain of our products and product candidates. Accordingly, our business is subject to risks associated with international manufacturing. For example, the Trump Administration has called for substantial changes to U.S. foreign trade policy, including the possibility of imposing greater restrictions on international trade and significant increases in tariffs on goods imported into the United States, and has increased tariffs on certain goods imported into the United States from China. The institution of additional protectionist trade measures could adversely affect our manufacturing costs, and in turn our business, financial condition, operating results and cash flows.

**Risks Related to Our Dependence on Third Parties**

***We have no manufacturing facilities, and we are dependent on a limited number of third parties for the manufacture and supply of ZEJULA and our product candidates, including our immuno-oncology assets. If we experience problems with any of these third parties, the manufacturing of our products or our product candidates could be delayed, which could cause significant harm to our competitive position and our ability to generate and grow revenues from our approved products, to our ability to complete clinical trials and obtain regulatory approval for our product candidates, and to our future results of operations.***

We do not own or operate facilities for the manufacture of our products or product candidates. Our ability to successfully develop and commercialize our products and our product candidates will require us to establish large scale manufacturing capabilities through our contract manufacturing organizations, or CMOs. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We currently work with two CMOs for the production of ZEJULA drug substance, and one other CMO, for ZEJULA drug product supply, for our clinical and commercial needs.

As we continue to commercialize ZEJULA and develop our other product candidates, including our immuno-oncology assets, we will have a greater need for both clinical study supply and commercial manufacturing capacity. We have limited experience manufacturing pharmaceutical products on a commercial scale, and some of our suppliers, including our supplier of ZEJULA drug product, and our suppliers of both drug substance and drug product for our immuno-oncology assets, have limited capacity and will need to continue to increase their scale of production to meet our projected needs for both clinical and commercial manufacturing. Manufacturing commercial quantities of our products, including ZEJULA, to meet our projections will require our third-party manufacturers to invest substantial additional funds to increase capacity and to hire and retain additional personnel who have applicable large-scale commercial manufacturing experience. Our third-party manufacturers may not successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all. Because of the complex nature of our compounds, our manufacturers may not be able to manufacture our compounds at an acceptable cost or in sufficient quantities or in a timely manner necessary to make commercially successful products, or may require us to pay significant costs, including for capital improvements to their facilities.

If our contract manufacturers or other third parties fail to deliver our products, including ZEJULA, for commercial sale on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be required to delay or suspend commercialization of our current products or other potential future products, which would likely cause significant harm to our competitive position in the marketplace and our ability to generate and grow revenues from our approved products, and to our future results of operations.

For development of our immuno-oncology antibody product candidates, we currently work with one CMO for the production of biologics. For each of our product candidates, we may elect to pursue arrangements with other CMOs for manufacturing clinical supplies for later-stage trials and for commercialization. We have not yet qualified alternate suppliers in the event the current CMOs we utilize are unable to scale production, or if we otherwise experience any problems with them. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications) and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and similar foreign authorities require that our product candidates and approved products be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the FDA or an equivalent foreign regulatory authority to issue a warning or untitled letter, withdraw approvals previously granted to us for our products or product candidates, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction, or imposition of civil and criminal penalties.

Any significant disruption in our supplier relationships could severely harm our business. We source key materials from third parties, either directly through agreements with suppliers or indirectly through our manufacturers who have agreements with suppliers. For example, we source key raw materials for ZEJULA drug substance from one supplier. Such suppliers may not sell these key materials to us or our manufacturers at the times we need them or on commercially reasonable terms. In certain cases, we do not have any control over the process or timing of the acquisition of these key materials by our manufacturers. Any significant delay in the supply of a product or product candidate or its key materials for an ongoing clinical study could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these key materials for products or product candidates after regulatory approval, the commercial launch of our product candidates could be delayed or there could be a shortage in supply, which would impair our ability to generate revenues from the sale of our products and product candidates.

Because we have relied and plan to continue to rely on third parties for the foregoing preclinical and clinical functions, our internal capacity to perform these functions is limited. Switching or adding additional CMOs involves additional cost, requires management time and focus, and could result in substantial delays in our development programs. Identifying, qualifying and managing the performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CMO commences work and the new CMO may not provide the same type or level of services as the original provider. If any of our relationships with our third-party CMOs terminates, we may not be able to enter into arrangements with alternative CMOs or do so on commercially reasonable terms.

**Item 6. Exhibits.**

The exhibits listed below are filed or furnished as part of this Quarterly Report on Form 10-Q.

**EXHIBIT INDEX**

| Exhibit Number | Exhibit Description |
|---|---|
| 10.1 | Amendment No. 1 to Exclusive License Agreement, dated July 16, 2018, by and between the Company and Millennium Pharmaceuticals, Inc. |
| 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 |

**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 2, 2018

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

Date: November 2, 2018

**Exhibit 10.1**

**AMENDMENT NO. 1**
**TO EXCLUSIVE LICENSE AGREEMENT**

This Amendment No. 1 (this "**Amendment**") to the Exclusive License Agreement, dated July 27, 2017 (the "**Agreement**"), between TESARO, Inc. ("**TESARO**") and Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Ltd. ("**Licensee**"), is entered into as of July 16, 2018 ("**Amendment Effective Date**"). TESARO and Licensee are sometimes referred to herein individually as a "**Party**" and together as the "**Parties**". Capitalized terms used but not otherwise defined in this Amendment shall have the same meaning as set forth in the Agreement.

