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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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	**27-2249687**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1000 Winter Street **Waltham, Massachusetts**	**02451**
(Address of Principal Executive Offices)	(Zip Code)

(339) 970-0900

(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant has submitted electronically 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 November 3, 2017, there were 54,381,928 shares of the registrant's Common Stock, par value $0.0001 per share, outstanding.

TESARO, INC.
FORM 10-Q
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2017

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

TESARO, INC.

Condensed Consolidated Balance Sheets

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

	December 31, 2016 (as revised)	September 30, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 785,877	$ 521,265
Accounts receivable	6,195	27,680
Inventories	14,700	50,527
Other current assets	10,515	22,257
Total current assets	817,287	621,729
Intangible assets, net	12,877	43,155
Property and equipment, net	6,640	9,877
Restricted cash	1,694	2,521
Other assets	3,795	8,436
Total assets	$ 842,293	$ 685,718
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,236	$ 5,984
Accrued expenses	68,700	123,076
Deferred revenue, current	95	95
Other current liabilities	2,978	2,287
Total current liabilities	77,009	131,442
Convertible notes, net	131,775	140,362
Deferred revenue, non-current	305	235
Other non-current liabilities	5,086	6,318
Total liabilities	214,175	278,357
Commitments and contingencies *(Notes 11 and 13)*		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at both December 31, 2016 and September 30, 2017; no shares issued or outstanding at both December 31, 2016 and September 30, 2017	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at both December 31, 2016 and September 30, 2017; 53,621,679 and 54,365,390 shares issued and outstanding at December 31, 2016 and September 30, 2017, respectively	5	5
Additional paid-in capital	1,604,798	1,697,544
Accumulated other comprehensive loss	(2,924)	(2,366)
Accumulated deficit	(973,761)	(1,287,822)
Total stockholders' equity	628,118	407,361
Total liabilities and stockholders' equity	$ 842,293	$ 685,718

See accompanying notes to condensed consolidated financial statements.

TESARO, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016 (as revised)	2017	2016 (as revised)	2017
Revenues:				
Product revenue, net	$ 1,326	$ 41,755	$ 2,844	$ 72,723
License, collaboration and other revenues	15,661	101,011	50,253	102,580
Total revenues	16,987	142,766	53,097	175,303
Expenses:				
Cost of sales – product	378	6,216	691	10,280
Cost of sales – intangible asset amortization	464	1,254	1,391	4,723
Research and development	60,783	73,388	163,630	210,910
Selling, general and administrative	37,685	83,998	104,052	246,239
Acquired in-process research and development	1,940	—	9,940	7,000
Total expenses	101,250	164,856	279,704	479,152
Loss from operations	(84,263)	(22,090)	(226,607)	(303,849)
Interest expense	(4,119)	(4,424)	(12,220)	(13,117)
Interest income	532	1,133	843	2,933
Other income	—	243	—	243
Loss before income taxes	(87,850)	(25,138)	(237,984)	(313,790)
Provision for income taxes	—	139	—	271
Net loss	$ (87,850)	$ (25,277)	$ (237,984)	$ (314,061)
Net loss per share applicable to common stockholders - basic and diluted	$ (1.72)	$ (0.47)	$ (5.17)	$ (5.82)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	51,151	54,241	45,994	53,971
Comprehensive loss:				
Net loss	$ (87,850)	$ (25,277)	$ (237,984)	$ (314,061)
Other comprehensive income (loss):				
Unrealized gain (loss) on pension obligation	1	46	(98)	137
Foreign currency translation adjustments	—	131	—	421
Other comprehensive income (loss)	1	177	(98)	558
Comprehensive loss	$ (87,849)	$ (25,100)	$ (238,082)	$ (313,503)

See accompanying notes to condensed consolidated financial statements.

TESARO, INC.

Condensed Consolidated Statements of Cash Flows

(all amounts in 000's)
(Unaudited)

	Nine Months Ended September 30,	
	2016 (as revised)	**2017**
Operating activities		
Net loss	$ (237,984)	$ (314,061)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	9,940	7,000
Depreciation and amortization expense	2,254	7,092
Stock-based compensation expense	34,064	66,925
Non-cash interest expense	7,692	8,588
Changes in operating assets and liabilities:		
Accounts receivable	(15,550)	(21,484)
Inventories	(11,057)	(35,827)
Other assets	(4,551)	(12,415)
Accounts payable	(4,766)	692
Accrued expenses	15,628	49,375
Deferred revenues	562	(70)
Other liabilities	(728)	1,000
Net cash used in operating activities	(204,496)	(243,185)
Investing activities		
Acquisition of product candidates, technology licenses and milestone payments	(9,000)	(42,000)
Purchase of property and equipment	(1,820)	(4,926)
Change in restricted cash	(120)	(840)
Net cash used in investing activities	(10,940)	(47,766)
Financing activities		
Proceeds from sale of common stock, net of issuance costs	613,913	(8)
Proceeds from exercise of stock options and Employee Stock Purchase Plan	18,692	25,849
Net cash provided by financing activities	632,605	25,841
Effect of exchange rate changes on cash and cash equivalents	—	498
Increase (decrease) in cash and cash equivalents	417,169	(264,612)
Cash and cash equivalents at beginning of period	230,146	785,877
Cash and cash equivalents at end of period	$ 647,315	$ 521,265
Non-cash investing and financing activities		
Stock option exercise proceeds receivable as of period end	$ —	$ 71
Leasehold improvement assets funded by lessor	$ —	$ 585
Purchase of property and equipment - cash not paid as of period end	$ 115	$ 328
Acquired in-process research and development - milestone not paid as of period end	$ 940	$ —
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 6,038	$ 6,038
Income taxes paid	$ —	$ 468

See accompanying notes to condensed consolidated financial statements.

TESARO, INC.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Description of Business

TESARO, Inc., or the Company or TESARO, was incorporated in Delaware 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 products or 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, its ability to successfully commercialize its products, 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 commercialization of its products and 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 (oral formulation) in November 2015. The FDA approved the intravenous formulation of VARUBI on October 25, 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. On March 27, 2017, the FDA approved the Company's second commercial product, ZEJULA® (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.

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 a discussion of certain revisions to prior period financial statements made in connection with 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.

Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. These interim financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the Company's financial position and results of operations for the interim periods ended September 30, 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 nine months ended September 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

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 September 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	$ —	$ —

		September 30, 2017			
Description	**Balance Sheet Classification**	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets:					
Money market funds	Cash and cash equivalents	$ 487,471	$ 487,471	$ —	$ —
Total assets		$ 487,471	$ 487,471	$ —	$ —

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 September 30, 2017, the carrying value of the Convertible Notes, net of unamortized discount and debt issuance costs, was $140.4 million and the estimated fair value of the principal amount was $751.4 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 is revising 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 12, "Revenue Recognition".

Intangible Assets

The Company maintains definite-lived intangible assets related to milestone payments made to third parties subsequent to regulatory approval for acquired and in-licensed product candidates. These assets are amortized over their remaining useful lives, which are generally estimated to be the remaining patent life. If the Company's estimate of the product's useful life is shorter than the remaining patent life, then the shorter period is used. Intangible assets are amortized using the economic consumption method if anticipated future revenues can be reasonably estimated. The straight-line method is used when future revenues cannot be reasonably estimated, with a cumulative catch-up of

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

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 September 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	$ 1,326	$ 2,799	$ (1,473)
License, collaboration and other revenues	15,661	931	14,730
Cost of sales – product	378	424	(46)
Loss from operations	(84,263)	(97,566)	13,303
Net loss	(87,850)	(101,153)	13,303
Net loss per share applicable to common stockholders - basic and diluted	$ (1.72)	$ (1.98)	$ 0.26

	Nine months ended September 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	$ 2,844	$ 4,408	$ (1,564)
License, collaboration and other revenues	50,253	36,190	14,063
Cost of sales – product	691	738	(47)
Loss from operations	(226,607)	(239,153)	12,546
Net loss	(237,984)	(250,530)	12,546
Net loss per share applicable to common stockholders - basic and diluted	$ (5.17)	$ (5.45)	$ 0.28

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

	Nine months ended September 30, 2016 (in thousands)		
	As revised under Topic 606	As originally reported under Topic 605	Effect of change
Net loss	$ (237,984)	$ (250,530)	$ 12,546
Adjustments to reconcile net loss to net cash used in operating activities:			
Accounts receivable	(15,550)	(2,535)	(13,015)
Other assets	(4,551)	(4,512)	(39)
Accrued expenses	15,628	15,698	(70)
Deferred revenues	562	(16)	578
Cash and cash equivalents at beginning of period	230,146	230,146	—
Cash and cash equivalents at end of period	$ 647,315	$ 647,315	$ —

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 up-front, 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 the three months ended September 30, 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 12, "Revenue Recognition" and Note 13, "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 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 Nine Months Ended September 30,	
	2016	2017
Outstanding stock options and Employee Stock Purchase Plan	7,045	7,033
Unvested restricted stock units	666	1,174
Shares issuable upon conversion of Convertible Notes	—	3,559
	7,711	11,766

In September 2014, the Company issued Convertible Notes, which provide in certain situations for the conversion of the outstanding principal amount of the Convertible Notes into shares of the Company's common stock at a predefined conversion rate. See Note 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 September 30, 2016 and 2017.

4. Inventories

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

	December 31, 2016	September 30, 2017
Raw materials	$ 13,263	$ 31,685
Work in process	584	16,810
Finished goods	853	2,032
Total inventories	$ 14,700	$ 50,527

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.

As of September 30, 2017, the carrying value of the Convertible Notes, net of unamortized discount and debt issuance costs, was $140.4 million and the estimated fair value of the principal amount was $751.4 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 nine months ended September 30, 2016 and 2017 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2017	2016	2017
Contractual interest expense	$ 1,509	$ 1,509	$ 4,528	$ 4,528
Amortization of debt discount	2,460	2,779	7,236	8,172
Amortization of debt issuance costs	150	136	456	416
Total interest expense	$ 4,119	$ 4,424	$ 12,220	$ 13,116

6. Accrued Expenses

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

	December 31, 2016	September 30, 2017
	(as revised)	
Research and development	$ 36,759	$ 40,460
Salaries, bonuses and other compensation	20,654	29,699
Accrued inventory	—	27,032
Accrued royalty	2,059	4,116
Accrued other	9,228	21,769
Total accrued expenses	$ 68,700	$ 123,076

7. 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2017	2016	2017
Research and development	$ 5,605	$ 8,545	$ 13,826	$ 23,532
Selling, general and administrative	7,314	16,471	20,238	43,393
Total stock-based compensation expense	$ 12,919	$ 25,016	$ 34,064	$ 66,925

Stock Options

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

	Shares	Weighted-average exercise price per share
Outstanding at December 31, 2016	6,978,621	$ 40.65
Granted	674,707	162.02
Exercised	(552,720)	43.10
Cancelled	(86,563)	57.98
Outstanding at September 30, 2017	7,014,045	$ 51.92
Vested at September 30, 2017	3,987,711	$ 30.94

At September 30, 2017, there was approximately $127.1 million of unrecognized compensation cost related to unvested stock options, which the Company expects to recognize over a remaining weighted-average period of 2.3 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	617,181	166.42
Vested	(170,196)	50.87
Forfeited	(33,122)	101.80
Unvested restricted stock units at September 30, 2017	1,173,986	$ 115.15

At September 30, 2017, there was approximately $114.7 million of unrecognized compensation cost related to unvested RSUs, which the Company expects to recognize over a remaining weighted-average period of 3.0 years.

In July 2016, the Company issued 15,000 RSUs with service and performance conditions to certain employees, none of which vested during the three months ended September 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 $0.4 million and $0.9 million of related expense during the three and nine months ended September 30, 2017, respectively.

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 September 30, 2017, 176,561 shares remained available for issuance. During the nine months ended September 30, 2016 and 2017, the Company issued 25,225 and 17,684 shares under the 2012 ESPP, and recognized approximately $0.7 million and $1.4 million in related stock-based compensation expense, respectively.

8. 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.

In July 2016, the Company sold 5,347,500 shares of common stock, which included 697,500 shares pursuant to the full exercise of the underwriters' option, in an underwritten public offering at a price to the public of $81.00 per share, resulting in gross proceeds of approximately $433.1 million. Net proceeds to the Company after deducting fees, commissions and other expenses related to the offering were approximately $408.9 million. The shares were issued pursuant to an automatic shelf registration statement on Form S-3.

9. Income Taxes

Deferred tax assets and deferred tax liabilities are determined based on temporary differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some portion or all of the deferred tax assets will not be realized.

The Company does not recognize a tax benefit for uncertain tax positions unless it is more likely than not that the position will be sustained upon examination by tax authorities, including resolution of any related appeals or litigation processes, based on the technical merits of the position. The tax benefit that is recorded for these positions is measured at the largest amount of cumulative benefit that has greater than a 50 percent likelihood of being realized upon ultimate settlement. Deferred tax assets that do not meet these recognition criteria are not recorded and the Company recognizes a liability for uncertain tax positions that may result in tax payments. If such unrecognized tax benefits were realized and not subject to valuation allowances, the entire amount would impact the tax provision. As of September 30, 2017, the Company's uncertain tax positions were subject to valuation allowances.

The Company recorded provisions for income taxes for the three and nine months ended September 30, 2017 of $0.1 million and $0.3 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.

10. Intangible Assets

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

	December 31, 2016	September 30, 2017	Estimated useful life
Acquired and in-licensed rights	$ 15,000	$ 50,000	8-13 Years
Less accumulated amortization	(2,123)	(6,845)	
Total intangible assets, net	$ 12,877	$ 43,155	

The increase in acquired and in-licensed rights as of September 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 incurred upon the FDA approval of ZEJULA on March 27, 2017, and a milestone of $10.0 million paid to OPKO Health, Inc., which was incurred upon the first commercial sale of VARUBY in Europe in May 2017.

The Company recorded $0.5 million and $1.3 million in amortization expense related to intangible assets during the three months ended September 30, 2016 and 2017, respectively, and $1.4 million and $4.7 million during the nine months ended September 30, 2016 and 2017, respectively. Estimated future amortization expense for intangible assets as of September 30, 2017 is $1.3 million for the remainder of 2017, $5.0 million per year for 2018, 2019, 2020, and 2021, and $21.8 million thereafter.

11. 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 September 30, 2017 were $1.6 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.

12. 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 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 received insignificant returns to date and believes that returns of its products will continue to 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.

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 $1.3 million and $41.8 million for the three months ended September 30, 2016 and 2017, respectively. These totals included $1.3 million and $2.4 million from sales of VARUBI/VARUBY, respectively, and zero and $39.4 million from sales of ZEJULA, respectively. Total net product revenue was $2.8 million and $72.7 million for the nine months ended September 30, 2016 and 2017, respectively. These totals included $2.8 million and $7.4 million from sales of VARUBI/VARUBY, respectively, and zero and $65.3 million from sales of ZEJULA, respectively. The following table summarizes activity in each of the product revenue allowance and reserve categories for the nine months ended September 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	1,143	798	5	1,946
Adjustment related to prior period sales	—	—	—	—
Credit or payments made during the period	(1,622)	(547)	—	(2,169)
Balance at September 30, 2016	$ 334	$ 673	$ 13	$ 1,020
Balance at December 31, 2016	$ 177	$ 1,312	$ 18	$ 1,507
Provision related to current period sales	6,567	6,924	155	13,646
Adjustment related to prior period sales	—	62	—	62
Credit or payments made during the period	(5,906)	(4,311)	—	(10,217)
Balance at September 30, 2017	$ 838	$ 3,987	$ 173	$ 4,998

License, Collaboration and Other Revenues

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

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. 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 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 nine months ended September 30, 2016 (as revised) and 2017 (in thousands):

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Nine months ended September 30, 2016				
Contract assets	$ 1,000	$ —	$ —	$ 1,000
Contract liabilities:				
Deferred revenue	$ 92	$ 653	$ (90)	$ 655
Nine months ended September 30, 2017				
Contract assets	$ 1,000	$ —	$ —	$ 1,000
Contract liabilities:				
Deferred revenue	$ 400	$ —	$ (70)	$ 330

During the three and nine months ended September 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 September 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	$ —	$ —

	Nine Months Ended September 30,	
Revenue recognized in the period from:	**2016**	**2017**
Amounts included in the contract liability at the beginning of the period	$ 45	$ 70
Performance obligations satisfied in previous periods	$ —	$ —

13. License and Collaboration Arrangements

Out-Licenses

Takeda Pharmaceutical Co., Ltd.

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

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

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

The Company evaluated the Takeda 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 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 these amounts have been determined to relate predominantly to the license granted to Takeda and therefore are recognized at the later of when the performance obligation is satisfied or the related sales occur. The Company considered Takeda's right to sublicense and manufacture certain niraparib products, 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 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. 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 three months ended September 30, 2017, the Company allocated $100.0 million of the transaction price to the license and recognized this amount as revenue concurrent with the transfer of the license. Revenue associated with the initial supply of niraparib materials will be recognized when delivered to Takeda. Under the Takeda Agreement, for the three and nine months ended September 30, 2017, the Company recognized $100.0 million within license, collaboration and other revenues in its consolidated statements of operations and comprehensive loss.

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).

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 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 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 September 30, 2017, the Company had recognized $34.7 million as license and collaboration revenue under the Collaboration Agreement. The remaining transaction price of $0.3 million is recorded in deferred revenue as of September 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 nine months ended September 30, 2017, the Company recognized $0.9 million and $2.5

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.

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.

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 12 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 nine months ended September 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 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 nine months ended September 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 nine months ended September 30, 2017, the Company incurred $2.6 million and $6.5 million in external costs related to this study, of which $1.2 million and $3.2 million is reimbursable by Merck, respectively. At September 30, 2017, $2.3 million of cost-sharing receivable from Merck has been recorded in other current assets on the condensed consolidated balance sheets.

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 ZEJULA® (niraparib) in the U.S., and VARUBI®/VARUBY® (the oral formulation of rolapitant) in the U.S. and Europe, and the expected timing of launch of the intravenous, or IV, formulation of rolapitant in the U.S.; the potential timing of launch of ZEJULA in Europe; 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, risks related to competition, 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.

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. In October 2017, the United States Food and Drug Administration, or FDA, approved our new drug application, or NDA, for the intravenous, or IV, formulation of rolapitant. We expect to commence sales of VARUBI IV in the U.S. in the fourth quarter of 2017. 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.

