TESARO, INC.

FORM 10-Q
(Quarterly Report)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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 March 31, 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 May 3, 2017, there were 53,864,741 shares of the registrant's Common Stock, par value $0.0001 per share, outstanding.

TESARO, INC.
FORM 10-Q
FOR THE THREE MONTHS ENDED MARCH 31, 2017

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PART I FINANCIAL INFORMATIO N

Item 1. Financial Statements .

TESARO, INC.

Condensed Consolidated Balance Sheet s

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

	December 31, 2016 (as revised)	March 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 785,877	$ 672,239
Accounts receivable	6,195	6,061
Inventories	14,700	15,643
Other current assets	10,515	13,625
Total current assets	817,287	707,568
Intangible assets, net	12,877	37,387
Property and equipment, net	6,640	8,618
Restricted cash	1,694	2,316
Other assets	3,795	5,116
Total assets	$ 842,293	$ 761,005
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,236	$ 10,343
Accrued expenses	68,700	68,975
Accrued milestone obligation	—	24,790
Deferred revenue, current	95	95
Other current liabilities	2,978	3,264
Total current liabilities	77,009	107,467
Convertible notes, net	131,775	134,532
Deferred revenue, non-current	305	282
Other non-current liabilities	5,086	5,516
Total liabilities	214,175	247,797
Commitments and contingencies (*Notes 10 and 12*)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at both December 31, 2016 and March 31, 2017; no shares issued or outstanding at both December 31, 2016 and March 31, 2017	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at both December 31, 2016 and March 31, 2017; 53,621,679 and 53,815,936 shares issued and outstanding at December 31, 2016 and March 31, 2017, respectively	5	5
Additional paid-in capital	1,604,798	1,626,533
Accumulated other comprehensive loss	(2,924)	(2,844)
Accumulated deficit	(973,761)	(1,110,486)
Total stockholders' equity	628,118	513,208
Total liabilities and stockholders' equity	$ 842,293	$ 761,005

See accompanying notes to condensed consolidated financial statements.

TESARO, INC.

Condensed Consolidated Statements of Operation s and Comprehensive Loss

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

	Three Months Ended March 31,	
	2016 (as revised)	2017
Revenues:		
Product revenue, net	$ 276	$ 2,139
License, collaboration and other revenues	24	934
Total revenues	300	3,073
Expenses:		
Cost of sales – product	79	444
Cost of sales – intangible asset amortization	464	490
Research and development	52,709	66,122
Selling, general and administrative	30,149	69,262
Acquired in-process research and development	4,000	—
Total expenses	87,401	136,318
Loss from operations	(87,101)	(133,245)
Interest expense	(3,981)	(4,267)
Interest income	102	841
Loss before income taxes	(90,980)	(136,671)
Provision for income taxes	—	54
Net loss	$ (90,980)	$ (136,725)
Net loss per share applicable to common stockholders - basic and diluted	$ (2.22)	$ (2.55)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	40,966	53,685
Comprehensive loss:		
Net loss	$ (90,980)	$ (136,725)
Other comprehensive gain (loss):		
Unrealized gain (loss) on pension obligation	(99)	45
Foreign currency translation adjustments	—	35
Other comprehensive gain (loss)	(99)	80
Comprehensive loss	$ (91,079)	$ (136,645)

See accompanying notes to condensed consolidated financial statements.

TESARO, INC.

Condensed Consolidated Statements of Cash Flow s

(all amounts in 000's)
(Unaudited)

	Three Months Ended March 31,	
	2016	2017
	(as revised)	
Operating activities		
Net loss	$ (90,980)	$ (136,725)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	4,000	—
Depreciation and amortization expense	733	954
Stock-based compensation expense	9,461	18,401
Non-cash interest expense	2,472	2,757
Changes in operating assets and liabilities:		
Accounts receivable	2,561	134
Inventories	(4,886)	(179)
Other assets	(656)	(3,462)
Accounts payable	4,293	5,119
Accrued expenses	3,923	(1,847)
Deferred revenues	(15)	(22)
Other liabilities	1,478	172
Net cash used in operating activities	(67,616)	(114,698)
Investing activities		
Acquisition of product candidate and technology licenses and milestone payments	(4,000)	—
Purchase of property and equipment	(380)	(1,790)
Change in restricted cash	—	(510)
Net cash used in investing activities	(4,380)	(2,300)
Financing activities		
Proceeds from sale of common stock, net of issuance costs	154,972	(8)
Proceeds from exercise of stock options	1,338	3,323
Net cash provided by financing activities	156,310	3,315
Effect of exchange rate changes on cash and cash equivalents	—	45
Increase (decrease) in cash and cash equivalents	84,314	(113,638)
Cash and cash equivalents at beginning of period	230,146	785,877
Cash and cash equivalents at end of period	$ 314,460	$ 672,239
Non-cash investing and financing activities		
Stock option exercise proceeds receivable as of period end	$ 82	$ 103
Leasehold improvement assets funded by lessor	$ —	$ 585
Purchase of property and equipment - cash not paid as of period end	$ —	$ 301
Supplemental disclosure of cash flow information		
Cash paid for interest	$ —	$ 3,019
Milestone obligation not paid as of period end	$ —	$ 24,790

See accompanying notes to condensed consolidated financial statements.

TESARO, INC.

Notes to Condensed Consolidated Financial Statement s
(Unaudited)

1. Description of Business

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

On September 1, 2015, the Company's first commercial product, VARUBI® (rolapitant), was approved by the United States Food and Drug Administration, or FDA, in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. The Company commenced sales of VARUBI during the fourth quarter of 2015. 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. 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 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 license and collaboration arrangements. Management expects operating losses and negative operating cash flows to continue for the foreseeable future. As the Company continues to incur losses, the transition to profitability is dependent upon the successful development, approval, and commercialization of its products and product candidates and the achievement of a level of revenues adequate to support its cost structure. The Company believes that its currently available funds in addition to cash generated from sales of its products will be sufficient to fund the Company's operations through at least the next 12 months from the issuance of this Quarterly Report on Form 10-Q. Management's belief with respect to its ability to fund operations is based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, the Company may need to seek additional funding.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements are unaudited and have been prepared by TESARO in conformity with accounting principles generally accepted in the United States of America, or GAAP. Certain amounts in the prior period financial statements have been reclassified to conform to the presentation of the current period financial statements. See " *New Accounting Pronouncements - Recently Adopted* " below for discussion of the Company's adoption of new revenue recognition guidance retroactive to January 1, 2015. Otherwise, these reclassifications had no significant effects on the previously reported net loss.

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

structure.

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 March 31, 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 months ended March 31, 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 gain (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 March 31, 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	$ 776,186	$ 776,186	$ —	$ —
Total assets		$ 776,186	$ 776,186	$ —	$ —

		March 31, 2017			
Description	**Balance Sheet Classification**	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets:					
Money market funds	Cash and cash equivalents	$ 637,445	$ 637,445	$ —	$ —
Total assets		$ 637,445	$ 637,445	$ —	$ —

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 March 31, 2017, the carrying value of the Convertible Notes, net of unamortized discount and debt issuance costs, was $134.5 million and the estimated fair value of the principal amount was $892.8 million. The Convertible Notes are discussed in more detail in Note 5, "Convertible Notes".

Revenue Recognition

Effective January 1, 2017, the Company adopted Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers* , using the full retrospective transition method. Under this method, the Company will revise its consolidated financial statements for the years ended December 31, 2015 and 2016, and applicable interim periods within those years, as if Topic 606 had been effective for those periods. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for net product revenue and license, collaboration and other revenues, see Note 11, "Revenue Recognition".

Intangible Assets

The Company maintains definite-lived intangible assets related to certain capitalized milestones. These assets are amortized over their remaining useful lives, which are 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. 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 March 31, 2016 (in thousands, except per share data)		
	As revised under Topic 606	As originally reported under Topic 605	Effect of change
Product revenue, net	$ 276	$ 173	$ 103
License, collaboration and other revenues	24	134	(110)
Cost of sales - product	79	76	3
Loss from operations	(87,101)	(87,091)	(10)
Net loss	(90,980)	(90,970)	(10)
Net loss per share applicable to common stockholders - basic and diluted	$ (2.22)	$ (2.22)	$ -

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

	Three months ended March 31, 2016 (in thousands)		
	As revised under Topic 606	As originally reported under Topic 605	Effect of change
Net loss	$ (90,980)	$ (90,970)	$ (10)
Adjustments to reconcile net loss to net cash used in operating activities:			
Accounts receivable	2,561	(377)	2,938
Other assets	(656)	(282)	(374)
Accrued expenses	3,923	3,725	198
Deferred revenues	(15)	2,737	(2,752)
Cash and cash equivalents at beginning of period	230,146	230,146	—
Cash and cash equivalents at end of period	$ 314,460	$ 314,460	$ —

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

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

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 Months Ended March 31,	
	2016	2017
Outstanding stock awards and Employee Stock Purchase Plan	7,068	7,366
Unvested restricted stock units	537	1,093
Shares issuable upon conversion of Convertible Notes	20	4,186
	7,625	12,645

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 March 31, 2016 and 2017.

4. Inventories

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

	December 31, 2016	March 31, 2017
Raw materials	$ 13,263	$ 13,165
Work in process	584	1,736
Finished goods	853	742
Total inventories	$ 14,700	$ 15,643

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 March 31, 2017, the carrying value of the Convertible Notes, net of unamortized discount and debt issuance costs, was $134.5 million and the estimated fair value of the principal amount was $892.8 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 months ended March 31, 2016 and 2017 (in thousands):

	Three Months Ended March 31,	
	2016	2017
Contractual interest expense	$ 1,509	$ 1,509
Amortization of debt discount	2,315	2,615
Amortization of debt issuance costs	157	143
Total interest expense	$ 3,981	$ 4,267

6. Stock-Based Compensation

The Company maintains several equity compensation plans, including the TESARO, Inc. 2012 Omnibus Incentive Plan, or the 2012 Incentive Plan, the TESARO, Inc. 2010 Stock Incentive Plan, or the 2010 Incentive Plan, the TESARO, Inc. 2015 Non-Employee Director Stock Incentive Plan, or the 2015 Director Plan, and the TESARO, Inc. 2012 Employee Stock Purchase Plan, or the 2012 ESPP.

On April 27, 2012, the stockholders of the Company approved the 2012 Incentive Plan, which had been previously adopted by the board of directors. Upon effectiveness of the 2012 Incentive Plan, the Company ceased making awards under the 2010 Incentive Plan. The 2012 Incentive Plan initially allowed the Company to grant awards for up to 1,428,571 shares of common stock plus the number of shares of common stock available for grant under the 2010 Incentive Plan as of the effectiveness of the 2012 Incentive Plan (an additional 6,857 shares) plus the number of shares of common stock related to awards outstanding under the 2010 Incentive Plan that terminate by expiration, forfeiture, cancellation, cash settlement or otherwise. The number of shares available for grants of awards under the 2012 Incentive Plan is increased automatically on January 1 by a number of shares of common stock equal to the lesser of 4% of the shares of common stock outstanding at such time or the number of shares determined by the Company's board of directors. Most recently, on January 1, 2016 and 2017, the number of shares authorized for issuance under the 2012 Incentive Plan was increased by 1,611,191 shares and 2,144,867 shares, respectively. Awards under the 2012 Incentive Plan may include the following award types: stock options, which may be either incentive stock options or nonqualified stock options; stock appreciation rights; restricted stock; RSUs; dividend equivalent rights; performance shares; performance units; cash-based awards; other stock-based awards, including unrestricted shares; or any combination of the foregoing. The exercise price of stock options granted under the 2012 Incentive Plan is equal to the closing price of a share of the Company's common stock on the grant date.

On May 14, 2015, the stockholders of the Company approved the 2015 Director Plan, which had been previously adopted by the board of directors in order to have a plan in addition to the 2012 Incentive Plan for purposes of granting awards to non-employee directors. The 2015 Director Plan allows the Company to grant awards for up to 500,000 shares of common stock. Awards under the 2015 Director Plan may include the following award types: stock options; stock appreciation rights; restricted stock; RSUs; unrestricted stock; or any combination of the foregoing. The exercise price of stock options granted under the 2015 Director Plan is equal to the closing price of a share of the Company's common stock on the grant date. On May 11, 2016, the Company's stockholders approved an amendment to the 2015 Director Plan that limits the maximum number of shares of stock subject to awards granted in any calendar year to any non-employee director of the Company to 50,000 shares and affirms that 500,000 shares are reserved for issuance under the 2015 Director Plan.

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 March 31,	
	2016	2017
Research and development	$ 3,743	$ 7,125
Selling, general and administrative	5,718	11,276
Total stock-based compensation expense	$ 9,461	$ 18,401

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	491,590	167.45
Exercised	(78,251)	42.59
Cancelled	(44,280)	45.22
Outstanding at March 31, 2017	7,347,680	$ 49.09
Vested at March 31, 2017	3,634,361	$ 26.90

At March 31, 2017, there was approximately $143.4 million of total unrecognized compensation cost related to unvested stock options, which the Company expects to recognize over a remaining weighted-average period of 2.6 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	455,975	173.77
Vested	(116,006)	43.88
Forfeited	(7,075)	56.54
Unvested restricted stock units at March 31, 2017	1,093,017	$ 108.19

At March 31, 2017, there was approximately $111.4 million of unrecognized compensation cost related to unvested RSUs, which the Company expects to recognize over a remaining weighted-average period of 3.4 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 March 31, 2017. Vesting of these awards is contingent on the occurrence of certain milestone events and fulfillment of any remaining service condition. As a result, the related compensation cost is recognized as an expense when achievement of the milestone is considered probable. The Company recognized $0.5 million of related expense during the three months ended March 31, 2017.

ESPP

Under the Company's 2012 ESPP, an aggregate of 275,000 shares of common stock have been reserved for issuance pursuant to purchase rights granted to the Company's employees or to employees of the Company's designated subsidiaries. As of March 31, 2017, 194,245 shares remained available for issuance. During the three months ended March 31, 2016 and 2017, the Company did not issue any shares under the 2012 ESPP, and recognized approximately $0.3 million and $0.5 million in related stock-based compensation expense, respectively.

7. Common Stock Transactions

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

8. Income Taxes

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

The Company does not recognize a tax benefit for uncertain tax positions unless it is more likely than not that the position will be sustained upon examination by tax authorities, including resolution of any related appeals or litigation processes, based on the technical merits of the position. The tax benefit that is recorded for these positions is measured at the largest amount of cumulative benefit that has greater than a 50 percent likelihood of being realized upon ultimate settlement. Deferred tax assets that do not meet these recognition criteria are not recorded and the Company recognizes a liability for uncertain tax positions that may result in tax payments. If such unrecognized tax benefits were realized and not subject to valuation allowances, the entire amount would impact the tax provision. As of March 31, 2017, the Company's uncertain tax positions were subject to valuation allowances.

The Company recorded a provision for income taxes in the three months ended March 31, 2017 of $0.1 million. The provision for income taxes consists of current tax expense, which relates primarily to the Company's subsidiary operations in foreign tax jurisdictions.

9. Intangible Assets

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

	December 31, 2016	March 31, 2017	Estimated useful life
Acquired and in-licensed rights	$ 15,000	$ 40,000	8-13 Years
Less accumulated amortization	(2,123)	(2,613)	
Total intangible asset, net	$ 12,877	$ 37,387	

The increase in acquired and in-licensed rights as of March 31, 2017 was due to the milestone of $25.0 million owed to Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., or Merck, which was triggered by the FDA approval of ZEJULA on March 27, 2017.

The Company recorded $0.5 million and $0.5 million in amortization expense related to intangible assets during the three months ended March 31, 2016 and 2017, respectively. Estimated future amortization expense for intangible assets as of March 31, 2017 is $2.8 million for the remainder of 2017, $3.8 million per year for 2018, 2019, 2020, and 2021, and $19.3 million thereafter.

10. Commitments and Contingencies

The Company leases approximately 124,000 square feet of office space in Waltham, Massachusetts under a non-cancelable operating lease agreement. The Company also leases 7,100 square feet of office space in Zug, Switzerland. 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 March 31, 2017 were $4.0 million for the remainder of the year ending December 31, 2017 and $5.6 million, $5.6 million, $2.9 million and $0.2 million for the years ending December 31, 2018, 2019, 2020 and 2021 respectively. No amounts are due thereafter.

The Company has entered into agreements with certain vendors for the provision of services, including services related to data management, clinical and commercial operation support and diagnostic test development, that the Company is not able to terminate for convenience under its contracts, and thus avoid any and all future obligations to the vendors. Under such agreements, the Company is contractually obligated to make certain minimum payments to the vendors, with the exact amounts in the event of termination to be based on the timing of the termination and the exact terms of the agreement.

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

Legal Proceedings

The Company may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities, including claims or disputes related to patents that have been issued or that are pending in the field of research on which the Company is focused. The Company is not a party to any material litigation and does not have contingency reserves established for any litigation liabilities.

11. Revenue Recognition

Product Revenue, Net

The Company sells its products principally to a limited number of specialty distributors and specialty pharmacy providers in the U.S., 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 not received any returns to date and believes that returns of its products will be minimal.

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

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

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

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 only source of product revenue has been from the U.S. sales of the oral formulation of VARUBI, which it began shipping to Customers in November 2015. The following table summarizes activity in each of the product revenue allowance and reserve categories for the three months ended March 31, 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	82	50	-	132
Adjustment related to prior period sales	-	-	-	-
Credit or payments made during the period	(9)	(24)	-	(33)
Balance at March 31, 2016	$ 886	$ 448	$ 8	$ 1,342
Balance at December 31, 2016	177	1,312	18	1,507
Provision related to current period sales	736	562	8	1,306
Adjustment related to prior period sales	-	-	-	-
Credit or payments made during the period	(756)	(1,157)	-	(1,913)
Balance at March 31, 2017	$ 157	$ 717	$ 26	$ 900

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 customer and the customer 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 customer'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 customer exercises these options , any additional payments are recorded in license, collaboration and other revenues when the customer 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 customers 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 customer and the transfer of the promised goods or services to the customer will be one year or less.

The following table presents changes in the Company's contract assets and liabilities during the three months ended March 31, 2016 (as revised) and 2017 (in thousands):

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Three months ended March 31, 2016				
Contract assets	$ 1,000	$ -	$ -	$ 1,000
Contract liabilities:				
Deferred revenue	$ 92	$ -	$ (15)	$ 77
Three months ended March 31, 2017				
Contract assets	$ 1,000	$ -	$ -	$ 1,000
Contract liabilities:				
Deferred revenue	$ 399	$ -	$ (23)	$ 376

During the three months ended March 31, 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 March 31,	
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	$ -	$ -

12. License and Collaboration Arrangements

Out-Licenses

Janssen Biotech, Inc.

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

Under the terms of the Collaboration Agreement, the Company granted Janssen licenses under certain patent rights and know-how relating to niraparib for prostate cancer worldwide, except for Japan. Janssen will conduct all development and commercialization of niraparib in the field of prostate cancer worldwide (excluding Japan). With the exception of China, under the Collaboration Agreement, the Company retained all rights worldwide to develop and commercialize niraparib outside of prostate cancer.

