TESARO, Inc.
Form 10-Q
August 08, 2017
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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 June 30, 2017

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 (State or Other Jurisdiction of Incorporation or Organization)	27-2249687 (I.R.S. Employer Identification No.)
1000 Winter Street Waltham, Massachusetts (Address of Principal Executive Offices)	02451 (Zip Code)

(339) 970-0900

(Registrant's Telephone Number, Including Area Code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 (Do not check if a smaller reporting company)	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 August 3, 2017, there were 54,180,974 shares of the registrant's Common Stock, par value $0.0001 per share, outstanding.

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TESARO, INC.

FORM 10-Q
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2017

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PART IFINANCIAL INFORMATION

Item 1. Financial Statements.

TESARO, INC.

Condensed Consolidated Balance Sheets

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

(Unaudited)

	December 31, 2016 (as revised)	June 30, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 785,877	$ 507,941
Accounts receivable	6,195	23,149
Inventories	14,700	28,285
Other current assets	10,515	23,045
Total current assets	817,287	582,420
Intangible assets, net	12,877	44,408
Property and equipment, net	6,640	9,958
Restricted cash	1,694	2,522
Other assets	3,795	6,087
Total assets	$ 842,293	$ 645,395
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,236	$ 45
Accrued expenses	68,700	99,589
Deferred revenue, current	95	95
Other current liabilities	2,978	2,701
Total current liabilities	77,009	102,430
Convertible notes, net	131,775	137,447
Deferred revenue, non-current	305	258
Other non-current liabilities	5,086	5,346

Total liabilities	214,175	245,481
Commitments and contingencies (Notes 10 and 12)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at both December 31, 2016 and June 30, 2017; no shares issued or outstanding at both December 31, 2016 and June 30, 2017	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at both December 31, 2016 and June 30, 2017; 53,621,679 and 54,165,714 shares issued and outstanding at December 31, 2016 and June 30, 2017, respectively	5	5
Additional paid-in capital	1,604,798	1,664,997
Accumulated other comprehensive loss	(2,924)	(2,543)
Accumulated deficit	(973,761)	(1,262,545)
Total stockholders' equity	628,118	399,914
Total liabilities and stockholders' equity	$ 842,293	$ 645,395

See accompanying notes to condensed consolidated financial statements.

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TESARO, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

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

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016 (as revised)	2017	2016 (as revised)	2017
Revenues:				
Product revenue, net	$ 1,242	$ 28,829	$ 1,518	$ 30,968
License, collaboration and other revenues	34,568	635	34,592	1,569
Total revenues	35,810	29,464	36,110	32,537
Expenses:				
Cost of sales – product	234	3,620	313	4,064
Cost of sales – intangible asset amortization	463	2,979	927	3,469
Research and development	50,138	71,400	102,847	137,522
Selling, general and administrative	36,218	92,979	66,367	162,241
Acquired in-process research and development	4,000	7,000	8,000	7,000
Total expenses	91,053	177,978	178,454	314,296
Loss from operations	(55,243)	(148,514)	(142,344)	(281,759)
Interest expense	(4,120)	(4,426)	(8,101)	(8,693)
Interest income	209	959	311	1,800
Loss before income taxes	(59,154)	(151,981)	(150,134)	(288,652)
Provision for income taxes	—	78	—	132
Net loss	$ (59,154)	$ (152,059)	$ (150,134)	$ (288,784)
Net loss per share applicable to common stockholders - basic and diluted	$ (1.29)	$ (2.82)	$ (3.46)	$ (5.36)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	45,808	53,982	43,387	53,834

Comprehensive loss:				
Net loss	$ (59,154)	$ (152,059)	$ (150,134)	$ (288,784)
Other comprehensive income (loss):				
Unrealized gain (loss) on pension obligation	1	46	(98)	91
Foreign currency translation adjustments	—	255	—	290
Other comprehensive income (loss)	1	301	(98)	381
Comprehensive loss	$ (59,153)	$ (151,758)	$ (150,232)	$ (288,403)

See accompanying notes to condensed consolidated financial statements.

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TESARO, INC.

Condensed Consolidated Statements of Cash Flows

(all amounts in 000's)

(Unaudited)

	Six Months Ended June 30,	
	2016 (as revised)	2017
Operating activities		
Net loss	$ (150,134)	$ (288,784)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	8,000	7,000
Depreciation and amortization expense	1,479	4,931
Stock-based compensation expense	21,146	41,909
Non-cash interest expense	5,082	5,672
Changes in operating assets and liabilities:		
Accounts receivable	1,152	(16,954)
Inventories	(7,275)	(6,959)
Other assets	(2,112)	(10,950)
Accounts payable	5,859	(5,146)
Accrued expenses	6,506	19,746
Deferred revenues	417	(46)
Other liabilities	(49)	94
Net cash used in operating activities	(109,929)	(249,487)
Investing activities		
Acquisition of product candidate and technology licenses and milestone payments	(8,000)	(42,000)
Purchase of property and equipment	(590)	(4,309)
Change in restricted cash	—	(846)
Net cash used in investing activities	(8,590)	(47,155)
Financing activities		
Proceeds from sale of common stock, net of issuance costs	204,969	(8)
Proceeds from exercise of stock options and Employee Stock Purchase Plan	3,608	18,348
Net cash provided by financing activities	208,577	18,340
Effect of exchange rate changes on cash and cash equivalents	—	366
Increase (decrease) in cash and cash equivalents	90,058	(277,936)

Cash and cash equivalents at beginning of period	230,146	785,877
Cash and cash equivalents at end of period	$ 320,204	$ 507,941
Non-cash investing and financing activities		
Stock option exercise proceeds receivable as of period end	$ 2,875	$ 35
Leasehold improvement assets funded by lessor	$ —	$ 585
Purchase of property and equipment - cash not paid as of period end	$ 139	$ 118
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 3,019	$ 3,019

See accompanying notes to condensed consolidated financial statements.

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TESARO, INC.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Description of Business

TESARO, Inc., or the Company or TESARO, was incorporated in Delaware on March 26, 2010 and commenced operations in May 2010. Headquartered in Waltham, Massachusetts, TESARO is an oncology-focused biopharmaceutical company dedicated to improving the lives of cancer patients. TESARO acquires, in-licenses, develops, and commercializes oncology products and product candidates. As part of its business strategy, the Company intends to continue to in-license or acquire additional product candidates across various stages of development. The Company operates in one segment. The Company is subject to a number of risks, including, but not limited to, dependence on key individuals, regulatory and manufacturing risks, risks associated with intellectual property, the need to develop additional commercially viable products, competition from other companies, many of which are larger and better capitalized, and the need to obtain adequate additional financing to fund the development and potential commercialization of its product candidates and further its in-licensing and acquisition activities.

On September 1, 2015, the Company's first commercial product, VARUBI® (rolapitant), was approved by the United States Food and Drug Administration, or FDA, in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. The Company commenced sales of VARUBI in November 2015. On March 27, 2017, the FDA approved the Company's second commercial product, ZEJULATM (niraparib), 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 Company commenced sales of ZEJULA in the United States in April 2017. On April 26, 2017, the European Commission approved VARUBY® (oral rolapitant tablets) for the prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults. The Company commenced sales of VARUBY in Europe in May 2017.

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.

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. Certain amounts in the prior period financial statements have been reclassified to conform to the presentation of the current period financial statements. See "New Accounting Pronouncements - Recently Adopted" below for discussion of the Company's adoption of new revenue recognition guidance retroactive to January 1, 2015. Otherwise, these reclassifications had no significant effects on the previously reported net loss.

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.

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Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. These interim financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the Company's financial position and results of operations for the interim periods ended June 30, 2016 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, 2016 and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016. The significant accounting policies used in preparation of these condensed consolidated financial statements for the three and six months ended June 30, 2017 are consistent with those discussed in Note 2 to the consolidated financial statements in the Company's 2016 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. On an ongoing basis, management evaluates its estimates, including estimates related to net product revenues, license, collaboration and other revenues, accrued clinical trial and manufacturing development expenses, stock-based compensation expense, inventory and intangible assets and related amortization. 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, 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 is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. The fair value hierarchy prioritizes valuation inputs based on the observable nature of those inputs. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of investment credit quality. The hierarchy defines three levels of valuation inputs:

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

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

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

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The following table presents information about the Company's financial assets and liabilities that have been measured at fair value as of December 31, 2016 and June 30, 2017 and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

		December 31, 2016			
Description	Balance Sheet Classification	Total	Level 1	Level 2	Level 3
Assets:					
Money market funds	Cash and cash equivalents	$ 766,186	$ 766,186	$ —	$ —
Total assets		$ 766,186	$ 766,186	$ —	$ —

		June 30, 2017			
Description	Balance Sheet Classification	Total	Level 1	Level 2	Level 3
Assets:					
Money market funds	Cash and cash equivalents	$ 471,335	$ 471,335	$ —	$ —
Total assets		$ 471,335	$ 471,335	$ —	$ —

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

In September 2014, the Company issued $201.3 million aggregate principal amount of 3.00% 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 June 30, 2017, the carrying value of the Convertible Notes, net of unamortized discount and debt issuance costs, was $137.4 million and the estimated fair value of the principal amount was $824.6 million. The Convertible Notes are discussed in more detail in Note 5, "Convertible Notes".