- *Niraparib* is an orally active and potent poly (ADP-ribose) polymerase, or PARP, inhibitor. On March 27, 2017, the FDA approved ZEJULA (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, or MAA, for niraparib for the maintenance treatment of patients with platinum-sensitive, recurrent ovarian cancer who are in response to platinum-based chemotherapy, to the European Medicines Agency, or EMA. In September 2017, the EMA's Committee for Medicinal Products for Human Use rendered a positive opinion for this MAA. Pending final approval by the European Commission, we intend to commence the launch of ZEJULA in the European Union by the end of 2017, on a country-by-country basis. 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 August 2017, we commenced the dosing of the first patient in a Phase 1, dose escalation study for our third immuno-oncology antibody, TSR-033, which targets LAG-3. 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.

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 the TOPACIO trial to evaluate the preliminary safety and efficacy of niraparib plus KEYTRUDA® in patients with triple negative breast cancer and patients with ovarian cancer. Enrollment of the TOPACIO trial is now complete in both cohorts.

- 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 13, "License and Collaboration Arrangements" in the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

As of September 30, 2017, we had an accumulated deficit of $1.3 billion. Our net losses were $314.1 million, $374.2 million, $247.7 million, and $171.0 million for the nine months ended September 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 launches and commercialization of VARUBI and ZEJULA; (ii) the advancement of clinical trial and other development and regulatory activities under our current development programs for 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. For example, if our MAA for niraparib is approved, we will owe a $15.0 million milestone payment to Merck Sharp & Dohme Corp., a subsidiary of Merck. 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, 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 September 30, 2017, our principal source of liquidity was cash and cash equivalents, which totaled $521.3 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 September 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 Takeda, Janssen, Zai Lab and Hengrui. Takeda has licensed the rights to develop and commercialize niraparib for the treatment of all tumor types in Japan, and all tumor types excluding prostate cancer in certain other specified countries. Janssen has licensed the rights to develop, manufacture and commercialize niraparib worldwide (except for Japan) for the treatment of prostate cancer. Zai Lab has licensed the rights to develop and commercialize niraparib for 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:

- 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;
- pre-commercial license fees and milestone payments related to the acquisition of in-licensed product candidates, which are reported on our statements of operations as acquired in-process research and development;
- fees and costs related to regulatory filings and 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.

Research and development costs are expensed as incurred. License fees and development milestone payments related to in-licensed products and technology are expensed as acquired in-process research and development if it is determined at that point that they have no established alternative future use. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations and information provided to us by our vendors.

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

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

	Nine Months Ended September 30,	
	2016 (as revised)	2017
Rolapitant Expenses		
Acquired in-process research and development	$ —	$ —
Research and development	13,018	7,825
Rolapitant total	13,018	7,825
Niraparib Expenses		
Acquired in-process research and development	940	—
Research and development	72,758	63,629
Niraparib total	73,698	63,629
Immuno-Oncology Platform Expenses		
Acquired in-process research and development	9,000	7,000
Research and development	23,034	41,925
Immuno-Oncology Platform total	32,034	48,925
Personnel and Other Expenses	54,820	97,531
Total	**$ 173,570**	**$ 217,910**

For further discussion of the changes in our research and development expenses with respect to the nine months ended September 30, 2017 and the corresponding period of 2016, see "Results of Operations — Comparison of the Nine Months Ended September 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, 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.

Results of Operations

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

(data in thousands)	Three Months Ended September 30, 2016 (as revised)	2017	Increase/ (Decrease)
Revenues:			
Product revenue, net	$ 1,326	$ 41,755	$ 40,429
License, collaboration and other revenues	15,661	101,011	85,350
Total revenues	16,987	142,766	125,779
Expenses:			
Cost of sales – product	378	6,216	5,838
Cost of sales – intangible asset amortization	464	1,254	790
Research and development	60,783	73,388	12,605
Selling, general and administrative	37,685	83,998	46,313
Acquired in-process research and development	1,940	—	(1,940)
Total expenses	101,250	164,856	63,606
Loss from operations	(84,263)	(22,090)	62,173
Other income (expense), net	(3,587)	(3,048)	539
Loss before income taxes	(87,850)	(25,138)	62,712
Provision for income taxes	—	139	139
Net loss	$ (87,850)	$ (25,277)	$ 62,573

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 September 30, 2016 and 2017, respectively (in thousands).

	Three months ended September 30, 2016 (as revised)	2017	Change
ZEJULA (U.S. only)	$ —	$ 39,375	$ 39,375
VARUBI/VARUBY			
U.S.	1,326	2,334	1,008
International	—	46	46
Total	1,326	2,380	1,054
Product revenue, net	$ 1,326	$ 41,755	$ 40,429

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 September 30, 2017, the average net sales price per unit to us was approximately 89% 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 September 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. The average net sales price per unit to us was approximately 52% of WAC for the three months ended September 30, 2017 as compared to 58% of WAC for the same period in 2016.

License, Collaboration and Other Revenues. License, collaboration and other revenues of $15.7 million for the three months ended September 30, 2016 were primarily related to an up-front license payment of $15.0 million from Zai Lab, which was substantially recognized as license revenue during the period. License, collaboration and other revenues of $101.0 million for the three months ended September 30, 2017 primarily relate to the $100.0 million up-front payment we received under our license agreement with Takeda.

Cost of Sales - Product. Cost of sales of $0.4 million and $6.2 million for the three months ended September 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 September 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 $1.3 million for the three months ended September 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 nine months ended September 30, 2017: a $25.0 million milestone incurred upon the FDA approval of ZEJULA, and a $10.0 million milestone incurred upon the first commercial sale of VARUBY in Europe.

Research and Development Expenses. Research and development expenses were $60.8 million for the three months ended September 30, 2016, compared to $73.4 million for the three months ended September 30, 2017, an increase of $12.6 million. Significant changes resulting in this increase included:

- an increase of $11.1 million in personnel and other costs (excluding stock-based compensation), primarily related to increased research and development headcount supporting the growth of our development activities;
- an increase of $6.2 million in costs associated with our immuno-oncology platform due to increased costs related to the TSR-042 clinical trials, biologics manufacturing and non-clinical and other immuno-oncology program research activities; and
- a decrease of $5.5 million in costs associated with our niraparib program, primarily related to manufacturing costs, due to our policy of expensing such costs prior to regulatory approval and capitalizing such costs thereafter.

In addition, stock-based compensation expense included in research and development expenses increased by $2.9 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 $37.7 million for the three months ended September 30, 2016, compared to $84.0 million for the three months ended September 30, 2017, an increase of $46.3 million. The increase was primarily due to increases of: $18.8 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; $18.3 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 $9.2 million in stock-based compensation expense.

Acquired In-Process Research and Development. Acquired in-process research and development expenses for the three months ended September 30, 2016 were $1.9 million, comprised of a $1.0 million milestone to AnaptysBio and a $0.9 million milestone to Merck. There were no acquired in-process research and development expenses for the three months ended September 30, 2017.

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 $0.6 million during the three months ended September 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.

Comparison of the Nine Months Ended September 30, 2016 and 2017

(data in thousands)	Nine Months Ended September 30, 2016 (as revised)	2017	Increase/ (Decrease)
Revenues:			
Product revenue, net	$ 2,844	$ 72,723	$ 69,879
License, collaboration and other revenues	50,253	102,580	52,327
Total revenues	53,097	175,303	122,206
Expenses:			
Cost of sales – product	691	10,280	9,589
Cost of sales – intangible asset amortization	1,391	4,723	3,332
Research and development	163,630	210,910	47,280
General and administrative	104,052	246,239	142,187
Acquired in-process research and development	9,940	7,000	(2,940)
Total expenses	279,704	479,152	199,448
Loss from operations	(226,607)	(303,849)	(77,242)
Other income (expense), net	(11,377)	(9,941)	1,436
	(237,984)	(313,790)	(75,806)
Provision for income taxes	—	271	271
Net loss	$ (237,984)	$ (314,061)	$ (76,077)

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

	Nine months ended September 30, 2016 (as revised)	2017	Change
ZEJULA (U.S. only)	$ —	$ 65,321	$ 65,321
VARUBI/VARUBY			
U.S.	2,844	7,353	4,509
International	—	49	49
Total	2,844	7,402	4,558
Product revenue, net	$ 2,844	$ 72,723	$ 69,879

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 nine months ended September 30, 2017, the average net sales price per unit to us was approximately 89% 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 nine months ended September 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 55% of WAC for the nine months ended September 30, 2017 as compared to 59% of WAC for the same period in 2016.

License, Collaboration and Other Revenues. License, collaboration and other revenues of $50.3 million for the nine months ended September 30, 2016 were primarily related to up-front license payments of $35.0 million from Janssen and $15.0 million from Zai Lab, which were substantially recognized as license revenue during the period. License, collaboration and other revenues of $102.6 million for the nine months ended September 30, 2017 primarily relate to the $100.0 million up-front payment we received under our license agreement with Takeda.

Cost of Sales - Product. Cost of sales of $0.7 million and $10.3 million for the nine months ended September 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 $1.4 million and $4.7 million for the nine months ended September 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 nine months ended September 30, 2017: a $25.0 million milestone incurred upon the FDA approval of ZEJULA, and a $10.0 million milestone incurred upon the first commercial sale of VARUBY in Europe.

Research and Development Expenses. Research and development expenses were $163.6 million for the nine months ended September 30, 2016, compared to $210.9 million for the nine months ended September 30, 2017, an increase of $47.3 million. Significant changes resulting in this increase included:

- an increase of $34.1 million in personnel and other costs (excluding stock-based compensation), primarily related to increased research and development headcount supporting the growth of our development activities;
- an increase of $18.9 million in costs associated with our immuno-oncology platform due to increased costs related to the TSR-042 clinical trials, biologics manufacturing and non-clinical and other immuno-oncology program research activities; and
- a decrease of $9.1 million in costs associated with our niraparib program, primarily related to manufacturing costs, due to our policy of expensing such costs prior to regulatory approval and capitalizing such costs thereafter.

In addition, stock-based compensation expense included in research and development expenses increased by $9.7 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 $104.1 million for the nine months ended September 30, 2016, compared to $246.2 million for the nine months ended September 30, 2017, an increase of $142.1 million. The increase was primarily due to increases of: $53.7 million in salaries, benefits and other personnel-related costs (excluding stock-based compensation), primarily due to the hiring of sales, marketing, medical affairs and other support personnel associated with the commercialization of VARUBI and ZEJULA, plus hiring to support our international operations; $65.3 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 $23.2 million in stock-based compensation expense.

Acquired In-Process Research and Development. Acquired in-process research and development expenses were $9.9 million for the nine months ended September 30, 2016, comprised of $9.0 million in milestones to AnaptysBio and a $0.9 million milestone to Merck. Acquired in-process research and development expenses for the nine months ended September 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 $2.1 million during the nine months ended September 30, 2017, primarily due to higher balances of interest-bearing cash equivalents. Interest expense increased by $0.9 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 September 30, 2017, our principal source of liquidity was cash and cash equivalents, which totaled $521.3 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 through September 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. We also received an up-front license fee of $100.0 million from Takeda relating to the niraparib out-license agreement during the three months ended September 30, 2017.

Cash Flows

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

	Nine Months Ended September 30,	
	2016 (as revised)	2017
Net cash provided by (used in):		
Operating activities	$ (204,496)	$ (243,185)
Investing activities	(10,940)	(47,766)
Financing activities	632,605	25,841
Effect of exchange rate changes on cash and cash equivalents	—	498
Increase (decrease) in cash and cash equivalents	$ 417,169	$ (264,612)

Cash Flows from Operating Activities

The use of cash in operating activities during both the nine months ended September 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 $38.7 million for the nine months ended September 30, 2017 compared to the nine months ended September 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 offset by a $100.0 million up-front license payment received in August 2017 from Takeda and a $35.0 million up-front license payment received from Janssen in April 2016.

Cash Flows from Investing Activities

The increase of $36.8 million in net cash used in investing activities for the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016 was due primarily to $42.0 million in milestones paid during the current year period, compared to $9.0 million in milestones paid during the prior year period. The current year period included a $25.0 million milestone related to the 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 $9.0 million in immuno-oncology development milestones. In addition, cash used for purchases of property and equipment increased from $1.8 million to $4.9 million, primarily due to the expansion of the leased office space at our U.S. headquarters.

Cash Flows from Financing Activities

The decrease of $606.8 million in net cash provided by financing activities for the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016 was primarily due to cash proceeds of $613.9 million from the closing of our March 2016 and April 2016 private placements of common stock and our July 2016 public offering of common stock. There were no similar financing transactions in the nine months ended September 30, 2017. In addition, cash proceeds from exercises of stock options and purchases under our Employee Stock Purchase Plan increased from $18.7 million in the prior year period to $25.8 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 for 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 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 clinical trials for niraparib and immuno-oncology assets;
- 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
- 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 September 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 are revising 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 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 received insignificant returns to date and believe that returns of our products will continue to 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 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 nine months ended September 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	1,143	798	5	1,946
Adjustment related to prior period sales	—	—	—	—
Credit or payments made during the period	(1,622)	(547)	—	(2,169)
Balance at September 30, 2016	$ 334	$ 673	$ 13	$ 1,020
Balance at December 31, 2016	$ 177	$ 1,312	$ 18	$ 1,507
Provision related to current period sales	6,567	6,924	155	13,646
Adjustment related to prior period sales	—	62	—	62
Credit or payments made during the period	(5,906)	(4,311)	—	(10,217)
Balance at September 30, 2017	$ 838	$ 3,987	$ 173	$ 4,998

License, Collaboration and Other Revenues

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 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 nine months ended September 30, 2016 (as revised) and 2017 (in thousands):

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Nine months ended September 30, 2016				
Contract assets	$ 1,000	$ —	$ —	$ 1,000
Contract liabilities:				
Deferred revenue	$ 92	$ 653	$ (90)	$ 655
Nine months ended September 30, 2017				
Contract assets	$ 1,000	$ —	$ —	$ 1,000
Contract liabilities:				
Deferred revenue	$ 400	$ —	$ (70)	$ 330

During the three and nine months ended September 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 September 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	$ —	$ —

	Nine Months Ended September 30,	
Revenue recognized in the period from:	**2016**	**2017**
Amounts included in the contract liability at the beginning of the period	$ 45	$ 70
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 September 30, 2017 and December 31, 2016, we had cash and cash equivalents of $521.3 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 September 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

During the fiscal quarter covered by this report, we implemented a new enterprise resource planning, or ERP, system which is expected to improve the efficiency of certain financial and related transaction processes. This system provides functionality to effectively support our expanding global operations. This implementation has resulted in certain business and operational changes. In connection with the implementation, we updated processes that are part of our internal control over financial reporting to accommodate related changes to our accounting procedures and business processes. Otherwise, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter covered by this report that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

An investment in our stock involves a high degree of risk. You should carefully consider the 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 no revenue from VARUBI IV, and our only other late clinical-stage product candidate, niraparib in additional indications, has 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, 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 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;
- 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, 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 VARUBI IV. 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.

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.

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

The development and commercialization of new drug products is highly competitive. We face substantial competition with respect to VARUBI in both oral and IV formulation. VARUBI competes with EMEND, an NK-1 receptor antagonist marketed by Merck, as well as AKYNZEO, an oral combination NK-1 receptor antagonist and 5-HT_3 receptor antagonist (netupitant plus ALOXI (palonosetron HCl)) that is marketed by Helsinn Healthcare, and Sandoz's generic version of aprepitant. Additionally, Heron Therapeutics has filed with the FDA for approval of its aprepitant IV formulation product, CINVANTI™. VARUBI would face additional competition if additional generics are introduced to the market, or other products are developed and approved, for the treatment and prevention of CINV, or if an IV formulation of AKYNZEO is developed.

There are a number of large pharmaceutical and biotechnology companies that market and sell products or are pursuing the development of products that we expect will compete with ZEJULA. There are currently two commercially available PARP inhibitors. AstraZeneca Plc's LYNPARZA™ (olaparib) was initially approved by the FDA for use by ovarian cancer patients with a germline BRCA mutation who have been treated with three or more prior lines of chemotherapy, and also by the European Commission following a positive opinion by the EMA for use as a monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy. LYNPARZA was granted a new approval in August 2017 by the FDA for use as a maintenance treatment for recurrent, epithelial ovarian, fallopian tube or primary peritoneal adult cancer who are in response to platinum-based chemotherapy, regardless of BRCA status. Clovis Oncology, Inc.'s RUBRACA™ (rucaparib) was approved in December 2016 by the FDA for use as a monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. Clovis has also filed with the FDA for expanded approval of RUBRACA as a second-line and later maintenance treatment for all women with ovarian cancer who have responded to their latest treatment with platinum chemotherapy, regardless of BRCA status, and has filed for initial approval with the European Commission for advanced ovarian cancer in patients with a deleterious BRCA-mutation. We believe the additional products in clinical development targeting the PARP pathway consist of: Pfizer's talazoparib (MDV3800) and AbbVie's ABT-888 (veliparib), both currently in Phase 3 clinical trials; Eisai, Inc.'s E-7016 and E-7449, currently in Phase 2 and Phase 1/2 clinical trials, respectively; and AbbVie's ABT-767, BeiGene/EMD Serono (Merck KGaA)'s BGB-290, Checkpoint Therapeutics' CK-102 (formerly CEP-9722) and Hengrui's fluzoparib, each currently in Phase 1 clinical trials. Both LYNPARZA and rucaparib have received "orphan drug designation" from the EMA, which provides certain benefits including market exclusivity for up to ten years in the approved indication post-approval. In addition to other PARP inhibitors, ZEJULA also competes with AVASTIN™ (bevacizumab), Roche's angiogenesis inhibitor, which received an expanded FDA approval in 2016 to treat patients with platinum-sensitive recurrent ovarian cancer as a part of a combination regimen with chemotherapy, and has been approved by the European Commission since 2011 for treatment of women with recurrent ovarian cancer with platinum-containing chemotherapy.

A number of pharmaceutical and biotechnology companies are also pursuing the development of cancer immunotherapies that may compete with our immunotherapy product candidates. We are aware of several companies that have antibody-based products on the market or in clinical development that are directed at the same biological targets as some of our collaboration programs with AnaptysBio, and several other companies with immuno-oncology antibodies or programs in the preclinical or research phase. For further detail on the specific competition that VARUBI, ZEJULA and our product candidates face, see Part I, Item 1, "Business – Competition" of our Annual Report on Form 10-K for the year ended December 31, 2016.

Many of the approved drugs with which our products or product candidates may compete are well-established therapies or products and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. Any of our product candidates that are approved may be priced at a significant premium over competitive generic products. This may make it difficult for us to execute our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product candidates.

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

Item 6. Exhibits.

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

EXHIBIT INDEX

Exhibit Number	Exhibit Description
10.1*	Exclusive License Agreement, dated July 27, 2017, by and between the Company and Millennium Pharmaceuticals, Inc.
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
EX-101.INS	XBRL Instance Document
EX-101.SCH	XBRL Taxonomy Extension Schema Document
EX-101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
EX-101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
EX-101.LAB	XBRL Taxonomy Extension Label Linkbase Document
EX-101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* 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.