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

The Company received a $35.0 million up-front, non-refundable license fee from Janssen. Assuming successful development and commercialization of niraparib products for prostate cancer, the Company could receive up to an additional $43.0 million in clinical milestones and $372.0 million in regulatory and sales milestones as well as tiered, double-digit royalties on aggregate net sales of products in the field of prostate cancer. Janssen is responsible for funding all development and commercialization of niraparib in prostate cancer worldwide (excluding Japan), including research, development, manufacturing, regulatory and commercialization activities. Janssen may terminate the Collaboration Agreement at any time after April 5, 2017 upon 90 days' written notice, upon termination of the Company's license agreement with Merck or in the event of certain safety concerns. Either party may terminate the Collaboration Agreement for uncured material breach or bankruptcy. Unless earlier terminated, the Collaboration Agreement will continue in effect until the date on which the royalty term and all payment obligations with respect to all products in all countries have expired.

The Company assessed this arrangement in accordance with Topic 606 and concluded that the contract counterparty, Janssen, is a customer. The Company identified the following material promises under the contract: (1) the licenses under certain patent rights relating to niraparib for prostate cancer worldwide, except for Japan, and transfer 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.

The transaction price includes 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 licensees' efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Janssen and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

During the second quarter of 2016, the Company allocated $34.5 million of the transaction price to the license and recognized this amount as revenue concurrent with the transfer of the license and certain development and regulatory know-how that occurred within 30 days of entering into the Collaboration Agreement. Revenue allocated to the participation in the Joint Committees performance obligation, $0.5 million, is being recognized on a straight-line basis over a period of five years, which, in management's judgment, is the best measure of progress towards satisfying the performance obligation and represents the Company's best estimate of the period of the obligation to participate in the Joint Committees. Through March 31, 2017, the Company had recognized $34.6 million as license and collaboration revenue under the Collaboration Agreement. The remaining transaction price of $0.4 million is recorded in deferred revenue as of March 31, 2017 on the consolidated balance sheets and will be recognized as revenue over a period of forty-eight months.

Revenue associated with the manufacturing supply services is recognized when the material is delivered to Janssen. Through March 31, 2017, the Company had recognized $2.7 million 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. The Company retains all rights outside of the China Territories to develop and commercialize niraparib with the exception of prostate cancer.

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

country basis, until the later of expiration of the last patent in the China Territories covering the niraparib product, or ten years from the first commercial sale in such country. The Zai Agreement may also be terminated by Zai Lab at any time upon prior written notice, or by either party for material breach or insolvency.

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

The Company evaluated the Zai Agreement under Topic 606. Based on that evaluation, the up-front, non-refundable fees and the reimbursement received for the initial supply of materials constituted the amount of the consideration to be included in the transaction price and have been allocated to the performance obligations identified based on the Company's best estimate of the relative stand-alone selling price. None of the clinical or regulatory development milestones have been included in the transaction price, as all such milestone amounts are not within the control of the Company or the licensee and are not considered probable to occur until those approvals are received. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license granted to Zai Lab and therefore are recognized at the later of when the performance obligation is satisfied or the related sales occur. The Company concluded the option to co-market niraparib is not a repurchase right as Zai Lab would continue to control its rights to commercialize niraparib in its licensed territories if the Company exercised its right. The Company further assessed and concluded that the probability of exercise of this right is remote, and the transaction price received and described above was properly allocated to the performance obligations under this agreement and recognized to revenue as those performance obligations were satisfied by the Company. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

During the third quarter of 2016, the Company allocated $14.8 million of the transaction price to the license and recognized this amount as revenue concurrent with the transfer of the license. Revenue allocated to the technical assistance performance obligation, $0.2 million, was recognized on a straight-line basis through the service period which was substantially completed during the fourth quarter of 2016. In addition, revenue associated with the initial manufacturing supply services was recognized upon delivery of the materials during the fourth quarter of 2016. Through both December 31, 2016 and March 31, 2017, the Company has recognized $15.7 million as revenues within license, collaboration and other revenues in the Company's consolidated statements of operations and comprehensive loss under the Zai Agreement.

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 FDA. The Company is also entitled to an additional payment of $1.0 million contingent on the achievement of regulatory approval. 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. Through both December 31, 2016 and March 31, 2017, the Company has recognized $2.0 million as revenues within license, collaboration and other revenues in the Company's consolidated statements of operations and comprehensive loss under this agreement.

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 months ended March 31, 2016 and 2017, the Company incurred $0.8 million and $2.1 million in external costs related to this study, of which $0.4 million and $1.0 million is reimbursable by Merck, respectively. At March 31, 2017, $1.1 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 Analysi s 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 ZEJULA ™ (niraparib); our commercialization plans for rolapitant, including the progress of the commercial launch of VARUBI® (the oral formulation) in the U.S., and the potential timing of launches of the intravenous, or IV, formulation in the U.S. and of the oral formulation 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 may continue, and possibly increase, for the foreseeable future; the expected impact of recent accounting pronouncements and guidance on our financial statements; and our needs for additional capital and the forecast of the period of time through which our financial resources will be adequate to support our operations .

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

These forward-looking statements involve substantial risks and uncertainties that could cause actual future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the development or launch of any new pharmaceutical product and the execution and completion of clinical trials, uncertainties surrounding the timing of availability of data from our clinical trials, uncertainties regarding ongoing discussions with and actions by regulatory authorities, patient accrual rates for clinical trials, manufacturing and supply risks, risks relating to intellectual property, and other matters that could affect the timing of data, the potential regulatory approval, or the commercial availability of our product candidates or the success of any product. The following information and any forward-looking statements should be considered in light of these factors and the factors discussed elsewhere in this Quarterly Report on Form 10-Q, and in light of factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2016, including under the heading "Risk Factors".

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

TESARO, the TESARO logo, VARUBI, VARUBY and ZEJULA are trademarks of TESARO, Inc. in the United States and in other selected countries. All other brand names or trademarks appearing in this report are the property of

their respective holders. Unless the context requires otherwise, references in this report to "TESARO", the "Company," "we," "us," and "our" refer to TESARO, Inc.

Overview

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

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

- *Rolapitant* is a potent and long-acting neurokinin-1, or NK-1, receptor antagonist for the prevention of chemotherapy induced nausea and vomiting, or CINV. The oral form of rolapitant, VARUBI, is approved in the United States for use in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. The European Commission also approved oral rolapitant for the prevention of delayed nausea and vomiting associated with highly and moderately emetogenic chemotherapy in adults in April 2017. We will market rolapitant in the European Union under the brand name VARUBY®. We are also developing an intravenous, or IV, formulation of rolapitant. We submitted a new drug application, or NDA, for rolapitant IV to the United States Food and Drug Administration, or FDA, in March 2016. In January 2017, the FDA issued a Complete Response Letter requesting additional information regarding the in vitro release method utilized to characterize the drug product and demonstrate comparability of drug product produced by our two proposed commercial manufacturers of rolapitant IV that were included in the NDA. We resubmitted the NDA with such information to the FDA in April 2017, and the FDA will need to review and approve the resubmitted NDA in order for us to be allowed to market and sell rolapitant IV in the U.S.

- *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. We have several ongoing clinical trials evaluating niraparib for the treatment of ovarian or breast cancers, and we expect to initiate further clinical trials of niraparib during 2017. We are also collaborating with various other organizations to evaluate niraparib in combination with other therapeutics for the treatment of various cancers. Based on research related to PARP inhibitors generally, we believe niraparib may also be active in the treatment of several other tumor types. In October 2016, we submitted a Marketing Authorization Application for niraparib for the maintenance treatment of patients with platinum-sensitive, recurrent ovarian cancer who are in response to platinum-based chemotherapy, which the European Medicines Agency has accepted for review. In March 2017, following an interim analysis of data by the independent data monitoring committee, we ceased enrollment in our BRAVO study (assessing niraparib in patients with breast cancer who are germline BRCA mutation carriers) after a determination that it is unlikely to produce data that is interpretable and therefore suitable for registration in this indication. Also in March 2017, we announced plans for expansion of our niraparib clinical development program, including studies of niraparib alone or in combination with other therapeutics for the treatment of ovarian, breast, lung, and prostate cancers.

- *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. We initiated a Phase 1, dose escalation study in March 2016, and in April 2017, initiated a registrational development program in metastatic microsatellite high endometrial cancer for our first immuno-oncology antibody, TSR-042, which targets PD-1. 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. We submitted an investigational new drug application, or IND, to the FDA in April 2017 for our antibody candidate targeting LAG-3, TSR-033. Pending FDA clearance, we expect to initiate a Phase 1 study in mid-2017. 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 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 companies with regard to selected indications or geographies for our in-licensed product candidates. We have entered into the following collaboration and license agreements:

- In May 2015, we entered into a research agreement with Merck Sharp & Dohme B.V., a subsidiary of Merck & Co., Inc., or Merck, to perform a trial to evaluate the preliminary safety and efficacy of niraparib plus KEYTRUDA® in patients with triple negative breast cancer and patients with ovarian cancer.

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

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

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

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

For further discussion of these agreements, see Note 12, “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 March 31, 2017, we had an accumulated deficit of $1.1 billion. Our net losses were $136.7 million, $374.2 million, $247.7 million, and $171.0 million for the three months ended March 31, 2017 and the years ended December 31, 2016, as revised, 2015, as revised, and 2014, respectively. We expect to incur significant expenses and operating losses for the foreseeable future. Overall, we expect operating expenses to continue to increase over current levels as we incur increased costs related to: (i) our ongoing U.S. and international commercialization and pre-commercial activities including executing related marketing and promotional programs for the commercialization of VARUBI and ZEJULA; (ii) the advancement of clinical trial and other development and regulatory activities under our current development programs such as niraparib, TSR-042, TSR-033 and TSR-022, and our collaborations; (iii) costs related to expanding our international operations; and (iv) other research and development activities and potential future collaborative or in-licensed development programs. In addition, future license payments or milestone payments could cause our total operating expenses and cash usage to fluctuate. If we obtain regulatory approval for any of our other product candidates, or if we anticipate the near term possibility of obtaining regulatory approval, we expect that we will incur significant additional commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, 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 March 31, 2017, our principal source of liquidity was cash and cash equivalents, which totaled $672.2 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 March 31, 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 our product, VARUBI, in the United States.

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

Research and Development Expenses

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

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

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

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development,

primarily due to the increased size and duration of later-stage clinical trials and manufacturing costs. We expect that our total future research and development costs will continue to increase over current levels, depending on the progress of our clinical development programs. We also anticipate increasing costs associated with our collaborations, manufacturing activities, and potential development milestone payments. More specifically, we expect costs to increase, including as we: continue our currently ongoing Phase 2 and 3 trials, continue our manufacturing development and validation, and initiate additional investigative and collaborative studies related to niraparib; continue clinical, manufacturing and regulatory development activities for the IV formulation of rolapitant; incur potential research and development related milestones; incur increased discovery, development and manufacturing related expenses associated with our immuno-oncology platform and related collaborations; lease additional facility space; and hire additional development and scientific personnel.

We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our product candidates or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our currently unapproved product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rates and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as based upon an assessment of each product candidate's commercial potential. If we experience delays in the completion of, or the termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our future ability to generate product revenues from any of these product candidates will be delayed or jeopardized. These occurrences would harm our business, financial condition and prospects, perhaps significantly, which would require us to alter our current operation 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 three months ended March 31, 2016 and 2017 (in thousands):

	Three Months Ended March 31,	
	2016 (as revised)	2017
Rolapitant Expenses		
Acquired in-process research and development	$ —	$ —
Research and development	5,774	3,558
Rolapitant total	5,774	3,558
Niraparib Expenses		
Acquired in-process research and development	—	—
Research and development	24,703	23,344
Niraparib total	24,703	23,344
Immuno-Oncology Platform Expenses		
Acquired in-process research and development	4,000	—
Research and development	6,175	10,523
Immuno-Oncology Platform total	10,175	10,523
Personnel and Other Expenses	16,057	28,697
Total	**$ 56,709**	**$ 66,122**

For further discussion of the changes in our research and development expenses with respect to the three months ended March 31, 2017 and the corresponding period of 2016, see "Results of Operations — Comparison of the Three Months Ended March 31, 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, patent review, consulting and accounting services.

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

Other Income and Expense

Other income and expense consists primarily of interest expense related to the Convertible Notes and interest income earned on cash and cash equivalents. A portion of the interest expense on the Convertible Notes is non-cash expense relating to accretion of the debt discount and amortization of issuance costs.

Results of Operations

Comparison of the Three Months Ended March 31, 2016 and 2017

(data in thousands)	Three Months Ended March 31, 2016 (as revised)	Three Months Ended March 31, 2017	Increase/ (Decrease)
Revenues:			
Product revenue, net	$ 276	$ 2,139	$ 1,863
License, collaboration and other revenues	24	934	910
Total revenues	300	3,073	2,773
Expenses:			
Cost of sales - product	79	444	365
Cost of sales - intangible asset amortization	464	490	26
Research and development	52,709	66,122	13,413
Selling, general and administrative	30,149	69,262	39,113
Acquired in-process research and development	4,000	—	(4,000)
Total expenses	87,401	136,318	48,917
Loss from operations	(87,101)	(133,245)	(46,144)
Other income (expense), net	(3,879)	(3,426)	453
Loss before income taxes	(90,980)	(136,671)	(45,691)
Provision for income taxes	—	54	54
Net loss	$ (90,980)	$ (136,725)	$ (45,745)

Product Revenue . We recorded $0.3 million and $2.1 million of net product revenue for the three months ended March 31, 2016 (as revised) and 2017, respectively. These amounts relate to sales of VARUBI, our first commercial product, which we began shipping in November of 2015. We distribute our product in the U.S. principally through a limited number of specialty distributors and to a lesser extent though 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 Wholesale Acquisition Cost, or WAC, which is the gross list price at which our direct customers purchase each unit of VARUBI, is currently $562 per unit. For net product revenues for the three months ended March 31, 2017, the average net sales price per unit to us (after accounting for fees, rebates, chargebacks, and other discounts or reserves, or, the gross-to-net adjustment) was approximately $349 or approximately 62% of WAC. We expect that our gross-to-net adjustment to VARUBI revenues will be higher in the future (and net revenue per unit will be lower) as a result of increased concessions and potential changes to our customer and payor mix.

License, Collaboration and Other Revenues . License, collaboration and other revenues of $0.9 million for the three months ended March 31, 2017 relates to our license agreement with Janssen.

Cost of Sales - Product. Cost of sales of $0.1 million and $0.4 million for the three months ended March 31, 2016 (as revised) and 2017, respectively, consists of costs associated with the manufacturing of VARUBI and royalties owed to our licensor for such sales, as well as costs of product provided under our sampling and other commercial programs and certain period costs. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, certain of the costs of VARUBI units recognized as revenue during the three months ended March 31, 2016 and 2017 were expensed prior to the September 2015 FDA approval, 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 for each of the three months ended March 31, 2016 and 2017 consists of amortization of intangible assets recorded as a result of milestones paid to our licensors, upon or after regulatory approval of our products.

Research and Development Expenses. Research and development expenses were $66.1 million for the three months ended March 31, 2017, compared to $52.7 million for the three months ended March 31, 2016, an increase of $13.4 million. The increase was primarily due to higher personnel and related costs. Significant changes resulting in this increase included:

- an increase of $9.6 million in personnel and other costs (excluding stock-based compensation), primarily related to increased research and development headcount supporting the growth of our development activities; and
- an increase of $4.3 million in costs associated with our immuno-oncology platform due to increased costs related to the TSR-042 Phase 1 clinical trial, biologics manufacturing as well as non-clinical and other immuno-oncology program research activities.

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

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

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $69.3 million for the three months ended March 31, 2017, compared to $30.1 million for the three months ended March 31, 2016, an increase of $39.2 million. The increase was primarily due to increases of: $14.5 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; $19.1 million in professional and consulting fees and other expenses related to commercial and pre-commercial activities such as global marketing and promotional programs and market research as well as other corporate operational activities; and $5.6 million in stock-based compensation expense.

Acquired In-Process Research and Development . Acquired in-process research and development expenses for the three months ended March 31, 2016 were $4.0 million, comprised of a milestone paid to AnaptysBio. Our obligation to pay this milestone was triggered by the clearance of our IND for TSR-042, which occurred in January 2016. There were no acquired in-process research and development expenses for the three months ended March 31, 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 $0.7 million during the three months ended March 31, 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.

Liquidity and Capital Resources

Sources of Liquidity

As of March 31, 2017, our principal source of liquidity was cash and cash equivalents, which totaled $672.2 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 March 31, 2017, including our 2012 initial public offering, we raised a total of $1.6 billion in net cash proceeds from private placements of convertible preferred stock and common stock, public offerings of common stock and the issuance of convertible notes.

Cash Flows

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

	Three Months Ended March 31,	
	2016	2017
	(as revised)	
Net cash provided by (used in):		
Operating activities	$ (67,616)	$ (114,698)
Investing activities	(4,380)	(2,300)
Financing activities	156,310	3,315
Effect of exchange rate changes on cash and cash equivalents	—	45
Increase (decrease) in cash and cash equivalents	$ 84,314	$ (113,638)

Cash Flows from Operating Activities

The use of cash in operating activities during both the three months ended March 31, 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 $47.1 million for the three months ended March 31, 2017 compared to the three months ended March 31, 2016, primarily due to increased external expenses related to commercialization activities and increased external research and development expenses as we continued to progress the niraparib development program and the immuno-oncology platform. Higher costs associated with increased employee headcount related to our commercial efforts and both our general and administrative and research and development activities also contributed to the increase in cash used in operating activities. These factors were partially offset by lower external costs associated with our oral rolapitant development program.

Cash Flows from Investing Activities

The decrease of $2.1 million in net cash used in investing activities for the three months ended March 31, 2017 compared to the three months ended March 31, 2016 was due primarily to a $4.0 million milestone paid to AnaptysBio during the prior year period, while we paid no milestones during the current year period.

Cash Flows from Financing Activities

The decrease of $153.0 million in net cash provided by financing activities for the three months ended March 31, 2017 compared to the three months ended March 31, 2016 was primarily due to cash proceeds of $155.0 million from the closing of our March 2016 private placement of common stock. There were no similar financing transactions in the three months ended March 31, 2017.

Operating Capital Requirements

We expect to incur significant expenses and operating losses for the foreseeable future. Overall, we expect operating expenses to continue to increase over current levels as we incur increased costs related to: (i) our ongoing U.S. and international commercialization and pre-commercial activities including executing related marketing and promotional programs for the commercialization of VARUBI and ZEJULA; (ii) the advancement of clinical trial and other development and regulatory activities under our current development programs including niraparib, TSR-042, TSR-033 and TSR-022, and our collaborations; (iii) costs related to expanding our international operations; and (iv) other research and development activities and potential future collaborative or in-licensed development programs. We 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 than those that we currently expect;
- the initiation, progress, timing, costs and results of clinical trials for our product candidates and any future product candidates we may in-license, including our current and potential future Phase 2 and 3 clinical trials for niraparib;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities;
- the discovery, preclinical and clinical development plans that are or will be established for potential product candidates under our immuno-oncology collaboration with MDACC;

- the attainment of milestones and our obligations to make milestone payments, royalty payments, or both to OPKO Health, Inc., Merck, or AnaptysBio or to any other current or future product candidate licensor, if any, under our in-licensing agreements;
- the number and characteristics of product candidates that we in-license and develop;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the amount and timing of potential conversion requests, if any, and interest expense associated with our Convertible Notes; and
- 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 March 31, 2017, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K.