Revenue Recognition

Effective January 1, 2017, the Company adopted Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers, using the full retrospective transition method. Under this method, the Company will revise its consolidated financial statements for the years ended December 31, 2015 and 2016, and applicable interim periods within those years, as if Topic 606 had been effective for those periods. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an

entity determines are within the scope of Topic 606, the entity 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 entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for net product revenue and license, collaboration and other revenues, see Note 11, “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

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amortization expense for milestone payments that do not result in additional intellectual property rights and/or incremental cashflows. Amortization expense is recorded as a component of cost of sales in the condensed consolidated statements of operations.

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.

New Accounting Pronouncements - Recently Adopted

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09, which amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in ASC Topic 605, Revenue Recognition, and creates a new Topic 606, Revenue from Contracts with Customers. In 2015 and 2016, the FASB issued additional ASUs related to Topic 606 that delayed the effective date of the guidance and clarified various aspects of the new revenue guidance, including principal versus agent considerations, identifying performance obligations, and licensing, and they include other improvements and practical expedients. The Company adopted this new standard on January 1, 2017 using the full retrospective transition method, and has elected to use the following practical expedients that are permitted under the rules of the adoption, which have been applied consistently to all contracts within all reporting periods presented:

- For completed contracts that had variable consideration, the Company has used the transaction price at the date the contract was completed rather than estimating variable consideration amounts in the comparative reporting periods. Therefore, the Company did not need to estimate its discounts, returns, chargebacks, rebates, co-pay assistance and other allowances on product sales made in the comparative reporting periods.

- For all reporting periods presented before January 1, 2017, the Company has not disclosed the amount of the transaction price allocated to the remaining performance obligations or an explanation of when the Company expects to recognize that amount as revenue.

Impact of Adoption

The Company, as a result of adopting Topic 606 on January 1, 2017, has revised its comparative financial statements for the prior year as if Topic 606 had been effective for that period. As a result, the following financial statement line items for fiscal year 2016 were affected.

Condensed Consolidated Statements of Operations and Comprehensive Loss

	Three months ended June 30, 2016 (in thousands, except per share data)		
	As revised under Topic 606	As originally reported under Topic 605	Effect of change
Product revenue, net	$ 1,242	$ 1,436	$ (194)
License, collaboration and other revenues	34,568	35,125	(557)
Cost of sales – product	234	238	(4)
Loss from operations	(55,243)	(54,496)	(747)
Net loss	(59,154)	(58,407)	(747)
Net loss per share applicable to common stockholders - basic and diluted	$ (1.29)	$ (1.28)	$ (0.01)

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	Six months ended June 30, 2016 (in thousands, except per share data)		
	As revised under Topic 606	As originally reported under Topic 605	Effect of change
Product revenue, net	$ 1,518	$ 1,609	$ (91)
License, collaboration and other revenues	34,592	35,259	(667)
Cost of sales – product	313	314	(1)
Loss from operations	(142,344)	(141,587)	(757)
Net loss	(150,134)	(149,377)	(757)
Net loss per share applicable to common stockholders - basic and diluted	$ (3.46)	$ (3.44)	$ (0.02)

Condensed Consolidated Balance Sheets

	December 31, 2016 (in thousands)		
	As revised under Topic 606	As originally reported under Topic 605	Effect of change
Accounts receivable	$ 6,195	$ 5,343	$ 852
Other current assets	10,515	8,919	1,596
Accrued expenses	68,700	68,271	429
Deferred revenue, current	95	288	(193)
Deferred revenue, non-current	305	—	305
Customer deposit	—	15,000	(15,000)
Accumulated deficit	$ (973,761)	$ (990,668)	$ 16,907

Condensed Consolidated Statement of Cash Flows

	Six months ended June 30, 2016 (in thousands)		
	As revised under Topic 606	As originally reported under Topic 605	Effect of change
Net loss	$ (150,134)	$ (149,377)	$ (757)
Adjustments to reconcile net loss to net cash used in operating activities:			
Accounts receivable	1,152	169	983
Other assets	(2,112)	(2,296)	184
Accrued expenses	6,506	6,421	85
Deferred revenues	417	912	(495)
Cash and cash equivalents at beginning of period	230,146	230,146	—

Cash and cash equivalents at end of period	$ 320,204	$ 320,204	$ —

The most significant change above relates to the Company's license, collaboration and other revenues and the impact of the potential payment to Zai Lab (Shanghai) Co., Ltd., or Zai Lab, upon exercise of the option to co-market niraparib in China, Hong Kong and Macao, or the China Territories. Under Topic 605, even though the Company believed it was remote that this option would be exercised, the Company had concluded that the contract price was not fixed or determinable under the revenue recognition criteria and accordingly no revenue had been previously recognized. Therefore, the upfront, non-refundable license fee of $15.0 million received by the Company in the fourth quarter of 2016 was deferred and recorded as a customer deposit as of December 31, 2016. Under Topic 606, the Company determined the probability is remote that it will exercise the option and accordingly, the potential future payments to Zai Lab have no impact on the transaction price. Further, the Company evaluated this option to co-market niraparib under Topic 606 and concluded that this option is not a repurchase right and accordingly recognized revenue in 2016 for the transaction price received as and when the performance obligations under this agreement were satisfied by the Company. For further discussion of the adoption of this standard, see Note 11, "Revenue Recognition" and Note 12, "License and Collaboration Arrangements".

In January 2017, the FASB issued ASU No. 2017-01, which clarifies the definition of a business. To be considered a business (instead of an asset), an acquisition would have to include an input and a substantive process that together significantly contribute to the ability to create outputs. The new guidance provides a framework to evaluate

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when an input and a substantive process are present (including for early stage companies that have not generated outputs). To be a business without outputs, there will now need to be an organized workforce. The new guidance narrows the definition of the term "outputs" to be consistent with how it is described in Topic 606. Under the final definition, an output is the result of inputs and substantive processes that provide goods or services to customers, other revenue, or investment income, such as dividends and interest. The new guidance is effective on a prospective basis for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years, with early adoption permitted. The Company elected to early adopt this ASU effective January 1, 2017. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements, although this guidance could impact its accounting conclusions for certain future transactions, such as in-licensing agreements.

New Accounting Pronouncements – Recently Issued

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 the 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 does not expect this new guidance to have a material impact on its consolidated financial statements.

3. Net Loss per Share

Basic and diluted net loss per common share is calculated by dividing net loss applicable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. The Company's potentially dilutive shares, which include outstanding stock options, 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 Six Months Ended June 30,

	2016	2017
Outstanding stock options	7,080	7,204
Unvested restricted stock units	587	1,158
Shares issuable upon conversion of Convertible Notes	—	3,932
	7,667	12,294

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 5, "Convertible Notes", 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 expected generally to reduce the potential dilution, and/or offset, to an extent, the cash payments the Company may choose to make in excess of the principal amount, 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 Company currently intends to settle the par value of the Convertible Notes in cash and any excess conversion premium in shares. Accordingly, the par value of the Convertible Notes will not be included in the calculation of diluted net income per share, but the dilutive effect of the conversion premium will be considered in the calculation of diluted net income per share using the treasury stock method. The share figures in the table above represent the estimated incremental shares that would be issued, after consideration of the Capped Calls, assuming conversion of all of the outstanding Convertible Notes as of June 30, 2016 and 2017.

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4. Inventories

The following table presents inventories as of December 31, 2016 and June 30, 2017 (in thousands):

	December 31, 2016	June 30, 2017
Raw materials	$ 13,263	$ 19,742
Work in process	584	7,083
Finished goods	853	1,460
Total inventories	$ 14,700	$ 28,285

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

5. 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.

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As of June 30, 2017, the carrying value of the Convertible Notes, net of unamortized discount and debt issuance costs, was $137.4 million and the estimated fair value of the principal amount was $824.6 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 Company currently intends to settle the par value of the Convertible Notes in cash and any excess conversion premium in shares.

The following table presents total interest expense recognized related to the Convertible Notes during the three and six months ended June 30, 2016 and 2017 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2017	2016	2017
Contractual interest expense	$ 1,509	$ 1,509	$ 3,019	$ 3,019
Amortization of debt discount	2,461	2,779	4,775	5,394
Amortization of debt issuance costs	150	136	307	279
Total interest expense	$ 4,120	$ 4,424	$ 8,101	$ 8,692

6. 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 on January 1 by a number of shares of common stock equal to the lesser of 4% of the shares of common stock outstanding at such time or the number of shares determined by the Company's board of directors. Most recently, on January 1, 2016 and 2017, the number of shares authorized for issuance under the 2012 Incentive Plan was increased by 1,611,191 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.

On May 14, 2015, the stockholders of the Company approved the 2015 Director Plan, which had been previously adopted by the board of directors in order to have a plan in addition to the 2012 Incentive Plan for purposes of granting awards to non-employee directors. 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. On May 11, 2016, the Company's stockholders approved an amendment to the 2015 Director Plan that limits the maximum number of shares of stock subject to awards granted in any calendar year to any non-employee director of the Company to 50,000 shares and affirms that 500,000 shares are reserved for issuance under the 2015 Director Plan.