SIGNATURES

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

TESARO, INC.

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

Date: November 7, 2017

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

Date: November 7, 2017

Exhibit 10.1

EXCLUSIVE LICENSE AGREEMENT

by and between

TESARO, INC.

and

MILLENNIUM PHARMACEUTICALS, INC.

Dated as of July 27, 2017

EXCLUSIVE LICENSE AGREEMENT

This EXCLUSIVE LICENSE AGREEMENT (this "**Agreement**") is entered into as of July 27, 2017 (the "**Effective Date**") by and between TESARO, INC., a Delaware corporation having an address at 1000 Winter Street, Suite 3300, Waltham, Massachusetts 02451, U.S.A. ("**TESARO**"), and MILLENNIUM PHARMACEUTICALS, INC., a Delaware corporation and wholly-owned subsidiary of Takeda Pharmaceutical Company Limited having an address at 40 Landsdowne Street, Cambridge, MA 02139, U.S.A ("**Licensee**"). TESARO and Licensee are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, TESARO is an oncology-focused biopharmaceutical company which owns or controls certain intellectual property rights related to niraparib, a proprietary poly (ADP-ribose) polymerase, or PARP, inhibitor;

WHEREAS, Licensee desires to license from TESARO such intellectual property rights in the Licensed Territory, and to commercially develop, manufacture, use and sell the Product (as hereinafter defined) based upon the same throughout the Licensed Territory; and

WHEREAS, TESARO desires to grant such a license to Licensee on the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the premises and the mutual promises and covenants contained in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

ARTICLE 1. DEFINITIONS

All references to particular Exhibits, Articles or Sections shall mean the Exhibits to, and Articles and Sections of, this Agreement, unless otherwise specified. For the purposes of this Agreement and the Exhibits hereto, the following words and phrases shall have the following meanings:

Section 1.1 "**Accounting Standards**" means U.S. generally accepted accounting principles or International Financial Reporting Standards, consistently applied.

Section 1.2 "**Additional Materials**" shall have the meaning set forth in Section 2.4.2(a).

Section 1.3 "**Affiliate**" means, with respect to any Person, any other Person which controls, is controlled by or is under common control with such Person, now or in the future, for as long as such control exists. For purposes of this Section, "control" shall mean the direct or indirect ownership of more than fifty percent (50%) of the voting or economic interest of a Person,

or the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of a Person. For clarity, once a Person ceases to be an Affiliate of a Party, then, without any further action, such Person shall cease to have any rights, including license and sublicense rights, under this Agreement by reason of being an Affiliate of such Party. For any avoidance of doubt, the Parties acknowledge and agree that, as of the Effective Date, [***] (collectively "[***]") are not Affiliates of Licensee under the foregoing definition.

Section 1.4 "**Affordable Basis**" means making a product available to patients for no more than [***]. In determining Affordable Basis, the Parties recognize that, to the extent that a Party engages a Third Party in the Commercialization of a product on an Affordable Basis in a country, such Third Party shall be entitled to a reasonable profit margin that is customary in the generic drug industry for that country; provided, that the applicable Party uses commercially reasonable efforts to minimize such Third Party profits.

Section 1.5 "**Agreement**" shall have the meaning set forth in the preamble.

Section 1.6 "**Alliance Manager**" shall have the meaning set forth in Section 5.1.7.

Section 1.7 "**Anti-Corruption Laws**" means all applicable Laws, conventions and international financial institution rules regarding corruption, bribery, ethical business conduct, money laundering, political contributions, gifts and gratuities, or lawful expenses to public officials and private persons, agency relationships, commissions, lobbying, books and records, and financial controls.

Section 1.8 "**Audited Party**" shall have the meaning set forth in Section 3.9.

Section 1.9 "**Authorized Generic Product**" means, subject to TESARO's approval right under Section 6.5.1(e), a Product authorized by Licensee to be sold by [***], in accordance with [***].

Section 1.10 "**AZ Agreements**" means the following agreements between TESARO and AstraZeneca UK Limited ("**AZ**"), as amended from time to time: the Patent License Agreement, dated October 4, 2012, between AZ (the Institute of Cancer Research) and TESARO; and the Patent License Agreement, dated October 4, 2012, between AZ (University of Sheffield) and TESARO.

Section 1.11 "**Bulk Product**" means (a) for clinical purposes, (i) the Product and placebo (as necessary) in unlabeled bulk capsule form, or (ii) if available, the Product and placebo (as necessary) in tablet form, and (b) for commercial purposes, (i) the Product in unlabeled bulk capsule form, or (ii) if available, the Product in tablet form.

Section 1.12 "**Business Day**" means any day other than a day which is a Saturday, a Sunday or any day banks are authorized or required to be closed in the United States.

Section 1.13 "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31, for so long as this Agreement is in effect; provided, however, that (a) the first Calendar Quarter of the Term shall extend from the Effective Date until the end of the first full Calendar Quarter thereafter, and (b) the last Calendar Quarter of the Term shall end upon the expiration of this Agreement.

Section 1.14 "**Calendar Year** " means each successive period of twelve (12) months commencing on January 1 and ending on December 31, for so long as this Agreement is in effect; provided, however, that (a) the first Calendar Year of the Term shall commence on the Effective Date and end on December 31, 2017, and (b) the last Calendar Year of the Term shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.

Section 1.15 "**Commercialization**" with respect to a product shall mean any and all activities directed to the marketing, promotion, distribution, offering for sale and selling such product, importing and exporting such product for sale, and interacting with Regulatory Authorities regarding the foregoing. Cognates of the word "**Commercialization**" shall have correlative meanings.

Section 1.16 "**Competing Activities**" shall have the meaning set forth in Section 6.5.1(d).

Section 1.17 "**Compound API**" means the active pharmaceutical ingredient for the Licensed Compound.

Section 1.18 "**Confidential Information**" shall have the meaning set forth in Section 8.1.1.

Section 1.19 "**Control**" or "**Controlled**" means the possession of the right to grant licenses or sublicenses or to disclose proprietary or trade secret information without violating the terms of any agreement or other arrangement with a Third Party and without misappropriating or infringing the proprietary or trade secret information of a Third Party or being obligated to pay any royalties or other consideration therefor.

Section 1.20 "**Cover**" means, with respect to a Patent Right, an invention that, in the absence of ownership of, or a license under, such Patent Right, the practice of such invention would infringe a Valid Claim of such Patent Right (including in the case of a Patent Right that is a patent application prosecuted in good faith, a Valid Claim of such patent application as if such patent application were an issued patent). Cognates of the word "**Cover**" shall have correlative meanings.

Section 1.21 "**Defending Party**" shall have the meaning set forth in Section 4.3.

Section 1.22 "**Designee**" shall have the meaning set forth in Section 9.5(d).

Section 1.23 "**Development**" or "**Develop**" means all preclinical and development activities and all clinical drug development activities, including, among other things: drug discovery, toxicology, formulation, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining and maintaining Marketing Approval (including, without limitation, post-Marketing Approval studies), and regulatory affairs related to all of the foregoing. Cognates of the word "**Development**" shall have correlative meanings.

Section 1.24 "**Development Plan**" shall have the meaning set forth in Section 5.2.

Section 1.25 "**Diligent Efforts**" means the performance of obligations or tasks in a manner consistent with the reasonable practices of companies in the biopharmaceutical industry having similar financial resources for the Development or Commercialization (as applicable) of a product having similar technical and regulatory factors and similar market potential, profit potential and strategic value, and that is at a similar stage in its Development or product life cycle as the Product, in each case based on conditions then prevailing and without regard to any competitive internal program of Licensee. Diligent Efforts requires that the Party (a) promptly assign responsibility for such obligations to specific employees who are held accountable for progress and monitoring such progress on an ongoing basis, (b) set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations, and (c) consistently make and implement decisions and allocate adequate resources designed to advance progress with respect to such obligations.

Section 1.26 "**Drug Re-Examination Period**" means the Japanese Ministry of Health, Labour and Welfare's inspection period as set forth in Article 14-4 of the Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.

Section 1.27 "**Effective Date**" shall have the meaning set forth in the Preamble.

Section 1.28 "**Excluded CMOs**" shall have the meaning set forth in Section 5.9.3.

Section 1.29 "**Executive Officers**" means (a) with respect to TESARO, the President, or his or her designee, and (b) with respect to Licensee, President, Global Oncology Business Unit, or his or her designee.

Section 1.30 "**Expiration Event**" has the meaning set forth in Section 6.5.1(e).

Section 1.31 "**FCPA**" means the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et seq.) as amended.

Section 1.32 "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

Section 1.33 "**First Commercial Sale**" means, with respect to a country in the Licensed Territory, the first sale of commercial quantities of a Product in such country to a Third Party on

arm's length terms by Licensee, its Affiliate or Sublicensee for use in the Licensed Field after receipt of Marketing Approval in such country. Sales for test marketing, sampling and promotional uses, clinical trial purposes, early access programs or compassionate or similar use shall not be considered to constitute a First Commercial Sale; provided, that any sale of a Product for any amount greater than an Affordable Basis for early access programs or compassionate or similar use shall constitute a First Commercial Sale.

Section 1.34 "**Generic Competition**" with respect to a particular Product, on a country-by-country basis, shall exist if during any [***] in such country there is one or more Generic Products with respect to a Product being sold in such country and the sales of such Generic Product(s) accounts for [***] of aggregate unit sales of the Product and its Generic Products in the given country during such [***] as determined by reference to applicable sales data obtained from QuintilesIMS or from such other reasonable Third Party source for such sales data. For clarity, a Generic Product marketed or sold by or on behalf of Licensee, a member of the Takeda Group or [***] shall not qualify as a Generic Product for purposes of determining whether Generic Competition exists.

Section 1.35 "**Generic Product**" means, with respect to a particular Product that has received Marketing Approval in a country, a product sold by a Third Party in such country that (a) has been approved as a generic drug of that Product by the applicable Regulatory Authority, or (b) is sold for use by human patients for the same indication as the Product and has the same active pharmaceutical ingredient, dosage form, strength, quality, direction and dose as the Product. For clarity, a "**Generic Product**" is not an Authorized Generic Product.

Section 1.36 "**Governmental Authority**" means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.

Section 1.37 "**Infringement**" means any infringement as determined by Law, including, without limitation, direct infringement, contributory infringement or any inducement to infringe. Cognates of the word "**Infringement**" shall have correlative meanings.

Section 1.38 "**Infringer**" shall have the meaning set forth in Section 4.2.1.

Section 1.39 "**Initial Materials**" shall have the meaning set forth in Section 2.4.2(a).

Section 1.40 "**Insolvency Event**" means, in relation to either Party, any of the following: (a) that Party becomes unable to, or shall admit in writing its inability to, pay its debts as they become due; (b) that Party shall commence any case, proceeding or other action (i) under any existing or future Law of any jurisdiction relating to bankruptcy, insolvency, reorganization or relief of debtors, seeking to have an order for relief entered with respect to it, or seeking to adjudicate it a bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, winding-up, liquidation, dissolution, composition or other relief with respect to it or its debts, or (ii) seeking appointment of a receiver, trustee, custodian, conservator or other similar official for it or for all

or any substantial part of its assets, or any such Party shall make a general assignment for the benefit of its creditors; (c) there shall be commenced against such Party any case, proceeding or other action of a nature referred to in clause (b) above that (I) results in the entry of an order for relief or any such adjudication or appointment or (II) remains undismissed, undischarged or unbonded for a period of sixty (60) days; (d) there shall be commenced against such Party any case, proceeding or other action seeking issuance of a warrant of attachment, execution, distraint or similar process against all or any substantial part of its assets that results in the entry of an order for any such relief that shall not have been vacated, discharged, or stayed or bonded pending appeal within sixty (60) days from the entry thereof; or (e) such Party shall take any action in furtherance of, or indicating its consent to, approval of, or acquiescence in, any of the acts set forth in clauses (b), (c) or (d) above.

Section 1.41 "**Janssen Agreement**" means that certain Collaboration and License Agreement, dated April 5, 2016, between TESARO and Janssen Biotech, Inc. ("**Janssen**"), as such agreement may be amended from time to time.

Section 1.42 "**Joint Steering Committee**" or "**JSC**" shall have the meaning set forth in Section 5.1.1.

Section 1.43 "**Know-How**" means techniques, technology, trade secrets, inventions (whether patentable or not), methods, know-how, data and results (including pharmacological, toxicological and clinical data and results), analytical and quality control data and results, regulatory documents, and other information, compositions of matter, cells, cell lines, assays, animal models and other physical, biological, or chemical material.

Section 1.44 "**Law**" means, individually and collectively, any and all laws, ordinances, rules, directives, administrative circulars and regulations of any kind whatsoever of any Governmental Authority within the applicable jurisdiction.

Section 1.45 "**Licensed Compound**" means TESARO's proprietary PARP Inhibitor known as Niraparib, having the chemical structure set forth in Exhibit A, and any pharmaceutically acceptable salt, polymorph, crystal form, prodrug or solvate thereof.

Section 1.46 "**Licensed Field**" means (a) in Japan, the treatment, diagnosis and prevention of any disease or conditions in humans, and (b) in South Korea, Taiwan, Russia and Australia, the treatment, diagnosis and prevention of any disease or conditions in humans, other than the treatment, diagnosis and prevention of prostate cancer.

Section 1.47 "**Licensed Know-How**" means all Know-How owned or Controlled by TESARO as of the Effective Date or that becomes owned or Controlled by TESARO at any time during the Term that is reasonably necessary for the Development, Manufacture or Commercialization of the Licensed Compound or Product in the Licensed Field in the Licensed Territory. Licensed Know-How does not include Licensed Patents.

Section 1.48 "**Licensed Patents**" means all Patent Rights owned or Controlled by TESARO as of the Effective Date or that become owned or Controlled by TESARO at any time during the Term that relate to the Licensed Field and the Licensed Territory and that Cover (a) the compositions of matter of the Licensed Compound or Product, (b) methods or processes directed to the Manufacture of the Licensed Compound or Product, or (c) methods of use, administration or formulation of the Licensed Compound or Product, including the Patent Rights set forth on Exhibit B hereto.

Section 1.49 "**Licensed Territory**" means (a) Japan, South Korea, Taiwan, Russia and Australia, and (b) such additional countries as may from time to time be added upon mutual written agreement of the Parties.

Section 1.50 "**Licensed Territory Filings and Approvals**" shall have the meaning set forth in Section 5.12.

Section 1.51 "**Licensee**" shall have the meaning set forth in the Preamble.

Section 1.52 "**Licensee Indemnified Parties**" shall have the meaning set forth in Section 7.1.1.

Section 1.53 "**Licensee Know-How**" means all Know-How owned or Controlled by Licensee or its Affiliates as of the Effective Date or during the Term that is reasonably necessary for the Development, Manufacture or Commercialization of the Licensed Compound or Product in the TESARO Territory for all uses. Licensee Know-How does not include Licensee Patents.

Section 1.54 "**Licensee Patents**" means all Patent Rights owned or Controlled by Licensee or its Affiliates as of the Effective Date or during the Term that relate to all uses in the TESARO Territory and that Cover (a) the compositions of matter of the Licensed Compound or Product, (b) methods or processes directed to the Manufacture of the Licensed Compound or Product, or (c) methods of use, administration or formulation of the Licensed Compound or Product.

Section 1.55 "**Losses**" shall have the meaning set forth in Section 7.1.1.

Section 1.56 "**Manufacture**" means all activities related to the manufacturing of a pharmaceutical product, or any ingredient thereof, including but not limited to test method development and stability testing, characterization, formulation, process development, manufacturing for use in non-clinical or clinical studies, manufacturing scale-up, quality assurance/quality control development, quality control testing (including in-process release and stability testing), packaging, release of product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of product, and regulatory activities related to all of the foregoing.

Section 1.57 "**Manufacturing Cost**" means a supplier's reasonable and necessary internal and Third Party costs incurred in Manufacturing or acquisition of product or a component thereof, determined in accordance with such supplier's standard cost accounting policies that are in accordance with Accounting Standards and consistently applied across such supplier's Manufacturing network to other products that such supplier Manufactures or acquires and shall not include inter-company profits among such supplier and its Affiliates. Costs included will be consistent with the activities outlined in the definition of "Manufacture."

Section 1.58 "**Marketing Approval**" means, with respect to the Licensed Compound or Product in a particular country or jurisdiction, all approvals (including where applicable, pricing and reimbursement approvals), registrations, licenses or authorizations from any Regulatory Authority that are necessary for the Manufacture, use, storage, import, marketing and sale of the Product in such country or jurisdiction.

Section 1.59 "**Milestone Events**" shall have the meaning set forth in Section 3.2.

Section 1.60 "**Milestone Payments**" shall have the meaning set forth in Section 3.2.

Section 1.61 "**Merck Agreement**" means that certain License Agreement, dated May 22, 2012, between TESARO and Merck, Sharp & Dohme Corp. ("**Merck**"), as amended by Amendment No. 1 to License Agreement, dated as of April 5, 2016, as such agreement may be further amended from time to time.

Section 1.62 "**Net Sales**" means the gross invoice price of Product sold by Licensee, its Affiliates or Sublicensees for the sales of such Product to a Third Party in the Licensed Territory after deducting, if not previously deducted and in accordance with Accounting Standards, from the amount invoiced:

(i) trade and quantity discounts other than early payment cash discounts;

(ii) returns, rebates, chargebacks and other allowances;

(iii) retroactive price reductions that are actually allowed or granted;

(iv) sales commissions paid to Third Party distributors and/or selling agents;

(v) deductions to gross invoice price of Product imposed by Regulatory Authorities or other governmental entities;

(vi) a fixed amount equal to three percent (3%) of the amount invoiced to cover bad debt, early payment cash discounts, transportation and insurance and custom duties; and

(vii) the standard inventory cost of devices or delivery systems used for dispensing or administering Product.

The sale of a Product on an Affordable Basis for early access programs, compassionate use or similar use shall not be considered a Net Sale.

Section 7.1 "**PARP Inhibitors**" means compounds having a primary mechanism of action that inhibits poly (ADP-ribose) polymerase.

Section 7.2 "**Party**" or "**Parties**" shall have the meaning set forth in the Preamble.

Section 7.3 "**Patent Challenge**" shall have the meaning set forth in Section 9.2.2.

Section 7.4 "**Patent Rights**" means any provisional and non-provisional patents and patent applications, together with all additions, divisions, continuations, continuations-in-part, substitutions, reissues, re-examinations, extensions, registrations, patent term extensions, supplemental protection certificates, renewals and foreign counterparts thereof.