Critical Accounting Policies

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

Revenue Recognition

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

Product Revenue, Net

We sell our products principally to a limited number of specialty distributors and specialty pharmacy providers in the U.S., or collectively, our Customers. These Customers subsequently resell our products to health care providers and patients. In addition to distribution agreements with Customers, we enter into arrangements with health care providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of our products.

Revenues from product sales are recognized when the Customer obtains control of our product, which occurs at a point in time, typically upon delivery to the Customer. When we perform shipping and handling activities after the transfer of control to the Customer (e.g., when control transfers prior to delivery), they are considered as fulfillment activities, and accordingly, the costs are accrued when the related revenue is recognized. Taxes collected from Customers relating to product sales and remitted to governmental authorities are excluded from revenues. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less.

Reserves for Variable Consideration

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

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

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

Provider Chargebacks and Discounts: Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from us. Customers charge us for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by Customers, and we generally issue credits for such amounts within a few weeks of the Customer's notification to us of the resale. Reserves for chargebacks consists 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 only source of product revenue has been U.S. sales of the oral formulation of VARUBI, which we began shipping to Customers in November 2015. The following table summarizes activity in each of the product revenue allowance and reserve categories for the three months ended March 31, 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	82	50	-	132
Adjustment related to prior period sales	-	-	-	-
Credit or payments made during the period	(9)	(24)	-	(33)
Balance at March 31, 2016	$ 886	$ 448	$ 8	$ 1,342
Balance at December 31, 2016	177	1,312	18	1,507
Provision related to current period sales	736	562	8	1,306
Adjustment related to prior period sales	-	-	-	-
Credit or payments made during the period	(756)	(1,157)	-	(1,913)
Balance at March 31, 2017	$ 157	$ 717	$ 26	$ 900

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 customer and the customer 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 customer'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 customer exercises these options , any payments are recorded in license, collaboration and other revenues when the customer 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 customers 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 customer and the transfer of the promised goods or services to the customer will be one year or less.

The following table presents changes in the balances of our contract assets and liabilities during the three months ended March 31, 2016 (as revised) and 2017 (in thousands):

Three months ended March 31, 2016	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Contract assets	$ 1,000	$ -	$ -	$ 1,000
Contract liabilities:				
Deferred revenue	$ 92	$ -	$ (15)	$ 77

Three months ended March 31, 2017				
Contract assets	$ 1,000	$ -	$ -	$ 1,000
Contract liabilities:				
Deferred revenue	$ 399	$ -	$ (23)	$ 376

During the three months ended March 31, 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 March 31,	
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	$ -	$ -

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 Disclosure s About Market Risk.

We are exposed to market risk related to changes in interest rates. As of March 31, 2017 and December 31, 2016, we had cash and cash equivalents of $672.2 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 March 31, 2017.

Item 4. Controls and Procedures .

Management's Evaluation of our Disclosure Controls and Procedures

Our principal executive officer and our principal financial officer, after evaluating the effectiveness of our "disclosure controls and procedures" (as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act, Rule 13a-15(e) or Rule 15d-15(e)), with the participation of our management, has concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures are effective and are designed to ensure that information we are required to disclose in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure, and is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. It should be noted that any system of controls is designed to provide reasonable, but not absolute, assurances that the system will achieve its stated goals under all reasonably foreseeable circumstances. Our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures are effective at a level that provides such reasonable assurances.

Changes in Internal Control Over Financial Reporting

During the quarter ended March 31, 2017, we implemented certain internal controls in connection with our adoption of ASC Topic 606. There were no other 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 INFORMATIO N

Item 1. Legal Proceedings .

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

Item 1A. Risk Factors.

An investment in our stock involves a high degree of risk. You should carefully consider the following discussion of risk factors, in its entirety, in addition to the other information contained in this Quarterly Report on Form 10-Q, our Annual Report on Form 10-K for the year ended December 31, 2016 and the other filings we make with the U.S. Securities and Exchange Commission. We cannot assure you that any of the events discussed in the risk factors below or in our other filings will not occur. These risks, or other events that we do not currently anticipate or that we currently deem immaterial, may have a material adverse effect on our business, prospects, financial condition and results of operations.

Risks Related to Our Business and Industry

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

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

We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical and well-controlled clinical studies, and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. The process to develop, obtain regulatory approval for and commercialize product candidates is long, complex and costly both inside and outside of the United States. Even if a product candidate were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations, including use restrictions for certain patient populations; warnings, precautions or contraindications; or burdensome post-approval study or risk management requirements.

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

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

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

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

- the effectiveness of our marketing, sales and distribution strategy and operations;
- the ability of our third-party manufacturers to manufacture commercial supplies of our products, to remain in good standing with regulatory agencies, and to develop, validate and maintain commercially viable manufacturing processes that are, to the extent required, compliant with current good manufacturing practice, or cGMP, regulations;
- the degree to which the approved labeling supports promotional initiatives for commercial success;
- the availability of reimbursement from managed care plans and other third-party payors and the willingness and ability of patients to pay for our products;
- a continued acceptable safety profile of our products and product candidates;
- any new or unexpected results from additional clinical trials or further analysis of clinical data of completed clinical trials by us or our competitors;
- our ability to enforce our intellectual property rights;
- our ability to avoid third-party patent interference or patent infringement claims; and
- maintaining compliance with all applicable regulatory requirements.

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

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

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

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

- our inability to recruit, train, retain and incentivize adequate numbers of qualified and effective sales and marketing personnel;
- the inability of sales personnel to generate sufficient sales leads and to obtain access to physicians or persuade adequate numbers of physicians to use or prescribe our products;
- the lack of complementary products currently offered by our sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- our inability to effectively manage a geographically dispersed sales and marketing team, both in the United States and Europe.

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

Item 6. Exhibits .

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

SIGNATURE S

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: May 9, 2017

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

Date: May 9, 2017

EXHIBIT INDEX

Exhibit Number	Exhibit Description
10.1	Fifth Amendment to Lease Agreement, dated February 9, 2017, by and between the Company and BP Bay Colony LLC.
10.2*	Master Supply Agreement, dated July 18, 2016, by and between the Company and STA Pharmaceutical Hong Kong Limited.
10.3*	Commercial Supply Agreement, dated December 15, 2016, by and between the Company and Corden Pharma Colorado, Inc.
10.4*	Drug Product Supply Agreement, dated January 10, 2017, by and between the Company and Charles River Laboratories Contract Manufacturing PA, LLC.
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
EX-101.INS	XBRL Instance Document
EX-101.SCH	XBRL Taxonomy Extension Schema Document
EX-101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
EX-101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
EX-101.LAB	XBRL Taxonomy Extension Label Linkbase Document
EX-101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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

Exhibit 10.1

FIFTH AMENDMENT TO LEASE

FIFTH AMENDMENT TO LEASE (this "Fifth Amendment") dated as of this 9th day of February, 2017 by and between BP BAY COLONY LLC, a Delaware limited liability company ("Landlord"), and TESARO, INC., a Delaware corporation ("Tenant").

RECITALS

By Lease dated October 15, 2012 (the "Lease"), Landlord did lease to Tenant and Tenant did hire and lease from Landlord certain premises containing 23,814 square feet of rentable floor area in the building known as 1000 Winter Street, Waltham, Massachusetts (the "Building") and consisting of (i) 13,576 rentable square feet located on the second (2nd) and third (3rd) floors of the Building (referred to collectively in the Lease as the "Original Premises"), and (ii) 10,238 rentable square feet located on the first (1st) floor of the Building (referred to in the Lease as the "Expansion Premises").

By First Amendment to Lease dated as of January 6, 2014 (the "First Amendment"), Tenant yielded up the Expansion Premises, and Landlord did lease to Tenant, and Tenant did hire and lease from Landlord, certain additional premises containing 39,666 rentable square feet located on the second (2nd) floor of the Building (the "First Additional Premises"), upon the terms and conditions set forth in the First Amendment.

By Second Amendment to Lease dated as of April 23, 2015 (the "Second Amendment"), Landlord did lease to Tenant, and Tenant did hire and lease from Landlord, certain additional premises containing 17,738 rentable square feet (the "Second Additional Premises"), consisting of (a) 10,238 square feet of rentable floor area located on the first (1st) floor of the Building (the "First Floor Second Additional Premises"), being the same space referred to above as the Expansion Premises and previously yielded up by Tenant pursuant to the First Amendment, and (b) 7,500 square feet of rentable floor area located on the third (3rd) floor of the Building (the "Third Floor Second Additional Premises"), upon the terms and conditions set forth in the Second Amendment.

By Third Amendment to Lease dated as of August 2, 2016 (the "Third Amendment"), Landlord did lease to Tenant, and Tenant did hire and lease from Landlord, certain additional premises containing 44,634 square feet of rentable floor area consisting of (a) 17,091 square feet of rentable floor area located on the second (2nd) floor of the Building (the "Second Floor Third Additional Premises"), and (b) 27,543 square feet of rentable floor area located on the third (3rd) floor of the Building (the "Third Floor Third Additional Premises"), upon the terms and conditions set forth in the Third Amendment. The Second Floor Third Additional Premises and the Third Floor Third Additional Premises are sometimes collectively referred to herein as the "Third Additional Premises").

By Fourth Amendment to Lease dated as of October 6, 2016 (the "Fourth Amendment"), Landlord did lease to Tenant, and Tenant did hire and lease from Landlord, certain additional

premises containing 8,784 square feet of rentable floor area located on the third (3rd) floor of the Building (the "Fourth Additional Premises"), upon the terms and conditions set forth in the Fourth Amendment.

Landlord and Tenant have agreed that Tenant will assume all obligations with respect to the performance of Landlord's Existing Premises Third Floor Work (as defined in the Third Amendment) and that Landlord's obligations with respect to Landlord's Existing Premises Third Floor Work shall be eliminated as more particularly set forth is this Fifth Amendment.

NOW THEREFORE, in consideration of One Dollar ($1.00) and other good and valuable consideration in hand this date paid by each of the parties to the other, the receipt and sufficiency of which are hereby severally acknowledged, and in further consideration of the mutual promises herein contained, Landlord and Tenant hereby agree to and with each other as follows:

1. Landlord and Tenant hereby agree that Landlord shall be released of all obligation to perform or manage Landlord's Existing Premises Third Floor Work (as defined in Exhibit C attached to the Third Amendment), including but not limited to, preparation of the Existing Premises Plans (as defined in Exhibit C attached to the Third Amendment), and any design, permitting or other obligations with respect to Landlord's Existing Premises Third Floor Work. Further, Tenant hereby indemnifies Landlord and its agents and affiliates against any loss, cost or damage relating to Landlord's Existing Premises Third Floor Work arising from the design or plans related to same regardless of whether Landlord or its agents or affiliates prepared, reviewed or approved any such plans or aspects of the design.

2. Tenant agrees to reimburse Landlord for all out-of-pocket design costs (i.e. architect and engineering fees) incurred in connection with the Landlord's Existing Premises Third Floor Work within thirty (30) days after billing from Landlord.

3. Except as otherwise expressly provided herein, all capitalized terms used herein without definition shall have the same meanings as are set forth in the Lease.

4. Except as herein amended, the Lease, as previously amended, shall remain unchanged and in full force and effect. All references to the "Lease" shall be deemed to be references to the Lease as amended by the First Amendment, the Second Amendment, the Third Amendment and the Fourth Amendment and as herein amended.

5. Each of Landlord and Tenant hereby represents and warrants to the other that all necessary action has been taken to enter this Fifth Amendment and that the person signing this Fifth Amendment on its behalf has been duly authorized to do so.

6. The parties acknowledge and agree that this Fifth Amendment may be executed by electronic signature, which shall be considered as an original signature for all purposes and shall have the same force and effect as an original signature. Without limitation, "electronic signature" shall include faxed versions of an original signature or electronically scanned and transmitted versions (e.g., via pdf) of an original signature.

[page ends here]

EXECUTED as of the date and year first above written.

WITNESS:

_____

LANDLORD :

BP BAY COLONY LLC, a Delaware limited liability company

BY: BP BAY COLONY HOLDINGS LLC, a Delaware limited liability company, its sole member

BY: BOSTON PROPERTIES LIMITED PARTNERSHIP, a Delaware limited partnership, its member

BY: BOSTON PROPERTIES, INC., a Delaware Corporation, its general partner

By: _ /s/ David C. Provost_____
Name: _ David C. Provost_____
Title: __ SVP_____

WITNESS :

_____

TENANT :

TESARO, INC., a Delaware corporation

By: _ /s/ Timothy Pearson_____
Name: _ Timothy Pearson_____
Title: _ EVP & CFO__ _____

Exhibit 10.2

MASTER SUPPLY AGREEMENT

This **MASTER SUPPLY AGREEMENT** (" **Agreement** ") dated as of July 18, 2016 is hereby made by and between **STA Pharmaceutical Hong Kong Limited** , a company with a registered place of business at Flat/Room 1303, 13/F Beverly House, 93-107 Lockhart Road, Wanchai, Hong Kong (" **STA** ") , and **TSRO Bio GmbH** , a company with a principal place of business at Dammstrasse 19, 6300 Zug, Switzerland (together with its affiliates, " **TESARO** "). STA and TESARO are individually referred to herein as a " **Party** ", and collectively referred to as the " **Parties** ".

RECITALS

WHEREAS, TESARO wishes to purchase the materials referred to as [***] (each, a " **Product** " or collectively the " **Products** ") from STA ; and

WHEREAS, STA is willing to manufacture and deliver each Product in accordance with the terms and under the conditions set out in this Agreement.

NOW, THEREFORE, IT IS AGREED AS FOLLOWS:

1. DEFINITIONS

1.1 The following words and expressions written with an initial capital shall have the following meanings assigned to them, unless it is clear from the context that they are used in a different meaning or it is the only reasonable interpretation in the given context:

" **Affiliate** " when used with reference to any Party, means any person controlling, controlled by, or under common control with, such Party. For these purposes, "control" shall refer to: (i) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract or otherwise; or (ii) the ownership, directly or indirectly, of at least 50% of the voting securities or other ownership interest of a Person;

" **Agreement** " means this master supply agreement and its Appendices, which form an integral part thereof;

" **Appendix** " means an appendix to this Agreement;

" **Background IPR** " means any Intellectual Property Right owned or controlled by either Party prior to the Effective Date or developed by or on behalf of such Party independently of the activities performed by such Party under this Agreement;

" **Change** " means any change that may impact the quality or safety of the Product, including changes in any process, primary packaging components, analytical specifications or methods, Product Specifications, Production Facility, equipment, raw materials or storage;

“ **Delivery Date** ” means the date on which each Product should be delivered as set forth in an Order;

“ **Effective Date** ” means the date first written above;

“ **Force Majeure Event** ” means any unforeseen event which is beyond the reasonable control of the Parties or any foreseeable occurrence the consequences of which may not reasonably be avoided (including, without limitation, any strike, lockout or other industrial action, Act of God, war or threat of war, act of terrorism, malicious damage or prohibition or restriction by governments or other legal authority) which prevents performance of this Agreement, in whole or in part, by either Party;

“ **Governmental Authority** ” means any (i) national, state, provincial, local or any foreign or supranational government; (ii) governmental, regulatory or administrative authority, agency or commission; or (iii) court, tribunal or judicial or arbitral body;

“ **Incoterms** ” means the trade terms and conditions published by the International Chamber of Commerce and entitled Incoterms 2010;

“ **Intellectual Property Right** ” means know-how, patents, trademarks, trade names, design rights, copyrights or any rights or property similar to any of the foregoing in any part of the world, whether registered or not;

“ **Improvement** ” means any change, improvement, modification or development to any Product or Product Specifications;

“ **Order** ” means a purchase order issued by TESARO to STA stating quantities of Product that TESARO commits to purchase from STA , the required delivery date and any other information required or permitted to be specified in accordance with Section 6.1;

“ **Parties** ” mean STA and TESARO;

“ **Price** ” means the price as described in Appendix B;

“ **Product Specifications** ” means the specification applicable to each Product as detailed in Appendix A;

“ **Production Facility** ” means STA’s manufacturing facility located at: Shanghai SynTheAll Pharmaceutical Co., Ltd., 9 Yuegong Road West, Jinshan District.

“ **Quality Agreement** ” means a written agreement between the Parties that describes the Parties’ quality control, technical, quality assurance and regulatory responsibilities relating to the Manufacture and release of Product;

“ **Reprocess** ” and “ **Reprocessing** ” mean introducing a Product back into the process and repeating appropriate manipulation steps that are part of the established Manufacturing Process. Continuation of a process step after an in-process control test showing the process to be incomplete is not considered Reprocessing; and

" **Rework** " and " **Reworking** " means subjecting Product to one or more processing steps that are different from the established Manufacturing Process.

1.2 Reference to articles, paragraphs and Appendices in this Agreement, shall be a reference to articles, paragraphs and Appendices contained in this Agreement, unless otherwise expressly stated.

2. GENERAL

2.1 The terms and conditions of this Agreement shall apply without exception to the manufacture, supply and sale of the Products by STA to TESARO under Orders.

2.2 In the event of any conflict or discrepancy between the provisions of this Agreement and the provisions of an Order, the provisions of this Agreement shall prevail.

3. SCOPE OF THE AGREEMENT

3.1 STA agrees to manufacture and sell each Product to TESARO, and TESARO hereby agrees to purchase each Product from STA, in accordance with the terms and conditions set forth in this Agreement.

3.2 Within 60 days of executing this Agreement, the Parties shall enter into a mutually acceptable Quality Agreement. This Quality Agreement will be subject to the terms of this Agreement. The Quality Agreement may be modified from time to time by mutual written agreement. The Quality Agreement shall be negotiated in good faith by the Parties.

4. GOVERNANCE COMMITTEE

4.1 Within thirty (30) days of execution of the Agreement, the Parties will form a Governance Committee (the " **Committee** "). The Committee will consist of up to three (3) representatives from each Party, including the Primary Contact (" **PC** ") and Quality Representative from each Party. The Committee will provide a forum for routine communication and discussion of Agreement deliverables and responsibilities.

4.1 During the term of this Agreement, the Committee will schedule and hold routine meetings, at defined intervals acceptable to the Committee, but no less frequently then quarterly, with a minimum of one (1) face-to-face meeting annually. The PCs at each Party will develop agendas as well as supporting material requirements, define required participation and generate meeting notes for distribution. The Parties will each bear all expenses of their representatives relative to their participation both on the Committee and in the meetings of the Committee. Nothing prevents the Committee, or its respective members, from meeting on an ad hoc basis as required.

4.1 The Committee shall undertake the following responsibilities:

a. review the most current forecasts and Orders to ensure alignment on Agreement deliverables and Product requirements;

b. review the current status of all applicable critical inventories, Product batches, packaged Product batches, and any other items deemed appropriate by the Committee;

c. act as a forum for discussion of operational, technical and quality issues, and any and all other relationship-driven issues as required;

d. advise the Parties regarding activities involved in day-to-day, tactical operations; provided, that the Committee may involve additional subject matter experts from each Party as required to address specific activities and decisions; and

e. recommend creation and resourcing of sub-teams as required to address specific issues.

4.1 The individual members of the Committee are set forth below. Each Party may change any of its representatives to the Committee upon prior written notice to the other Party.