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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 June 30,		Six Months Ended June 30,	
	2016	2017	2016	2017
Research and development	$ 4,479	$ 7,862	$ 8,222	$ 14,987
Selling, general and administrative	7,206	15,646	12,924	26,922
Total stock-based compensation expense	$ 11,685	$ 23,508	$ 21,146	$ 41,909

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, 2016	6,978,621	$ 40.65
Granted	661,657	162.65
Exercised	(373,078)	43.65
Cancelled	(62,837)	50.38
Outstanding at June 30, 2017	7,204,363	$ 51.62
Vested at June 30, 2017	3,779,553	$ 28.34

At June 30, 2017, there was approximately $142.6 million of unrecognized compensation cost related to unvested stock options, which the Company expects to recognize over a remaining weighted-average period of 2.5 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, 2016	760,123	$ 58.55
Granted	566,446	169.31
Vested	(150,162)	46.51
Forfeited	(18,473)	85.74
Unvested restricted stock units at June 30, 2017	1,157,934	$ 113.86

At June 30, 2017, there was approximately $118.5 million of unrecognized compensation cost related to unvested RSUs, which the Company expects to recognize over a remaining weighted-average period of 3.2 years.

In July 2016, the Company issued 15,000 RSUs with service and performance conditions to certain employees, of which 5,073 vested during the three months ended June 30, 2017. Vesting of these awards is contingent on the occurrence of certain milestone events and fulfillment of any remaining service condition. As a result, the related compensation cost is recognized as an expense when achievement of the milestone is considered probable. The Company recognized $0.5 million of related expense during the six months ended June 30, 2017.

ESPP

Under the Company’s 2012 ESPP, an aggregate of 275,000 shares of common stock have been reserved for issuance pursuant to purchase rights granted to the Company’s employees or to employees of the Company’s designated subsidiaries. As of June 30, 2017, 176,561 shares remained available for issuance. During the six months ended June 30, 2016 and 2017, the Company issued 25,225 and 17,684 shares under the 2012 ESPP, and recognized approximately $0.5 million and $1.0 million in related stock-based compensation expense, respectively.

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7. Common Stock Transactions

In March 2016, the Company sold 4,404,658 shares of common stock in a private placement offering at a price of $35.19 per share, to certain accredited investors, including funds affiliated with three of its directors and current investors, resulting in gross proceeds of approximately $155.0 million. The price per share was equal to the volume weighted average price for the ten-day period ending on March 17, 2016. There were no placement agents used for this financing. The sale and issuance of the shares of common stock in the private placement was made in reliance on the exemption afforded by Section 4(a)(2) under the Securities Act of 1933 and Regulation D promulgated under the Securities Act.

In April 2016, the Company sold 1,130,198 shares of common stock to Johnson & Johnson Innovation – JJDC, Inc., or JJDC, at a price per share of $44.24, for an aggregate purchase price of approximately $50.0 million. The price per share was equal to the volume weighted average price for the five-day period ending on April 4, 2016. There were no placement agents used, or any underwriting discounts or commissions paid in connection with the transaction. The sale and issuance of the shares of common stock was made in reliance on the exemption afforded by Section 4(a)(2) under the Securities Act of 1933 and Regulation D promulgated under the Securities Act.

8. 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 June 30, 2017, the Company’s uncertain tax positions were subject to valuation allowances.

The Company recorded provisions for income taxes for the three and six months ended June 30, 2017 of $0.1 million and $0.1 million, respectively. The provision for income taxes consists of current tax expense, which relates primarily to the Company’s subsidiary operations in foreign tax jurisdictions.

9. Intangible Assets

The following table presents intangible assets as of December 31, 2016 and June 30, 2017 (in thousands):

	December 31, 2016	June 30, 2017	Estimated useful life
Acquired and in-licensed rights	$ 15,000	$ 50,000	8-13 Years
Less accumulated amortization	(2,123)	(5,592)	
Total intangible assets, net	$ 12,877	$ 44,408	

The increase in acquired and in-licensed rights as of June 30, 2017 was due to a milestone of $25.0 million paid to Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., or Merck, which was triggered by the FDA approval of ZEJULA on March 27, 2017, and a milestone of $10.0 million paid to OPKO Health, Inc., which was triggered by the first commercial sale of VARUBY in Europe in May 2017.

The Company recorded $0.5 million and $3.0 million in amortization expense related to intangible assets during the three months ended June 30, 2016 and 2017, respectively, and $0.9 million and $3.5 million during the six months ended June 30, 2016 and 2017, respectively. Estimated future amortization expense for intangible assets as of June 30, 2017 is $2.5 million for the remainder of 2017, $5.0 million per year for 2018, 2019, 2020, and 2021, and $21.8 million thereafter.

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10. Commitments and Contingencies

The Company leases approximately 150,000 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 June 30, 2017 were $3.1 million for the remainder of the year ending December 31, 2017 and $6.9 million, $6.9 million, $3.6 million, $0.3 and $0.1 million for the years ending December 31, 2018, 2019, 2020, 2021 and 2022, respectively.

The Company has entered into agreements with certain vendors for the provision of services, including services related to data management, clinical and commercial operation support and diagnostic test development, 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 exact terms of the agreement.

The Company has certain obligations under licensing agreements with third parties that are contingent upon achieving various development, regulatory and commercial milestones. Pursuant to these license agreements, the Company is required to make milestone payments if certain development, regulatory and commercial sales milestones are achieved, and may have certain additional research funding obligations. Also, pursuant to the terms of each of these license agreements, when and if commercial sales of a product commence, the Company will pay royalties to its licensors on net sales of the respective products.

Legal Proceedings

The Company may periodically become subject to legal proceedings and claims arising in connection with 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. The Company is not a party to any material litigation and does not have contingency reserves established for any litigation liabilities.

11. Revenue Recognition

Product Revenue, Net

The Company sells its products principally to a limited number of specialty distributors and specialty pharmacy providers, 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. The Company expenses incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that the Company would have recognized is one year or less.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from discounts, returns, chargebacks, rebates, co-pay assistance and other allowances that are offered within contracts between the Company and its Customers, health care providers, payors and other indirect customers relating to the Company's sales of its products. These reserves are

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based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the Customer) or a current liability (if the amount is payable to a party other than a Customer). Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract. The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances: The Company generally provides Customers with discounts which include incentive fees that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, the Company receives sales order management, data and distribution services from certain Customers. To the extent the services received are distinct from the Company's sale of products to the Customer, these payments are classified in selling, general and administrative expenses in the condensed consolidated statements of operations and comprehensive loss of the Company.

Product Returns: Consistent with industry practice, the Company generally offers Customers a limited right of return for product that has been purchased from the Company based on the product's expiration date, which lapses upon shipment to a patient. The Company estimates the amount of its product sales that may be returned by its Customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product return liabilities using available industry data and its own historical sales information, including its visibility into the inventory remaining in the distribution channel. The Company has not received any returns to date and believes that returns of its products will be minimal.

Provider Chargebacks and Discounts: Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by Customers, and the Company generally issues credits for such amounts within a few weeks of the Customer's notification to the Company of the resale. Reserves for chargebacks consist of credits that the Company expects to issue for units that remain in the distribution channel inventories at each reporting period end that the Company expects will be sold to qualified healthcare providers, and chargebacks that Customers have claimed but for which the Company has not yet issued a credit.

Government Rebates: The Company is subject to discount obligations under state Medicaid programs and Medicare. The Company estimates its Medicaid and Medicare rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses on the consolidated balance sheet. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

Payor Rebates: The Company contracts with various private payor organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its products. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

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Other Incentives: Other incentives which the Company offers include voluntary patient assistance programs, such as co-pay assistance programs, which are intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

To date, the Company's sources of product revenue have been U.S. sales of ZEJULA and the oral formulation of VARUBI, and limited sales of VARUBY in Europe. Total net product revenue was $1.2 million and $28.8 million for the three months ended June 30, 2016 and 2017, respectively. These totals included $1.2 million and $2.9 million from sales of VARUBI/VARUBY, respectively, and zero and $25.9 million from sales of ZEJULA, respectively. Total net product revenue was $1.5 million and $31.0 million for the six months ended June 30, 2016 and 2017, respectively. These totals included $1.5 million and $5.0 million from sales of VARUBI/VARUBY, respectively, and zero and $25.9 million from sales of ZEJULA, respectively. The following table summarizes activity in each of the product revenue allowance and reserve categories for the six months ended June 30, 2016 (as revised) and 2017 (in thousands):

	Chargebacks, discounts and fees	Government and other rebates	Returns	Total
Balance at December 31, 2015	$ 813	$ 422	$ 8	$ 1,243
Provision related to current period sales	602	368	2	972
Adjustment related to prior period sales	—	—	—	—
Credit or payments made during the period	(605)	(209)	—	(814)
Balance at June 30, 2016	$ 810	$ 581	$ 10	$ 1,401

Balance at December 31, 2016	$ 177	$ 1,312	$ 18	$ 1,507
Provision related to current period sales	3,251	3,264	73	6,588
Adjustment related to prior period sales	—	62	—	62
Credit or payments made during the period	(2,730)	(2,343)	—	(5,073)
Balance at June 30, 2017	$ 698	$ 2,295	$ 91	$ 3,084

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. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Licenses of Intellectual Property: If the license to the Company’s intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance

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obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration and other revenues and earnings in the period of adjustment.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the licensee’s discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the licensee exercises these options, any additional payments are recorded in license, collaboration and other revenues when the licensee obtains control of the goods, which is upon delivery.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its out-licensing arrangements.