Section 7.5 "**Permitted Distribution Activities**" shall have the meaning set forth in Section 2.7.2.

Section 7.6 "**Person**" means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

Section 7.7 "**Pharmacovigilance Agreement**" shall have the meaning set forth in Section 5.10.

Section 7.8 "**PMDA**" means the Pharmaceutical and Medical Devices Agency of Japan and any successor agency thereto.

Section 7.9 "**Post-Execution Affiliate**" shall have the meaning set forth in Section 6.5.1(d).

Section 7.10 "**Pre-Effective Date Wholesaler Agreements**" shall have the meaning set forth in Section 2.7.2.

Section 7.11 "**Primary Packaged Product**" means the Product that has been placed into a container closure system that is suitable for medicinal products, including among other types of containers, bottles and blister packs (also known as brite stock).

Section 7.12 "**Product**" means any pharmaceutical composition, dosage form or preparation that contains as its sole active ingredient the Licensed Compound.

Section 7.13 "**Regulatory Authority**" means any Governmental Authority or other authority responsible for granting Marketing Approvals for the Product.

Section 7.14 "**Regulatory Materials**" means materials developed or compiled in preparation for Regulatory Authority meetings, regulatory applications, submissions, dossiers, notifications, registrations, Marketing Approvals and/or other filings made to or with, or other approvals granted by, a Regulatory Authority with respect to the Licensed Compound or Product in a particular regulatory jurisdiction.

Section 7.15 "**Reimbursement Rate**" means a rate per hour for Technical Assistance provided by TESARO equal to [***], which may be prorated as necessary.

Section 7.16 "**Royalties**" shall have the meaning set forth in Section 3.3.1.

Section 7.17 "**Royalty Term**" means, on a Product-by-Product and country-by-country basis, the period commencing upon the First Commercial Sale of such Product in a particular country in the Licensed Territory and continuing until the later of (a) expiration of the last to expire Valid Claim of a Licensed Patent covering or claiming such Product (or the Licensed Compounds contained in, or comprising, such Product), or (b) the [***] anniversary of the date of the First Commercial Sale of such Product in such country.

Section 7.18 "**Subject Transaction**" shall have the meaning set forth in Section 6.5.1(d).

Section 7.19 "**Sublicensee(s)**" means any Person to which Licensee has granted a permitted sublicense in accordance with the terms of this Agreement.

Section 7.20 "**Supply Agreements**" shall have the meaning set forth in Section 5.9.1.

Section 7.21 "**Takeda Group**" means Takeda Pharmaceutical Company Limited and its Affiliates.

Section 7.22 "**Technical Assistance**" shall have the meaning set forth in Section 5.9.2.

Section 7.23 "**Term**" shall have the meaning set forth in Section 9.1.

Section 7.24 "**TESARO**" shall have the meaning set forth in the Preamble.

Section 7.25 "**TESARO Indemnified Parties**" shall have the meaning set forth in Section 7.1.2.

Section 7.26 "**TESARO Territory**" means the entire world other than the Licensed Territory.

Section 7.27 "**TESARO Vendors**" shall have the meaning set forth in Section 5.11.

Section 7.28 "[***]" means [***].

Section 7.29 "**Third Party**" means a Person other than (a) TESARO or any of its Affiliates and (b) Licensee or any of its Affiliates.

Section 7.30 "**Transferred Materials**" shall have the meaning set forth in Section 2.4.2(a).

Section 7.31 "**Upstream Agreements**" means the AZ Agreements and the Merck Agreement.

Section 7.32 "**Upstream Licensors**" means AZ and Merck.

Section 7.33 "**Valid Claim**" means a claim of an issued and unexpired patent included within the Licensed Patents that has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and that has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer.

Section 7.34 "**VAT**" shall have the meaning set forth in Section 3.10.2.

ARTICLE 2. LICENSE GRANT

Section 2.1 **Grant to Licensee.** Subject to the terms and conditions of this Agreement (including Section 2.5), TESARO hereby grants to Licensee an exclusive (even as to TESARO and its Affiliates), royalty-bearing, sublicenseable (but only in accordance with Section 2.2), license under the Licensed Patents and the Licensed Know-How to Develop, Manufacture (but only in accordance with the following sentence) and Commercialize the Licensed Compound and the Product in the Licensed Field in the Licensed Territory during the Term. Notwithstanding the foregoing or any other provision of this Agreement to the contrary, Licensee's right to Manufacture the Licensed Compound and the Product in the Licensed Field in the Licensed Territory shall be limited to the right to use the Compound API, the Bulk Product and/or Primary Packaged Product to be provided by TESARO under the Supply Agreements to Manufacture Products for use by Licensee, its Affiliates, and its Sublicensees in the Licensed Field in the Licensed Territory unless otherwise agreed by TESARO in writing.

Section 2.2 **Sublicenses by Licensee.** Licensee shall have the right to grant sublicenses under the license granted by TESARO to Licensee under Section 2.1 to its Affiliates, contractors and other Third Parties; provided, that (a) TESARO provides its prior written consent to such sublicense, such consent not to be unreasonably withheld, conditioned or delayed, except that a sublicense to an Affiliate shall not require TESARO's consent only for so long as such Affiliate remains an Affiliate of Licensee, and (b) no sublicense may be granted to a Post-Execution Affiliate engaged in Competing Activities. Notwithstanding any provision in this Agreement to the contrary, [***] are not Affiliates of Licensee under this Agreement as of the Effective Date

and TESARO shall have right to withhold its consent in its sole discretion to any sublicense proposed to be granted by Licensee to [***]. Each sublicense agreement shall be consistent with, and shall be subject to, the terms and conditions of this Agreement, and Licensee shall remain responsible for the performance of its obligations under this Agreement, regardless of whether Licensee may have delegated those obligations to its Sublicensees. Without limitation of the requirement to obtain TESARO's prior written consent as set forth in subsection (a) above, Licensee shall, within thirty (30) days after granting any sublicense, notify TESARO of the grant of such sublicense and provide TESARO with a copy of such sublicense, which may be redacted to remove any sensitive information not necessary for TESARO to verify its compliance with the terms of this Agreement.

Section 2.3 **Grant to TESARO.** Subject to the terms and conditions of this Agreement, Licensee hereby grants to TESARO a perpetual, non-exclusive, royalty-free, sublicenseable (including through multiple tiers) license under the Licensee Patents and the Licensee Know-How, including any data relating to the Licensed Compound and Product generated by Licensee in connection with this Agreement, to the extent necessary or useful to Develop, Manufacture and Commercialize the Licensed Compound and the Product in the TESARO Territory for all uses. Notwithstanding the foregoing, if the Licensee Patents include any Patent Rights that have uses other than in connection with the Development, Manufacture or Commercialization of the Licensed Compound or Product (e.g., Patent Rights that are not specific to the Licensed Compound or Product), then upon the request of Licensee, TESARO and Licensee shall negotiate in good faith commercially reasonable financial terms and conditions for the portion of the license to TESARO relating to such Licensee Patents. Upon the request of TESARO from time to time during the Term, Licensee shall promptly (a) deliver to TESARO a list of all Licensee Patents then in existence, and (b) transfer and deliver to TESARO copies in English of all tangible embodiments of the Licensee Know-How then within its Control.

Section 2.4 **Transfer of Licensed Know-How and Materials.**

2.4.1 Licensed Know-How. Beginning on the Effective Date until the date that is [***] following the Effective Date, TESARO shall transfer and deliver to Licensee copies of tangible embodiments of the Licensed Know-How within its Control as of the Effective Date and through the period described above and respond to any requests for other information or documentation that is readily available and in within TESARO's control, in each case to the extent necessary or useful to Develop, Manufacture or Commercialize the Product in the Licensed Field in the Licensed Territory and consistent with the license granted to Licensee in Section 2.1. TESARO shall thereafter during the Term, through the JSC, notify Licensee of and provide to Licensee a copy of any new material tangible embodiments of the Licensed Know-How that come into TESARO's Control that have not already been provided to Licensee and are consistent with the license granted to Licensee in Section 2.1. All of the foregoing tangible embodiments shall be provided in English. If following the aforementioned period, Licensee identifies in writing particular material documents, data or information that

are within the Licensed Know-How and are consistent with the license granted to Licensee in Section 2.1, but were not previously delivered to Licensee, TESARO shall promptly provide such material to Licensee upon request to the extent that such items are readily available and within its Control.

2.4.2 Materials.

(a) Transferred Materials. As soon as practicable after the Effective Date but in no event later than the applicable delivery date that is set forth on Exhibit E, TESARO shall provide to Licensee (i) the quantities of non-clinical use materials (e.g., to enable technology transfer and conduct stability studies), and (ii) Bulk Product and/or Primary Packaged Product, in each case as listed in Exhibit E (collectively, the "**Initial Materials**"). Upon Licensee's written request and to the extent TESARO is reasonably able to fulfill such request, TESARO shall provide to Licensee such additional quantities of non-clinical use materials reasonably necessary for the Development, Manufacture or Commercialization of the Licensed Compound and Products in the Licensed Territory (the "**Additional Materials**," and together with the Initial Materials, the "**Transferred Materials**"). All Transferred Materials shall be provided at [***], which shall be promptly reimbursed by Licensee. Exhibit E sets forth the cost to be paid by Licensee for the Initial Materials. The Initial Materials set forth in Exhibit E to be used in the first human clinical trial in Japan will be subject to the clinical Supply Agreement and related quality agreement to be agreed pursuant to Section 5.9.1, except that the supply cost for such materials shall be [***]. Upon receipt of any request for Additional Materials from Licensee, TESARO shall promptly provide to Licensee the cost information for such Additional Materials. The Transferred Materials provided by TESARO hereunder shall not be used by Licensee for any purpose other than the Development, Manufacture or Commercialization of the Licensed Compounds and the Products in the Licensed Territory in accordance with this Agreement.

(b) Additional Quantities of Compound API, Bulk Product and Primary Packaged Product. Any quantities of Compound API, Bulk Product and/or Primary Packaged Product to be used by Licensee for clinical and commercial uses that are in excess of the Initial Materials shall be supplied by TESARO to Licensee under the terms of the Supply Agreements to be agreed pursuant to Section 5.9.1, which shall include terms for the delivery of relevant documents, including batch records, certificates of analysis and certificates of compliance associated with the Manufacture of such Compound API, Bulk Product and/or Primary Packaged Product.

Section 2.5 No Other Rights.

2.5.1 General Acknowledgement. Licensee acknowledges that the rights and licenses granted under this Article 2 and elsewhere in this Agreement are limited to the scope expressly granted. Accordingly, except for the rights expressly granted under this Agreement, no right, title, or interest of any nature whatsoever is granted, whether by implication, estoppel, reliance, or otherwise, by TESARO to Licensee. All rights that are not specifically granted herein are reserved to TESARO.

2.5.2 Japanese Rights under Janssen Agreement. Without limiting Section 2.5.1 and except as otherwise provided in this Section 2.5.2, the rights and licenses granted under this Article 2 and elsewhere in this Agreement do not include the sublicense of any rights or licenses granted by Janssen to TESARO under the Janssen Agreement under any Company Technology to Exploit any Compound or Product in Japan in the Company Field or in the TESARO Field (as such terms are defined in the Janssen Agreement). Upon the written request and for the benefit of Licensee, TESARO shall (a) exercise its right under Section 3.2(a) of the Janssen Agreement to request that Janssen grant to TESARO a non-exclusive, royalty-bearing, non-transferable license, with the right to grant sublicenses, under the Company Technology to Exploit Products in Japan on commercially reasonable terms, and (b) use reasonable efforts to, in consultation with and subject to the approval by Licensee of the final terms of such license, negotiate and agree on the terms of such license with Janssen and, if applicable, participate in the dispute resolution process set forth in Section 3.2(a) of the Janssen Agreement if TESARO and Janssen are unable to reach agreement on the terms of such license; provided, that [***] any royalties, consideration or other amounts payable to Janssen in connection with any such license.

Section 2.6 Limited Exploitation Rights. Without limiting the provisions of Section 2.5, Licensee agrees (on behalf of itself and its Affiliates), and shall cause each of its Sublicensees to agree, not to use any Licensed Know-How or Licensed Patents for any products other than the Product, in any field other than the Licensed Field or outside the Licensed Territory.

Section 2.7 PARP Inhibitor Exclusivity.

2.7.1 Exclusivity. As partial consideration for TESARO granting to Licensee the license set forth in Section 2.1, during the Term, Licensee shall not, and shall cause its Affiliates to not, itself or in cooperation with or through others, in the Licensed Territory, discover, research, develop, manufacture or commercialize any PARP Inhibitor other than the Licensed Compound and Product hereunder. In the event Licensee wishes to obtain the right (by licensing, merger or acquisition or otherwise) to discover, research, develop, manufacture or commercialize any PARP Inhibitor other than the Licensed Compound and Product in the Licensed Territory, Licensee shall notify TESARO in writing, and TESARO may determine, [***]. Without limitation of the foregoing, Licensee shall not use, or provide to others,

TESARO's Confidential Information received by Licensee under this Agreement relating to the Licensed Compound or Product, in the discovery, research, development, manufacture or commercialization of any PARP Inhibitor other than the Licensed Compound and Product outside the Licensed Territory.

2.7.2 Permitted Distribution Activities. Notwithstanding the first sentence of Section 2.7.1, Licensee shall have the right to distribute any pharmaceutical products containing a PARP Inhibitor other than the Licensed Compound and Product in the Licensed Territory if and only if Licensee is obligated to distribute such pharmaceutical products through its wholesaler channels under any agreement that has been executed prior to the Effective Date (the "**Pre-Effective Date Wholesaler Agreements**") (such activities, the "**Permitted Distribution Activities**"). For clarity, the Permitted Distribution Activities shall be limited to the distribution of the products described in the foregoing sentence and shall not include the right to promote, market or otherwise engage in any other activities to commercialize such products. [***].

2.7.3 Licensee Covenants. Licensee shall notify TESARO in writing within thirty (30) days if (a) Licensee or any of its Affiliates acquires rights to any PARP Inhibitor outside the Licensed Territory, (b) Licensee, by itself, through an Affiliate or in cooperation with or through others, commences the research, development, manufacture or commercialization of any PARP Inhibitor other than the Licensed Compound and Product outside the Licensed Territory, or (c) Licensee or any of its Affiliates becomes obligated to conduct Permitted Distribution Activities under a Pre-Effective Date Wholesaler Agreement. If Licensee provides written notice to TESARO under Section 2.7.3(a) or (b) above, Licensee shall (i) not disclose or grant access to, and shall establish and maintain appropriate fire-walls and other procedures to prevent the disclosure of or access to, TESARO's Confidential Information, including Licensed Know-How and any other information relating to the Licensed Compound or Product that is not part of the public domain, by any employees or agents of Licensee, its Affiliates or its partners and collaborators involved in the research, development, manufacture or commercialization of such PARP Inhibitor, and (ii) confirm to TESARO that such firewalls and other procedures have been implemented as part of the written notice provided to TESARO under Section 2.7.3(a) or (b).

Section 2.8 **Section 365(n) of the Bankruptcy Code.** All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code. Each Party shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or equivalent legislation in any other jurisdiction. Upon the bankruptcy of either Party, the other Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property, and such, if not already in its possession, shall be promptly delivered to such

other Party, unless the Party in bankruptcy elects to continue, and continues, to perform all of its obligations under this Agreement.

ARTICLE 3. FEES, ROYALTIES, & PAYMENTS

Section 3.1 **Upfront Payment.** Within [***] of the Effective Date, Licensee shall pay to TESARO a one-time, non-refundable, non-creditable upfront payment of One Hundred Million Dollars (US$100,000,000). Notwithstanding the immediately above, if TESARO breaches its representation and warranty set forth in Section 6.2(k) below and such representation and warranty is not true and correct within thirty (30) days of the Effective Date, then upon written request of Licensee, TESARO shall refund to Licensee Thirty Million Dollars (US$30,000,000) within ten (10) days of such request, as the sole and exclusive remedy of Licensee for a breach of such representation and warranty, and thereafter the Licensed Territory shall only include Japan.

Section 3.2 **Milestone Payments.** Licensee shall pay to TESARO certain milestone payments ("**Milestone Payments**") following the occurrence of certain milestone events, as set forth in Section 1 of Exhibit C (the "**Milestone Events**"). Licensee shall pay to TESARO the applicable Milestone Payment within [***] after the occurrence of the applicable Milestone Event. For clarity, each Milestone Payment is payable only once, and each of the Milestone Payments shall be non-refundable and non-creditable. Notwithstanding the foregoing, if Licensee's Development activities cause TESARO to owe Merck a milestone payment under the "Development Milestone" section of Section 7.02 of the Merck Agreement but no corresponding Milestone Payment is payable by Licensee to TESARO under this Section 3.2, then Licensee shall pay to TESARO for payment to Merck, in accordance with the terms of this Agreement, or Licensee and TESARO shall coordinate to enable Licensee to pay directly to Merck, the amount of the milestone payment owed by TESARO to Merck.

Section 3.3 **Royalties.**

3.3.1 Royalty Rate. Subject to the remainder of this Section 3.3, Licensee shall pay to TESARO on a Product-by-Product basis a running royalty on Net Sales of each Product sold by Licensee, its Affiliates and Sublicensees in the Licensed Field in the Licensed Territory at the rates forth in Section 2 of Exhibit C for the duration of the Royalty Term (collectively, "**Royalties**").

3.3.2 Royalty Reductions.

(a) If a Product is generating Net Sales in a country in the Licensed Territory during the Royalty Term at a time when there is no Licensed Patent in such country that contains a Valid Claim Covering the composition of matter or use of the Licensed Compound included in such Product, then the Royalty rate applicable to the Net Sales in such country for such Product shall be reduced by [***].

(b) In the event that Licensee is required to obtain a license under any Patent Rights from any Third Party(ies) in order to make, have made, use, offer to sell, sell or import the Licensed Compounds, (i) [***] of the royalties actually paid under such Third Party Patent Right licenses by Licensee in connection with the Manufacture, use, sale or import, as applicable, of the Licensed Compound in a country for a Calendar Quarter shall be creditable against the Royalty payments due TESARO by Licensee with respect to the sale of such Licensed Compound in such country; provided, however, that in no event shall the Royalties owed by Licensee to TESARO for such Calendar Quarter in such country be reduced by more than [***] pursuant to this Section 3.3.2(b); or (ii) if no royalty is paid, or in addition to a royalty, a lump sum payment is made for such Third Party Patent Right licenses, then [***] of the lump sum payment actually paid shall be creditable against the next Milestone Payment then due TESARO under Section 3.2; provided, however, that in no event shall the aggregate payments to be creditable against Milestone Payments due TESARO exceed [***].