	STA	Client
Primary Contact	[***]	[***]
Quality Representative	[***]	[***]
Technical Representative	[***]	[***]

5. PRODUCTION OF EACH PRODUCT

5.1 Capacity; Safety Stock

STA shall maintain capacity adequate to fulfil [***] percent ([***]%) of TESARO's requirements for each Product. STA agrees to establish and maintain a minimum of three (3) months (based on the most recent rolling forecast) safety stock of each Product. STA shall provide written notice to TESARO as soon as practicable of any event that would reasonably be expected to adversely affect STA's capacity to supply the Products to TESARO hereunder. TESARO shall purchase from STA whatever quantities of the Products remain in Client's safety stock of Product inventory at the time of expiration or termination of the Agreement.

5.2 Specifications and requirements

STA hereby represents, warrants and covenants to TESARO that STA shall produce each Product in conformity with:

(i) the Product Specifications (as specified in Appendix A), using methods of analysis mutually accepted by both parties;

(ii) all applicable laws and regulations related to the manufacture of Product at the Production Facility, including to the extent applicable, Current Good Manufacturing

Practices ("cGMP") and all applicable anti-corruption laws, including without limitation the U.S. Foreign Corrupt Practices Act and the U.K. Bribery Act 2010; and

(iii) the applicable Order .

Additionally, STA hereby represents, warrants and covenants to TESARO that STA (a) except to the extent permitted by applicable law, will not make any payments or other transfers of value, directly or indirectly, in connection with this Agreement to a healthcare provider, government official, hospital and/or any similar person or entity; and (b) the performance of the services hereunder will not violate any proprietary rights of any third party, including, without limitation, confidential relationships and patent and copyright rights.

TESARO's prior written consent shall be required for any amendment to the Product Specifications.

If each Product does not conform with (i), (ii) and (iii) above at the time that it is delivered to TESARO, such Product shall be referred to in this Agreement as " **Nonconforming Product** " and shall be regarded as having " **Nonconformity** ." STA agrees to promptly notify TESARO in writing if STA obtains knowledge of its delivery to TESARO of any Nonconforming Product. In addition to the foregoing, STA shall notify TESARO immediately, and in any event within forty-eight (48) hours, of learning of any situation that may require a recall of each Product or may result in a Change.

5.3 Raw materials

STA shall purchase at its own expense from qualified third parties all raw materials that are required for the manufacture of each Product and the maintenance of the safety stock described in Section 5.1.

5.4 Production Facility

STA shall provide TESARO with one year prior written notice of any change in the location of the Production Facility. TESARO shall have the right, but not the obligation, at TESARO's expense and upon reasonable notice, to audit the Production Facility for compliance with this Agreement. Such audits shall be conducted during STA's normal business hours. STA shall promptly notify TESARO of any inspection of the Production Facility and shall promptly provide TESARO with copies of all regulatory and other correspondence with Governmental Authorities pertaining to each Product or that may reveal or result in a Change.

5.5 STA shall allow TESARO personnel access to the manufacturing facility during times that Product is being manufactured. TESARO personnel shall adhere to all STA facility, access, and operational guidelines and procedures during visits to the facility. Facility visits shall be allowed during normal operating hours; provided, that exceptions shall be allowed to cover manufacturing operations that occur during times other than normal business hours after prior approval of STA (not to be unreasonably withheld).

6. FORECASTS – VOLUMES – ORDERS

6.1 Within ten (10) business days of execution of this Agreement, and prior to the beginning of each calendar quarter during the term of this Agreement, TESARO shall submit to STA a good faith eighteen (18) month rolling forecast of the quantities of each Product TESARO expects to order. The first six months of the rolling forecast shall be binding upon TESARO. The binding portion of the rolling forecast may only be changed by mutual agreement of the Parties. TESARO will submit Orders for each Product corresponding to the binding portion of the forecast, including anticipated delivery dates, quantity, any designated consignee, and other required information and notes, six (6) months in advance of anticipated Product delivery.

6.2 All Orders shall be deemed accepted by STA upon delivery of an order acknowledgement by STA; provided, that if STA fails to deliver a sales order acknowledgement within five (5) days of the date of submission of any Order, then STA shall be deemed to have accepted the Order. Notwithstanding the foregoing, STA shall not have the right to reject any Order (i) to the extent relating to the binding portion of the forecast, or (ii) to the extent that such Order is for [***]% or less of the quantity of Product set forth in the non-binding portion of the forecast.

6.3 This Agreement sets forth the exclusive contract terms between the Parties with respect to, and shall apply to, all orders for each Product. Any terms in any Order, sales order, invoice or other notice submitted by either Party to the other Party that are different from or additional to the provisions hereof shall be null and void notwithstanding STA's delivery of, and TESARO's acceptance of, Product under any Order, sales order, invoice or other notice containing such terms.

6.4 During the term of this agreement, TESARO shall order from STA not less than [***]% of its and its Affiliates' total annual requirement of each Product. Promptly after the beginning of each calendar year, TESARO shall provide to STA a summary of the amount and source of each Product that TESARO and its Affiliates purchased during the previous year, and supporting documentation reasonably requested by STA , subject to TESARO's obligations of confidentiality under its agreements with third party suppliers.

7. DELIVERY AND STORAGE

7.1 Each Product shall be delivered to TESARO or designee FCA (Incoterms 2010) to the designated carrier to be agreed to by the Parties prior to shipment.

7.2 Product shall be loaded and transported to the designated carrier at STA risk and liability. It is TESARO's or its designee's responsibility to contract for transport and to take out all necessary insurance to cover damage to the Product after such Product has been delivered to the designated carrier.

7.3 Prior to delivery, all Products at the Production Facility will be stored in a clean, secured, segregated area. For each Product that has been stored for more than [***] months after Batch completion, STA will charge TESARO storage fees ("Storage Fees") at a monthly rate of USD[***] per 1200*1200 mm pallet. If any Product will go through any further downstream processing at STA, the storage fee will be waived.

8. DELIVERY DATE

8.1 The Product shall be delivered by STA within [***] ([***]) days of the Delivery Date defined in the applicable Purchase Order.

8.2 To the extent that STA fails to deliver Product in accordance with any Order, STA shall use its best efforts to make up such Order as soon as possible; provided, that TESARO shall have the right to cancel, at no charge to TESARO, any Order that is delivered more than thirty (30) days after the Delivery Date.

8.3 If a delivery delay is caused by any Force Majeure Event or by any act or omission by TESARO, the Delivery Date shall be extended by such period as is considered reasonable under the circumstances by both Parties.

9. PRICE AND PAYMENT

9.1 Each Product shall be sold and delivered to TESARO for the total price as defined in Appendix B (exclusive of Value Added Tax).

9.2 STA shall be solely responsible for all transport costs, taxes, excise, customs and/or export duties to the designated carrier arising from Product purchased hereunder.

9.3 TESARO or designee will be solely responsible for all transport costs, taxes, excise, customs and/or import duties from the designated carrier to ultimate destination arising from Product purchased hereunder.

9.4 All invoices, to the extent relating to Product that has been accepted by TESARO, shall be sent by email to [***] or to such other email address as may be provided by TESARO in writing from time to time and shall be payable by TESARO within 30 days of the date of receipt by TESARO of an invoice from STA.

9.5 All payments shall be made in US Dollars.

9.6 In the event that the total amount of an invoice has not been paid within thirty (30) days of the due date, a late fee equal to [***] will be charged.

10. [***]

11. INSPECTION AND RETURN

11.1 STA shall include a proper Certificate of Analysis with each shipment of Product. All Product shall be received subject to TESARO's prior right of inspection and rejection.

11.2 TESARO shall have a reasonable time, but not more than [***] ([***]) days after delivery, to inspect delivered Product and to reject any Nonconforming Product. With respect to latent Nonconformities and Nonconformities not discoverable by TESARO within [***] ([***]) days of delivery through the use of reasonable inspection methods and procedures, TESARO shall give notice to STA within [***] ([***]) days following detection of any such Nonconformity.

11.3 If as the result of the receiving inspection, any Product is found to have a Nonconformity, TESARO shall notify STA, and at TESARO's option, STA shall promptly (i) refund the invoice price for the Nonconforming Product, or (ii) Rework or Reprocess the Nonconforming Product, at STA's cost and expense, so that the Nonconforming Product can be deemed to conform to Product Specifications and the other requirements set forth in Sections 5.2 (ii) and (iii). If such Rework or Reprocess is not possible or is reasonably disapproved by TESARO, then STA will , at STA's expense, replace the Nonconforming Product with Product that conforms with the requirements set forth in Section 5.2. In either case, STA shall be responsible at its expense for arranging for the removal of the Nonconforming Product from TESARO's or its designee's facility.

11.4 If the representatives of the Parties do not reach an agreement in terms of Non-confirming Product, then TESARO and STA shall (each acting reasonably and in good faith) elect an independent third party expert to review the data and/or conduct testing and make a final determination regarding the cause of the non-conformance and the steps to be undertaken (if any) to overcome the non-conformance, which shall be binding upon both TESARO and STA. The fees and expenses of the testing and/or consultant, as applicable, incurred in making such determination will be paid by the party against whom the determination is made.

12. WARRANTY - LIABILITY

12.1 STA warrants that all Product delivered to TESARO shall conform to the Product Specifications and the other requirements set forth in Sections 5.2(ii) and (iii) and be free of material defects in manufacture and materials (the " **Warranty** "). The Warranty (i) is in addition to all other warranties, express, implied, statutory and common law, and (ii) survives STA's delivery of the Product, TESARO's receipt, inspection, acceptance, use and payment of the Product and the termination or expiration of this Agreement .

12.2 STA does not make any other warranties, express or implied, including, without limitation, any warranty of merchantability or fitness for a particular use or purpose with respect to the Product.

12.3 Notwithstanding anything provided to the contrary in this Agreement, except for a breach of Sections 17 or 19, willful misconduct, gross negligence or STA's indemnification obligations under Section 12.5, in no event and under no circumstances shall any Party be liable to the other Party for any indirect, consequential, special, incidental or punitive damages.

12.4 Except for a breach of Sections 17 or 19, wilful misconduct, gross negligence or STA's indemnification obligations under Section 12.5, STA's aggregate liability in respect of all claims arising out of or in connection with this Agreement shall be limited to [***].

12.5 STA shall indemnify, defend and hold harmless TESARO and its Affiliates, and its and their respective officers, directors, employees and agents harmless from and against all costs and expenses actually incurred, including the reasonable fees of attorneys, arising out of or resulting from (i) the gross negligence or wrongful intentional acts or

omissions of STA or its Affiliates, (ii) a breach of any representation, warranty or express covenant made by STA under this Agreement, or (iii) any claim for personal injury or infringement of third party intellectual property rights in connection with the manufacturing and supply of each Product by STA and its Affiliates under this Agreement.

13. INSURANCE

STA shall maintain at its own cost with reputable insurers, sufficient and adequate insurance coverage for the furtherance of its obligations under this Agreement.

14. CHANGE CONTROL – REQUIRED CHANGE

STA shall implement any Change as required by any competent Governmental Authority within the timeframe required by such competent Governmental Authority or, if none, within the timeframe agreed between the Parties. In the event STA is required to make any Changes by any competent Governmental Authority or said Changes are mandated by applicable laws and regulations, the Party becoming aware thereof shall promptly notify the other Party and provide the other Party with all relevant documents delivered to it by the Governmental Authority, if applicable. STA shall provide TESARO with the change implementation documentation promptly after the date of such notification. All the additional costs incurred by said changes will be borne by TESARO. Notwithstanding the foregoing, in the event that any Change renders all Product unsuitable for TESARO's intended use, TESARO shall have the right to terminate this Agreement upon thirty (30) days prior written notice to STA.

15. PRODUCT IMPROVEMENT

From time to time during the term of this Agreement, either Party may submit to the other Party written proposals for the adoption, implementation or development of any change, improvement, modification, or development of any Improvement to a Product. All Improvements shall be the sole and exclusive property of TESARO, and STA hereby assigns to TESARO all of its right, title, interest and ownership in such Improvements, and any intellectual property rights in such Improvements, including, but not limited to, patents, patent applications, and copyrights ("IP Rights"). STA agrees to execute or cause its agents and employees to execute any documents reasonably necessary or desirable to secure or perfect TESARO's legal rights and worldwide ownership in such Improvements and IP Rights. STA shall treat the Improvements and IP Rights as TESARO confidential information and shall not use them for the benefit of any party other than TESARO or for any purpose other than in connection with the Services. If any Improvement results in cost savings, the Parties shall promptly negotiate in good faith the allocation of such cost savings as between the Parties.

16. FORCE MAJEURE

16.1 The obligations of each Party pursuant this Agreement shall be suspended during any period and to the extent that a Party is prevented or hindered from complying with them by any Force Majeure Event.

16.2 In the event of either Party being so hindered or prevented, the Party affected shall give notice to the other Party of the suspension and its cause as soon as reasonably practicable. The party being so hindered or prevented shall recommence performance as soon as possible after such Force Majeure Event has been resolved. In the event the cause continues for more than four (4) months, either Party may terminate this Agreement by giving two (2) months prior written notice.

17. CONFIDENTIALITY

17.1 The Parties undertake to keep confidential and shall not use for any purpose other than the performance of such Party's obligations under this Agreement, and shall cause its Affiliates and such Party's and its Affiliates' respective directors, officers, employees and advisors to keep confidential and not to use for any purpose other than the performance of such Party's obligations under this Agreement, all information acquired from the other Party or its Affiliates, in connection with this Agreement and the transactions contemplated hereby, including, without limitation, all information concerning the Products, the materials, the processes, Intellectual Property Rights, the contents and existence of this Agreement and all Product Specifications and other quality standards hereunder, other than any information that: (i) is or hereafter becomes generally available to the public other than by reason of any default with respect to a confidentiality obligation; (ii) was already known to the receiving Party, without obligation of confidentiality to the disclosing party, as evidenced by prior written documents in the receiving Party's possession; or (iii) is disclosed to the receiving Party by a Third Party who or which is not in default of any confidentiality obligation to the disclosing Party.

17.2 Each receiving Party shall transmit, and shall cause each of its Affiliates to transmit, this information only to those of its employees, agents or representatives who shall need same for the purpose of this Agreement and shall ensure that such employees, agents or representatives are bound by and will honor a similar duty of confidentiality. The receiving Party shall protect such confidential information with a degree of care not less than that used in managing its own confidential information, and in any case no less than a reasonable standard of care. The receiving Party shall have the right to disclose the confidential information of the disclosing Party to third parties to the extent required to be disclosed pursuant to applicable law, court or governmental order or the requirements of a securities listing exchange, provided that (i) to the extent practicable, the receiving Party has provided the disclosing Party with advance notice of such compelled disclosure, (ii) the receiving Party reasonably cooperates with any request by the disclosing Party to seek confidential treatment of such information, and (iii) the receiving Party discloses only that portion of the disclosing Party's confidential information that is required to be disclosed.

17.3 The obligations of confidentiality and rights set forth in this article shall remain effective for a period of 10 years after the expiration or termination of this Agreement ; provided, that such obligations shall continue with respect to the trade secrets of either Party for so long as such trade secrets are protected under applicable law.

18. ASSIGNMENT

This Agreement may not be sub-contracted or assigned in whole or in part by any Party without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed. Nevertheless, it is understood that this Agreement may be assigned by either Party without the consent of the other Party to an Affiliate of such Party. Additionally, TESARO shall have the right to assign this Agreement without the consent of STA to the purchaser of or successor-in-interest to all or substantially all of TESARO's assets to which this Agreement pertains, whether by merger, sale, reorganization, reincorporation, operation of law or otherwise.

19. INTELLECTUAL PROPERTY RIGHTS

Each Party remains the sole and exclusive owner of its Background IPR. Nothing in this Agreement shall affect a Party's or its Affiliates ' rights to its Background IPR nor imply grant of any licence or right to such Party's Background IPR. Notwithstanding the foregoing, during the term of this Agreement, TESARO hereby grants to STA a non-exclusive, fully paid-up license under its Background IPR solely for the purpose of performing its obligations hereunder. STA acknowledges and agrees that (a) it shall have no right or license to use TESARO's Background IPR or any other Intellectual Property Rights owned or controlled by TESARO except to manufacture and supply the Products to TESARO in accordance with the terms and conditions of this Agreement, and (b) it shall not manufacture or supply the Products for any third party. Any inventions created or developed in connection with the provision of the services and any Intellectual Property Rights therein that are derived directly from STA Background IPR ("Manufacturing Improvements") shall be owned by STA. STA hereby grants to TESARO a non-exclusive, fully paid-up, sub-licensable, perpetual and irrevocable license to manufacture and commercialize Products under any Manufacturing Improvements that are necessary for the manufacture or commercialization of the Products.

20. TERM - TERMINATION

20.1 This Agreement shall be in effect from the Effective Date and, unless terminated earlier in accordance with this Section 20, shall remain in force for a period of five (5) years. The term may be extended by TESARO upon written notice provided to STA at least thirty (30) days prior to the end of the initial term for an additional term of one (1) year.

20.2 Either Party may terminate the Agreement at any time by giving notice in writing if the other Party is in material breach of its obligations under the Agreement and, if such breach has not been remedied within thirty (30) days of a written notice thereof from the non-breaching Party.

20.3 Either Party may terminate the Agreement at any time with immediate effect by giving notice in writing if the other Party becomes insolvent or bankrupt, is placed into administration, receivership or liquidation, commences proceedings to be wound up, enters into any voluntary arrangement with its creditors, or on the occurrence of any similar event under the laws of its domicile.

20.4 TESARO may terminate the Agreement at any time upon one hundred and eighty days (180) days prior written notice to STA.

20.5 Upon expiration or termination of the Agreement, except for termination by TESARO in accordance with Sections 16.2, or 20.2, then (a) TESARO shall take delivery of and pay for any Product under any Orders outstanding as of the date of expiration or termination and to the extent consistent with the binding portion of the most recent rolling forecast, and (b) STA shall promptly return to TESARO, at TESARO's expense and direction, any remaining inventory of Product and raw materials. The following provisions shall survive the expiration or termination of this Agreement for any reason: Sections 5.2, 11.2, 11.3, 12, 13, 15, 17, 19, 21, 22, 23 and this Section 20.5.

21. NOTICES

21.1 All notices, requests, claims, demands and other communications under this Agreement shall be delivered to the Parties in person or sent to the addresses set forth in the heading hereof by internationally recognized overnight express courier service. Any notices, requires, claims, demands or other communications delivered to TESARO shall be addressed to the attention of the General Counsel.

21.2 Any notice, requests, claims, demands and other communication delivered or made as set out above shall be effective upon receipt and shall be deemed to be received, if delivered in person, at the time of delivery, or if delivered by internationally recognized overnight express courier service, the next business day after such notice, request, claim, demand or other communication was deposited with such service.

22. MISCELLANEOUS

22.1 This Agreement and its Appendices contain the entire agreement and understanding between the Parties with respect to the subject matter hereof and supersedes and replaces all prior agreements and understandings, whether written or oral, with respect to the same subject matter, still in force between the Parties.

22.2 This Agreement may not be modified or amended except by a written agreement that explicitly refers to this Agreement and that is signed by both Parties.