The Company receives payments from its licensees based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company’s right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

The following table presents changes in the Company’s contract assets and liabilities during the six months ended June 30, 2016 (as revised) and 2017 (in thousands):

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Six months ended June 30, 2016				
Contract assets	$ 1,000	$ —	$ —	$ 1,000
Contract liabilities:				
Deferred revenue	$ 92	$ 470	$ (53)	$ 509
Six months ended June 30, 2017				
Contract assets	$ 1,000	$ —	$ —	$ 1,000
Contract liabilities:				
Deferred revenue	$ 400	$ —	$ (47)	$ 353

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During the three and six months ended June 30, 2016 (as revised) 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 June 30,	
Revenue recognized in the period from:	2016	2017
Amounts included in the contract liability at the beginning of the period	$ 15	$ 23
Performance obligations satisfied in previous periods	$ —	$ —

	Six Months Ended June 30,	
Revenue recognized in the period from:	2016	2017
Amounts included in the contract liability at the beginning of the period	$ 30	$ 47
Performance obligations satisfied in previous periods	$ —	$ —

12. License and Collaboration Arrangements

Out-Licenses

Janssen Biotech, Inc.

On April 5, 2016, the Company entered into separate transactions with Janssen Biotech, Inc., or Janssen, and its affiliate, Johnson & Johnson Innovation – JJDC, Inc., or JJDC, consisting of a collaboration and license agreement with Janssen, or the Collaboration Agreement, and a stock purchase agreement and investor agreement, each with JJDC (the “Stock Purchase Agreement” and the “Investor Agreement,” respectively, and collectively with the Collaboration Agreement, the “Agreements”).

Under the terms of the Collaboration Agreement, 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). With the exception of China, under the Collaboration Agreement, the Company retained all rights worldwide to develop and commercialize niraparib outside of prostate cancer.

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, 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. 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 after April 5, 2017 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

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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.

Under the Collaboration Agreement, in order to evaluate the appropriate transaction price, the Company determined that the up-front amount constituted the entirety of the consideration to be included in the transaction price and to be allocated to the performance obligations based on the Company's best estimate of their relative stand-alone selling prices. For the license, the stand-alone selling price was calculated using an income approach model and included the following key assumptions: the development timeline, revenue forecast, discount rate and probabilities of technical and regulatory success. The relative selling price of the Company's Joint Committee participation was based on a full-time equivalent rate for the level of effort required, which can be reasonably estimated to be incurred over the performance period, which is the development period. The Company believes that a change in the assumptions used to determine its best estimate of selling price for the license most likely would not have a significant effect on the allocation of consideration received (or receivable) to the performance obligations.

At execution, the transaction price included only the $35.0 million up-front consideration received. None of the clinical or regulatory milestones has been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Janssen and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

During the second quarter of 2016, the Company allocated $34.5 million of the transaction price to the license and recognized this amount as revenue concurrent with the transfer of the license and certain development and regulatory know-how that occurred within 30 days of entering into the Collaboration Agreement. Revenue allocated to the participation in 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. Through June 30, 2017, the Company had recognized $34.6 million as license and collaboration revenue under the Collaboration Agreement. The remaining transaction price of $0.4 million is recorded in deferred revenue as of June 30, 2017 on the consolidated balance sheets and will be recognized as revenue over the remaining period of 45 months.

Revenue associated with the manufacturing supply services is recognized when the material is delivered to Janssen. For the three and six months ended June 30, 2017, the Company recognized $0.6 million and $1.6 million, respectively, as other revenues within license, collaboration and other revenues in the Company's consolidated statements of operations and comprehensive loss under the Collaboration Agreement.

Additionally, the Company considered whether the Stock Purchase Agreement and the Investor Agreement with JJDC would be subject to combination with the Collaboration Agreement. The Company determined that they should not be combined because the deliverables and terms in these arrangements are not closely interrelated or interdependent in terms of payment or functionality, the arrangements were negotiated separately, and the common stock was sold at approximately its fair value.

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Zai Lab (Shanghai) Co., Ltd.

On September 28, 2016, or the Effective Date, 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 the China Territories. Zai Lab will conduct all development and commercialization of niraparib in the China Territories, except for prostate cancer. The Company retains all rights outside of the China Territories to develop and commercialize niraparib with the exception of 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 the following performance obligations under the contract: (1) exclusive license with rights to develop and commercialize niraparib to Zai Lab for the China Territories; (2) provision of technical assistance related to the know-how transfer for the development of niraparib; and (3) initial supply to Zai Lab of certain materials for the manufacture of niraparib. In addition, the Company may also become responsible for manufacturing of certain niraparib products and materials for commercial sale in certain instances based on regulatory requirements in the China Territories for which the Company will receive reimbursement that approximates stand-alone selling price. The Zai Agreement also provides the Company with an option to co-market niraparib in the China Territories with Zai Lab, in return for certain consideration. This co-marketing right must be exercised by the Company no later than twelve months prior to the launch of niraparib in the China Territories. In addition, the Zai Agreement provides the Company with a right of first refusal with respect to licenses for two novel, discovery-stage immuno-oncology programs from Zai Lab.

The Company evaluated the Zai Agreement under Topic 606. Based on that evaluation, the up-front, non-refundable fees and the reimbursement received for the initial supply of materials constituted the amount of the consideration to be included in the transaction price and have been allocated to the performance obligations identified based on the Company’s best estimate of the relative stand-alone selling price. None of the clinical or regulatory development milestones have been included in the transaction price, as all such milestone amounts are not within the control of the Company or the licensee and are not considered probable to occur until those approvals are received. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license granted to Zai Lab and therefore are recognized at the later of when the performance obligation is satisfied or the related sales occur. The Company concluded the option to co-market niraparib is not a repurchase right as Zai Lab would continue to control its rights to

commercialize niraparib in its licensed territories if the Company exercised its right. The Company further assessed and concluded that the probability of exercise of this right is remote, and the transaction price received and described above was properly allocated to the performance obligations under this agreement and recognized to revenue as those performance obligations were satisfied by the Company. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

During the third quarter of 2016, the Company allocated $14.8 million of the transaction price to the license and recognized this amount as revenue concurrent with the transfer of the license. Revenue allocated to the technical assistance performance obligation, $0.2 million, was recognized on a straight-line basis through the service period which was substantially completed during the fourth quarter of 2016. In addition, $0.7 million of revenue associated with the initial manufacturing supply services was recognized upon delivery of the materials during the fourth quarter of 2016. No revenues were recognized under the Zai Agreement during the three and six months ended June 30, 2017.

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 has licensed the rights to develop, manufacture and commercialize rolapitant in the

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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 has evaluated the terms of this arrangement under Topic 606 and has determined that there are 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 includes the $1.0 million up-front consideration received and a future regulatory development milestone of $1.0 million. This future milestone payment relates to the submission of the clinical trial application with the China Food and Drug Administration, or the China FDA. The Company is also entitled to an additional payment of $1.0 million contingent on the achievement of regulatory approval from the China FDA. However, as this milestone is not within the control of the Company or Hengrui, the amount has not been included in the transaction price by the Company. Any consideration related to sales-based milestones (including royalties at percentage rates in the low teens) will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license granted to Hengrui. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

During the third quarter of 2015, the Company allocated $1.9 million of the transaction price to the license and recognized this amount as revenue concurrent with the transfer of the license. Revenue allocated to the technical assistance performance obligation, $0.1 million, was recognized on a straight-line basis through the service period and was substantially completed during the fourth quarter of 2016. No revenues were recognized under this agreement during the three and six months ended June 30, 2017.

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 six months ended June 30, 2017, the Company incurred $1.8 million and $3.9 million in external costs related to this study, of which $0.9 million and $1.9 million is reimbursable by Merck, respectively. At June 30, 2017, $1.1 million of cost-sharing receivable from Merck has been recorded in other current assets on the condensed consolidated balance sheets.

13. Subsequent Event

On July 27, 2017, the Company entered into an exclusive license agreement with Millennium Pharmaceuticals, Inc. a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, or Takeda. Pursuant to the 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.

The Company will receive a $100 million up-front payment within ten (10) days of executing the agreement and is eligible to receive additional milestone payments of up to $240 million related to the achievement of certain development and commercial goals. 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 license 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.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2016.

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 ZEJULATM (niraparib) in the U.S., and VARUBI®/VARUBY® (the oral formulation of rolapitant) in the U.S. and Europe, and the potential timing of launch of the intravenous, or IV, formulation of rolapitant in the U.S.; our intent to in-license or acquire additional product candidates; our expectations regarding product revenues and license, collaboration and other revenues; our expectations regarding product returns; 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, with respect to each of our niraparib, TSR-042, TSR-022 and TSR-033 programs; our expected gross-to-net adjustment ranges for our products; our expectations regarding our discovery and development plans for immunotherapy antibodies, including the expected timing; our anticipated milestone and royalty payment obligations; our expectations that we will continue to incur significant expenses, including increases in our selling, general and administrative expenses, and that our operating losses and negative operating cash flows will continue, and possibly increase, for the foreseeable future; the expected impact of recent accounting pronouncements and guidance on our financial statements; 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.

Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report on Form 10-Q. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report on Form 10-Q, they may not be predictive of results or developments in future periods.

These forward-looking statements involve substantial risks and uncertainties that could cause actual future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the development or launch of any new pharmaceutical product and the execution and completion of clinical trials, uncertainties surrounding the timing of availability of data from our clinical trials, uncertainties regarding ongoing discussions with and actions by regulatory authorities, patient accrual rates for clinical trials, manufacturing and supply risks, risks relating to intellectual property, and other matters that could affect the timing of data, the potential regulatory approval, or the commercial availability of our product candidates or the success of any product. The following information and any forward-looking statements 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, 2016, including under the heading “Risk Factors”.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

TESARO, the TESARO logo, VARUBI, VARUBY 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.