(c) If at any time Generic Competition exists in a given country with respect to a Product, then Licensee's obligation to pay Royalties with respect to such Product in such country shall be reduced by [***] effective as of the first date when Generic Competition exists with respect to such Product in such country.

3.3.3 Minimum Royalties. Notwithstanding the foregoing, the Royalties due from Licensee to TESARO under this Agreement with respect to the Net Sales of the Product in the Licensed Territory in a particular Calendar Quarter shall be no less than the royalties owed by TESARO to Upstream Licensors under the Upstream Agreements with respect to such Net Sales plus [***] of such Net Sales. Licensee shall make to TESARO any payments necessary to give effect to this Section 3.3.3 with thirty (30) days after TESARO provides written notice thereof.

3.3.4 Upstream Royalties. TESARO shall be solely responsible for the payment of royalties and other payments owed by TESARO to Upstream Licensors on account of the Development, Manufacture and Commercialization of the Product by Licensee in the Licensed Territory.

Section 3.4 **Manner of Payment.** All payments to be made by Licensee hereunder shall be made in U.S. Dollars by wire transfer of immediately available funds to such bank account as shall be designated by TESARO. Except as otherwise provided in this Agreement, all payments to be made by Licensee under this Agreement shall be due within [***] of the date of invoice. Late payments shall bear interest at the rate provided in Section 3.8.

Section 3.5 **Sales Reports and Royalty Payments.** Any Royalty payments due under this Agreement will be calculated and reported for each Calendar Quarter within [***] of the end of each Calendar Quarter in which the applicable Net Sales were recorded. Each Royalty report shall state on a Product-by-Product basis: (a) Net Sales of the Product in the applicable Calendar Quarter, including an itemized calculation of any deductions taken from gross sales to arrive at Net Sales for the applicable Calendar Quarter; (b) a calculation of the amount of the Royalty payment due on such Net Sales during the applicable Calendar Quarter; and (c) the amount of withholding taxes, if any, required by applicable Law to be deducted or withheld with respect to such Royalties. Royalties will be paid within [***] of the end of each Calendar Quarter in which the applicable Net Sales were recorded.

Section 3.6 **Financial Records.** Licensee will maintain, and shall cause its Affiliates and Sublicensees to maintain, records as are required to determine, in accordance with this Agreement, Net Sales and Royalties due under this Agreement. Licensee will maintain such records until the later of (a) three (3) years after the end of the period to which such records pertain, (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or (c) such longer period as may be required under applicable Law.

Section 3.7 **Currency Conversion; Remittance.** All payments due hereunder shall be converted into U.S. Dollars using the conversion rate for the relevant period as reported by Reuters Ltd (at http://reuters.com/finance/currencies/quote) on the last Business Day of the relevant period. Licensee shall be solely responsible for taking any and all measures necessary to remit the payments due to TESARO hereunder outside the Licensed Territory.

Section 3.8 **Late Payments.** In the event that any payment due hereunder is not made when due, the payment shall accrue interest beginning on the day following the due date thereof, calculated at the annual rate of the sum of (a) [***] plus (b) the U.S. Prime Interest Rate quoted by *The Wall Street Journal*, Internet U.S. Edition at http://www.wsj.com/public/page/news-fixed-income-bonds.html on the date said payment is due, the interest being compounded on the last day of each Calendar Quarter; provided, however, that in no event shall said annual interest rate exceed the maximum rate permitted by applicable Law. Each such payment when made shall be accompanied by all interest so accrued. Said interest and the payment and acceptance thereof shall not negate or waive the right of any Party to seek any other remedy, legal or equitable, to which it may be entitled because of the delinquency of any payment including, but not limited to, termination of this Agreement as set forth in Article 9.

Section 3.9 **Records and Audits.** TESARO will have the right, once annually at its own expense, to have a nationally recognized, independent, certified public accounting firm selected by it review any such records of Licensee and its Affiliates and Sublicensees (the "**Audited Party**") in the location(s) where such records are maintained by the Audited Party upon reasonable written notice (which shall be no less than thirty (30) days' prior written notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the

basis and accuracy of payments made under Section 3.3 within the thirty-six (36) month period preceding the date of the request for review. No Calendar Year will be subject to audit under this Section 3.9 more than once and an audit under this Section 3.9 shall not occur more than once in any Calendar Year; provided, that the foregoing limitation shall not limit TESARO from conducting additional audits in the event that TESARO should "have cause" to reasonably believe that this Agreement has been breached or that the initial audit was flawed on the basis of the materials provided to the auditors. Should such inspection lead to the discovery of a discrepancy to TESARO's detriment, Licensee will, within twenty (20) days after the conclusion of such inspection, pay any undisputed amount of the discrepancy together with interest at the rate set forth in Section 3.8. TESARO will pay the full cost of the review unless the underpayment of amounts due to TESARO is greater than [***] of the amount due for the entire period being examined, in which case Licensee will pay the cost of such review. Any undisputed overpayment of Royalties by Licensee revealed by an examination will be paid by TESARO within twenty (20) days of the conclusion of such inspection. In no event will TESARO be responsible for late payment of withholding taxes or penalties related thereto, and Licensee shall indemnify and hold TESARO harmless for any such late payment or penalties.

Section 3.10 Taxes.

3.10.1 Withholding. In the event that any Law requires Licensee to deduct or withhold taxes with respect to any payment to be made by Licensee pursuant to this Agreement, Licensee will notify TESARO of such requirement prior to making the payment to TESARO and provide such assistance to TESARO, including the provision of such documentation as may be required by a tax authority, as may be reasonably necessary in TESARO's efforts to claim an exemption from or reduction of such taxes. Licensee will, in accordance with such Law, deduct or withhold taxes from the amount due, remit such taxes to the appropriate tax authority when due, and furnish TESARO with proof of payment of such taxes within thirty (30) days following the payment. If taxes are paid to a tax authority, Licensee shall provide reasonable assistance to TESARO to obtain a refund of taxes withheld, or obtain a credit with respect to taxes paid. If no such refund or credit is received by TESARO within sixty (60) days of the date that such taxes are paid to a tax authority, Licensee will pay to TESARO within ten (10) days of written notice thereof by TESARO the difference between (a) the amount of the payment to be made by Licensee pursuant to this Agreement exclusive of the payment of such taxes, and (b) the amount of the payment that was actually paid to TESARO after such taxes are paid to a tax authority.

3.10.2 VAT. All payments due to TESARO from Licensee pursuant to this Agreement shall be paid net of any value-added tax ("**VAT**") required to be paid by Licensee to tax authorities in the Licensed Territory (which, if applicable, shall be payable by Licensee upon receipt of a valid VAT invoice); provided, that Licensee shall use commercially reasonable efforts to assist TESARO to minimize and obtain all available exemptions from such VAT or other taxes. If Licensee is required to withhold and/or TESARO is required to report any such tax, Licensee

shall promptly provide TESARO with applicable receipts evidencing payment of such tax and other documentation reasonably requested by TESARO.

ARTICLE 4. PATENT PROSECUTION, MAINTENANCE, & INFRINGEMENT

Section 4.1 **Prosecution and Maintenance.** As between the Parties, TESARO shall have the first right to file, prosecute and maintain all Patent Rights within the Licensed Patents in the Licensed Territory. All costs and expenses incurred in connection with such prosecution and maintenance activities shall be borne by TESARO, provided that Licensee shall reimburse TESARO for fifty percent (50%) of such costs and expenses within forty-five (45) days of an invoice therefor in the event that such prosecution and maintenance activities are necessary for the Development and/or Commercialization of the Licensed Compound and Product in the Licensed Territory. TESARO shall consult with Licensee and keep Licensee reasonably informed of the status of such Licensed Patents in the Licensed Territory. TESARO shall provide Licensee a reasonable opportunity to review and comment on all material filings and correspondence with patents offices with respect to the prosecution and maintenance of Licensed Patents in the Licensed Territory, and TESARO shall consider Licensee's comments regarding such filings and correspondence in good faith. TESARO shall notify Licensee of any decision to cease prosecution and/or maintenance of any such Licensed Patents in the Licensed Territory and TESARO shall permit Licensee, to the extent permitted under the Upstream Agreements and at Licensee's discretion and sole expense, to continue prosecution or maintenance of such Licensed Patent.

Section 4.2 **Enforcement.**

4.2.1 TESARO Enforcement. Each Party will notify the other promptly in writing when any Infringement of any Licensed Patent or Licensed Know-How by a Third Party (an "**Infringer**") is uncovered or reasonably suspected in the Licensed Territory. TESARO shall have the first right to enforce any Patent Right within the Licensed Patents against any Infringement or alleged Infringement thereof in the Licensed Territory. TESARO may, at its sole option and expense, institute suit against any such Infringer or alleged Infringer and control and defend such suit. Licensee shall reasonably cooperate in any such litigation instituted by TESARO. Licensee shall have the right to participate in such action with counsel of its own choice and expense. TESARO shall not enter into any settlement of any claim described in this Section 4.2.1 that admits to the invalidity or unenforceability of the Licensed Patents, incurs any financial or other liability on the part of Licensee or requires an admission of liability, wrongdoing or fault on the part of Licensee, in each case without Licensee's prior written consent, not to be unreasonably withheld, conditioned or delayed.

4.2.2 Licensee Enforcement. If TESARO elects not to enforce any Patent Right within the Licensed Patents against Infringement or alleged Infringement thereof in the Licensed Territory pursuant to Section 4.2.1, then it shall so notify Licensee in writing within thirty (30) days of receiving notice or otherwise becoming aware that an Infringement exists. If TESARO

does not notify Licensee in writing of its intent to initiate proceedings or take other appropriate action with respect to ceasing the applicable Infringement within such thirty (30) day period, Licensee may, to the extent permitted under the Upstream Agreements and at Licensee's sole option and expense, institute suit against any such Infringer or alleged Infringer and control and defend such suit with counsel selected by Licensee. TESARO shall reasonably cooperate in any such litigation at Licensee's request and expense, including by joining any such suit as a party. Licensee shall not enter into any settlement of any claim described in this Section 4.2.2 that admits to the invalidity or unenforceability of the Licensed Patents, incurs any financial or other liability on the part of TESARO or requires an admission of liability, wrongdoing or fault on the part of TESARO, in each case without TESARO's prior written consent, not to be unreasonably withheld, conditioned or delayed.

4.2.3 Progress Reports. The Party initiating or defending any enforcement action described in this Section 4.2 shall keep the other Party reasonably informed of the progress of any such enforcement action.

4.2.4 Expenses; Recovery. Any damages, settlements or other monetary awards recovered in any such action shall first be applied to reimburse each Party's costs and expenses in connection therewith. Any such recovery in excess of such costs and expenses shall be retained by the enforcing Party; provided, that if Licensee is the enforcing Party, then such recovery shall be deemed Net Sales and subject to Royalty payments to TESARO under Section 3.3.

Section 4.3 **Defense of Third Party Claims.** If either (a) the Product Manufactured or Commercialized by or under authority of Licensee becomes the subject of a Third Party's claim or assertion of Infringement of a patent relating to the Manufacture or Commercialization of the Product in the Licensed Field in the Licensed Territory, or (b) if a declaratory judgment action is brought naming either Party as a defendant and alleging invalidity of any of the Licensed Patents, the Party first having notice of the claim or assertion shall promptly notify the other Party, and the Parties shall promptly confer to consider the claim or assertion and the appropriate course of action. Unless the Parties otherwise agree in writing, each Party shall have the right to defend itself against a suit that names it as a defendant (the "**Defending Party**"). None of the Parties shall enter into any settlement of any claim described in this Section 4.3 that admits to the invalidity or unenforceability of the Licensed Patents, incurs any financial or other liability on the part of the other Party or requires an admission of liability, wrongdoing or fault on the part of the other Party without such other Party's prior written consent, not to be unreasonably withheld, conditioned or delayed. In any event, the other Party shall reasonably assist the Defending Party and cooperate in any such litigation at the Defending Party's reasonable request and expense. If the Defending Party is deemed responsible in connection with any suit or claim subject to this Section 4.3, any resulting damages, settlement amounts and expenses shall be borne by the Defending Party. If both Parties are Defending Parties and are both deemed responsible in connection with any suit or

claim subject to this Section 4.3, any resulting damages, settlement amounts and expenses shall be borne by the Parties in proportion to their relative responsibility.

Section 4.4 **Patent Marking.** Licensee will mark, and will cause its Affiliates and Sublicensees to mark, the Product with all Licensed Patents in accordance with applicable Law, which marking obligation will continue for as long as (and only for as long as) required under applicable Law.

ARTICLE 5. GOVERNANCE & OBLIGATIONS OF THE PARTIES

Section 5.1 **Joint Steering Committee**.

5.1.1 Establishment of JSC. The Parties will establish a joint steering committee to review and oversee the Development and Commercialization of the Licensed Compounds and Products in the Licensed Field in the Licensed Territory and to coordinate the Parties' activities under this Agreement (the "**Joint Steering Committee**" or "**JSC**"). Within thirty (30) days after the Effective Date, each Party shall appoint three (3) representatives to the JSC, at least one (1) of which shall have sufficient seniority and relevant expertise within the applicable Party's organization to have the necessary decision-making authority in order for the JSC to fulfill its responsibilities. The JSC may change its size from time to time by mutual consent of the Parties; provided, that the JSC will consist at all times of an equal number of representatives of each of TESARO and Licensee. Each Party may at any time replace its JSC representatives upon written notice to the other Party. From time to time, the JSC may establish subcommittees to oversee particular projects or activities as it deems necessary or advisable, including with respect to the establishment between the Parties of a system for supply chain management and for the exchange of Product safety information, in each case directed to the Licensed Territory. Each subcommittee shall consist of an equal number of members from each Party with such expertise as the JSC determines is appropriate from time to time.

5.1.2 Chairperson of the JSC. Licensee shall select from its representatives a chairperson for the JSC, and Licensee may change its designated chairperson from time to time upon written notice to the other Party. The chairperson will be responsible for calling meetings, preparing and circulating an agenda and relevant materials (including drafts of, updates to, or any proposed changes to the Development Plan) to the other Party at least ten (10) Business Days in advance of each meeting, and preparing and issuing minutes of each meeting within ten (10) Business Days thereafter for approval by the JSC.

5.1.3 JSC Responsibilities. The JSC shall be responsible for:

(a) coordinating the activities of the Parties under this Agreement along with the Alliance Managers and providing an additional forum to facilitate communications between the Parties under this Agreement;

(b) reviewing, discussing and approving changes to the Development Plan, overseeing the implementation of the Development Plan, and reviewing and discussing the data and results of the Development activities under the Development Plan, in each case subject to Section 5.1.5 below;

(c) reviewing and discussing the Development and Commercialization of the Licensed Compound and Product in the Licensed Territory;

(d) discussing at a high-level and exchanging relevant information relating to the Development and Commercialization activities for the Licensed Compound and Product undertaken by TESARO and its Affiliates outside of the Licensed Territory (i) to the extent relevant to the Development and Commercialization of the Licensed Compound and Product in the Licensed Territory, and (ii) to the extent that TESARO has the right to disclose such information to Licensee;

(e) discussing at a high-level potential opportunities for coordination or collaboration between the Parties, with or without Third Parties, with respect to the Development and Commercialization of the Licensed Compound and Product that may be mutually beneficial to the Parties, in each case to the extent that each Party has the right to discuss such opportunities with the other Party; and

(f) performing such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or allocated to it by the Parties in writing by mutual agreement.

5.1.4 Meetings. The JSC shall meet at least one (1) time every six (6) months during any period in which any Development activities (except for any activities not necessary to obtain Marketing Approval, such as post-marketing surveillance activities or post-Marketing Approval clinical studies) in the Licensed Territory are ongoing and once (1) per year thereafter, and may meet at other times as mutually agreed by the Parties. The JSC meetings may occur in person or by telephone or videoconference; provided, that the Parties will hold one (1) in-person meeting per year at a location to be mutually agreed by the Parties. Each Party will bear its own costs associated with attending JSC meetings. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend JSC meetings in a non-voting capacity. Each individual attending a JSC meeting (whether as a JSC member or invitee) shall be bound by written non-use, non-disclosure terms and conditions at least as restrictive as those set forth in this Agreement with respect to the Confidential Information of the other Party.

5.1.5 Dispute Resolution. The members of each Party on the JSC shall collectively have one vote. Except as otherwise provided in this Section 5.1.5, decisions of

the JSC shall be made by unanimous vote; provided, that at least one (1) representative from each Party participates in such vote. If the JSC does not reach unanimity with respect to a particular matter, and the JSC is unable to resolve the dispute within fifteen (15) Business Days, then either Party may, by written notice to the other, have such matter referred to the Executive Officers, who shall meet promptly and negotiate in good faith to resolve the dispute. If the Executive Officers cannot resolve such dispute within fifteen (15) Business Days, then (a) TESARO shall have final decision-making authority on any matter that may have an impact on or effect on the Development, Manufacture or Commercialization of the Licensed Compounds and Products outside of the Licensed Field and/or outside of the Licensed Territory, provided, however, that TESARO shall consider in good faith Licensee's opinions if the matter would also have a non-trivial impact on or effect on the Development, Manufacture or Commercialization of the Licensed Compound or Products in the Licensed Territory, and (b) Licensee shall have final decision-making authority on any matter that is solely and exclusively related to the Licensed Territory.

5.1.6 Limitations on Authority of JSC. The JSC will have sole authority with respect to the responsibilities assigned to it in Section 5.1.3 and elsewhere in this Agreement. The JSC shall not have any authority to amend, modify or waive compliance with this Agreement. For clarity, neither TESARO nor Licensee will have any right to unilaterally modify, waive or amend its own compliance with the terms of this Agreement.

5.1.7 Alliance Manager. TESARO and Licensee shall as soon as practicable after the Effective Date appoint one employee who is responsible for coordinating the activities of the Parties under this Agreement and provide a forum to facilitate communications between the Parties under this Agreement (each such employee, an "**Alliance Manager**").

Section 5.2 **Development Plan.** The Development of Licensed Compounds and Products in the Licensed Field in the Licensed Territory shall be conducted by Licensee pursuant to a Development plan that will include a description of the Development activities to be performed in support of the Marketing Approval of the Products in the Licensed Field in the Licensed Territory, including projected timelines for completion of such activities (the "**Development Plan**"). The initial Development Plan agreed to by the Parties is attached hereto as Exhibit D. Any material changes to the Development Plan shall require the approval of the JSC. Not later than thirty (30) days after December 31 of each Calendar Year, Licensee shall submit to the JSC an updated Development Plan for the pending Calendar Year. Such update shall take into account completion, commencement, changes in or cessation of Development activities not contemplated by the then-current Development Plan in sufficient detail to reflect the continued diligence of Licensee and shall reflect effort and resources consistent with other priority projects of Licensee. TESARO shall have the right to comment on such annual plan. In the event TESARO reasonably disagrees with the plan, Licensee shall consider in good faith TESARO's comments for revising the plan. Notwithstanding anything to the contrary set forth in this Agreement, Licensee shall not have the right to use the Product in Development or Commercialization activities using a dosage amount

and/or dosage schedule that is not being used by TESARO in its Development and Commercialization activities for the Product in the TESARO Territory without TESARO's prior written consent.