22.3 All terms and provisions of this Agreement are severable and any term, provision or application thereof which may be prohibited or not enforceable by law, shall not affect the remainder of this Agreement or any other application of such term or provision.

22.4 Any failure or delay by a Party in exercising any right under this Agreement, the exercise or partial exercise of any right under this Agreement, or any reaction or absence of reaction by a Party in the event of breach by the other Party of one or more provisions of this Agreement, shall not operate or be construed as a waiver (either express or implied, in whole or in part) of its rights under this Agreement or under said provision(s) or preclude the further exercise of any such rights. Any waiver of a right must be express and in writing.

22.5 Each Party shall bear the costs incurred by it in connection with the preparation and the performance of this Agreement.

23. APPLICABLE LAW - JURISDICTION

This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware.

IN WITNESS WHEREOF , the Parties have caused their respective duly authorized representatives to execute this Agreement as of the Effective Date.

FOR AND ON BEHALF OF STA PHARMACEUTICAL HONG KONG LIMITED:

___ Fu Xiaoyong_____ [name]

___ VP of STA R&D_____ [title]

___ 2016.08.08_____
Date

___ /s/ Fu Xiaoyong_____
Signature

FOR AND ON BEHALF OF TSRO Bio GmbH.:

__ Orlando Oliveira_____ [name]

__ 2nd of August, 2016_____ [title] __ SVP & GM International_____
Date

__ /s/ Orlando Oliveira_____
Signature

Appendix A: Product Specifications
Appendix B: Prices

Appendix A: Product Specifications

[***]

[***] INDICATES SIX 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.

Appendix B: Price

Product Name: [***]

PO Quantity (kg)	Unit Price ($/kg)	Lead Time (weeks)
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

Note:

1) Shipping term is FCA.
2) Price includes Value Added Tax (VAT)
3) Minimum order quantity is [***]
4) Lead Time is defined as from PO to delivery date

[***] 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.

Product Name: [***]

PO Quantity (kg)	Unit Price ($/kg)	Lead Time
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

Note:

1) Shipping term is FCA.
2) Price listed includes Value Added Tax (VAT)
3) Minimum order quantity is [***]
4) Lead Time is defined as from PO to delivery date

[***] 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.

Product Name: [***]

PO Quantity (kg)	Unit Price ($/kg)	**Lead Time**
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

Note:

1) Shipping term is FCA.

2) Price listed above includes Value Added Tax (VAT)

3) Price listed above excludes the cost of two starting materials: [***]

4) Minimum order quantity is [***]

5) Lead Time is defined as from PO to delivery date and assuming the [***] are in stock.

Exhibit 10.3

COMMERCIAL SUPPLY AGREEMENT

This **COMMERCIAL SUPPLY AGREEMENT** is entered into as of the 15th day of December, 2016 (the " **Effective Date** "), by and between Corden Pharma Colorado, Inc., having a principal place of business at 2075 55th Street, Boulder, CO 80301 USA (" **Supplier** "), and **TESARO Bio GmbH** , having a principal place of business at Poststrasse 6, 6300 Zug, Switzerland (together with its Affiliates, " **TESARO** "). Each of Supplier and TESARO may be referred to in this Agreement, individually, as a " **Party** " and, collectively, as the " **Parties** ".

Background

A. TESARO is a biopharmaceutical company developing and commercializing a product known as niraparib.

B. Supplier is a contract manufacturer with the capabilities and facilities necessary to be able to provide process commercial manufacturing services with respect to pharmaceutical products.

C. TESARO desires to engage Supplier to manufacture a commercial supply of niraparib API in the quantities from time to time ordered by TESARO, and Supplier is willing to perform such services for TESARO, in each case subject to the terms and conditions set forth in this Agreement.

Agreement

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained in this Agreement, the Parties agree as follows:

SECTION 1. **DEFINITIONS .** As used in this Agreement, the following words and phrases will have the following meanings, whether used in the singular or plural:

1.1 " **AAA** " has the meaning set forth in Section 15.3(a) .

1.2 " **Affiliate** " as to a Party, means any entity which, directly or indirectly, controls, is controlled by, or is under common control with such Party. For the purposes of this definition, " **control** " refers to any of the following: (a) direct or indirect ownership of fifty percent (50%) or more of the voting securities entitled to vote for the election of directors in the case of a corporation, or of fifty percent (50%) or more of the equity interest with the power to direct management in the case of any other type of legal entity; or (b) any other arrangement where an entity possesses, directly or indirectly, the power to direct the management or policies of another entity, whether through ownership of voting securities, by contract or otherwise.

1.3 " **Agreement** " means this Commercial Supply Agreement, together with all Appendices attached hereto and accepted Purchase Orders (as amended by the applicable Change Order), as amended from time to time by the Parties in accordance with Sections 7.2 and 16.4 .

1.4 " **Applicable Laws** " means all laws, statutes, regulations, rules and guidances applicable to (a) activities performed under this Agreement in the jurisdiction where they are performed, other than activities described in clauses (b) and (c) of this paragraph, (b) Manufacturing in the jurisdiction of Manufacture, and (c) the supply, use, marketing or sale of Product in any jurisdiction where such Product is to be supplied, used, marketed or sold, including laws, statutes, regulations, rules and guidance related to Manufacture of Product that apply by reason of the supply, use, marketing or sale of Product in such jurisdiction; provided, that notwithstanding anything to the contrary in this Agreement, with regard to the supply, use, marketing or sale of Product, Product Manufactured by Supplier will only be required to comply with the Applicable Laws, regulations, guidelines, and directives, including cGMP, of (i) the FDA, the EMA, and PMDA, and (ii) such other comparable Regulatory Authority (ies) in the Territory as the Parties agree in writing, such agreement not to be unreasonably withheld, conditioned or delayed.

1.5 " **Certificate of Analysis** " as to any batch of Product, means a certificate attesting to the results of testing of such batch of Product against the criteria specified in relevant Product Specifications, and including test methods, specification parameters and the pass/fail criteria, used to show that a particular batch of such Product meets Product Specifications, and a statement attesting that a particular batch of a Product was Manufactured in accordance with cGMP and the Product Specifications.

1.6 " **cGMP** " means current good manufacturing practices applicable to the Manufacture of Product as follows: (a) current good manufacturing practices promulgated by the FDA, as specified in the United States Code of Federal Regulations and FDA's guidance documents, as such practices govern the Manufacture of Product intended for use in the United States; (b) current good manufacturing practices as defined in the Q7A Guidance on Good Manufacturing Practices of the International Conference on Harmonization of Technical Requirements of Pharmaceuticals for Human Use (ICHQ7A) and other ICH guidelines applicable to the Manufacture of the drug substance; (c) current good manufacturing practices or equivalent standards promulgated by Regulatory Authorities of Japan; and (d) current good manufacturing practices or equivalent standards promulgated by such other countries of the Territory in which Product is intended to be supplied, used, marketed or sold and which other countries are agreed to in writing between the Parties, such agreement not to be unreasonably withheld, conditioned or delayed.

1.7 " **Change Order** " means a written instrument executed by both Parties setting forth a Proposed Change in reasonable detail.

1.8 " **Claims** " has the meaning set forth in Section 12.1 .

1.9 " **Committee** " has the meaning set forth in Section 2.4(a) .

1.10 " **Component Specifications** " means the specifications for Components including, but not limited to, written release specifications and testing instructions, as specified in the Product Specifications or as otherwise mutually agreed upon in writing by the Parties.

1.11 " **Components** " means any key starting materials and other raw materials and ingredients used in the Manufacture of a Product, including TESARO-Supplied Components .

1.12 " **Confidential Information** " as to TESARO means (a) any information of a confidential or proprietary nature, including, but not limited to, scientific, technical, trade and business information, provided by or on behalf of TESARO to Supplier under this Agreement; (b) the TESARO Materials; and (c) TESARO's plans and timelines related to Product, in each case, whether or not labeled or identified as confidential. " **Confidential Information** " as to Supplier means (i) any information of a confidential or proprietary nature, including, but not limited to, any scientific, technical, trade and business information, provided by or on behalf of Supplier to TESARO or any of its Affiliates under this Agreement, but not including TESARO Materials, and (ii) the Supplier Materials, in each of (i) and (ii) whether or not labeled or identified as confidential.

1.13 " **Debarred Individual or Debarred Entity** " has the meaning set forth in Section 11.3(c) .

1.14 " **Deficiency Notice** " has the meaning set forth in Section 5.3(a) .

1.15 " **Deliverables** " means the physical deliverables under this Agreement, including shipments of the Product.

1.16 " **Disclosing Party** " has the meaning set forth in Section 9.1 .

1.17 " **Dispute** " has the meaning set forth in Section 15.2 .

1.18 " **Effective Date** " has the meaning set forth in the Preamble.

1.19 " **EMA** " means the European Medicines Agency, or any successor entity thereto.

1.20 " **Executive Officers** " has the meaning set forth in Section 15.2 .

1.21 " **Facilities** " means the Supplier facility used in the conduct of the Manufacturing Services, as specified in Exhibit A and any other Supplier facility approved in writing by TESARO prior to use in the performance of the Manufacturing Services.

1.22 " **FDA** " means the United States Food and Drug Administration, or any successor entity thereto.

1.23 " **Firm Order** " has the meaning set forth in Section 4.1 .

1.24 " **Force Majeure Event** " has meaning set forth in Section 16.2 .

1.25 " **Improvements** " means all discoveries, inventions, designs, improvements, enhancements, ideas, concepts, techniques, know-how, writings, software, documentation or other works of authorship, whether or not copyrightable or patentable.

1.26 " **Independent Expert** " has the meaning set forth in Section 5.3(c) .

1.27 " **Inspection Period** " has the meaning set forth in Section 5.3(a) .

1.28 " **Intellectual Property Rights** " means intellectual property rights, including, without limitation, patents, copyrights, trademarks, applications, service marks, trade names, applications for any of the foregoing, firmware, trade secrets, mask works, industrial design rights, rights of priority, know-how, concepts, processes, data rights, design flows, methodologies, and any and all other legal rights protecting proprietary intangible property.

1.29 " **Liability** " has the meaning set forth in Section 12.1 .

1.30 " **Manufacture** ", " **Manufacturing** " or " **Manufactured** " will mean all steps, processes and activities of Supplier to produce Product (or any step, process or activity therein), including the manufacture, production, Component sourcing, other than TESARO-Supplied Components, and testing as applicable, packaging, labeling, warehousing, quality control testing (including in-process, release and stability testing, when applicable), release, preparation for shipping and storing of any Product, either as part of the Manufacturing Services.

1.31 " **Manufacturing Services** " means the Manufacture by Supplier of commercial batches of Product ordered by TESARO.

1.32 " **Materials** " means documentation, information, biological, chemical or other materials (whether raw materials, packaging materials, or otherwise), equipment, formulations, processes, methods, data, specifications, reports, work product or any other information.

1.33 " **Nonconforming Product** " means any Product supplied to TESARO by Supplier under this Agreement that does not conform with the Product Requirements at the time that such Product is delivered to TESARO. Each Nonconforming Product shall be regarded as having a " **Nonconformity** ".

1.34 " **Party** " and " **Parties** " each have the meaning set forth in the Preamble.

1.35 " **PC** " has the meaning set forth in Section 2.4(a) .

1.36 " **PMDA** " means the Pharmaceuticals and Medical Device Agency in Japan, or any successor entity thereto.

1.37 " **Product** " means the product described in Exhibit B , as amended from time to time by mutual written agreement of the Parties.

1.38 " **Product Requirements** " has the meaning set forth in Section 7.1 .

1.39 " **Product Specifications** " means, as to a Product, the written release specifications, as attached hereto as Exhibit C , and as amended from time to time by mutual agreement of the Parties in accordance with Section 7.2 .

1.40 " **Proposed Change** " has the meaning set forth in Section 7.2(a) .

1.41 " **Proposing Party** " has the meaning set forth in Section 7.2(a) .

1.42 " **Purchase Order** " has the meaning set forth in Section 4.2(a) .

1.43 " **Quality Agreement** " has the meaning set forth in Section 5.2 .

1.44 " **Recall** " means any action (a) by TESARO to recover title to or possession of quantities of the Product sold or shipped to Third Parties (including, without limitation, the voluntary withdrawal of the Product from the market), or (b) by any Regulatory Authorities to seize or destroy the Product. A Recall shall also include any action by either Party to refrain from selling or shipping quantities of the Product to Third Parties which would be subject to a Recall if sold or shipped.

1.45 " **Receiving Party** " has the meaning set forth in Section 9.1 .

1.46 " **Records** " has the meaning set forth in Section 7.12 .

1.47 " **Regulatory Authority** " means the FDA, the EMA the PMDA or any other governmental or regulatory body, agency authority or entity which regulates, directs or controls the manufacture, clinical testing, commercialization or use of pharmaceutical products in, or with respect to, the country of manufacture or sale within the Territory which are agreed to in writing between the Parties, such agreement not to be unreasonably withheld, conditioned or delayed.

1.48 " **Regulatory Filings** " means the governmental filings required to obtain approval to conduct clinical trials of a Product, or to market and sell a Product in a given country within the Territory, including, but not limited to, Product registrations and Product marketing approvals, as applicable, in each such country.

1.49 " **Required Change** " has the meaning set forth in Section 7.2(b) .

1.50 " **Retention Period** " has the meaning set forth in Section 7.12 .

1.51 " **Rolling Forecast** " has the meaning set forth in Section 4.1 .

1.52 " **Supplier** " has the meaning set forth in the Preamble.

1.53 " **Supplier Indemnified Parties** " has the meaning set forth in Section 12.1 .

1.54 " **Supplier Materials** " means (a) Confidential Information of Supplier, (b) Materials developed, created, or acquired by or on behalf of Supplier (i) prior to the Effective

Date, or (ii) independent of this Agreement and without reliance upon or access to Confidential Information of TESARO, (c) Materials generated, conceived, developed, created, invented, made or reduced to practice by Supplier in the course of the Manufacturing Services that are related to the Manufacture of products generally and are not specific to the Product, and (d) Improvements to any of the foregoing, in each case, whether or not labeled or identified as confidential, including in each case any Intellectual Property Rights associated with the foregoing.

1.55 " **Supplier Personnel** " has the meaning set forth in Section 13.2 .

1.56 " **Supplier-Responsible Recall** " has the meaning set forth in Section 5.6(c) .

1.57 " **Supply Price** " shall have the meaning set forth in Section 6.1 .

1.58 " **Term** " has the meaning set forth in Section 10.1 .

1.59 " **Territory** " means any country worldwide.

1.60 " **TESARO** " has the meaning set forth in the Preamble.

1.61 " **TESARO Indemnified Parties** " has the meaning set forth in Section 12.2 .

1.62 " **TESARO Materials** " means (a) Confidential Information of TESARO, (b) Materials developed, created, or acquired by or on behalf of TESARO (i) prior to the Effective Date, or (ii) independent of this Agreement and without reliance upon or access to Confidential Information of Supplier, including without limitation the TESARO-Supplied Components hereunder, (c) Materials generated, conceived, developed, created, invented, made or reduced to practice by Supplier in the course of the Manufacturing Services that is specific to Product and not related to Manufacture of other product, and (d) Improvements to any of the foregoing, in each case, including in each case any Intellectual Property Rights associated with the foregoing.

1.63 " **TESARO-Supplied Components** " means the specific raw materials, ingredients, and other materials to be provided by TESARO, as listed in Exhibit D or the applicable Purchase Order, as updated by TESARO in writing, from time to time.

1.64 " **Third Party** " or " **Third Parties** " means any person or entity, as applicable, other than TESARO or Supplier or any of their respective Affiliates.

SECTION 2. MANUFACTURING SERVICES .

2.1 Manufacture and Sale of Product . During the Term, TESARO will purchase from Supplier, and Supplier shall manufacture and supply to TESARO, Product for TESARO's use in the commercial manufacture of TESARO's product niraparib in accordance with the terms of this Agreement.

2.2 Components . Except as set forth in Section 3.1 , Supplier will purchase, at its own cost, all Components and equipment used in Manufacturing Services, which cost shall be included in the Supply Price. All such Components will conform to the applicable Component Specifications. The Components identified in Exhibit E will be supplied by TESARO-approved suppliers.

2.3 Capacity; Inventory . Supplier shall maintain capacity adequate to fulfill up to [***] percent ([***]%) of TESARO requirements for Product as set forth in the binding period of each Rolling Forecast. Additionally, during the Term, Supplier shall purchase and maintain at its expense an adequate amount of safety stock, but not less than three (3) months' worth of safety stock based on the latest Rolling Forecast, of all Components . In the event that any safety stock becomes unusable because it is expired, is too old to be usable, or has become obsolete, TESARO shall reimburse Supplier for the cost of all such safety stock. Supplier shall provide written notice to TESARO as soon as practicable of any event that would reasonably be expected to materially and adversely affect Supplier's capacity to supply the Product to TESARO hereunder.

2.4 Governance Committee .

(a) *Composition* . Within 30 days of execution of the Agreement, the Parties will form a Governance Committee (the " **Committee** "). The Committee will consist of up to three (3) representatives from each Party, including the primary contact (" **PC** ") and quality representative from each Party, in each case listed in subsection (d) below. The Committee will provide a forum for routine communication and discussion of Agreement deliverables and responsibilities.

(b) *Meetings* . During the Term, the Committee will schedule and hold routine meetings, at defined intervals acceptable to the Committee, but no less frequently then quarterly, with a minimum of two (2) face-to-face meetings annually alternately at the Parties' facilities or at such locations as the Parties may otherwise agree. The PCs at each Party will develop agendas as well as supporting material requirements, define required participation and generate meeting notes for distribution. Each Party will bear all expenses of its representatives relative to their participation both on the Committee and in the meetings of the Committee. Nothing prevents the Parties or the Committee or its respective members from meeting on an ad hoc basis, as required.

(c) *Responsibilities* . The Committee shall undertake the following responsibilities:

(i) review the most current Rolling Forecast and Firm Orders to ensure alignment on Agreement deliverables;

(ii) review current status of all applicable critical inventories, including packaging materials, Products and packaged Products, and any other items deemed appropriate by the Committee;

(iii) act as a forum for discussion of operational, technical, and quality issues, and any and all other relationship-driven issues, as required;

(iv) advise the Parties regarding activities involved in day-to-day, tactical operations, involving additional subject matter experts from each Party as required to address specific activities and decisions; and

(v) recommend creation and resourcing of sub-teams as required to address specific issues.

(d) *Committee Designation Contact List*. The individual members of the Committee are set forth below. Each Party may change any of its representatives to the Committee upon prior written notice to the other Party.

	Supplier	TESARO
Primary Contact	[***]	[***]
Quality Representative	[***]	[***]
Technical Representative	[***]	[***]

SECTION 3. **TESARO RESPONSIBILITIES .**

3.1 TESARO-Supplied Components. Except as expressly set forth in this Agreement or as otherwise agreed upon by the Parties, TESARO will be responsible for sourcing and providing to Supplier all TESARO-Supplied Components , at TESARO's own cost, for all Manufacturing Services. Notwithstanding anything in this Agreement to the contrary, Supplier will not be in breach of its obligation to supply Product or perform the Manufacturing Services by the agreed to delivery date if the delivery or performance delay is the result of TESARO's failure to meet its material obligations in accordance with the terms of this Agreement. TESARO acknowledges that such failure is reasonably likely to cause a delay in the performance of Supplier's obligations hereunder and delivery of the Product. TESARO will promptly advise Supplier in writing of any delays in the delivery of TESARO-Supplied Components. Supplier will promptly advise TESARO in writing of any TESARO-Supplied Components that are lost or damaged.