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Overview

We are an oncology-focused biopharmaceutical company dedicated to improving the lives of cancer patients. We have in-licensed and are currently developing and commercializing several oncology-related product candidates, including rolapitant, niraparib, and the product candidates under our immuno-oncology platform.

A summary description of our current products and product candidates is as follows:

- 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 oral form of rolapitant, VARUBI, is approved in the United States for use in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. The European Commission also approved oral rolapitant for the prevention of delayed nausea and vomiting associated with highly and moderately emetogenic chemotherapy in adults in April 2017. We market rolapitant in the European Union under the brand name VARUBY®, and commenced sales of VARUBY in May 2017 on a country-by-country basis. We are also developing an intravenous, or IV, formulation of rolapitant. We submitted a new drug application, or NDA, for rolapitant IV to the United States Food and Drug Administration, or FDA, in March 2016. In January 2017, the FDA issued a Complete Response Letter requesting additional information regarding the in vitro release method utilized to characterize the drug product and demonstrate comparability of drug product produced by our two proposed commercial manufacturers of rolapitant IV that were included in the NDA. We resubmitted the NDA with such information to the FDA in April 2017, and the FDA will need to review and approve the resubmitted NDA in order for us to be allowed to market and sell rolapitant IV in the U.S. The target Prescription Drug User Fee Act action date is October 25, 2017.

- Niraparib is an orally active and potent poly (ADP-ribose) polymerase, or PARP, inhibitor. On March 27, 2017, the FDA approved ZEJULATM (niraparib) 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 Company commenced sales of ZEJULA in the United States in April 2017. In October 2016, we submitted a Marketing Authorization Application for niraparib for the maintenance treatment of patients with platinum-sensitive, recurrent ovarian cancer who are in response to platinum-based chemotherapy, which the European Medicines Agency has accepted for review. In March 2017, following an interim analysis of data by the independent data monitoring committee, we ceased enrollment in our BRAVO study (assessing niraparib in patients with breast cancer who are germline BRCA mutation carriers) after a determination that it is unlikely to produce data that is interpretable and therefore suitable for registration in this indication. Also in March 2017, we announced plans for expansion of our niraparib clinical development program, including studies of niraparib alone or in combination with other therapeutics for the treatment of ovarian, breast, lung, and prostate cancers. In June 2017, we announced that initial data from our TOPACIO trial of niraparib plus KEYTRUDA® (pembrolizumab) demonstrated a disease control rate of 69% in patients with platinum-resistant ovarian cancer. We are also collaborating with various other organizations to evaluate niraparib in combination with other therapeutics for the treatment of various cancers.

· Immuno-Oncology Platform: In March 2014, we entered into a collaboration and exclusive license agreement with AnaptysBio, Inc., or AnaptysBio, for the discovery and development of antibodies for several immuno-oncology targets. As part of our collaboration with AnaptysBio, we received exclusive rights to monospecific antibody product candidates targeting PD-1, TIM-3, and LAG-3, and certain bi-specific antibody product candidates. In April 2017, we initiated a registrational development program in metastatic microsatellite high endometrial cancer for our first immuno-oncology antibody, TSR-042, which targets PD-1, and in May 2017, we completed a Phase 1 dose escalation study of TSR-042 in which no dose limiting toxicities were observed. In July 2016, we commenced the dosing of the first patient in a Phase 1, dose escalation study for our second immuno-oncology antibody, TSR-022, which targets TIM-3. In May 2017, the FDA cleared our investigational new drug application, or IND, for our antibody candidate targeting LAG-3, TSR-033. We initiated a Phase 1 study of TSR-033 in August 2017. We are also currently developing one bi-specific antibody targeting PD-1 and LAG-3, and a combination of TSR-042 plus TSR-022. In addition, we are evaluating our immuno-oncology anti-tumor agents, including TSR-042, in preclinical combination studies with niraparib and other anti-tumor agents.

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Although our strategy focuses on in-licensing, developing and commercializing cancer therapeutics, we also may collaborate with other entities with regard to selected indications or geographies for our in-licensed product candidates. We have entered into the following collaboration and license agreements:

- In May 2015, we entered into a research agreement with Merck Sharp & Dohme B.V., a subsidiary of Merck & Co., Inc., or 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.

- In July 2015, we entered into a license agreement with Jiangsu Hengrui Medicine Co., Ltd., or Hengrui, pursuant to which Hengrui has licensed the rights to develop, manufacture and commercialize rolapitant in China, Hong Kong and Macao, or the China Territories.

- In February 2016, we entered into a collaboration with the Institute for Applied Cancer Science at The University of Texas MD Anderson Cancer Center, or MDACC, to discover and develop small molecule product candidates against undisclosed immuno-oncology targets. Under the terms of the agreement, we will receive exclusive worldwide rights to develop and commercialize any small molecule product candidates that result from this collaboration. MDACC will be responsible for conducting research activities aimed at identifying clinical candidates with defined characteristics targeting certain immuno-oncology targets. We will fund research, development, and commercialization expenses for this collaboration.

- In April 2016, we entered into a global prostate cancer collaboration and license agreement with Janssen Biotech, Inc., or Janssen, under which we granted Janssen licenses under certain patent rights and know-how relating to the development, manufacturing and commercialization of niraparib, for prostate cancer worldwide, except for Japan.

- In September 2016, we entered into a collaboration, development and license agreement with Zai Lab (Shanghai) Co., Ltd., or Zai Lab. Under the terms of this agreement, we granted to Zai Lab an exclusive license to develop and commercialize niraparib for the territories of China, Hong Kong and Macao, or the China Territories. This agreement also provides us with a right of first refusal with respect to licenses for two novel, discovery-stage immuno-oncology programs from Zai Lab.

- In July 2017, we entered into a license agreement with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, or Takeda, for the commercialization and clinical development of niraparib. This agreement includes the development of niraparib for the treatment of all tumor types in Japan, and all tumor types excluding prostate cancer in South Korea, Taiwan, Russia and Australia. Takeda will be responsible for development of niraparib in Japan and the four specified countries, including all associated expenses.

For further discussion of these agreements, see Note 12, “License and Collaboration Arrangements” and Note 13, “Subsequent Event”, in the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

As of June 30, 2017, we had an accumulated deficit of $1.3 billion. Our net losses were $288.8 million, $374.2 million, $247.7 million, and $171.0 million for the six months ended June 30, 2017 and the years ended December 31, 2016, as revised, 2015, as revised, and 2014, respectively. 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 VARUBI and ZEJULA; (ii) the advancement of clinical trial and other development and regulatory activities under our current development programs such as niraparib, TSR-042, TSR-033 and TSR-022, and our collaborations; (iii) costs related to expanding our international operations; and (iv) other research and development activities and potential future collaborative or in-licensed development programs. 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. Furthermore,

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we expect to incur increasing selling, general and administrative costs associated with our anticipated growth and continuing operation as a public company, and we will continue to incur substantial interest expense related to our outstanding convertible debt. 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 VARUBI and 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.

Public Offerings of Common Stock, Private Placements of Securities and Issuance of Convertible Notes. As of June 30, 2017, our principal source of liquidity was cash and cash equivalents, which totaled $507.9 million. Since our inception on March 26, 2010, we have funded our operations primarily through public offerings of our common stock, the private placement of our equity securities and issuance of convertible notes. From inception through June 30, 2017, we received $1.6 billion in proceeds, net of underwriting discounts and commissions and offering expenses, from private placements of convertible preferred stock and common stock, public offerings of common stock and the issuance of convertible notes.

Financial Operations Overview

Revenues

Product revenue is derived from sales of ZEJULA and VARUBI in the United States, and VARUBY in Europe.

License, collaboration and other revenues relate to our license agreements with Janssen, Zai Lab and Hengrui. 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 the China Territories, except for prostate cancer. Hengrui has licensed the rights to develop, manufacture and commercialize rolapitant in the China Territories.

Research and Development Expenses

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

- 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;
- employee-related expenses, including salaries, bonuses, benefits, travel and stock-based compensation expense;
- fees and expenses incurred under agreements with contract research organizations, investigative sites, research consortia and other entities in connection with the conduct of clinical trials and preclinical studies and related services, such as administrative, data management, laboratory and biostatistics services;
- the cost of acquiring, developing and manufacturing active pharmaceutical ingredients for product candidates that have not received regulatory approval, clinical trial materials and other research and development materials;
- fees and costs related to regulatory filings and operations;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent, utilities, maintenance of facilities, insurance and other supplies; and
- other costs associated with clinical, preclinical, discovery and other research activities.

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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 Phase 2 and 3 trials, continue our manufacturing development and validation, and initiate additional investigative and collaborative studies related to niraparib; continue manufacturing and regulatory development activities for the IV formulation of rolapitant; incur potential 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.