**WHEREAS**, the Parties desire to amend the Agreement to expand the Licensed Territory on a limited basis to enable Licensee to make initial regulatory filings in the newly added countries pending the Parties mutual agreement on Licensee's support for TESARO's obligations under the Janssen Agreement; and

**WHEREAS**, the Parties wish to negotiate in good faith the process and conditions according to which Licensee will support TESARO to comply with its obligations under the Janssen Agreement in any country or jurisdiction of the Licensed Territory (other than Japan) (the "**Janssen Shared Countries**").

**NOW, THEREFORE,** in consideration of the foregoing premises and the mutual convenants herein contained, the Parties hereby agree as follows:

**1. Amendments to the Agreement**. The Parties agree that, effective as of the Effective Amendment Date, the Agreement is amended as follows:

**a. Expansion of Licensed Territory**. Sections 1.46 and 1.49 of the Agreement are replaced in their entirety with the following:

**"Section 1.41a 'Janssen's Field'** means the diagnosis, treatment or prevention of prostate cancer in humans."

**"Section 1.46 'Licensed Field'** means (a) in Japan, the treatment, diagnosis and prevention of any disease or conditions in humans, and (b) in the remaining countries of the Licensed Territory other than Japan, the treatment, diagnosis and prevention of any disease or conditions in humans, other than the treatment, diagnosis and prevention of prostate cancer."

**"Section 1.49 'Licensed Territory'** means (a) Japan, South Korea, Taiwan, Russia, Australia, (b) Armenia, Belarus, Kazakhstan and Kyrgyzstan (the "**Regulatory Only Countries**"), provided that Licensee shall not have any Commercialization rights and

obligations in respect of the Regulatory Only Countries unless and until the Parties reach mutual agreement on Licensee's support for TESARO's compliance with its obligations under the Janssen Agreement in the Janssen Shared Countries in accordance with Section 6.6.1a, and (c) such additional countries as may from time to time be added upon mutual written agreement of the Parties."

For any avoidance of doubt and solely for the purpose of applying this Amendment, if and to the extent applicable to any and all provisions contained in the Agreement, the "Effective Date" therein shall read the "Amendment Effective Date".

**b. Janssen Agreement.** A new Section 6.6.1a shall be added to the Agreement as follows:

"Licensee is informed with respect to certain of TESARO`s obligations under the Janssen Agreement (a true and correct copy of which (other than certain redacted financial terms) has been provided by TESARO to Licensee), particularly concerning TESARO`s obligations for: (i) regulatory activities related to Janssen's prostate filings in accordance with Section 5.3 of the Janssen Agreement: (ii) distribution and supply activities in accordance with Section 6.2 of the Janssen Agreement; and (iii) revenue allocation related to prostate and non-prostate sale in accordance with Section 8.3 of the Janssen Agreement. TESARO and Licensee agree to continue negotiations in good faith with the aim to agree and define the process and conditions according to which Licensee will support TESARO to comply with its obligations under the Janssen Agreement, including the aforementioned sections. For the avoidance of doubt, unless and until the Parties reach such mutual agreement, Licensee shall not have any Commercialization rights or obligations in any of the Regulatory Only Countries, other than as set forth in the Agreement as amended by this Amendment No. 1."

**2. Miscellaneous**. Except as modified in this Amendment, the remainder of the Agreement shall remain in full force and effect. Section 10.4 (Arbitration) and Section 10.8 (Governing Law) shall apply mutatis mutandis to this Amendment. This Amendment may be executed in one or more counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. Signatures to this Amendment transmitted by facsimile transmission, by electronic mail in "portable document format" (".pdf") form, or by any other electronic means intended to preserve the originals graphic and pictorial appearance of a document, will have the same effect as physical delivery of the paper document bearing the original signatures, and shall be deemed original signatures by both Parties.

**[Signatures follow on next page]**

**IN WITNESS WHEREOF**, the Parties hereto have caused this Amendment to be executed by their duly authorized representatives as of the Amendment Effective Date.

| **TESARO, INC.** | **MILLENNIUM PHARMACEUTICALS, INC.** |
|---|---|
| By: /s/ Mary Lynne Hedley<br>(duly authorized signatory) | By: /s/ Christophe Bianchi<br>(duly authorized signatory) |
| Mary Lynne Hedley | Christophe Bianchi |
| President & Chief Operating Officer | President, Global Oncology Business Unit |

**Exhibit 31.1**

**CERTIFICATION**

I, Leon O. Moulder, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of TESARO, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2018

/s/ Leon O. Moulder, Jr.
Leon O. Moulder, Jr.
Chief Executive Officer
(principal executive officer)

**Exhibit 31.2**

**CERTIFICATION**

I, Timothy R. Pearson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of TESARO, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2018

/s/ Timothy R. Pearson
Timothy R. Pearson
Executive Vice President and Chief Financial Officer
(principal financial officer)

**Exhibit 32.1**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of TESARO, Inc., or the Company, on Form 10-Q for the period ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leon O. Moulder, Jr., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leon O. Moulder, Jr.
Leon O. Moulder, Jr.
Chief Executive Officer

November 2, 2018

**Exhibit 32.2**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of TESARO, Inc., or the Company, on Form 10-Q for the period ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Timothy R. Pearson, Executive Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

November 2, 2018