3.2 TESARO Personnel. TESARO shall provide Supplier with reasonable access to knowledgeable TESARO personnel for consultation regarding Confidential Information of TESARO, TESARO-Supplied Components and the Manufacturing Services.

3.3 Notice of Hazardous Materials. Prior to Supplier commencing the Manufacturing Services, TESARO shall inform Supplier of all material characteristics, including all health, environmental and safety characteristics, of the TESARO-Supplied Components to the extent known by TESARO, and when appropriate, provide Supplier with a Material Safety Data Sheet

on TESARO-Supplied Components and Product. TESARO shall promptly notify Supplier of any new hazards or potential new hazards to the environment or the health and safety of Supplier Personnel relating to the TESARO-Supplied Components or Product of which TESARO becomes aware.

3.4 Applicable Law . TESARO shall (a) comply, in all material respects, with all Applicable Laws applicable to its operations and the use or sale of the Product and the finished formulated product containing the Product, (b) be responsible for obtaining and maintaining any establishment licenses or permits required by the FDA or other Regulatory Authorities or by Applicable Law that pertains to the handling, storage, and distribution of the Product after TESARO has obtained title to the Product.

SECTION 4. ORDERS AND FORECASTS .

4.1 Forecasts . Within ten (10) business days of the Effective Date, and prior to the beginning of each calendar quarter during the Term, TESARO shall submit to Supplier a good faith eighteen (18) month rolling forecast of the quantities of Product TESARO expects to order (the " **Rolling Forecast** "). The [***] ([***]) months of the Rolling Forecast shall be binding upon TESARO (the " **Firm Order** "). Months [***] ([***]) shall be binding to [***] percent ([***]%) of the Rolling Forecast. The binding portion of the Rolling Forecast may only be changed by the mutual agreement of the Parties.

4.2 Purchase Orders .

(a) All purchases shall be pursuant to purchase orders (each, a " **Purchase Order** ") submitted by TESARO to Supplier. Each Purchase Order shall specify (i) the order number, (ii) the quantity of the Product ordered, (iii) the requested delivery date, which shall be no fewer than ninety (90) days after the submission of the Purchase Order, (iv) the delivery address, (v) requested delivery dates for all Products set forth in the Firm Order for which a Purchase Order has not previously been submitted, and (vi) any other Manufacturing Services to be provided in connection with the Manufacture of Product. All Purchase Orders shall be deemed accepted by Supplier upon receipt; provided, that Supplier may reject any portion of a Purchase Order that exceeds [***] percent ([***]%) of the projections set forth in the most recent Rolling Forecast if Supplier provides to TESARO written notice of such rejection within ten (10) days of the date of the applicable Purchase Order. Once accepted, a Purchase Order becomes part of this Agreement and no changes may be made without mutual written agreement of Supplier and TESARO. This Agreement sets forth the exclusive contract terms between the Parties with respect to, and shall apply to, all orders for the Product. Any terms in a Purchase Order, sales order, invoice or other notice submitted by either Party to the other Party that are different from or additional to the provisions hereof shall be null and void notwithstanding Supplier's delivery of, and TESARO's acceptance of, the Product under any Purchase Order, sales order, invoice or other notice containing such terms.

4.3 Supply of TESARO-Supplied Components . TESARO shall supply Supplier, at TESARO's expense, with sufficient quantities of TESARO-Supplied Components for Supplier's use in performing the Manufacturing Services. Supplier will give TESARO a monthly inventory report of the TESARO-Supplied Components held by Supplier. The TESARO-Supplied Components will be held by Supplier on behalf of TESARO. Title to the TESARO-Supplied Components will at all times remain the property of TESARO. Supplier shall store the TESARO-Supplied Components in accordance with TESARO's instructions and shall only use the TESARO-Supplied Components to perform the Manufacturing Services. Upon expiration or termination of this Agreement, Supplier shall, at the election of TESARO, return to TESARO, or dispose of, all unused TESARO-Supplied Components supplied by TESARO in accordance with TESARO's instructions and at TESARO's cost and expense.

4.4 Notice of Inability to Supply . Supplier shall notify TESARO within five (5) days of (a) any damage to the Facility or other issue relating to the Facility that will or could reasonably affect or delay Supplier's ability to Manufacture Product under this Agreement, or (b) the occurrence of any other event that may or will impact Supplier's ability to fill an accepted Purchase Order by the requested delivery date, or otherwise meet its obligations under this Agreement. The foregoing will not be deemed a limitation on Supplier's obligations or the rights of TESARO under this Agreement.

4.5 Delivery and Storage .

(a) Any Product Manufactured by Supplier pursuant to this Agreement will, after release by Supplier, or, at TESARO's request under quarantine pending final release by Supplier (i) be packaged and prepared for shipment in accordance with the shipping instructions provided by TESARO, and delivered FCA the Facility (Incoterms 2010), or (ii) be stored by Supplier at the Facility, as requested by TESARO and agreed by Supplier in advance in writing. Product will be shipped via a carrier designated in writing by TESARO, and will be packaged for delivery in accordance with the shipping instructions provided by TESARO to the location specified by TESARO in the applicable Purchase Order. All Products will be transported in accordance with the Product Specifications.

(b) Title and risk of loss will pass to TESARO in accordance with FCA the Facility (Incoterms 2010) upon delivery of Product, or upon release of Product by Supplier, if Product is, at TESARO's request, stored by Supplier.

(c) Prior to delivery, all Products at the Facilities will be stored in a clean and secured area and otherwise in accordance with the storage specifications for the Product as agreed upon between the Parties in writing.

SECTION 5. QUALITY CONTROL; INSPECTIONS .

5.1 Quality Control . Supplier will apply its quality control procedures and in-plant quality control checks to the Manufacture of Product for TESARO, in accordance with

Applicable Laws and other industry standards. In addition, Supplier will test and release Product in accordance with the Product Specifications. Supplier shall include a proper Certificate of Analysis with each shipment of Product.

5.2 Quality Agreement . Contemporaneous with the execution of this Agreement and, in any event, prior to Supplier's delivery of any Product to TESARO hereunder, the Parties shall enter into a separate quality agreement outlining the responsibilities and key contacts for quality and compliance-related issues in the Manufacture of the Product, including Recalls, complaints, returns, regulatory audits and compliance with the Product Specifications and cGMP (the " **Quality Agreement** "). In the event of a conflict between the terms of this Agreement and the terms of the Quality Agreement, the Quality Agreement shall govern for quality-related items, and for all other items the following order of priority shall apply: (i) first, the terms in the body of this Agreement, (ii) second, the terms in a Purchase Order (as modified by any Change Order) , and (iii) third, the terms of the Quality Agreement.

5.3 Inspection and Acceptance .

(a) TESARO shall take delivery of all Product released in accordance with the Quality Agreement for which a Purchase Order has been issued. All Product shall be received subject to TESARO's right of inspection and rejection. TESARO or TESARO's designee will have thirty (30) days following delivery of any shipment of Product (the " **Inspection Period** ") to inspect delivered Product and to reject all or any part of such shipment that contains Nonconforming Product, as determined by reasonable and customary visual inspection. Any shipment of the Product that is not rejected within the Inspection Period shall be deemed accepted by TESARO. Upon detection of any Nonconformity prior to the expiration of the Inspection Period, TESARO shall give notice to Supplier specifying the nature and type of the alleged Nonconformity (a " **Deficiency Notice** ") , including the lot and date of delivery, and may withhold payment for properly rejected Nonconforming Product. TESARO shall hold, at Supplier's expense, any allegedly non-conforming Product for inspection by Supplier or, at Supplier's request and expense, shall return the Product or part thereof to Supplier.

(b) Notwithstanding acceptance by TESARO of the Product in accordance with subsection (a) above, with respect to latent Nonconformities and Nonconformities not discoverable by TESARO within the Inspection Period through the use of reasonable inspection methods and procedures, TESARO will have twelve (12) months following delivery of any shipment of Product to deliver a Deficiency Notice to Supplier which shall be delivered within twenty (20) days following detection of any such Nonconformities.

(c) Upon receipt of a Deficiency Notice, Supplier shall have fifteen (15) days to advise TESARO in writing as to whether it agrees that the shipment includes Nonconforming Product. If Supplier does not respond to the Deficiency Notice within such fifteen (15) day period, the Deficiency Notice will be deemed accepted by Supplier. If Supplier notifies TESARO that its disagrees with TESARO's conclusion in the

Deficiency Notice that the shipment includes Nonconforming Product, then the Parties will mutually select an independent laboratory that meets the requirements of cGMP, if Product analysis is required, and an independent Third Party expert with manufacturing expertise, as appropriate, if any other evaluation is required, in either case, of recognized standing in the industry (each such laboratory or expert to be referred to as, an " **Independent Expert** "), to evaluate a representative sample of Product, using the testing methods described in the Product Specifications, to determine if the Product has a Nonconformity. This evaluation will be binding upon the Parties. If the evaluation certifies that the Product has a Nonconformity, then such Product shall be deemed rejected by TESARO and Supplier will be responsible for the cost of the evaluation. If the evaluation certifies that no Nonconformity exists, then TESARO will be deemed to have accepted delivery of the Product and TESARO will be responsible for the cost of the evaluation.

5.4 Rejection .

(a) Subject to Sections 5.3 , 5.4(b) through (c) and 5.5 , TESARO has the right to reject and return, at the expense of Supplier, any portion of any shipment of Product as to which (i) Supplier has not sent a response to the Deficiency Notice within fifteen (15) days from its receipt of a Deficiency Notice, (ii) an Independent Expert engaged under Section 5.3 has found is Nonconforming, or (iii) the Parties agree is Nonconforming, without invalidating any remainder of such shipment. For clarity, the Deficiency Notice will apply only to those portions of the shipment identified in the Deficiency Notice and the remedies set forth in this Section 5.4 will not apply to any other portions of such shipment.

(b) If TESARO rejects all or part of a shipment for Nonconformity in accordance with Section 5.3 , Supplier will , at TESARO's option, as soon as commercially practicable (i) replace the Nonconforming Products with Product that meets the Product Requirements, at Supplier's cost or (ii) refund to TESARO for the invoice price of any amounts paid in respect of the Nonconforming Product. In either case, Supplier shall be responsible for reimbursing TESARO for the cost of any lost TESARO-Supplied Components . Additionally, Supplier shall bear the cost of disposition for rejected Product for which it bears responsibility under this Section 5.4 .

(c) [***]

5.5 Nonconformity of TESARO-Supplied Components . Notwithstanding anything to the contrary in this Agreement, Product will not be considered to be Nonconforming if such Nonconformity is a result of a latent defect caused by TESARO-Supplied Components or TESARO-Supplied Components' nonconformity with the Components Specifications .

5.6 Recalls .

(a) Supplier and TESARO will each maintain records necessary to permit a Recall of the Product delivered to TESARO or customers of TESARO. Each Party will promptly notify the other Party of any information which might reasonably affect the marketability, safety or effectiveness of the Product or which might result in the Recall or seizure of the Product. Upon receipt of such information, each Party will stop making any further shipments of the Product in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by TESARO.

(b) If (i) any Regulatory Authority issues a directive, order or written request that the Product be Recalled, (ii) a court of competent jurisdiction orders a Recall, or (iii) TESARO determines that the Product should be Recalled or that a "Dear Doctor" letter is required for the Product, Supplier shall provide all assistance reasonably requested by TESARO with respect thereto.

(c) If a Recall or return results from, or arises out of, a failure by Supplier to Manufacture the Product in accordance with the Product Requirements, and such failure is not caused by nonconforming TESARO-Supplied Components or Product Specifications determined by TESARO (each, a " **Supplier-Responsible Recall** "), then (i) Supplier shall be responsible for TESARO's documented expenses of the Recall or return and for reimbursing TESARO for the cost of any lost TESARO-Supplied Components , (ii) Supplier shall promptly, at TESARO's option, (A) replace the Nonconforming Product with Product that meets the Product Requirements, at Supplier 's own cost, or (B) refund TESARO for the invoice price of any amounts paid in respect of the Nonconforming Product, (iii) Supplier shall bear the cost of disposition for any damaged, defective, Product that is returned or subject to a Recall. TESARO will give Supplier prompt written notice of any Recalls which TESARO believes are Supplier-Responsible Recalls. TESARO shall bear the sole cost and expense for all Recalls that are not Supplier-Responsible Recalls.

SECTION 6. PAYMENT TERMS .

6.1 Pricing . TESARO will pay Supplier for the performance of the Manufacturing Services in accordance with this Agreement and the pricing schedule set forth on Exhibit F (the " **Supply Price** "). The Supply Price will not be increased during the first year of the Term. Thereafter, the Parties will review the Supply Price on an annual basis. At least thirty (30) days prior to each anniversary of the Effective Date, Supplier shall submit to TESARO a revised Supply Price reflecting increases or decreases in the costs of producing Product for the upcoming year and any documentation reasonably requested by TESARO supporting such revised Supply Price. TESARO and Supplier will negotiate in good faith to agree on an amended Supply Price; provided , that that the annual increase to the Supply Price, to the extent attributable to increases in labor costs, shall not exceed the lesser of (a) the percentage increase over the relevant period in the Producer Price Index Pharmaceutical and Medicine Manufacturing PCU3254, as published by the United States Department of Labor, Bureau of Labor Statistics, or comparable successor

index, or (b) [***] percent ([***]%). Notwithstanding the foregoing, if the Product Requirements are revised, the Parties shall promptly negotiate in good faith any amendments to the Supply Price necessary to reflect such revisions.

6.2 Invoices . Supplier will invoice TESARO upon release in accordance with the Quality Agreement for all amounts due under each Purchase Order. Invoices will be addressed to TESARO and sent electronically to the attention of [***]. All invoices shall contain an itemized breakdown of all fees and expenses (and be accompanied by reasonable and relevant supporting documentation upon TESARO's written request). Payment on undisputed invoices will be due thirty (30) days after receipt of the applicable invoice by TESARO; provided , that TESARO may reasonably dispute any invoice or portion thereof to the extent that it reasonably believes that the charges reflected therein are inappropriate or lack a clear basis. Once such dispute is resolved, TESARO shall pay any remaining undisputed charges within thirty (30) days of the date that such resolution occurs. In the event any undisputed payment is not made on time, Supplier will be entitled, in addition to its other rights and remedies to assess a late fee on any undisputed amounts not paid when due, on a pro rata basis, at a rate of one and a half percent (1.5%) per month based on the number of days the relevant amount is overdue. Except as otherwise provided herein, each party shall pay all of its own expenses in connection with this Agreement, including raw materials, machinery, equipment and lab supplies, employees, agents, consultant and all personnel expenses. All payments due under this Agreement will be paid in U.S. Dollars by wire transfer of immediately available funds to the following bank account:

Beneficiary:
Corden Pharma Colorado, Inc.
2075 55th Street
Boulder, CO 80301

Bank:
[***]

6.3 Taxes . All fees are exclusive of value-added taxes, duties and charges, and TESARO is responsible for all such taxes, duties and charges. In addition, TESARO shall be solely responsible for any taxes including, but not limited to value-added tax or importation duties, related to TESARO-Supplied Components .

SECTION 7. COMPLIANCE AND REGULATORY MATTERS .

7.1 Compliance with Product Requirements . Supplier hereby represents, warrants and covenants to TESARO that the Product supplied to TESARO under this Agreement shall (a) conform to the Product Specifications, (b) be Manufactured, stored and packaged for shipment in accordance with the Product Requirements, TESARO's instructions or manufacturing requirements and all Applicable Laws, including, without limitation, cGMP, (c) be prepared for shipment in accordance with the shipping instructions provided by TESARO, and (d) conform to the applicable Purchase Order (items (a) through (d), collectively, the " **Product Requirements** ").

7.2 Modification of Product Specifications .

(a) In the event either Party (the " **Proposing Party** ") desires any modification to the Product Specifications, Quality Agreement or the process descriptions for the Product filed with the FDA and other Regulatory Authorities in the Territory (a " **Proposed Change** ") (but excluding, for the avoidance of doubt, any Required Change), the Proposing Party shall notify the other Party by providing the other Party with a description of the Proposed Change sufficient to permit the other Party to evaluate its feasibility and cost, including the Proposing Party's proposal regarding the allocation between the Parties of the cost associated with implementing such Proposed Change. In connection with any Proposed Change, Supplier shall prepare a report of the Manufacturing process, regulatory impact, and expense impact of implementing the Proposed Change, including identifying any additional equipment, materials, labor, or other expenses. If TESARO is the Proposing Party, Supplier shall invoice TESARO for the expense of preparing such report, and TESARO shall reimburse Supplier for such expense within 30 days after receiving Supplier's invoice therefor.

(b) If any modification to any Product Specifications or the process descriptions for the Product filed with the FDA and other Regulatory Authorities in the Territory is required by a Regulatory Authority (a " **Required Change** "), and the Parties fail to agree to changes to the Supply Price or responsibility for additional costs that may be incurred by Supplier due to such Required Change despite good faith attempts to reach such resolution, the matter shall be resolved pursuant to Section 15.2 ; provided , however nothing contained herein shall prevent either Party from taking any and all actions it reasonably believes are required to comply with all Applicable Laws and all obligations imposed by any Regulatory Authority. Supplier will implement any Required Change (but under no circumstances without the consent of TESARO), subject to agreement by the Parties on any conforming changes to the Supply Price or responsibility for additional costs that may be incurred by Supplier due to such Required Change. [***] Notwithstanding anything to the contrary set forth herein, TESARO shall remain obligated to reimburse Corden for all non-cancelable charges for all Product for which a Purchase Order has been issued as of the time of receipt of a notice from a Regulatory Authority that renders the Product unsaleable, but otherwise shall be relieved of the obligations to purchase additional forecasted quantities of Product, or the applicable portion thereof, to the extent that the action of a Regulatory Authority has rendered the Product unsaleable until the Required Change is implemented. Supplier shall be relieved of its obligation to manufacture Product to the extent TESARO is relieved of its obligation to purchase Product.

7.3 Facilities . Supplier will not use any facility in the Manufacture of Product other than the Facilities. Supplier shall ensure that the Facility and any other facilities or plants used to perform the Manufacturing Services or store the TESARO-Supplied Components or the Product is licensed by the applicable Regulatory Authorities. Supplier shall provide TESARO with at least twelve (12) months' prior written notice of any change in the Facility or any other facilities or

plants used to perform the Manufacturing Services or store the TESARO-Supplied Components or the Product.

7.4 Environmental Compliance. The generation, collection, storage, handling, transportation, movement and release of hazardous materials and waste generated by or on behalf of Supplier in connection with the Manufacture of Product will be the responsibility of Supplier, at the cost and expense of Supplier. Without limiting other legally applicable requirements, Supplier will prepare, execute, and maintain as the generator of waste, all licenses, registrations, approvals, authorizations, notices, shipping documents and waste manifests required under Applicable Laws. TESARO will provide Supplier the information set forth in Section 3.3.