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The following table presents research and development expenses and acquired in-process research and development expenses on a program-specific basis for our in-licensed products and product candidates for the six months ended June 30, 2016 and 2017 (in thousands):

	Six Months Ended June 30,	
	2016 (as revised)	2017
Rolapitant Expenses		
Acquired in-process research and development	$ —	$ —
Research and development	8,962	5,744
Rolapitant total	8,962	5,744
Niraparib Expenses		
Acquired in-process research and development	—	—
Research and development	47,842	44,204
Niraparib total	47,842	44,204
Immuno-Oncology Platform Expenses		
Acquired in-process research and development	8,000	7,000
Research and development	12,981	24,706
Immuno-Oncology Platform total	20,981	31,706
Personnel and Other Expenses	33,062	62,868
Total	$ 110,847	$ 144,522

For further discussion of the changes in our research and development expenses with respect to the six months ended June 30, 2017 and the corresponding period of 2016, see “Results of Operations — Comparison of the Six Months Ended June 30, 2016 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, communication expenses, pre-commercial and commercial consulting, advertising, market research and other activities necessary to prepare for and support the launches of VARUBI, ZEJULA and our potential products, and professional fees for legal, 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 VARUBI, rolapitant IV, ZEJULA and other products in our pipeline and continued research and development activities, as well as the continued costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel, 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 the Convertible Notes and interest income earned on cash and cash equivalents. A portion of the interest expense on the Convertible Notes is non-cash expense relating to accretion of the debt discount and amortization of issuance costs.

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Results of Operations

Comparison of the Three Months Ended June 30, 2016 and 2017

(data in thousands)	Three Months Ended June 30, 2016 (as revised)	2017	Increase/ (Decrease)
Revenues:			
Product revenue, net	$ 1,242	$ 28,829	$ 27,587
License, collaboration and other revenues	34,568	635	(33,933)
Total revenues	35,810	29,464	(6,346)
Expenses:			
Cost of sales – product	234	3,620	3,386
Cost of sales – intangible asset amortization	463	2,979	2,516
Research and development	50,138	71,400	21,262
Selling, general and administrative	36,218	92,979	56,761
Acquired in-process research and development	4,000	7,000	3,000
Total expenses	91,053	177,978	86,925
Loss from operations	(55,243)	(148,514)	(93,271)
Other income (expense), net	(3,911)	(3,467)	444
Loss before income taxes	(59,154)	(151,981)	(92,827)
Provision for income taxes	—	78	78
Net loss	$ (59,154)	$ (152,059)	$ (92,905)

Product Revenue. Net product revenue relates to sales of ZEJULA and VARUBI in the U.S. and sales of VARUBY in Europe. We distribute our products principally through a limited number of specialty distributors and through the specialty pharmacy channel. For further discussion regarding our revenue recognition policy, see the “Critical Accounting Policies” section below and Note 2, “Basis of Presentation and Significant Accounting Policies”, in the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. The following table presents net product revenues by product and geography for the three months ended June 30, 2016 and 2017, respectively (in thousands).

	Three months ended June 30,		
	2016	2017	Change

	(as revised)		
ZEJULA (U.S. only)	$ —	$ 25,945	$ 25,945
VARUBI/VARUBY			
U.S.	1,242	2,880	1,638
International	—	4	4
Total	1,242	2,884	1,642
Product revenue, net	$ 1,242	$ 28,829	$ 27,587

We began to recognize revenues on sales of ZEJULA in the U.S. starting in the second quarter of 2017. For net product revenues for the three months ended June 30, 2017, the average net sales price per unit to us was approximately 90% of the Wholesale Acquisition Cost, or WAC, which is the gross list price at which our direct customers purchase each unit.

We began to recognize revenues on sales of VARUBI in the U.S. in the fourth quarter of 2015 and in the EU starting in the second quarter of 2017. For the three months ended June 30, 2017 as compared to the same period in 2016, net VARUBI product revenues increased due to higher unit sales volumes and price increases, partially offset by higher discounts, rebates and chargebacks. This resulted in an average net sales price per unit to us of approximately 53% of WAC for the three months ended June 30, 2017 as compared to 60% of WAC for the same period in 2016.

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License, Collaboration and Other Revenues. License, collaboration and other revenues of $34.6 million for the three months ended June 30, 2016 were primarily related to an upfront license payment of $35.0 million from Janssen, which was substantially recognized as license revenue during the period. License, collaboration and other revenues of $0.6 million for the three months ended June 30, 2017 relate to our license agreement with Janssen.

Cost of Sales - Product. Cost of sales of $0.2 million and $3.6 million for the three months ended June 30, 2016 (as revised) and 2017, respectively, consists 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 increase was primarily related to the U.S. launch of ZEJULA in April 2017. 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 three months ended June 30, 2016 and 2017 were expensed prior to products' respective approval dates, and therefore are not included in cost of sales during these periods. We expect cost of sales to increase in relation to product revenues as we deplete these inventories.

Cost of Sales - Intangible Asset Amortization. Cost of sales of $0.5 million and $3.0 million for the three months ended June 30, 2016 and 2017, respectively, consists of amortization of intangible assets recorded as a result of milestones paid to our licensors, upon or after regulatory approval of our products. The increase was primarily related to two new milestone assets recorded during the six months ended June 30, 2017: a $25.0 million milestone triggered by the FDA approval of ZEJULA, and a $10.0 million milestone triggered by the first commercial sale of VARUBY in Europe.

Research and Development Expenses. Research and development expenses were $50.1 million for the three months ended June 30, 2016, compared to $71.4 million for the three months ended June 30, 2017, an increase of $21.3 million. Significant changes resulting in this increase included:

- an increase of $8.3 million in costs associated with our immuno-oncology platform due to increased costs related to the TSR-042 clinical trial, biologics manufacturing and non-clinical and other immuno-oncology program research activities; and

- an increase of $12.9 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.

In addition, stock-based compensation expense included in research and development expenses increased by $3.4 million, primarily due to increased awards of employee stock options and restricted stock units.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $36.2 million for the three months ended June 30, 2016, compared to $93.0 million for the three months ended June 30, 2017, an

increase of $56.8 million. The increase was primarily due to increases of: $21.0 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 VARUBI and ZEJULA, plus hiring to support our international operations; $27.1 million in professional and consulting fees and other expenses related to commercial and pre-commercial activities such as global marketing and promotional programs and market research as well as other corporate operational activities; and $8.4 million in stock-based compensation expense.

Acquired In-Process Research and Development. Acquired in-process research and development expenses for the three months ended June 30, 2016 were $4.0 million, comprised of a milestone paid to AnaptysBio. Our obligation to pay this milestone was triggered by the clearance of our IND for TSR-022, which occurred in May 2016. Acquired in-process research and development expenses for the three months ended June 30, 2017 were $7.0 million, comprised of 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 interest income earned on cash and cash equivalents. Interest income increased by $0.7 million during the three months ended June 30, 2017, primarily due to higher balances of interest-bearing cash equivalents. Interest expense increased by $0.3 million due to the accretion of the debt discount, which is a component of interest expense, and the use of the effective interest method.

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Comparison of the Six Months Ended June 30, 2016 and 2017

(data in thousands)	Six Months Ended June 30, 2016 (as revised)	2017	Increase/ (Decrease)
Revenues:			
Product revenue, net	$ 1,518	$ 30,968	$ 29,450
License, collaboration and other revenues	34,592	1,569	(33,023)
Total revenues	36,110	32,537	(3,573)
Expenses:			
Cost of sales – product	313	4,064	3,751
Cost of sales – intangible asset amortization	927	3,469	2,542
Research and development	102,847	137,522	34,675
General and administrative	66,367	162,241	95,874
Acquired in-process research and development	8,000	7,000	(1,000)
Total expenses	178,454	314,296	135,842
Loss from operations	(142,344)	(281,759)	(139,415)
Other income (expense), net	(7,790)	(6,893)	897
	(150,134)	(288,652)	(138,518)
Provision for income taxes	—	132	132
Net loss	$ (150,134)	$ (288,784)	$ (138,650)

Product Revenue. The following table presents net product revenues by product and geography for the six months ended June 30, 2016 and 2017, respectively (in thousands).

	Six months ended June 30, 2016 (as revised)	2017	Change
ZEJULA (U.S. only)	$ —	$ 25,945	$ 25,945
VARUBI/VARUBY			
U.S.	1,518	5,019	3,501
International	—	4	4
Total	1,518	5,023	3,505
Product revenue, net	$ 1,518	$ 30,968	$ 29,450

We began to recognize revenues on sales of ZEJULA in the U.S. starting in the second quarter of 2017. For net product revenues for the six months ended June 30, 2017, the average net sales price per unit to us was approximately 90% of WAC, which is the gross list price at which our direct customers purchase each unit.

We began to recognize revenues on sales of VARUBI in the U.S. in the fourth quarter of 2015 and in the EU starting in the second quarter of 2017. For the six months ended June 30, 2017, compared to the same period in 2016, net product revenues increased due to higher unit sales volumes and price increases, partially offset by higher discounts, rebates and chargebacks. This resulted in an average net sales price per unit to us of approximately 57% of WAC for the six months ended June 30, 2017 as compared to 61% of WAC for the same period in 2016.

License, Collaboration and Other Revenues. License, collaboration and other revenues of $34.6 million for the six months ended June 30, 2016 were primarily related to an upfront license payment of $35.0 million from Janssen, which was substantially recognized as license revenue during the period. License, collaboration and other revenues of $1.6 million for the six months ended June 30, 2017 relate to our license agreement with Janssen.

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Cost of Sales - Product. Cost of sales of $0.3 million and $4.1 million for the six months ended June 30, 2016 (as revised) and 2017, respectively, consists 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 increase was primarily related to the U.S. launch of ZEJULA in April 2017.