Section 5.3 **Responsibility.** Following the Effective Date and at all times during the Term, Licensee shall be solely responsible for all costs and expenses required to Develop, Manufacture and Commercialize the Product in the Licensed Field in the Licensed Territory, as well as all other costs and expenses associated with the Commercialization of the Product in the Licensed Territory, and except as expressly set forth herein shall have sole decision making authority with respect thereto. All Development, Manufacture and Commercialization activities undertaken by or on behalf of Licensee shall be in compliance with all applicable Law.

Section 5.4 **Diligence.** Licensee shall (directly and/or through one or more Affiliates and/or Sublicensees) use Diligent Efforts to Develop Licensed Compounds and Products in accordance with the then-applicable Development Plan and Commercialize Products in the Licensed Field in the Licensed Territory. Without limiting the generality of the foregoing, Licensee shall use Diligent Efforts to (a) Develop, obtain Marketing Approval for and Commercialize at least [***] hereunder, and (b) undertake the commercial launch of a Product in Japan promptly after, and in any case not later than [***] after, the date that the final Marketing Approval is granted with respect such Product in Japan. Any failure by Licensee to comply with the obligations set forth in this Section 5.4 shall be deemed to be a material breach for which TESARO may exercise its termination rights under Article 9 and any other available remedies at law or in equity.

Section 5.5 **Development Records.** Licensee shall maintain complete and accurate records of all work conducted by or on behalf of Licensee in furtherance of the Development of the Licensed Compound and Product and all material results, data and developments made in conducting such activities. Such records shall be maintained in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and in accordance with applicable Law.

Section 5.6 Data Sharing and Use.

5.6.1 Data Sharing. In addition to the adverse event and safety reporting to be undertaken under the safety data exchange agreement described in Section 5.10, each Party shall promptly provide the other Party, through the JSC if practicable or if not practicable directly to the other Party, with copies of all material data and reports generated from its Development of the Licensed Compound and Product in its territory to the extent owned or controlled by such Party and permitted to be disclosed by such Party and necessary or useful for the Development of the Licensed Compound or Product in the other Party's territory.

5.6.2 Use of Data and Results. Each Party shall have the right to use and reference any material data, including, but not limited to, Regulatory Materials generated from the Development of the Licensed Compound and Product in the other Party's territory and disclosed

under Section 5.6.1 in support of obtaining Marketing Approval for the Licensed Compound and Product in its territory.

Section 5.7 **Regulatory Activities.** Licensee shall apply for and maintain, at Licensee's sole cost and expense and in Licensee's name, all Marketing Approvals of Product in the Licensed Territory. Licensee shall be responsible for the preparation of all Regulatory Materials and all communications and interactions with Regulatory Authorities with respect to the Product in the Licensed Territory, both prior to and subsequent to receipt of Marketing Approval, and TESARO shall provide reasonable assistance requested by Licensee with respect thereto, including, without limitation, facilitation of any discussions between Licensee and Janssen to the extent such discussion is necessary or useful for the Marketing Approvals of Product in the Licensed Territory. Upon the request by a Regulatory Authority in the Licensed Territory to Licensee for any information or materials relating to the Licensed Compound or Product that have not already been provided to Licensee under the terms of this Agreement, TESARO shall promptly provide to Licensee such information or materials to the extent that such information or materials are in TESARO's possession, readily available and within TESARO's Control. Upon TESARO's reasonable request, Licensee shall, as soon as practicable, provide TESARO with (a) an electronic copy in English (or if the originals are not written in English together with the translations into English) of all material Regulatory Materials and correspondence with Regulatory Authorities, subject to reimbursement by TESARO of reasonable translation fees and (b) an electronic copy of all other Regulatory Materials and correspondence with Regulatory Authorities, in each case by or on behalf of Licensee with respect to the Development of the Licensed Compound and Product in the Licensed Territory.

Section 5.8 **Reporting Obligations.**

5.8.1 Reports. On January 31 and July 31 of each Calendar Year during any period in which activities described in the Development Plan are ongoing, Licensee shall submit to TESARO a report summarizing in reasonable detail Licensee's and its Affiliates' and Sublicensees' activities related to the Development, Manufacture (to the extent that Licensee has the right to and is conducting Manufacturing activities under this Agreement) and Commercialization of the Product during the preceding six (6) month period. On July 31 of each Calendar Year after the completion of the activities described in the Development Plan, Licensee shall submit to TESARO a report summarizing in reasonable detail Licensee's and its Affiliates' and Sublicensees' activities related to the Manufacture (to the extent that Licensee has the right to and is conducting Manufacturing activities under this Agreement) and Commercialization of the Product during the preceding year.

5.8.2 Commercial Launch Plan. At least [***] prior to the anticipated First Commercial Sale of a Product in Japan and as soon as practicable in advance of the anticipated First Commercial Sale of a Product in any other country in the Licensed Territory, Licensee

shall submit to TESARO its proposed commercial launch plan for such Product for TESARO's review and comment.

Section 5.9 Product Supply.

5.9.1 Supply Agreements. The Parties shall negotiate in good faith and attempt to agree (a) within [***] of the Effective Date, upon one supply agreement for the clinical supply, and (b) within a certain period of time to be agreed by the JSC or a subcommittee established thereby as soon as practicable after the Effective Date, upon another supply agreement for the commercial supply, in each case of Compound API, Bulk Product and/or Primary Packaged Product by TESARO to Licensee at TESARO's Manufacturing Cost plus [***] (collectively, the "**Supply Agreements**"), and a related quality agreement. Licensee will be solely responsible for using the Compound API, the Bulk Product and/or the Primary Packaged Product supplied by TESARO to Licensee under the Supply Agreements to Manufacture Products for use by Licensee, its Affiliates, and its Sublicensees in the Licensed Field in the Licensed Territory. Licensee acknowledges and agrees that (i) TESARO and/or its Affiliates have engaged certain Third Party contract manufacturers to manufacture the Compound API, the Bulk Product and/or the Primary Packaged Product to be supplied by TESARO to Licensee under the Supply Agreements, and (ii) the terms of the Supply Agreements shall be substantially consistent with the terms of TESARO's agreements with such Third Party contract manufacturers. Without limiting the foregoing, TESARO shall provide a reasonable opportunity for Licensee to review and comment on existing and new agreements or material amendments to TESARO's existing agreements with Third Party contract manufacturers related to the Licensed Territory and shall use reasonable efforts to include in any such agreements with Third Parties terms and conditions reasonably requested by Licensee, including those terms and conditions required under applicable Law for the Licensed Territory.

5.9.2 Technology Transfer. Without limiting Section 2.4.1, if the Supply Agreements include the supply of Compound API and/or Bulk Product, then upon Licensee's reasonable request, TESARO shall transfer to Licensee or its designated Third Party contract manufacturer all material Licensed Know-How necessary to Manufacture Products using the Compound API and/or Bulk Product. In connection with such technology transfer, TESARO shall provide reasonable technical assistance, at Licensee's request and Licensee's cost at the Reimbursement Rate, to enable Licensee or its designated Third Party contract manufacturer to Manufacture Products using the Compound API and/or Bulk Product (the "**Technical Assistance**"). Within thirty (30) days after the end of each Calendar Quarter, TESARO shall deliver to Licensee an invoice setting forth the number of hours of Technical Assistance provided by TESARO to Licensee during the prior Calendar Quarter and the amounts owed to TESARO with respect thereto.

5.9.3 Excluded CMOs. Notwithstanding anything to the contrary set forth in this Agreement, Licensee shall not engage the Third Parties set forth on Exhibit F hereto (the "**Excluded CMOs**") to Manufacture Products using the Compound API without TESARO's prior written consent. TESARO shall have the right to update Exhibit F from time to time upon written notice to Licensee; provided, that Licensee shall not be deemed to be in breach of this Section 5.9.3 if Licensee has, prior to the date that an Excluded CMO was added to Exhibit F by TESARO, engaged such Excluded CMO to Manufacture Products using the Compound API without TESARO's consent.

Section 5.10 Safety Data Exchange Agreement. Within [***] of the Effective Date, but in any event prior to commencement of any clinical trials with the Licensed Compound or Product in the Licensed Territory, the Parties will in good faith negotiate and finalize a separate safety data exchange agreement (the "**Pharmacovigilance Agreement**"), the terms of which shall set forth the obligations, procedures and timelines for exchanging information (such as the occurrence of adverse events and serious adverse events) observed in connection with the Product in order to enable each Party to comply with its safety reporting obligations to Regulatory Authorities in its respective territory. Prior to the execution of the Pharmacovigilance Agreement, each Party shall promptly notify the other Party of any information observed in connection with the Product necessary to enable such Party to comply with its safety reporting obligations to Regulatory Authorities in its respective territory. TESARO shall maintain the global safety database for the Licensed Compound and Product, which shall include adverse events and other information relating to the safety of the Licensed Compound and Product. Upon reasonable advanced request by Licensee, TESARO shall make the data maintained in the global safety database accessible and available to Licensee in the form in which such data is then-currently maintained by TESARO.

Section 5.11 Audit of TESARO and TESARO Vendors. Subject to the terms and conditions set forth in this Section 5.11, Licensee shall have the right to audit TESARO and any Third Party vendors and suppliers used by TESARO to carry out material activities in respect of the Development, Manufacture and Commercialization of the Licensed Compound and Product in the TESARO Territory (the "**TESARO Vendors**") (a) to the extent necessary for purposes of preparing Regulatory Materials and obtaining or maintaining Marketing Approval for the Licensed Compound and Product in the Licensed Territory, or (b) for the purpose of verifying that TESARO is complying with all good scientific, clinical, manufacturing and commercial practices consistent with industry standards and requirements (including, without limitation, any requirements of Regulatory Authorities in the Licensed Territory) across the TESARO Vendors. Licensee's audit rights under this Section 5.11 (i) are subject in all respects to the audit rights available to TESARO under the terms of its agreements with TESARO Vendors, and (ii) may only be exercised upon reasonable advance request by Licensee and on a reasonable basis and frequency. The Parties shall cooperate reasonably and in good faith via the JSC to plan and schedule any audits of TESARO Vendors. For clarity, this Section 5.11 shall not limit TESARO's right to audit the TESARO Vendors.

Section 5.12 **Government Filings.** The Parties acknowledge and agree that this Agreement shall be subject in all respects to any applicable filings and approvals required from any Governmental Authority in the Licensed Territory with respect to the execution and performance hereof ("**Licensed Territory Filings and Approvals**"). Licensee shall be solely responsible for making and obtaining all such Licensed Territory Filings and Approvals, at its sole cost and expense.

ARTICLE 6. REPRESENTATIONS AND WARRANTIES; COVENANTS

Section 6.1 **Mutual Warranties.** Each of TESARO and Licensee represent and warrant to the other that:

(a) it is duly organized and validly existing under the Law of the jurisdiction of its incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the individual executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action; and

(c) this Agreement is legally binding upon it and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material applicable Law.

Section 6.2 **Additional TESARO Warranties.** TESARO represents and warrants to Licensee that, as of the Effective Date:

(a) TESARO has the right to grant the licenses to the Licensed Patents and Licensed Know-How as set forth in Section 2.1. TESARO has not granted to any Third Party any rights or licenses under such Licensed Patents or Licensed Know-How that would conflict with the licenses granted to Licensee hereunder;

(b) to TESARO's knowledge, the Licensed Patents are not invalid or unenforceable in whole or in part;

(c) TESARO has no knowledge of any claim or litigation that has been brought or threatened in writing by any Third Party alleging that the Licensed Patents are invalid or unenforceable;

(d) TESARO and its Affiliates do not own or Control any Patent Rights that are necessary or useful to Develop, Manufacture or Commercialize the Product in the Licensed Field in the Licensed Territory other than the Licensed Patents listed on Exhibit B;

(e) TESARO has provided Licensee with a true and complete copy of each Upstream Agreement, and each Upstream Agreement is in full force and effect;

(f) TESARO has not received or given any written notice of default or termination under any Upstream Agreement, and to TESARO's knowledge, there is no act or omission by TESARO that would provide the counter-party the right to terminate any Upstream Agreement;

(g) it has not employed or used a contractor or consultant that has been debarred or subject to a similar sanction by any Regulatory Authority or that is the subject of any investigation or proceeding with respect thereto;

(h) TESARO has disclosed to Licensee all material correspondence between TESARO and the FDA in relation to Licensed Compound and/or Product requested by Licensee;

(i) TESARO has conducted, and has used reasonable efforts to cause its contractors to conduct, all preclinical and clinical studies for the Product and the manufacturing of the Product, in accordance in all material respects with (i) all applicable Laws, (ii) the published standards of any applicable Regulatory Authorities, and (iii) the scientific standards applicable to the conduct of such studies and activities, including current good laboratory practice, current good clinical practice and current good manufacturing practice, in each case to the extent necessary to support Licensee's Development, Manufacturing and Commercialization of the Licensed Compound and Product in the Licensed Territory;

(j) TESARO has (i) prepared, maintained and retained all Regulatory Materials pursuant to and in accordance in all material respects with all applicable Law, and (ii) such Regulatory Materials do not contain any materially false or misleading statements, in each case to the extent necessary to support Licensee's Development, Manufacturing and Commercialization of the Licensed Compound and Product in the Licensed Territory; and

(k) The first negotiation right of Janssen under Section 3.3 of the Janssen Agreement for the Licensed Territory (other than Japan) has been waived, expired or is no longer in effect.

Section 6.3 **Additional Licensee Warranties.** Licensee represents and warrants to TESARO that, as of the Effective Date, (a) neither Licensee nor any of its Affiliates owns or Controls rights to any PARP Inhibitor anywhere in the world, (b) neither Licensee nor any of its Affiliates is, by themselves or in cooperation with or through others, researching, developing, manufacturing or commercializing any PARP Inhibitor anywhere in the world, and (c) neither Licensee nor any of its Affiliates has any obligation to distribute any pharmaceutical product containing a PARP Inhibitor in the Licensed Territory under a Pre-Effective Date Wholesaler Agreement.

Section 6.4 **Disclaimer.** EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS ARTICLE 6 (REPRESENTATIONS AND WARRANTIES; COVENANTS), NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, OR VALIDITY OF PATENT CLAIMS. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION MADE OR WARRANTY GIVEN BY EITHER PARTY THAT EITHER PARTY WILL BE SUCCESSFUL IN OBTAINING ANY PATENT RIGHTS, OR THAT ANY PATENTS WILL ISSUE BASED ON A PENDING APPLICATION.

Section 6.5 **Parties' Covenants.**

6.5.1 Licensee Covenants. Licensee covenants to TESARO that:

(a) it will conduct, and will use reasonable efforts to cause its contractors to conduct, all preclinical and clinical studies for the Product and the manufacturing of the Product, in accordance in all material respects with (i) all applicable Law in the Licensed Territory, (ii) the published standards of any applicable Regulatory Authorities in the Licensed Territory, and (iii) the scientific standards applicable to the conduct of such studies and activities in the Licensed Territory, including current good laboratory practice, current good clinical practice and current good manufacturing practice;

(b) it will prepare, maintain and retain all Regulatory Materials in the Licensed Territory pursuant to and in accordance in all material respects with all applicable Law and will not make any materially false or misleading statement to a Regulatory Authority in connection with such Regulatory Materials;

(c) it will not knowingly employ any personnel or knowingly use a contractor or consultant that has been debarred or subject to a similar sanction by any Regulatory Authority or that is the subject of any investigation or proceeding with respect thereto;

(d) during the Term and for a period of [***] thereafter, Licensee shall not, and shall cause its Affiliates not to, directly or indirectly, develop, manufacture, market, promote, import, export, or sell, or assist any Third Party, directly or indirectly, to develop, manufacture, market, promote, import, export, or sell anywhere in the world, any generic version of the Product without the prior written consent of TESARO (collectively, "**Competing Activities**"); provided, that if Licensee is merged or consolidated with a Third Party or enters into any transaction with a Third Party that, in either case, is at the time of entering into the transaction, engaged in Competing Activities and, as a result of such transaction becomes an Affiliate of Licensee (a "**Subject Transaction**"), nothing in this section shall restrict such Third Party or its Affiliates ("**Post-Execution Affiliate**") from continuing to pursue or engage in the research, development, manufacture or commercialization of any product in connection with programs of such Post-Execution Affiliate existing prior to the effective time of such Subject Transaction, provided that:

(1) Licensee shall provide TESARO with written notice of any such Subject Transaction within [***] following the earlier of the first public announcement of the execution of any agreement with respect to such Subject Transaction and the closing date of such Subject Transaction; and

(2) such Post-Execution Affiliate's Competing Activities shall be kept separate from the activities of Licensee;

(e) Licensee shall seek TESARO's input in connection with its determination of the following matters: (i) the last to expire Valid Claim that prevents the entry of a Generic Product in Japan; and (ii) the expiration of the Drug Re-Examination Period for the primary indication of the Product in Japan (the last of (i) and (ii) to occur, the "**Expiration Event**"). [***]; and

(f) During the Term, Licensee shall not amend, waive or otherwise modify (or consent to any of the foregoing) [***] in any manner that would reasonably be expected to conflict with the terms of this Agreement, including the consideration payable to TESARO hereunder for the rights and licenses granted to Licensee, or the segregation of TESARO's Confidential Information, including Licensed Know-How and any other information related to the Licensed Compound or Product that is not part of the public domain, without TESARO's prior written consent.

6.5.2 TESARO Covenants. TESARO covenants to Licensee that:

(a) it will conduct, and will use reasonable efforts to cause its contractors to conduct, all preclinical and clinical studies for the Product and the manufacturing of the Product in accordance in all material respects with (i) all applicable Laws in the TESARO Territory, (ii) the published standards of any applicable Regulatory Authorities in the TESARO Territory, and (iii) the scientific standards applicable to the conduct of such studies and activities in the TESARO Territory, including current good laboratory practice, current good clinical practice and current good manufacturing practice, in each case to the extent necessary to support Licensee's Development and Commercialization of the Licensed Compound and Product in the Licensed Territory;

(b) it (i) will prepare, maintain and retain all Regulatory Materials in the TESARO Territory pursuant to and in accordance in all material respects with all applicable Law, and (ii) will not make any materially false or misleading statement to a Regulatory Authority in connection with such Regulatory Materials, in each case to the extent necessary to support Licensee's Development, Manufacturing and Commercialization of the Licensed Compound and Product in the Licensed Territory; and

(c) it will not knowingly employ any personnel or knowingly use a contractor or consultant that has been debarred or subject to a similar sanction by any Regulatory Authority or that is the subject of any investigation or proceeding with respect thereto.