7.5 Audit by TESARO. As provided in the Quality Agreement and upon at least ten (10) business days' prior written notice, and, subject to the next sentence, no more than once every calendar year during the Term per Facility, Supplier will permit two (2) (or such other number of persons agreed to by Supplier) TESARO representatives (which may include representatives of TESARO's Affiliates and any of their respective consultants) who are subject to confidentiality obligations no less stringent than the confidentiality obligations set forth in this Agreement, to conduct, during normal business hours during the Term and in a manner that does not unreasonably interfere with Supplier's business, quality assurance audits and inspections of Supplier's Records and the Facilities where the Product is Manufactured for TESARO to the extent reasonably necessary to verify compliance with this Agreement and any regulatory requirements to which TESARO is subject and which are applicable to the Manufacture, importation and marketing of the Product. Notwithstanding the foregoing, (a) any preparatory audits conducted in preparation for an approval inspection by a Regulatory Authority may be conducted in addition to the foregoing audit once every calendar year, (b) TESARO may conduct additional audits more frequently than once every calendar year in the event any audit conducted by TESARO (and with respect to which TESARO has provided a copy of the audit findings to Supplier) or an audit by a Regulatory Authority reveals a material compliance deficiency, and (c) unless otherwise provided in the Quality Agreement, the auditing party may not audit books and records pertaining to the same time period more than once unless subject to a prior finding of a material compliance deficiency. All information disclosed or ascertained by TESARO in connection with any audit or inspection that is not Confidential Information of TESARO will be deemed to constitute Confidential Information of Supplier, subject to the terms of Section 9. The costs of Supplier Personnel participating in any audit under this Section will be borne by Supplier. All other costs of any audit shall be borne exclusively by TESARO. TESARO agrees to require each of its representatives at the Facility to comply with posted policies or other written policies of Supplier of which TESARO is made aware, in each case to the extent policies are in compliance with Applicable Law.

7.6 Regulatory Authority Inspections.

(a) Supplier will be responsible for inspections of its Facilities by any Regulatory Authorities, and will, to the extent permitted by Applicable Law, within three (3) business days of receipt of notice from a Regulatory Authority, notify TESARO if such inspections are related to the Manufacture of Product or if the results of a non-

related inspection could reasonably be expected to impair the ability of Supplier to perform in accordance with this Agreement. With respect to inspections related to the Product, Supplier will, to the extent permitted by Applicable Law, (a) provide TESARO with copies of all documents, reports or communications received from or given to any Regulatory Authority associated therewith, (b) permit TESARO's representatives to be present on site and participate, as appropriate, based on questions or requests specific to TESARO or Product, and as permitted by Regulatory Authorities, in such inspections and participate in the wrap-up sessions, and (c) allow TESARO the opportunity to review and provide comments to Supplier with respect to matters related to the Product, and Supplier will draft any such correspondence to Regulatory Authorities taking into account TESARO's comments.

(b) Supplier will, upon receiving a request from TESARO, supply directly to the FDA or other Regulatory Authority technical information on the Product, the Manufacturing process and any other information required by the FDA or other Regulatory Authority to obtain or maintain any regulatory approvals with respect to the Product.

7.7 Cure of Deficiencies. Supplier will be responsible for correcting any deficiencies identified in any inspection of the Facilities conducted by any Regulatory Authority, at the cost of Supplier. In addition, following any audit provided for in Section 7.6, TESARO will discuss its observations and conclusions with Supplier and any corrective actions will be discussed by the Parties. If Supplier agrees that an item identified by TESARO is a deficiency (such agreement not to be unreasonably withheld, conditioned or delayed) for which Supplier is responsible, Supplier will exercise commercially reasonable efforts to correct such deficiency, at the sole cost of Supplier.

7.8 Interactions with Regulatory Authorities. TESARO will be solely responsible for (a) all contacts and communications with any Regulatory Authorities with respect to matters relating to the Product, and (b) complying with all FDA and applicable foreign regulatory requirements relating to the receipt, review, evaluation, and where applicable, investigation of all complaints received relating to the Product and for the reporting of adverse events relating to the Product. Supplier shall provide all reasonable assistance requested by TESARO in the investigation of all complaints received relating to the Product to the extent that such complaints may have arisen from the Manufacturing Services provided by Supplier hereunder. Unless required by Applicable Law, Supplier will have no contact or communication with any Regulatory Authority regarding the Product without the prior written consent of TESARO. Supplier will, to the extent permitted by Applicable Law, (i) notify TESARO immediately, and in no event later than one (1) business day, after Supplier receives any contact or communication from any Regulatory Authority relating in any way to the Product and will provide TESARO with copies of any such communication within one (1) business day of receipt of such communication by Supplier; (ii) consult with TESARO regarding the response to any inquiry or observation from any Regulatory Authority relating in any way to the Product and will allow TESARO at its discretion to control and/or participate in any further contacts or communications

relating to the Product; and (iii) comply with all reasonable requests and comments by TESARO with respect to all contacts and communications with any Regulatory Authority relating in any way to the Product.

7.9 Product Complaints. TESARO will have the sole responsibility for responding to questions and complaints regarding the Product from its customers. Questions or complaints regarding the Product received by Supplier from TESARO's customers, healthcare providers or patients will be promptly referred to TESARO. Supplier shall provide all assistance reasonably requested by TESARO to allow TESARO to determine the cause of and resolve any questions and complaints regarding the Product. This assistance may include follow-up investigations, including testing. In addition, Supplier will give TESARO any information reasonably requested by TESARO to respond properly to questions or complaints about the Product as set forth in the Quality Agreement. Unless it is determined that the cause of the complaint resulted from a failure by Supplier to Manufacture the Product in accordance with the Product Requirements, all costs incurred under this Section 7.9 shall be borne by TESARO.

7.10 Information.

(a) *Data Verification and Reports*. Upon request, Supplier will supply on an annual basis all Product data in its control, including release test results, complaint test results, and all investigations (in manufacturing, testing and storage), that TESARO reasonably requires in order to complete any filing under any applicable regulatory regime, including any annual report to be submitted to the FDA under Title 21 of the United States Code of Federal Regulations, Section 314.81(b)(2). Any additional data or report requested by TESARO beyond the scope of cGMP and customary FDA, European Medicines Agency or other Regulatory Authority requirements will be subject to an additional fee to be agreed upon between Supplier and TESARO.

(b) *Standard Operating Procedures*. Supplier will, upon request, provide to TESARO all Product standard operating procedures of Supplier relevant to the Manufacturing Services. During the Term, Supplier shall not, without TESARO's prior written consent, make any changes to its standard operating procedures that reasonably may be expected to result in a change to the Manufacturing process as described in the regulatory documents for the Product.

(c) *Other Data and Information*. Supplier will supply to TESARO, for use by TESARO and its Affiliates, licensees and sublicensees, such other data and information related to the Manufacturing Services as TESARO may, from time to time reasonably request, including, but not limited to, information in support of filings, if any, with Regulatory Authorities or in response to questions from Regulatory Authorities, concerning the Manufacture of Product.

7.11 TESARO Employees On-Site. As provided in the Quality Agreement, TESARO will have the right to have up to two (2) employees or other representatives who are subject to confidentiality obligations no less stringent than the confidentiality obligations set forth in this

Agreement, on site to observe the critical steps of the Manufacturing Services for a mutually agreed number of batches in the location at which the Manufacturing Services are being performed during Supplier's normal business hours or at such other reasonable time(s) as Supplier may agree to upon the request of TESARO, such agreement not to be unreasonably withheld, conditioned or delayed by Supplier. TESARO agrees to require each of its employees on site to comply with posted policies or other written policies of Supplier of which TESARO is made aware, in each case to the extent such policies are in compliance with Applicable Laws.

7.12 Records and Retained Samples. Supplier will maintain all materials, data and documentation obtained or generated by Supplier in the course of performing the Manufacturing Services under this Agreement, including all reference standards, retained samples of Product and key intermediates, and computerized records and files (the "**Records**") in a secure area reasonably protected from fire theft and destruction for the longer of (a) five (5) years after completion of the applicable Purchase Order under which such Records were generated, or (b) two (2) years past the last expiration date of Product supplied under this Agreement, or, in each case, such longer period as is required by Applicable Law (the "Retention Period"). At the end of the Retention Period, all Records will, at TESARO's option and request, either be (i) delivered to TESARO or to its designee in such form as is then currently in the possession of Supplier, (ii) retained by Supplier, at TESARO's cost, until further disposition instructions are received, or (iii) disposed of, at the direction and written request of TESARO. In no event will Supplier dispose of any Records without first giving TESARO a reasonable opportunity to have the Records transferred to TESARO. While in the possession and control of Supplier, Records will be available during audits or at other mutually agreed to times for inspection, examination, review or copying by TESARO and its representatives; provided, however, that Supplier may exclude or redact from such Records any confidential or proprietary information of Third Parties. Notwithstanding anything in this Section to the contrary, Supplier may retain copies of any Records as necessary to comply with Applicable Law, regulatory requirements or its obligations under this Agreement, subject to the obligations of confidentiality of Supplier under this Agreement.

SECTION 8. INTELLECTUAL PROPERTY.

8.1 Materials.

(a) All Deliverables and TESARO Materials shall be and/or remain the exclusive property of TESARO, subject to the rights and licenses granted to Supplier under Section 8.4. Supplier will use TESARO Materials provided by TESARO only as necessary to perform the Manufacturing Services.

(b) All Supplier Materials shall be and/or remain the exclusive property of Supplier, subject to the rights and licenses granted to Supplier under Section 8.4.

8.2 Improvements.

(a) Supplier hereby assigns to TESARO all of the right, title and interest of Supplier in and to all TESARO Materials and Deliverables, including all Intellectual Property Rights therein. Supplier agrees to promptly notify TESARO of the creation and/or existence of any Improvements related to the TESARO Materials and Deliverables and cooperate with and assist TESARO, at TESARO's expense, to apply for, and to execute any applications and/or assignments reasonably necessary to obtain any Intellectual Property Rights protections for TESARO Materials and Deliverables in TESARO's name as TESARO deems appropriate. All Improvements to TESARO Materials and Deliverables resulting from the Manufacturing Services that are "Works Made for Hire" as defined in the U.S. Copyright Act and other copyrightable works will be deemed, upon creation, to be assigned to TESARO. TESARO will be free to use the TESARO Materials and Deliverables for any and all lawful purposes.

(b) TESARO hereby assigns to Supplier all of the right, title and interest of Supplier in and to all Supplier Materials, including all Intellectual Property Rights therein. TESARO agrees to promptly notify Supplier of the creation and/or existence of all any Improvements related to Supplier Materials and cooperate with and assist Supplier, at Supplier's expense, to apply for, and to execute any applications and assignments reasonably necessary to obtain any Intellectual Property Rights protections for Supplier Materials in Supplier's name as Supplier deems appropriate.

(c) With respect to any Improvements that are not Improvements to TESARO Materials and Deliverables or Supplier Materials, (i) TESARO shall own Improvements that are solely invented by TESARO, and (ii) Supplier shall own all other Improvements, and if any such Improvements are jointly invented by TESARO and Supplier, then TESARO shall, and it hereby does, irrevocably assign to Supplier its entire right, title and interest in any such Improvements, and such Improvements shall be deemed included in the Supplier Materials for the purposes of this Agreement.

8.3 Third Party Technology. Supplier will not knowingly utilize in the Manufacture of Product under this Agreement or incorporate into the Manufacturing process any technology or materials covered by proprietary rights of a Third Party except as Supplier is freely permitted to do without further compensation by TESARO to Supplier or to any Third Party. TESARO will not knowingly utilize in the manufacture of TESARO-Supplied Components under this Agreement or incorporate into the Product Specifications any technology or materials covered by proprietary rights of a Third Party except as TESARO is freely permitted to do without further compensation by Supplier to TESARO or to any Third Party.

8.4 License Grants.

(a) *By TESARO*. During the Term, TESARO hereby grants to Supplier a non-exclusive, fully paid-up, royalty-free, non-transferable license of any Intellectual Property Rights owned or controlled by TESARO necessary for Supplier to perform the Manufacturing Services hereunder.

(b) *By Supplier*. Subject to Sections 9.3, Supplier hereby grants to TESARO a worldwide, nonexclusive, fully paid-up license, with the right to grant sublicenses, to any Supplier Materials which have been incorporated into the Manufacturing process and under any corresponding Intellectual Property Rights solely for use in Manufacturing of Product by TESARO or any of its Affiliates, or any of their respective licensees or sublicensees or by a Third Party, for the benefit of TESARO or any of its Affiliates.

(c) Except as expressly set forth herein, nothing in this Agreement transfers or conveys to (i) Supplier any right, title or interest in or to the TESARO Materials, or (ii) TESARO any right, title or interest in or to the Supplier Materials. All rights not expressly granted hereunder by a Party are expressly reserved to such Party and its licensors, if applicable.

SECTION 9. CONFIDENTIAL INFORMATION.

9.1 Obligation. A Party (the "**Receiving Party**") receiving or in the possession of Confidential Information of the other Party (the "**Disclosing Party**") will not, without the prior written consent of the Disclosing Party, (a) use the Disclosing Party's Confidential Information except for purposes of fulfilling the Receiving Party's obligations or exercising its rights under this Agreement or as otherwise expressly permitted under this Agreement, or (b) disclose the Disclosing Party's Confidential Information to any Third Party, except as otherwise expressly permitted under this Agreement. The Receiving Party may disclose Confidential Information of the other Party to those employees, directors, representatives, advisors, consultants, service providers, or agents of the Receiving Party who have a specific need to know such information for permitted uses under this Agreement and who are subject to restrictions on use and nondisclosure obligations at least as stringent as those obligations set forth in this Agreement. The obligations of each Party under this Section 9 relating to the other Party's Confidential Information will expire ten (10) years after expiration or termination of this Agreement, except that with respect to any Confidential Information comprising a trade secret of the Receiving Party, the obligations of the Receiving Party under this Section with respect to such Confidential Information will continue until the information becomes the subject of one of the exceptions set forth in Section 9.2. The disclosure of Confidential Information by the Disclosing Party under this Agreement does not constitute the grant of any license or any other rights, or generate any business arrangements, unless specifically set forth herein or in another writing.

9.2 Exceptions. Notwithstanding the foregoing, the obligations of confidentiality and nonuse under this Section 9 will not apply to, information of a Disclosing Party if such information:

(a) is already known to the Receiving Party prior to receipt or being generated under, or related to this Agreement, as evidenced by the Receiving Party's written records and without obligation of confidentiality;

(b) is disclosed to the Receiving Party without restriction after the Effective Date by a Third Party who has the right to make such disclosure on a non-confidential basis and is not providing such information on behalf of the Disclosing Party;

(c) is independently developed by or for the Receiving Party other than in connection with this Agreement without use of, reference to, or reliance on the Confidential Information of the Disclosing Party as evidenced by the Receiving Party's written records;

(d) becomes available to the general public without fault of the Receiving Party; or

(e) by a mutual agreement by the Parties, is released from confidential status.

In addition, notwithstanding anything in this Agreement to the contrary, the Receiving Party will be entitled to disclose Confidential Information of the Disclosing Party to the extent such disclosure is required by Applicable Law or pursuant to a subpoena or other court order of a proper authority; provided that, to the extent permitted by Applicable Law, the Receiving Party gives the Disclosing Party prompt written notice of such requirement prior to such disclosure and provides assistance to the Disclosing Party, at the reasonable request and expense, of the Disclosing Party in limiting the scope of the information to be provided or in obtaining an order protecting the information from public disclosure.

9.3 Other Permitted Disclosures and Use . Notwithstanding anything in this Agreement to the contrary, the Receiving Party and its Affiliates, licensees and sublicensees may use Confidential Information of the Disclosing Party if required for Regulatory Filings related to Product or for any other purposes that are consistent with the rights or licenses granted to Receiving Party under Section 8.4 . To the extent consistent with the foregoing sentence, Receiving Party may disclose Confidential Information of Disclosing Party (a) to any Regulatory Authority or other governmental authority, and (b), in the case of TESARO, to any Affiliate of TESARO or to any licensees and sublicensees; provided , that each such Affiliate is under an obligation of confidentiality and restrictions on use with respect to such information that are at least as restrictive as those applicable to TESARO under this Section.

9.4 Terms of Agreement . The terms and conditions of this Agreement are the Confidential Information of both Parties. Neither Party will disclose the existence of this Agreement or any terms and conditions of this Agreement except (a) with the other Party's prior written consent, (b) as required to comply with Applicable Law (including, without limitation, federal and state securities laws and regulations or listing requirements of any stock exchange or market), (c) to advisors, investors and potential investors and potential acquirers and, in the case of TESARO, to existing or potential collaborators, licensees and Third Party consultants and service providers, in each case on a need-to-know basis under circumstances that ensure confidentiality, or (d) in a public announcement permitted under Section 16.8 . Notwithstanding the foregoing, TESARO may publicly identify Supplier as one of its contract manufacturers and

as the source of Product supplied under this Agreement, and Supplier may publicly identify TESARO as a customer.

9.5 Remedies . Each Party acknowledges that the remedy at law for any breach of this Section 9 may be inadequate, and the full amount of damages that may result from such breach may not readily susceptible to being measured in monetary terms. Accordingly, in the event of a breach or threatened breach by either Party of this Section 9 , the other Party will be entitled to seek immediate injunctive relief and specific performance. Such remedies will be in addition to any other remedies that may be available in law or equity.

SECTION 10. TERM AND TERMINATION .

10.1 Term . This Agreement will become effective as of the Effective Date, and unless earlier terminated under this Section 10 , will continue in effect for five (5) years, and thereafter automatically be extended for successive renewal terms of two (2) years each, unless TESARO Party provides a notice of non-renewal at least six (6) months prior to the expiration of the initial term or the then applicable renewal term, and in the case of Supplier, provides a notice of non-renewal at least one year prior to the expiration of the initial term or the then-applicable renewal term, subject to earlier termination in accordance with the terms of this Agreement or the execution by both Parties of a document terminating this Agreement (such perio d between commencement and termination, the " **Term** ").

10.2 Voluntary Termination Right .

(a) *Termination for Convenience* . So long as no Purchase Orders remain outstanding, TESARO shall have the right to terminate this Agreement upon twelve (12) months' written notice and in the case of Supplier, shall have the right to terminate this Agreement upon eighteen (18) months' written notice; [***] .

(b) *Termination of the Product* . In the event TESARO provides Supplier with written notice that TESARO suspends the commercial sale (if such suspension is following approval by a Regulatory Authority to market and sell the Product) of the Product, on the condition that no Purchase Orders are outstanding at the time of such notice, and TESARO does not recommence the commercial sale of the Product for a period of nine (9) consecutive months following the date of such notice, then, following the expiration of such nine (9) month period, either TESARO or Supplier will have the right, but not the obligation, to terminate this Agreement.

10.3 Other Termination Rights .

(a) *For Breach* . Either Party may terminate this Agreement by giving the other Party ninety (90) days' prior written notice upon the material breach of any provision of this Agreement by such other Party if the breach is not remedied prior to the expiration of such period, except that with respect to a breach of payment obligations, the preceding period shall be limited to thirty (30) days.

(b) *For Bankruptcy*. Either Party shall have the right to terminate this Agreement by written notice to the other Party if the other Party ceases for any reason to carry on business, or becomes bankrupt or insolvent, makes an assignment for the benefit of its creditors or has a receiver or manager appointed in respect of all or any part of its assets (which appointment will not be vacated within sixty (60) days after filing) or is the subject of any proposal for a voluntary arrangement or enters into liquidation.