Cost of Sales - Intangible Asset Amortization. Cost of sales of $0.9 million and $3.5 million for the six months ended June 30, 2016 and 2017, respectively, consists of amortization of intangible assets recorded as a result of milestones paid to our licensors, upon or after regulatory approval of our products. The increase was primarily related to two new milestone assets recorded during the six months ended June 30, 2017: a $25.0 million milestone triggered by the FDA approval of ZEJULA, and a $10.0 million milestone triggered by the first commercial sale of VARUBY in Europe.

Research and Development Expenses. Research and development expenses were $102.8 million for the six months ended June 30, 2016, compared to $137.5 million for the six months ended June 30, 2017, an increase of $34.7 million. Significant changes resulting in this increase included:

- an increase of $12.6 million in costs associated with our immuno-oncology platform due to increased costs related to the TSR-042 clinical trial, biologics manufacturing and non-clinical and other immuno-oncology program research activities; and

- an increase of $22.5 million in personnel and other costs (excluding stock-based compensation), primarily related to increased research and development headcount supporting the growth of our development activities.

In addition, stock-based compensation expense included in research and development expenses increased by $6.8 million, primarily due to increased awards of employee stock options and restricted stock units.

The above increases were offset by a decrease of $2.7 million in external regulatory costs related to rolapitant.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $66.4 million for the six months ended June 30, 2016, compared to $162.2 million for the six months ended June 30, 2017, an increase of $95.8 million. The increase was primarily due to increases of: $35.2 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 VARUBI and ZEJULA, plus hiring to support our international operations; $46.4 million in professional and consulting fees and other expenses related to commercial and pre-commercial activities such as global marketing and promotional programs and market research as well as other corporate operational activities; and $14.0 million in stock-based compensation expense.

Acquired In-Process Research and Development. Acquired in-process research and development expenses were $8.0 million for the six months ended June 30, 2016, comprised of two $4.0 million milestone payments to AnaptysBio. Our obligations to pay these milestones were triggered by the clearances of our INDs for TSR-042 and TSR-022, which occurred in January 2016 and May 2016, respectively. Acquired in-process research and development expenses for the six months ended June 30, 2017 were $7.0 million, comprised of 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 interest income earned on cash and cash equivalents. Interest income increased by $1.5 million during the six months ended June 30, 2017, primarily due to higher balances of interest-bearing cash equivalents. Interest expense increased by $0.6 million, due to the accretion of the debt discount, which is a component of interest expense, and the use of the effective interest method.

Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2017, our principal source of liquidity was cash and cash equivalents, which totaled $507.9 million. Since our inception on March 26, 2010, we have funded our operations primarily through public offerings of our common stock, the private placement of our equity securities and the issuance of convertible notes. From inception

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through June 30, 2017, including our 2012 initial public offering, we raised a total of $1.6 billion in net cash proceeds from private placements of convertible preferred stock and common stock, public offerings of common stock and the issuance of convertible notes.

Cash Flows

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

	Six Months Ended June 30,	
	2016 (as revised)	2017
Net cash provided by (used in):		
Operating activities	$ (109,929)	$ (249,487)
Investing activities	(8,590)	(47,155)
Financing activities	208,577	18,340
Effect of exchange rate changes on cash and cash equivalents	—	366
Increase (decrease) in cash and cash equivalents	$ 90,058	$ (277,936)

Cash Flows from Operating Activities

The use of cash in operating activities during both the six months ended June 30, 2016 and 2017 resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. Net cash used in operating activities increased by $139.6 million for the six months ended June 30, 2017 compared to the six months ended June 30, 2016, primarily due to higher costs associated with increased employee headcount and increased external expenses related to commercialization activities for ZEJULA and VARUBI. Increases in headcount in research and development and general and administrative functions, as well as increased external research expenses to progress the immuno-oncology platform, also contributed to the increase in cash used in operating activities. These factors were partially offset by lower external costs associated with our rolapitant and niraparib development programs.

Cash Flows from Investing Activities

The increase of $38.6 million in net cash used in investing activities for the six months ended June 30, 2017 compared to the six months ended June 30, 2016 was due primarily to $42.0 million in milestones paid during the current year period, compared to $8.0 million in milestones paid during the prior year period. The current year period included a

$25.0 million milestone related to FDA approval of ZEJULA, a $10.0 million milestone related to the first commercial sale of VARUBY in Europe, and $7.0 million in immuno-oncology development milestones. The prior year period included $8.0 million in immuno-oncology development milestones. In addition, cash used for purchases of property and equipment increased from $0.6 million to $4.3 million, primarily due to the expansion of the leased office space at our U.S. headquarters.

Cash Flows from Financing Activities

The decrease of $190.2 million in net cash provided by financing activities for the six months ended June 30, 2017 compared to the six months ended June 30, 2016 was primarily due to cash proceeds of $205.0 million from the closing of our March 2016 and April 2016 private placements of common stock. There were no similar financing transactions in the six months ended June 30, 2017. In addition, cash proceeds from exercises of stock options and purchases under our Employee Stock Purchase Plan increased from $3.6 million in the prior year period to $18.3 million in the current year period.

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 VARUBI and ZEJULA; (ii) the advancement of clinical trial and other development and regulatory activities under our current development programs including niraparib, TSR-042, TSR-033 and TSR-022, and our collaborations; (iii) costs related to expanding our international operations; and (iv) other research and development activities and potential future collaborative or in-licensed development programs. We

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are subject to the risks incident in the development of new biopharmaceutical products, and 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 may require additional capital for the continuing commercialization of VARUBI and ZEJULA, further development and potential commercialization of our other product candidates, including any license payments or milestone obligations that may arise, required costs relating to our immuno-oncology development programs, and cash interest obligations related to our Convertible Notes. 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 Convertible Notes at maturity or, at our election, upon conversion. We believe our existing cash and cash equivalents 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.

Unless and until we can generate a sufficient amount of revenue from our products, we expect to finance future cash needs through public or private equity or debt offerings and may seek additional capital through arrangements with strategic partners or from other sources. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we 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 Convertible Notes and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

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

- our ability to generate revenues from sales of VARUBI, ZEJULA and future products;

- the cost of expanding our sales, marketing and distribution capabilities;

- the outcome, timing and cost of regulatory approvals by the FDA and comparable non-U.S. regulatory authorities, including the potential that the FDA or comparable non-U.S. regulatory authorities may require that we perform

more studies, including post-marketing commitments, than those that we currently expect;

· the initiation, progress, timing, costs and results of clinical trials for our product candidates and any future product candidates we may in-license, including our current and potential future Phase 2 and 3 clinical trials for niraparib;

· the cost and timing of completion of commercial-scale outsourced manufacturing activities;

· the discovery, preclinical and clinical development plans that are or will be established for potential product candidates under our immuno-oncology collaboration with MDACC;

· the attainment of milestones and our obligations to make milestone payments, royalty payments, or both to OPKO Health, Inc., Merck, or AnaptysBio or to any other current or future product candidate licensor, if any, under our in-licensing agreements;

· the number and characteristics of product candidates that we in-license and develop;

· the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

· the amount and timing of potential conversion requests, if any, and interest expense associated with our Convertible Notes; and

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· the effect of competing technological and market developments.

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

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, 2016.

Off-Balance Sheet Arrangements

As of June 30, 2017, 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 net product revenue, accrued research and development expenses and stock-based compensation expense. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. In making estimates and judgments, management employs critical accounting policies.

Revenue Recognition

Effective January 1, 2017, we adopted Topic 606, Revenue from Contracts with Customers, using the full retrospective transition method. Under this method, we will revise our consolidated financial statements for the years ended December 31, 2015 and 2016, and applicable interim periods within those years, as if Topic 606 had been effective for those periods. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity 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 entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract and identify, as a performance obligation, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, Net

We sell our products principally to a limited number of specialty distributors and specialty pharmacy providers in the U.S., or collectively, our Customers. These Customers subsequently resell our products to health care providers and patients. In addition to distribution agreements with Customers, we enter 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 our products.

Revenues from product sales are recognized when the Customer obtains control of our product, which occurs at a point in time, typically upon delivery to the Customer. When we perform 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

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activities, and accordingly, the costs are accrued when the related revenue is recognized. Taxes collected from Customers relating to product sales and remitted to governmental authorities are excluded from revenues. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from discounts, returns, chargebacks, rebates, co-pay assistance and other allowances that are offered within contracts between us and our Customers, health care providers, payors and other indirect customers relating to our product sales. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the Customer) or a current liability (if the amount is payable to a party other than a Customer). Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances: We generally provide Customers with discounts which include incentive fees that are explicitly stated in our contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, we receive sales order management, data and distribution services from certain Customers. To the extent the services received are distinct from our sale of products to the Customer, these payments are classified in selling, general and administrative expenses in the condensed consolidated statements of operations and comprehensive loss.

Product Returns: Consistent with industry practice, we generally offer Customers a limited right of return for product that has been purchased from us based on the product's expiration date, which lapses upon shipment to a patient. We estimate the amount of our product sales that may be returned by our Customers and record this estimate as a reduction of revenue in the period the related product revenue is recognized. We currently estimate product return liabilities using available industry data and our own historical sales information, including our visibility into the inventory remaining in the distribution channel. We have not received any returns to date and believe that returns of our products will be minimal.

Provider Chargebacks and Discounts: Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from us. Customers charge us for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by Customers, and we generally issue credits for such amounts within a few weeks of the Customer's notification to us of the resale. Reserves for chargebacks consist of credits that we expect to issue for units that remain in the distribution channel inventories at each reporting period end that we expect will be sold to qualified healthcare providers, and chargebacks that Customers have claimed but for which we have not yet issued a credit.