Section 6.6 Upstream Agreements.

6.6.1 Licensee Compliance. Licensee acknowledges and agrees that the rights and licenses granted by TESARO to Licensee under this Agreement are subject to the terms of the Upstream Agreements. Licensee agrees to promptly take any action (or omission, to the extent applicable to Licensee) reasonably requested by TESARO that is necessary or advisable to maintain compliance with the terms and conditions of the Upstream Agreements.

6.6.2 TESARO Covenants. During the Term, TESARO shall maintain each Upstream Agreement in full force and effect and shall not terminate, amend, waive or otherwise modify (or consent to any of the foregoing) its rights under any Upstream Agreement in any manner that materially diminishes the rights or licenses granted to Licensee hereunder or increases or generates any new payment obligation under any Upstream Agreement that would apply to Licensee without Licensee's prior written consent. During the Term, TESARO agrees to undertake to notify Licensee in writing of any threatened termination in writing of any of the Upstream Agreements or the Janssen Agreement by Merck, AZ or Janssen, as applicable.

Section 6.7 **Compliance with Law.** Each Party agrees that, in connection with the performance and exercise of its rights and obligations under this Agreement, it will comply with all applicable Law, including without limitation the FCPA and/or all applicable Anti-Corruption Laws. In particular, neither Party nor any of its directors, officers, employees or agents will, directly or indirectly, make, offer, promise, authorize, solicit or accept any unlawful payment, kickback, gift, rebate, or other thing of value to, from, or for the benefit of any Person to obtain or retain business for or with, or to direct business to, any Person.

ARTICLE 7. INDEMNIFICATION

Section 7.1 **Indemnity.**

7.1.1 Indemnification by TESARO. TESARO agrees to defend, indemnify and hold Licensee, its Affiliates and their respective directors, officers, employees and agents (the "**Licensee Indemnified Parties**") harmless from and against any claims, losses, costs, damages, fees or expenses (including legal fees and expenses) (collectively, "**Losses**") resulting from any Third Party claim (including product liability claims based upon the use of the Product) arising out of or otherwise relating to (a) the negligence or willful misconduct of TESARO, (b) the Development, Manufacture or Commercialization of the Product by or on behalf of TESARO, (c) the material breach of this Agreement by TESARO, or (d) any failure to meet the relevant specifications and warranties set forth in the Supply Agreements, or other manufacturing defect, in either case relating to the Compound API, Bulk Product and/or Primary Packaged Product existing at the time that it is delivered by TESARO to Licensee under the Supply Agreements; except, in each case, to the extent such Losses result from clause (a), (b), (c) or (d) of Section 7.1.2. In the event of any such claim against the Licensee Indemnified Parties by a Third Party, Licensee shall promptly notify TESARO in writing of the claim (provided, however, that any failure or delay to notify shall not excuse any obligations of TESARO except to the extent TESARO is actually prejudiced thereby) and TESARO shall solely manage and control, at its sole expense, the defense of the claim and its settlement; provided, however, that TESARO shall not settle any such claim without the prior written consent of Licensee if such settlement does not include a complete release from liability of the Licensee Indemnified Parties or if such settlement would involve the undertaking of any obligation by any Licensee Indemnified Party, would bind or impair any Licensee Indemnified Party, or includes any admission of wrongdoing by any Licensee Indemnified Party. The Licensee Indemnified Parties shall cooperate with TESARO and may, at their sole option and expense, be represented in any such action or proceeding by counsel of their own choosing.

7.1.2 Indemnification by Licensee. Licensee agrees to defend, indemnify and hold TESARO and its Affiliates and their respective directors, officers, employees and agents (the "**TESARO Indemnified Parties**") harmless from and against any Losses resulting from any Third Party claim (including product liability claims) arising out of or otherwise relating to (a) the negligence or willful misconduct of Licensee, its Affiliates, or Sublicensees, (b) the Development,

Manufacture or Commercialization of the Product by or on behalf of Licensee, its Affiliates, or Sublicensees, (c) the material breach of this Agreement by Licensee, or (d) any action or omission of Licensee, its Affiliates or Sublicensees that causes a breach of or results in non-compliance under the Upstream Agreements; except, in each case, to the extent such Losses result from clause (a), (b), (c) or (d) of Section 7.1.1. In the event of any such claim against the TESARO Indemnified Parties by a Third Party, TESARO shall promptly notify Licensee in writing of the claim (provided, however, that any failure or delay to notify shall not excuse any obligation of Licensee except to the extent Licensee is actually prejudiced thereby) and Licensee shall solely manage and control, at its sole expense, the defense of the claim and its settlement; provided, however, that Licensee shall not settle any such claim without the prior written consent of TESARO if such settlement does not include a complete release from liability of the TESARO Indemnified Parties or if such settlement would involve the undertaking of any obligation by any TESARO Indemnified Party, would bind or impair a TESARO Indemnified Party, or includes any admission of wrongdoing by any TESARO Indemnified Party. The TESARO Indemnified Parties shall cooperate with Licensee and may, at their sole option and expense, be represented in any such action or proceeding by counsel of their own choosing.

Section 7.2 **LIMITATION OF DAMAGES.** IN NO EVENT SHALL EITHER PARTY BE LIABLE HEREUNDER TO THE OTHER PARTY FOR ANY PUNITIVE, RELIANCE, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOST REVENUE, LOST PROFITS, OR LOST SAVINGS) HOWEVER CAUSED AND UNDER ANY THEORY, EVEN IF IT HAS NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE LIMITATIONS SET FORTH IN THIS SECTION 7.2 SHALL NOT APPLY WITH RESPECT TO (A) ANY BREACH OF ARTICLE 8 OR (B) THE INTENTIONAL MISCONDUCT OF A PARTY. NOTHING IN THIS SECTION 7.2 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY UNDER THIS ARTICLE 7 WITH RESPECT TO ANY DAMAGES PAID TO A THIRD PARTY IN CONNECTION WITH A THIRD-PARTY CLAIM.

Section 7.3 **Insurance.** At such time as Licensee or any of its Affiliates or Sublicensees begins to sell or distribute Product, Licensee shall, at its own expense, procure and maintain product liability insurance in the amount of [***]. All such policies shall name Merck as an additional insured, and insurers will waive all rights of subrogation against Merck. Upon TESARO's request, Licensee will promptly provide for itself and its Affiliates and Sublicensees copies of certificates of insurance evidencing such coverages. Licensee shall notify TESARO not less than twenty-five (25) days in advance of any material change or cancellation of any policy. Licensee shall continue to maintain such insurance in effect after the expiration or termination of this Agreement during any period in which Licensee or its Affiliates or Sublicensees continues to make, have made, use, sell, offer to sell or import Product. If any insurance is on a claims made basis, Licensee will maintain such insurance for a period of not less than [***] after it has ceased all commercial sale, distribution or use of any Product. The Parties acknowledge and agree that Licensee may meet its obligations under this Section 7.3 through self-insurance.

ARTICLE 8. CONFIDENTIALITY

Section 8.1 Confidential Information.

8.1.1 Definition. "**Confidential Information**" means all Know-How and other confidential or proprietary information, materials and data, whether or not marked as confidential or proprietary, which the disclosing Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates hereunder, whether made available orally, in writing or in electronic or other form, including information comprising or relating to concepts, discoveries, inventions, ideas, data, designs or formulae. Any confidential or proprietary information, materials or data of any Upstream Licensor which TESARO makes available to Licensee hereunder shall constitute Confidential Information of TESARO for purposes of this Article 8.

8.1.2 Confidential Information. During the Term and for a period of [***] after any termination or expiration of this Agreement, each Party agrees to keep in confidence and not to disclose to any Third Party, or use for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement or as otherwise specifically permitted under this Agreement, any Confidential Information of the other Party. The terms of this Agreement will be considered Confidential Information of both Parties, subject to permitted disclosures as set forth in this Article 8. The restrictions on the disclosure and use of Confidential Information set forth in this Article 8 will not apply to any Confidential Information that:

(a) was known by the receiving Party prior to disclosure by the disclosing Party hereunder (as evidenced by the receiving Party's written records or other competent evidence);

(b) is or becomes part of the public domain through no fault of the receiving Party or its Affiliates or Sublicensees;

(c) is disclosed to the receiving Party by a Third Party having a legal right to make such disclosure without violating any confidentiality or non-use obligation that such Third Party has to the disclosing Party and provided such Third Party is not disclosing such information on behalf of the disclosing Party; or

(d) is independently developed by personnel of the receiving Party who did not have access to the Confidential Information (as evidenced by the receiving Party's written records or other competent evidence).

In addition, if either Party is required to disclose Confidential Information of the other Party by regulation, Law or legal process, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the

United States or of any stock exchange, such Party shall provide prior written notice and a copy of such intended disclosure to such other Party if possible under the circumstances, will consider in good faith the other Party's comments, will disclose only such Confidential Information of such other Party as is required to be disclosed and will cooperate in the disclosing Party's efforts to obtain a protective order or to limit the scope of the required disclosures. Notwithstanding anything in this Agreement to the contrary, either Party may disclose to bona fide potential or existing investors or lenders, potential acquirors/acquirees, and such Party's consultants and advisors, the existence and terms of this Agreement to the extent necessary in connection with a proposed equity or debt financing of such Party, or a proposed acquisition or business combination or similar transaction, so long as such recipients are bound in writing to maintain the confidentiality of such information.

8.1.3 Permitted Disclosures. Each Party agrees that it and its Affiliates will provide or permit access to Confidential Information received from the other Party and such Party's Affiliates and representatives only to the receiving Party's employees, agents, consultants, Affiliates, advisors, contractors, potential and existing Sublicensees and distributors, in each case who, in such Party's reasonable judgment, have a need to know such Confidential Information to assist the receiving Party with the activities contemplated by this Agreement, and who are subject to obligations of confidentiality and non-use with respect to such Confidential Information similar to the obligations of confidentiality and non-use of the receiving Party under this Section 8.1. Each Party shall remain responsible for any failure by its Affiliates, and its and its Affiliates' respective employees, agents, consultants, advisors, contractors, Sublicensees and distributors, to treat such Confidential Information as required under this Section 8.1 (as if such Affiliates, employees, agents, consultants, advisors, contractors, Sublicensees and distributors were Parties directly bound to the requirements of this Section 8.1).

8.1.4 Restricted Disclosures. Notwithstanding anything to the contrary set forth in this Agreement, Licensee shall not have the right to, and shall ensure that its Affiliates and Sublicensees shall not, disclose (a) TESARO's Confidential Information, including Licensed Know-How or information relating to the Licensed Patents, and any other information relating to the Licensed Compound or Product that is not part of the public domain, or (b) the terms of this Agreement, to [***] for any reason without the prior written consent of TESARO. Licensee shall establish appropriate fire-walls and other procedures to prevent the disclosure of such information to [***] or any individuals associated with such entities, including any individuals that may from time-to-time be employed by or consult for Licensee or a member of the Takeda Group and also be seconded to or consult for [***]. The Parties acknowledge and agree that a breach of this Section 8.1.4 shall be deemed to be a material breach by Licensee for purposes of Section 9.2.1.

Section 8.2 **Return/Destruction of Materials.** Upon early termination of this Agreement in its entirety for any reason, each Party and its Affiliates shall immediately return to the other Party or destroy all Confidential Information of the other Party and its Affiliates in such Party's

possession, except for one (1) copy which may be retained in the recipient Party's confidential files for archive purposes.

Section 8.3 **Publicity.** The Parties agree not to (and to ensure that their respective Affiliates do not) issue any press releases or public announcements concerning this Agreement or the transactions contemplated hereby without the prior written consent of the other Party (which shall not be unreasonably withheld or delayed), except as required by applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded); provided, that the Party intending to disclose such information shall use reasonable efforts to provide the other Party with advance notice of such required disclosure, and an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party). Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate information concerning this Agreement which information was included in a press release or public disclosure which was previously disclosed under the terms of this Agreement or which contains only non-material factual information regarding this Agreement.

Section 8.4 **Relationship to the Confidentiality Agreement.** This Agreement supersedes that certain Confidentiality Agreement by and between TESARO and Licensee dated April 17, 2015, as amended effective as of March 21, 2017; provided, however, that all "Confidential Information" disclosed or received by the Parties thereunder will be deemed "Confidential Information" hereunder and will be subject to the terms and conditions of this Agreement.

ARTICLE 9. TERM & TERMINATION

Section 9.1 **Term.** This Agreement shall be effective as of the Effective Date and, unless terminated earlier by mutual written agreement of the Parties or pursuant to Sections 9.2, 9.3 or 9.4 below, shall continue in effect, on a country-by-country and Product-by-Product basis, until the expiration of the Royalty Term for such Product (the "**Term**"). Subject to the applicable terms of any Upstream Agreement, upon expiration of each Term with respect to a Product in a particular country in the Licensed Territory, Licensee's license pursuant to Section 2.1 shall become fully paid-up, irrevocable, perpetual and sublicensable without restriction.

Section 9.2 **Termination by TESARO.**

9.2.1 Breach. TESARO will have the right to terminate this Agreement in full upon delivery of written notice to Licensee in the event of any material breach by Licensee of any term or condition of this Agreement; provided, however, that such termination will not be effective if such breach has been cured within [***] after written notice thereof is given by TESARO to Licensee specifying the nature of the alleged breach; provided further, however, that to the extent such material breach involves (i) the failure to make a payment when due, such breach must be cured within [***] after written notice thereof is given by TESARO to Licensee, or (ii) a breach of Section 8.1.4, TESARO shall be entitled to terminate this Agreement immediately upon written

notice without any cure period. For clarity, termination of this Agreement under this Section 9.2.1 is not the exclusive right available to TESARO under this Agreement with respect to any uncured material breach by Licensee.

9.2.2 Termination for IP Challenge. TESARO will have the right to terminate this Agreement in full upon [***] advance written notice to Licensee in the event that (a) Licensee or any of its Affiliates or Sublicensees or any member of the Takeda Group directly or indirectly challenges in a legal or administrative proceeding anywhere in the world the patentability, enforceability or validity of (i) any Licensed Patents, or (ii) any other Patent Rights owned or Controlled by TESARO at any time during the Term that Cover (1) the compositions of matter of the Licensed Compound or Product, (2) methods or processes directed to the Manufacture of the Licensed Compound or Product, or (3) methods of use, administration or formulation of the Licensed Compound or Product (any such legal or administrative proceeding, a "**Patent Challenge**"), or (b) [***] directly or indirectly initiates a Patent Challenge and TESARO can establish by competent proof (which determination shall, in the event of any dispute between the Parties with respect thereto, be subject to arbitration in accordance with Section 10.4) that such Patent Challenge incorporates or is otherwise based in whole or in part on TESARO's Confidential Information, including Licensed Know-How or information relating to the Licensed Patents or any other information relating to the Licensed Compound or Product that is not part of the public domain; provided, however, that TESARO will not have the right to terminate this Agreement under this Section 9.2.2 for any such Patent Challenge if such Patent Challenge is dismissed within [***] of TESARO's notice to Licensee under this Section 9.2.2 and not thereafter continued.

9.2.3 Termination for Termination of Upstream Agreement. Subject to Section 6.6.2, and the second sentence of Section 6.6.1, if applicable , TESARO will have the right to terminate this Agreement in full upon written notice to Licensee upon the notice of the potential termination of any Upstream Agreement due to any action or inaction of the Licensee if such action or inaction is not cured prior to the expiration of any applicable cure-period in such Upstream Agreement.

9.2.4 Termination for Generic Product. TESARO shall have the right terminate this Agreement with respect to Japan upon [***] prior written notice to Licensee at any time after [***] of the date of the First Commercial Sale of a Generic Product in Japan; provided, that if at any time during the Term Licensee no longer has direct or indirect ownership of any voting or economic interest other than those arising from or in relation to the Pre-Effective Date Wholesaler Agreements in [***], Licensee shall have the right to provide TESARO written notice thereof, and upon receipt of such notice, TESARO's right to terminate under this Section 9.2.4 shall no longer be effective for so long as Licensee continues not to have any direct or indirect ownership of any voting or such economic interest in [***].

Section 9.3 Termination by Licensee.

9.3.1 Breach. Licensee will have the right to terminate this Agreement in full upon delivery of written notice to TESARO in the event of any material breach by TESARO of any term or condition of this Agreement; provided, however, that such termination will not be effective if such breach has been cured within [***] after written notice thereof is given by Licensee to TESARO specifying the nature of the alleged breach. For clarity, termination of this Agreement under this Section 9.3.1 is not the exclusive remedy available to Licensee under this Agreement with respect to any uncured material breach by TESARO. If Licensee has the right to terminate this Agreement under this Section 9.3.1, then in lieu of exercising such right of termination, Licensee shall have the right, in its sole discretion and upon delivery of written notice to TESARO, to continue to maintain this Agreement in full force and effect, including all rights and licenses granted by TESARO to Licensee hereunder, provided that (a) Licensee continues to perform all of its obligations and comply with all of its covenants set forth in this Agreement, including all payment and other obligations arising under the Upstream Agreements, and (b) Licensee shall have the right to deposit into a Third Party escrow account any amounts payable directly by Licensee to TESARO under this Agreement, other than amounts that are due under the Upstream Agreements, that Licensee reasonably and in good faith estimates are consistent with the damages suffered by Licensee as a result of TESARO's alleged uncured material breach pending resolution of any dispute relating to such alleged uncured material breach pursuant to Sections 10.3 and 10.4, with such amounts to be released to Licensee or TESARO, as applicable, promptly following resolution of such dispute.

9.3.2 Partial Termination. Licensee will have the right to terminate this Agreement on a country-by-country basis upon delivery of [***] prior written notice to TESARO.

Section 9.4 **Termination Upon Bankruptcy.** Either Party may terminate this Agreement if, at any time, any Insolvency Event occurs in relation to the other Party.

Section 9.5 **Effects of Termination.** Except as otherwise set forth in Section 9.6, upon early termination of this Agreement by either Party under this Article 9:

(a) Licensee will responsibly wind-down, in accordance with accepted pharmaceutical industry norms and ethical practices, any on-going clinical studies for which it has responsibility hereunder in which patient dosing has commenced or, if reasonably practicable and requested by TESARO, Licensee shall, and shall cause its Affiliates and Sublicensees to, complete such trials. Licensee will be responsible for any costs associated with such wind-down. TESARO will pay all costs incurred by either Party to complete such studies should TESARO request that such studies be completed.