Government Rebates: We are subject to discount obligations under state Medicaid programs and Medicare. We estimate our Medicaid and Medicare rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses on the consolidated balance sheet. For Medicare, we also estimate the number of patients in the prescription drug coverage gap for whom we will owe an additional liability under the Medicare Part D program. Our liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet

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been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at period end.

Payor Rebates: We contract with various private payor organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of our products. We estimate these rebates and record such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

Other Incentives: Other incentives which we offer include voluntary patient assistance programs such as co-pay assistance. Co-pay assistance programs are intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue, but remains in in the distribution channel inventories at period end.

To date, our sources of product revenue have been U.S. sales of ZEJULA and the oral formulation of VARUBI, and limited sales of VARUBY in Europe. The following table summarizes activity in each of the product revenue allowance and reserve categories for the six months ended June 30, 2016 (as revised) and 2017 (in thousands):

	Chargebacks, discounts and fees	Government and other rebates	Returns	Total
Balance at December 31, 2015	$ 813	$ 422	$ 8	$ 1,243
Provision related to current period sales	602	368	2	972
Adjustment related to prior period sales	—	—	—	—
Credit or payments made during the period	(605)	(209)	—	(814)
Balance at June 30, 2016	$ 810	$ 581	$ 10	$ 1,401

Balance at December 31, 2016	$ 177	$ 1,312	$ 18	$ 1,507
Provision related to current period sales	3,251	3,264	73	6,588
Adjustment related to prior period sales	—	62	—	62
Credit or payments made during the period	(2,730)	(2,343)	—	(5,073)
Balance at June 30, 2017	$ 698	$ 2,295	$ 91	$ 3,084

License, Collaboration and Other Revenues

We enter into out-licensing agreements which are within the scope of Topic 606, under which we license certain of our product candidates' rights to third parties. The terms of these arrangements typically include payment of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; payments for manufacturing supply services that we provide through our 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 we fulfill our obligations under each of our agreements, we perform 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) we satisfy each performance obligation. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We utilize key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Licenses of Intellectual Property: If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we will recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined

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performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration and other revenues and earnings in the period of adjustment.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. If we are entitled to additional payments when the licensee exercises these options, any payments are recorded in license, collaboration and other revenues when the licensee obtains control of the goods, which is upon delivery.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from any of our out-license arrangements.

We receive payments from our licensees based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due until we perform our obligations under these arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

The following table presents changes in the balances of our contract assets and liabilities during the six months ended June 30, 2016 (as revised) and 2017 (in thousands):

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Six months ended June 30, 2016				
Contract assets	$ 1,000	$ —	$ —	$ 1,000
Contract liabilities:				
Deferred revenue	$ 92	$ 470	$ (53)	$ 509
Six months ended June 30, 2017				
Contract assets	$ 1,000	$ —	$ —	$ 1,000
Contract liabilities:				
Deferred revenue	$ 400	$ —	$ (47)	$ 353

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During the three and six months ended June 30, 2016 (as revised) and 2017, we 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 June 30,	
Revenue recognized in the period from:	2016	2017
Amounts included in the contract liability at the beginning of the period	$ 15	$ 23
Performance obligations satisfied in previous periods	$ —	$ —

	Six Months Ended June 30,	
Revenue recognized in the period from:	2016	2017
Amounts included in the contract liability at the beginning of the period	$ 30	$ 47
Performance obligations satisfied in previous periods	$ —	$ —

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, 2016. Other than as described above, there have not been any material changes to our critical accounting policies since December 31, 2016.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of June 30, 2017 and December 31, 2016, we had cash and cash equivalents of $507.9 million and $785.9 million, respectively, consisting primarily of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates, particularly because our investments are in short-term securities. Our securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio. There has been no material change to our interest rate sensitivity during the three months ended June 30, 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.

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PART IIOTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently a party to any material legal proceedings.

Item 1A. Risk Factors.

An investment in our stock involves a high degree of risk. You should carefully consider the 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, 2016 and the other filings we make with the U.S. Securities and Exchange Commission. 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

Our future success is dependent primarily on our ability to successfully commercialize ZEJULA and VARUBI and to obtain regulatory approvals for and successfully commercialize our other product candidates.

The success of our business depends heavily upon our ability to develop and commercialize product candidates. We have recognized only limited product revenue from sales of ZEJULA and VARUBI, and our only other late clinical-stage product candidates, rolapitant IV and niraparib in additional indications, have not been approved for marketing and sale in any jurisdiction. Our other product candidates, including our immuno-oncology assets, are at earlier stages of development.

We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical and well-controlled clinical studies, and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is safe and effective for use for that target indication and that

the manufacturing facilities, processes and controls are adequate. The process to develop, obtain regulatory approval for and commercialize product candidates is long, complex and costly both inside and outside of the United States. Even if a product candidate were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations, including use restrictions for certain patient populations; warnings, precautions or contraindications; or burdensome post-approval study or risk management requirements.

Despite the results reported in clinical trials for niraparib, we do not know whether the clinical trials we are continuing to conduct or may in the future conduct will demonstrate adequate efficacy and safety to result in regulatory approval for niraparib in any additional indications or in any particular jurisdiction or jurisdictions other than those for which ZEJULA has been approved. If we do not obtain regulatory approvals for niraparib in the various additional indications for which it is being developed, or do not obtain such approvals in a timely manner, it would negatively affect our ability to generate revenue in the future and our growth prospects.

Our current business plan relies heavily on our ability to successfully commercialize ZEJULA, VARUBI, rolapitant IV, and our immuno-oncology assets. Our products and product candidates, if approved, may not achieve market acceptance or be commercially successful.

Our ability to successfully commercialize ZEJULA, VARUBI and our product candidates is critical to the execution of our business strategy. ZEJULA, VARUBI and, if approved, rolapitant IV and our immuno-oncology assets, may not achieve market acceptance among physicians, patients, and third-party payors, and may not be commercially successful. The degree of market acceptance and commercial success of our products and product candidates, if approved, will depend on a number of factors, including the following:

· the acceptance of our products by patients and the medical community and the availability, perceived advantages and relative cost, safety and efficacy of alternative and competing treatments;

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- the effectiveness of our marketing, sales and distribution strategy and operations;

- the ability of our third-party manufacturers to manufacture commercial supplies of our products, to remain in good standing with regulatory agencies, and to develop, validate and maintain commercially viable manufacturing processes that are, to the extent required, compliant with current good manufacturing practice, or cGMP, regulations;

- the degree to which the approved labeling supports promotional initiatives for commercial success;

- the availability of reimbursement from managed care plans and other third-party payors and the willingness and ability of patients to pay for our products;

- a continued acceptable safety profile of our products and product candidates;

- any new or unexpected results from additional clinical trials or further analysis of clinical data of completed clinical trials by us or our competitors;

- our ability to enforce our intellectual property rights;

- our ability to avoid third-party patent interference or patent infringement claims; and

- maintaining compliance with all applicable regulatory requirements.

As many of these factors are beyond our control, we cannot assure you that we will ever be able to generate meaningful revenue through product sales. Any inability on our part to successfully commercialize our products in the United States or any foreign territories where they may be approved, or any significant delay in such approvals, could have a material adverse impact on our ability to execute upon our business strategy and our future business prospects.

If we are unable to successfully expand our existing sales, marketing and distribution capabilities for ZEJULA, VARUBI and any future products for which we obtain marketing approval, we may be unable to generate significant revenue from sales of our products.

Prior to the launch of VARUBI in late 2015, we had not commercialized any drug products as a company. To achieve commercial success for ZEJULA, VARUBI and any future product candidate that may be approved by the FDA or comparable foreign regulatory authorities, including rolapitant IV, we must continue to expand our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We will be competing with companies that currently have extensive, well-funded, and more experienced sales and marketing operations. We may be unable to compete successfully against these more established companies.

We have built a field organization and other capabilities for the sales, marketing and distribution of VARUBI. We are continuing to expand this commercial organization to now also cover ZEJULA and eventually to cover rolapitant IV, if approved. There are significant risks involved with building and managing such a commercial organization, as well as transitioning to cover multiple products. Factors that may inhibit our efforts to effectively commercialize our current and future products include:

- our inability to recruit, train, retain and incentivize adequate numbers of qualified and effective sales and marketing personnel;

- the inability of sales personnel to generate sufficient sales leads and to obtain access to physicians or persuade adequate numbers of physicians to use or prescribe our products;

- the lack of complementary products currently offered by our sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

- our inability to effectively manage a geographically dispersed sales and marketing team, both in the United States and Europe.

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If we are unable to establish and maintain effective sales, marketing and distribution capabilities for our current and future products, we may not be able to generate significant product revenue and may not become profitable.

Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TESARO, INC.

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

Date: August 8, 2017

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

Date: August 8, 2017

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EXHIBIT INDEX

Exhibit Number	Exhibit Description
10.1*	Sixth Amendment to Lease Agreement, dated June 16, 2017, by and between the Company and BP Bay Colony LLC.
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
EX-101.INS	XBRL Instance Document
EX-101.SCH	XBRL Taxonomy Extension Schema Document
EX-101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
EX-101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
EX-101.LAB	XBRL Taxonomy Extension Label Linkbase Document
EX-101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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