(b) All sublicenses granted by Licensee pursuant to Section 2.2 will automatically terminate.

(c) All rights and licenses granted by TESARO to Licensee in Article 2 will terminate, and Licensee and its Affiliates and Sublicensees will cease all use of Licensed Know-How and Licensed Patents and all Development, Manufacture and Commercialization of the Licensed Compound and Product.

(d) All rights and licenses related to the Licensed Compound and Product in the Licensed Territory shall immediately revert to TESARO or to an Affiliate or Third Party designated by TESARO (each, a "**Designee**").

(e) All Marketing Approvals and other regulatory filings, documents and communications relating to the Product owned (in whole or in part) or otherwise controlled by Licensee or its Affiliates or Sublicensees, as such items exist as of the effective date of such termination (including all related completed and ongoing clinical studies) will be assigned to TESARO or its Designee and Licensee will provide to TESARO or its Designee one (1) copy of each of the foregoing and all documents contained in or referenced in any such items, together with the raw and summarized data for any clinical studies (and where reasonably available, electronic copies thereof). In the event of any failure to complete such assignment, Licensee hereby consents and grants to TESARO the right to access and reference (without any further action required on the part of Licensee, whose authorization to file this consent with any Regulatory Authority is hereby granted) any of the foregoing items.

(f) Licensee hereby grants to TESARO and its Affiliates, and TESARO and its Affiliates will automatically have, a perpetual and irrevocable, royalty-free and fully paid-up, non-exclusive license, with the right to grant sublicenses through multiple tiers, under Know-How and Patent Rights that are Controlled by Licensee or any of its Affiliates and their respective Sublicensees that are necessary or useful to Development, Manufacture or Commercialize the Product in the Licensed Territory (such license effective only as of and after the effective date of such termination).

(g) Upon TESARO's request, Licensee will assign (or, if applicable, will cause its Affiliates or Sublicensees to assign) to TESARO all of Licensee's (and such Affiliates' and Sublicensees') right, title and interest in and to any registered or unregistered trademarks or internet domain names that are specific to the Product (it being understood that the foregoing will not include any trademarks or internet domain names that contain the corporate or business name(s) of Licensee).

(h) Licensee agrees (and shall cause its Affiliates and Sublicensees to so agree) to fully cooperate with TESARO and its Designee(s) to facilitate a smooth, orderly and prompt transition of the Development, Manufacture and Commercialization of the Licensed Compound and the Product in the Licensed Territory to TESARO and/or its Designee(s). Upon request by TESARO, Licensee shall transfer to TESARO or its Designee(s) any quantity of the Product in its possession as of the effective date of termination. If Licensee is, at the time of such termination of this Agreement, party to any Third Party contracts with respect to the Product, then it shall provide TESARO notice and (to the extent permitted by the terms thereof to do so), copies thereof. Licensee shall assign to TESARO any such contracts requested by TESARO, to the extent it has the right under such contract(s) to do so (and shall use commercially reasonable efforts to obtain any required consents to assign such contracts to TESARO). In addition, Licensee shall provide any cooperation reasonably requested by TESARO to ensure uninterrupted supply of the Product in the Licensed Territory.

(i) Licensee agrees to take any other action necessary in order to ensure compliance with the terms of the Upstream Agreements.

For clarity, if Licensee terminates this Agreement as to a particular country or countries within the Licensed Territory in accordance with Section 9.3.2, then the foregoing provisions shall apply solely with respect to the country or countries that are subject to termination.

Section 9.6 **Effect of Termination (Material Breach by TESARO).** Upon any termination of this Agreement by Licensee pursuant to Section 9.3.1 resulting from a material breach of this Agreement by TESARO, then the provisions of Sections 9.5(a), (b) and (c) shall apply (except that compliance with subsection (a) shall be at the cost of TESARO), and Sections 9.5(d), (e), (f), (g), (h) and (i) shall have no effect. In addition if the material breach is a breach of Section 6.6.2 with respect to the Merck Agreement, then TESARO shall use reasonable efforts to cause Merck to enter into a direct license with Licensee for the Licensed Territory.

Section 9.7 **Survival.** The following provisions will survive termination or expiration of this Agreement: Sections 2.3, 2.8, 3.6, 3.8, 3.9, 3.10, 6.4, 6.5.1(d), 6.6.1, 9.5, 9.6 and this Section 9.7, and Articles 7, 8 and 10, as well as any applicable definitions in Article 1 and any other provisions which are expressed to survive termination or expiration or which are required to give effect to such termination or expiration. Termination or expiration of this Agreement will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration nor preclude either Party from pursuing all rights and remedies it may have hereunder or at Law or in equity with respect to any breach of this Agreement.

ARTICLE 10. MISCELLANEOUS

Section 10.1 **Entire Agreement; Amendment.** This Agreement and all Exhibits attached to this Agreement constitute the entire agreement between the Parties as to the subject matter hereof. All prior and contemporaneous negotiations, representations, warranties, agreements, statements, promises and understandings with respect to the subject matter of this Agreement are hereby superseded and merged into, extinguished by and completely expressed by this Agreement. None of the Parties shall be bound by or charged with any written or oral agreements, representations, warranties, statements, promises or understandings not specifically set forth in this Agreement. No amendment, supplement or other modification to any provision of this Agreement shall be binding unless in writing and signed by all Parties.

Section 10.2 **Independent Contractors.** The relationship between Licensee and TESARO created by this Agreement is solely that of independent contractors. This Agreement does not create any agency, distributorship, employee-employer, partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

Section 10.3 **Informal Discussions.** Except as otherwise provided herein, in the event of any controversy or claim arising out of or relating to this Agreement, or the rights or obligations of the Parties hereunder, or the relationship between the Parties with respect to the Licensed Compounds or Products, the Parties shall first try to settle their differences amicably between themselves. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and within thirty (30) days after such notice appropriate representatives of the Parties shall meet for attempted resolution by good faith negotiations. If such representatives are unable to resolve promptly such disputed matter within the said thirty (30) days, either Party may refer the matter by written notice to the Executive Officers for discussion and resolution. If such Executive Officers are unable to resolve such dispute within thirty (30) days of such written notice, either Party may initiate arbitration proceedings in accordance with the provisions of Section 10.4.

Section 10.4 **Arbitration.** All disputes arising out of or relating to this Agreement, or the rights or obligations of the Parties hereunder, or relating in any way to the relationship between the Parties with respect to the Licensed Compounds or Products, shall be finally and exclusively settled by arbitration by a panel of three (3) arbitrators, provided such dispute is not an "**Excluded Claim**." As used in this Section, the phrase "Excluded Claim" shall mean a dispute, controversy or claim that concerns (a) the validity or Infringement of a patent, trademark or copyright (which shall not, for clarity, include any dispute, controversy or claim as to whether TESARO has established the relevant competent proof referenced in Section 9.2.2), (b) any antitrust, anti-monopoly or competition Law or regulation, whether or not statutory, or (c) any matter for which a Party has final decision-making authority under Section 5.1.5.

10.4.1 The arbitration proceeding shall be conducted under the Commercial Arbitration Rules of the American Arbitration Association ("**AAA**") with such proceedings to be held in New York, New York, United States. The arbitrators will apply the substantive Law of the State of New York. In all cases, the arbitration proceedings shall be conducted in the English language, and all documents that are submitted in the proceeding shall be in the English language. Judgment upon the award rendered by arbitration may be issued and enforced by any court having competent jurisdiction.

10.4.2 If a Party intends to begin an arbitration to resolve a dispute, such Party shall provide written notice to the other Party, informing the other Party of such intention and any statement of claim required under the applicable arbitration rules. Within twenty (20) Business Days after its receipt of such notice, the other Party shall, by written notice to the Party initiating arbitration, add any additional issues to be resolved that would be considered mandatory counterclaims under New York Law. For clarity, the resolution of any disputes regarding such counterclaims shall be conducted in the same proceedings as the initial claims.

10.4.3 Within forty-five (45) days following the receipt of the notice of arbitration, the Party referring the matter to arbitration shall appoint an arbitrator and promptly notify the other Party of such appointment. The other Party shall, upon receiving such notice, appoint a second arbitrator within twenty one (21) days, and the two (2) arbitrators shall, within fifteen (15) days of the appointment of the second arbitrator, agree on the appointment of a third arbitrator who will act with them and be the chairperson of the arbitration panel. In the event that either Party shall fail to appoint an arbitrator within thirty (30) days after the commencement of the arbitration proceeding, the arbitrator shall be appointed by the AAA. In the event of the failure of the two (2) arbitrators to agree within sixty (60) days after the commencement of the arbitration proceeding to appoint the chairperson, the chairperson shall also be appointed by the AAA.

10.4.4 All of the arbitrators shall have significant legal or business experience in pharmaceutical licensing matters. The arbitrators shall not be employees, directors or shareholders of either Party or any of their Affiliates.

10.4.5 Each Party shall have the right to be represented by counsel throughout the arbitration proceedings.

10.4.6 To the extent possible, the arbitration hearings and award will be maintained in confidence.

10.4.7 In any arbitration pursuant to this Agreement, the award or decision shall be rendered by a majority of the members of the panel provided for herein, with each member having one (1) vote. The arbitrators shall render a written decision with their resolution of the dispute that shall set forth in reasonable detail the facts of the dispute and the

reasons for their decision. The decision of the arbitrators shall be final and non-appealable and binding on the Parties.

Section 10.5 **Injunctive Relief.** By agreeing to arbitration, the Parties do not intend to deprive any competent court of such court's jurisdiction to issue a pre-arbitral injunction, pre-arbitral attachment or other order in aid of the arbitration proceedings and the enforcement of any award or judgment. Without prejudice to such provisional remedies in aid of arbitration as may be available under the jurisdiction of a national court, the court of arbitration shall have full authority to grant provisional remedies and to award damages for failure of any Party to respect the court of arbitration's order to that effect.

Section 10.6 **Expenses of Arbitration and Expert Determination.** Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators; provided, however, that the arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges and travel expenses). Absent the filing of an application to correct or vacate the arbitration award as permitted by applicable Law, each Party shall fully perform and satisfy the arbitration award within fifteen (15) days of the service of the award.

Section 10.7 **Notice.** All notices or communications required or permitted to be given by either Party hereunder shall be deemed sufficiently given if mailed by registered mail or certified mail, return receipt requested, or sent by overnight courier, such as Federal Express, to the other Party at its respective address set forth below or to such other address as notified by the other Party from time to time pursuant to this Section 10.7. Mailed notices shall be deemed to be received on the third (3rd) Business Day following the date of mailing. Notices sent by overnight courier shall be deemed received the following Business Day.

If to Licensee: MILLENNIUM PHARMACEUTICALS, INC.
40 Landsdowne Street,
Cambridge, MA 02139
Attn: Regional General Counsel

If to TESARO: TESARO, Inc.
1000 Winter Street
Suite 3300
Waltham, MA 02451
Attn: General Counsel

with a copy (which shall not constitute notice) to:

Hogan Lovells US LLP
100 International Drive, Suite 2000
Baltimore, MD 21202
Attn: Asher M. Rubin

Section 10.8 **Governing Law.** This Agreement and any dispute arising from the performance of breach hereof shall be governed by and construed and enforced in accordance with the Laws of the State of New York without reference to conflicts of Laws principles which would direct the application of the Laws of another jurisdiction.

Section 10.9 **Compliance With Law; Severability.** Nothing in this Agreement shall be construed to require the commission of any act contrary to Law. If any one or more provisions of this Agreement is held to be invalid, illegal or unenforceable, the affected provisions of this Agreement shall be curtailed and limited only to the extent necessary to bring it within the applicable legal requirements and the validity, legality and enforceability of the remaining provisions of this Agreement shall not in any way be affected or impaired thereby.

Section 10.10 **Non-Use of Names.** Licensee shall not use the name, trademarks, tradenames, logos, or physical likeness of TESARO or any of its officers, directors or employees or any of the Upstream Licensors, or any adaptation of any of them, in any advertising, promotional or sales literature, without TESARO's prior written consent. Licensee shall require its Affiliates and Sublicensees to comply with the foregoing. TESARO shall not use the name, trademarks, tradenames, logos, or physical likeness of Licensee or any of its officers, directors or employees, or any adaptation of any of them, in any advertising, promotional or sales literature, without Licensee's prior written consent. TESARO shall require its Affiliates to comply with the foregoing.

Section 10.11 **Successors and Assigns.** Neither this Agreement nor any of the rights or obligations created herein, may be assigned by either Party, in whole or in part, without the prior written consent of the other Party, except that either Party shall be free to assign this Agreement (a) as a whole or in part without consent to an Affiliate, or (b) as a whole without consent in connection with any merger or sale of such Party or sale of all or substantially all of the assets of such Party related to the business-line or division of that Party that is the beneficiary of the rights and licenses granted under this Agreement; provided, that Licensee may not assign this Agreement in any circumstance to a Post-Execution Affiliate engaged in Competing Activities. This Agreement shall bind and inure to the benefit of the successors and permitted assigns of the Parties hereto. Any assignment of this Agreement in contravention of this Section 10.11 shall be null and void.

Section 10.12 **Waivers.** A Party's consent to or waiver, express or implied, of the other Party's breach of its obligations hereunder shall not be deemed to be or construed as a consent to or waiver of any other breach of the same or any other obligations of such breaching Party. A Party's failure to complain of any act, or failure to act, by the other Party, to declare the other Party in default, to insist upon the strict performance of any obligation or condition of this Agreement or to exercise any right or remedy consequent upon a breach thereof, no matter how long such failure continues, shall not constitute a waiver by such Party of its rights hereunder, of any such breach, or of any other obligation or condition. A Party's consent in any one instance shall not limit or waive the necessity to obtain such Party's consent in any future instance and in any event no consent or waiver shall be effective for any purpose hereunder unless such consent or waiver is in writing and signed by the Party granting such consent or waiver.

Section 10.13 **No Third Party Beneficiaries.** Except as expressly set forth herein, nothing in this Agreement shall be construed as giving any Person, other than the Parties hereto and their successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement or any provision hereof.

Section 10.14 **Headings; Exhibits.** Article and Section headings used herein are for convenient reference only, and are not a part of this Agreement. All Exhibits are incorporated herein by this reference.

Section 10.15 **Interpretation.** The terms "hereof", "herein" and "hereunder" and terms of similar import will refer to this Agreement as a whole and not to any particular provision hereof. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). The term "including" as used herein shall mean including, without limiting the generality of any description preceding such term. The language in all parts of this Agreement shall be deemed to be the language mutually chosen by the Parties. The Parties and their counsel have cooperated in the drafting and preparation of this Agreement, and this Agreement therefore shall not be construed against any Party by virtue of its role as the drafter thereof.

Section 10.16 **Counterparts.** This Agreement may be executed in one or more counterparts, each of which when taken together shall constitute one and the same agreement, and may be executed through the use of facsimiles or .pdf documents.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

TESARO, INC.	**MILLENNIUM PHARMACEUTICALS, INC.**
By: /s/ Mary Lynne Hedley, Ph.D.	By: /s/ Christophe Bianchi
Name: Mary Lynne Hedley, Ph.D.	Name: Christophe Bianchi
Title: President and Chief Operating Officer	Title: President, Global Oncology Business Unit

[***] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT A

LICENSED COMPOUND

Niraparib, formerly known as MK-4827, licensed to TESARO under the Merck Agreement, a potent and selective poly (ADP-ribose) polymerase (PARP) inhibitor, with the chemical name as follows:

[***]

[***] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT B

LICENSED PATENTS

[***]

[***] INDICATES FOUR PAGES OF MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT C

MILESTONES & ROYALTIES

1. Milestone Payments: The Milestone Events and corresponding Milestone Payments to be made pursuant to Section 3.2 of the Agreement are as follows:

Development Milestones

Milestone Event	Payment (in US millions)
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Subject to the last sentence of Section 3.2, each Milestone Event for a non-prostate indication shall be determined on a tumor type-by-tumor type basis (such as ovarian cancer and breast cancer), irrespective of dosage form, insofar as the Product that is the subject of each such Milestone Event is designed to dose patients orally. For the avoidance of doubt and by way of example, if the Product is first approved for 2nd-line therapy of ovarian cancer and then the indication is extended to 1st-line therapy of ovarian cancer, only the filing and approval for the 2nd-line therapy of ovarian cancer shall be deemed to be the triggering event for the Milestone Payment for such non-prostate indication. Subject to the last sentence of Section 3.2, the salvage line for ovarian cancer (i.e., patients who have had three (3) or more lines of prior therapy, like QUADRA) shall not [***].

Sales Milestones

Milestone Event	Payment (in US millions)
Upon the first time that annual Net Sales of Products in the Licensed Territory reaches [***]	[***]
Upon the first time that annual Net Sales of Products in the Licensed Territory reaches [***]	[***]
Upon the first time that annual Net Sales of Products in the Licensed Territory reaches [***]	[***]
Upon the first time that annual Net Sales of Products in the Licensed Territory reaches [***]	[***]
Upon the first time that annual Net Sales of Products in the Licensed Territory reaches [***]	[***]

2. Royalties: The Royalty rate payable under Section 3.3.1 of the Agreement shall be as follows:

Annual Net Sales of the Product in the Licensed Territory	Royalty Rate
Portion of annual Net Sales in the Licensed Territory below [***]	[***]

Annual Net Sales of the Product in the Licensed Territory	Royalty Rate
Portion of annual Net Sales in the Licensed Territory at or above [***] but below [***]	[***]
Portion of annual Net Sales in the Licensed Territory at or above [***] but below [***]	[***]
Portion of annual Net Sales in the Licensed Territory at or above [***] but below [***]	[***]
Portion of annual Net Sales in the Licensed Territory at or above [***] but below [***]	[***]
Portion of annual Net Sales in the Licensed Territory at or above [***]	[***]

[***] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT D

INITIAL DEVELOPMENT PLAN

[***]

[***] INDICATES FIVE PAGES OF MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT E

INITIAL MATERIALS

Type of Material	Purpose	Quantity of Material	Timing for Delivery	Cost
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

[***] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT F

EXCLUDED CMOS

[***]

[***] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Exhibit 31.1

CERTIFICATION

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

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

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

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

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

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

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

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

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

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

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

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

Date: November 7, 2017

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

Exhibit 31.2

CERTIFICATION

I, Timothy R. Pearson, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 7, 2017

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

Exhibit 32.1

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

In connection with the Quarterly Report of TESARO, Inc., or the Company, on Form 10-Q for the period ended September 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leon O. Moulder, Jr., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

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

November 7, 2017

Exhibit 32.2

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

In connection with the Quarterly Report of TESARO, Inc., or the Company, on Form 10-Q for the period ended September 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Timothy R. Pearson, Executive Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

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

November 7, 2017