10.4 Effects of Termination.

(a) *Confidential Information and Records*. Upon termination of this Agreement for any reason, each Party will deliver to the other, or destroy at the Disclosing Party's election, all Confidential Information and other Materials of the other Party, and each will cease to make use of the other Party's Confidential Information, except that neither Party will be obligated to return or destroy (i) or to cease to make use of any information that is included in any Regulatory Filing, or (ii) automatically generated copies stored on system back-up media.

(b) *Other Obligations on Termination*. Upon termination of this Agreement pursuant to this Section 10, neither TESARO nor Supplier will have any further obligations under this Agreement or the relevant Purchase Order, as applicable, except that (i) Supplier shall (A) subject to Subsection (B) below, suspend work as soon as practicable, (B) with respect to each terminated Purchase Order, perform only those Manufacturing Services and activities mutually agreed upon by TESARO and Supplier as being necessary or advisable in connection with the close-out of the relevant Purchase Order, (C) use commercially reasonable efforts to cancel any Third Party obligations, and (D) promptly after receipt of payment in full by TESARO of the amount referenced in Subsection (ii) below, deliver to TESARO all unexhausted materials ordered by Supplier for TESARO , all Product (including any work in process), and all unexhausted TESARO-Supplied Components, and (ii) TESARO shall, with respect to each terminated Purchase Order, pay Supplier all monies due and owing Supplier, up to the time of termination, for the Manufacturing Services actually performed, the Product and material referred to in Subsection (D) above, and all reasonable expenses incurred, and any reasonable commitments made by Supplier, in connection with such Purchase Order that are not cancelable by Supplier using commercially reasonable efforts.

10.5 Survival Provisions. Termination, expiration, cancellation or abandonment of this Agreement through any means and for any reason will not relieve the Parties of any obligation accruing prior thereto, including, but not limited to, the obligation to pay money, and will be without prejudice to the rights and remedies of either Party with respect to the antecedent breach of any of the provisions of this Agreement. Further, Sections 7.12, 8.4(b), 9, 10.4, 10.5, 11.4, 11.5, 12, 14, 15 and 16 will survive expiration or termination of this Agreement.

SECTION 11. **REPRESENTATIONS, WARRANTIES AND COVENANTS .**

11.1 Mutual Representations and Warranties . Supplier and TESARO each represent, warrant and covenant to the other that:

(a) it is, and shall remain, a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of organization;

(b) the execution and delivery of this Agreement has been authorized by all requisite corporate action, and his Agreement is and shall remain a valid and binding obligation of the executing Party, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors;

(c) it is under no contractual or other obligation or restriction that is inconsistent with its execution or performance of this Agreement;

(d) it will perform its obligations under this Agreement in accordance with this Agreement, the Product Requirements and the Quality Agreement, as applicable;

(e) that (i) its performance of its obligations under this Agreement does not and will not breach any agreement which obligates it to keep in confidence any confidential or proprietary information of any Third Party or to refrain from competing or providing services to a Third Party that competes, directly or indirectly, with such Third Party, and (ii) it will not disclose to the other Party any such confidential or proprietary information;

(f) that (i) it has and shall maintain all federal, state and local licenses or registrations necessary to, in the case of Supplier, the Manufacture and supply of the Product, and in the case of TESARO, the manufacture and supply of the formulated product containing the Product, (including, but not limited to the lawful handling, storage, dispensing and shipping of pharmaceutical products), (ii) each such license or registration is valid and in full force and effect, (iii) there is no pending or threatened suspension, revocation or cancellation of any such license or registration, and (iv) there is no basis for believing any such license or registration will not be renewable upon expiration;

(g) that (i) neither Party nor any of its officers or employees has received any notice or communication from the FDA or other Regulatory Authority requiring, recommending or threatening to initiate any action alleging noncompliance with Applicable Laws, (ii) there have not been and are not now any FDA Form 483 observations, civil, criminal or administrative actions, suits, demands, claims, complaints, hearings, investigations, demand letters, warning or untitled letters, proceedings or requests for information pending or in effect against Supplier or any of its officers and employees, and (iii) there is no act, omission, event or circumstance of which the Party has knowledge that would reasonably be expected to give rise to or form the basis for any

civil, criminal or administrative action, suit, demand, claim, complaint, hearing, investigation, demand letter, warning or untitled letter, proceeding or request for information of any such liability, in each case that would reasonably be expected to have an effect on the Party's ability to perform its obligations in accordance with this Agreement; and

(h) that it shall notify the other Party promptly of any breach of the representations, warranties or covenants set forth in this Section 11.1 , including without limitation, of any denial, revocation or suspension of, or any adverse action taken against, any required license or registration, or any material changes in such license or registration, that would limit the ability of Supplier to perform its obligations under this Agreement.

11.2 TESARO Representations and Warranties . TESARO represents, warrants and covenants to Supplier that:

(a) it owns or controls all of the rights in and to the TESARO Materials, TESARO-Supplied Components and Confidential Information provided by TESARO to Supplier;

(b) t o the best of TESARO's knowledge, the use of the foregoing as contemplated in the Manufacturing Services shall not infringe or misappropriate the Intellectual Property Rights of any Third Party , and that at the time of its execution of this Agreement there is no threatened litigation with respect to any of the foregoing and TESARO shall promptly notify Supplier in writing should it become aware of any claims or threatened claims asserting such infringement or misappropriation by any Third Party ;

(c) at the time of delivery to Supplier, all TESARO-Supplied Components will conform to all applicable Component Specifications, cGMP to the extent applicable and all other Applicable Laws and shall not be adulterated , contaminated or misbranded at the time of delivery to Supplier.

11.3 Supplier Representations and Warranties . Supplier represents, warrants and covenants to TESARO that:

(a) all Product supplied to TESARO under this Agreement shall conform in all respects with the Product Requirements;

(b) all Products supplied hereunder shall be free and clear of all security interests, liens or other encumbrances of any kind or character;

(c) that (i) neither Supplier nor, to Supplier's knowledge, any Supplier Personnel (x) has been debarred or subject to temporary denial of approval pursuant to 21 U.S.C. § 335a, or excluded, suspended, or declared ineligible under other Applicable Laws, including, but not limited to, 42 U.S.C. § 1320a-7, and (y) to the best of its

knowledge, is not under consideration to be excluded, suspended, declared ineligible or debarred or subject to a temporary denial of approval (a " **Debarred Individual or Debarred Entity** "); and (ii) Supplier will not knowingly use any Debarred Individual or Debarred Entity in the performance of any Manufacturing Services at any time during the Term; and

(d) to the best of its knowledge, Supplier's performance of its obligations under this Agreement and the use of any Intellectual Property Rights owned or controlled by Supplier in the performance of the Manufacturing Services will not infringe or misappropriate any Intellectual Property Right of any Third Party, and that at the time of its execution of this Agreement there is no threatened litigation with respect to any of the foregoing and Supplier shall promptly notify TESARO should it become aware of any claims alleging such infringement or misappropriation of any Third Party.

11.4 Restrictive Covenant . Supplier will not for itself or any of its Affiliates, nor shall it provide to any Third Party, directly or indirectly, any development, consulting, validation, contract manufacturing or any other services with respect to any product that incorporates the same active pharmaceutical ingredient as the Product during the Term of this Agreement and for a period of one (1) year thereafter, except that with respect to Third Parties, Supplier may provide such service to a Third Party that TESARO confirms to Supplier in writing has the necessary rights from TESARO to, manufacture, have manufactured and/or develop or have developed the product containing such active pharmaceutical ingredient, such written confirmation not to be unreasonably withheld, conditioned, or delayed.

11.5 DISCLAIMER OF WARRANTIES . EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT , NEITHER PARTY MAKES ANY OTHER WARRANTIES, OR REPRESENTATIONS UNDER THIS AGREEMENT EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT, AND ALL SUCH WARRANTIES ARE HEREBY DISCLAIMED BY EACH PARTY.

SECTION 12. INDEMNIFICATION; LIABILITY; INSURANCE .

12.1 TESARO Indemnification . TESARO will defend, indemnify and hold harmless Supplier and its Affiliates and their respective employees, directors, officers and agents (the " **Supplier Indemnified Parties** ") from and against all losses, liabilities, judgments, damages, costs, settlements, penalties, fines and other expenses (including reasonable attorney's fees) (" **Liabilities** ") incurred in connection with any Third Party claims, demands or lawsuits (" **Claims** ") in each case only to the extent arising from:

(a) the use or sale of the Product or the finished formulated drug product containing the Product, except for Liabilities falling under Section 12.2(b) below;

(b) infringement, misappropriation, or violation of any Third Party Intellectual Property Rights arising from or in connection with (i) the Product (if the Product Specifications were determined by TESARO), (ii) the finished formulated drug product containing the Product, or (iii) any TESARO Materials, except for claims falling under Section 12.2(c) below;

(c) the gross negligence or willful misconduct of any TESARO Indemnified Party (defined below);

(d) TESARO's breach of the representations, warranties and covenants set forth in this Agreement;

(e) except to the extent subject to the indemnification obligations of Supplier under Section 12.2(e) , injury to persons or damage to property that occurs on TESARO's premises or on the premises under the exclusive control of TESARO or its subcontractors arising from activities directly related to the Product, or

(f) TESARO's transportation, storage, use, handling and disposal of the Product after delivery by Supplier.

12.2 Supplier Indemnification . Supplier will defend, indemnify and hold harmless TESARO, its Affiliates, and their respective employees, directors, officers and agents (the " **TESARO Indemnified Parties** ") from and against all Liabilities incurred in connection with any Third Party Claims in each case only to the extent arising from:

(a) the gross negligence or willful misconduct of Supplier in the performance of its obligations under this Agreement;

(b) failure of the Product supplied under this Agreement to conform to the Product Requirements, except for Liabilities falling under Section 12.1(a) above;

(c) infringement, misappropriation, or violation of any Third Party Intellectual Property Rights arising from or in connection with any Supplier Materials, except for Liabilities falling under Section 12.1(b) above;

(d) Supplier's breach of the representations, warranties and covenants set forth in this Agreement;

(e) except to the extent subject to the indemnification obligations of Customer under Section 12.1(e) , injury to persons or damage to property that occurs on Supplier's premises or on the premises under the exclusive control of Supplier or its subcontractors arising from the activities directly related to the manufacture of the Product, or

(f) Supplier's transportation, storage, use, handling and disposal of hazardous materials related to its manufacture of Products.

12.3 Claims and Proceedings .

(a) Each Party will notify the other Party promptly in writing of any threatened or pending Claim or proceeding covered by this Section 12 and will include sufficient information to enable the other Party to assess the facts; provided , however , the failure to provide such notice within a reasonable period of time will not relieve the indemnifying Party of its obligations under this Section 12 except to the extent the indemnifying Party's ability to defend the Claim is materially prejudiced by such failure. Subject to Section 12.3(b) , the indemnifying Party will have the right to defend, negotiate, and settle such Claims. The indemnified Party will cooperate in good faith with the indemnifying Party, at the indemnifying Party's request and expense, in the defense of all such Claims for which indemnification is sought, with the indemnifying Party being permitted to maintain control of such defense through legal counsel selected by such Party. The indemnified Party shall be entitled to participate in the defense of such matter and to employ counsel at its own expense to assist therein; provided , however , that the indemnifying Party shall have final decision-making authority regarding all aspects of the defense of any Claim. The Parties understand that no insurance deductible will be credited against losses for which a Party is responsible under this Section 12 .

(b) Unless the indemnified Party otherwise expressly consents in writing, the indemnified Party will not be bound by a settlement or compromise entered into without its prior written consent unless the settlement contains an absolute waiver of liability for the indemnified Party and no admission of wrong-doing on behalf of the indemnified Party, and indemnifying Party has acted in compliance with the requirements of Section 12.3(a) . In no event will the indemnifying Party have any liability with respect to any settlement entered into without the indemnifying Party's prior written consent.

(c) The indemnification obligations in this Section 12 state the entire liability of either Party under this Agreement in respect of any Third Party Claim.

12.4 Limitation of Liability . NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, EXCEPT FOR DAMAGES RESULTING FROM (A) BREACHES BY A PARTY OF ITS DUTY OF CONFIDENTIALITY AND NON-USE IMPOSED UNDER SECTION 9, (B) A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, AND (C) A PARTY'S INDEMNIFICATION OBLIGATIONS HEREUNDER, (I) IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, PUNITIVE, OR INDIRECT DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, WHETHER OR NOT FORESEEABLE, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, AND (II) THE TOTAL LIABILITY OF SUPPLIER UNDER THIS AGREEMENT SHALL BE LIMITED TO [***]

12.5 Insurance . During the Term of this Agreement and thereafter until expiration of all Product Manufactured under this Agreement, each Party will maintain in full force and effect insurance in an amount of not less than [***] for each incident or occurrence and in the aggregate. At the request of a Party, the other Party will furnish the other with a certificate of insurance evidencing that it has such insurance coverage in force.

SECTION 13. ADDITIONAL SUPPLIER RESPONSIBILITIES AND SCOPE OF RELATIONSHIP .

13.1 Approvals . Supplier is responsible for obtaining and maintaining, at Supplier's cost, all approvals from any Regulatory Authority in the U.S., the European Union and Japan, or as otherwise required under Applicable Law, required to operate Facilities that are cGMP approved for the performance of the Manufacturing Services and for creating and maintaining all documentation required by such Regulatory Authorities in the Territory in respect of the performance of the Manufacturing Services at cGMP approved Facilities. TESARO is responsible for Product-specific documentation requirements of any Regulatory Authority in the U.S., the European Union and Japan, or as otherwise required under Applicable Law. Upon TESARO's request, Supplier shall supply data with respect to the Product as necessary for such Product-specific documentation.

13.2 Qualifications of Supplier Personnel . Supplier has, and will engage, employees and permitted subcontractors and/or consultants (" **Supplier Personnel** ") with the proper skill, training and experience to provide the Manufacturing Services. Supplier will be solely responsible for paying Supplier Personnel and providing any employee benefits that they are owed to Supplier Personnel. Before providing the Manufacturing Services, all Supplier Personnel must have agreed in writing to (a) confidentiality obligations consistent with the terms of this Agreement, and (b) effectively vest in Supplier any and all rights that such personnel might otherwise have in the results of their work and are adequate to permit Supplier to transfer such rights to TESARO in accordance with this Agreement.

13.3 Subcontracting . Supplier shall not subcontract or delegate any of its obligations to perform the Manufacturing Services except with the prior written consent of TESARO. In the event that TESARO provides its consent to the use of a subcontractor or delegate to perform a portion of the Manufacturing Services (a) Supplier will be fully liable for compliance by such subcontractor or delegate with the terms of this Agreement applicable to Supplier, and (b) the agreement between Supplier and such subcontractor or delegate must be consistent with Supplier's obligations under, and no less favorable to TESARO than, this Agreement, and shall include, among other things, the assignment of intellectual property to TESARO or to Supplier, and the protection of Confidential Information, in a manner consistent with Supplier's obligations under the terms of this Agreement.

13.4 Nonexclusive . Subject to the limitations set forth in Sections 11.4 , Supplier shall be free to provide services to Third Parties that are similar to or the same as the Manufacturing Services, in each case provided that such activity does not require disclosure or use of TESARO Materials. Similarly, subject to Section 4.1 , TESARO shall remain entitled to appoint Third

Parties to perform services similar to the Manufacturing Services, including appointing Third Parties to Manufacture Product for research, clinical or commercial uses provided that, except as permitted under Section 9.3, such activity does not require disclosure of Supplier Materials.

SECTION 14. **NOTICES .**

All notices hereunder will be in writing and will be delivered by electronic mail at the email address listed below or personally, by internationally recognized one or two-day courier service, registered or certified mail, postage prepaid, return receipt requested to the following address of the respective Party:

If to TESARO:

TESARO Inc.
1000 Winter Street
Suite 3300
Waltham, MA 02451
USA
Email: [***]
Attention: Kevin Johnston
Vice President, Commercial Manufacturing

With a copy to:
[***]
Joseph Farmer
Senior Vice President and General Counsel

If to Supplier:

Corden Pharma Colorado, Inc.
2075 55th Street
Boulder, CO 80301-2880
USA
Email: [***]
Attention: President

Notices will be effective (a) upon receipt if personally delivered, (b) on the third business day following the date of mailing if sent by certified or registered mail, (c) on the second business day following the date of delivery if sent by one or two day courier service, or (d) on the date sent (or if sent after normal business hours of the recipient, on the next business day in the jurisdiction of the recipient's business) if sent by electronic email. A Party may change its address listed above by written notice to the other Party provided in accordance with this Section.

SECTION 15. **APPLICABLE LAW; DISPUTE RESOLUTION; INJUNCTIVE RELIEF .**

15.1 Choice of Law . This Agreement will be construed, interpreted and governed by the laws of the State of New York, excluding any choice of law provision that would dictate the application of the laws of another jurisdiction. The Parties expressly reject any application to this Agreement of (i) the United Nations Convention on Contracts for the International Sale of Goods, and (ii) the 1974 Convention on the Limitation Period in the International Sale of Goods, as amended by that certain Protocol adopted in Vienna on April 11, 1980.

15.2 Dispute Resolution. The Parties recognize that bona fide disputes may arise which relate to the Parties' rights and obligations under this Agreement. Except as otherwise expressly set forth in this Agreement including, but not limited to, Section 5.3 , in such event the Parties shall first, prior to proceeding under Section 15.3 , try to settle such dispute amicably among themselves by referring such dispute, controversy or claim (a " **Dispute** ") to the Parties' respective chief executive officers, or any other executive officer designated by such chief executive officer (the " **Executive Officers** "). A dispute shall be referred to such Executive Officers upon one Party providing the other Party with written notice of referral of such Dispute to the Executive Officers. The Parties agree to attempt to resolve such Dispute through good faith discussions. If the Executive Officers fail to come to consensus on such Dispute within twenty (20) days of receipt of such written notice then either Party is free to initiate the dispute resolution procedures set forth in Section 15.3 .

15.3 Injunctive Relief . Notwithstanding anything contained in Section 15 , either Party may seek preliminary or injunctive measures or relief in any competent court having jurisdiction.

SECTION 16. **MISCELLANEOUS .**

16.1 Assignment . Neither Party may assign or transfer this Agreement without the prior written consent of the other Party. Notwithstanding the foregoing, either Party may assign this Agreement, without the other Party's consent, (a) to an Affiliate of such Party, (b) to any purchaser of all or substantially all of such Party's stock or assets, or the stock or assets to which this Agreement relates, or (c) to any successor, by way of merger, consolidation or similar transaction. Either Party may also assign this Agreement to its Affiliate; provided , that in the case of Supplier, the assignee has manufacturing resources and capabilities at least as substantial as Supplier and does not manufacture a product competitive to the Product. Any successor in interest of a Party shall assume all obligations under this Agreement including, in the case of a successor in interest to Supplier, the obligation to utilize the Facility in the performance of the Manufacturing Services. Subject to the foregoing, this Agreement will be binding upon, enforceable by, and inure to the benefit of the Parties and their respective successors and assigns.

16.2 Force Majeure . No Party shall be responsible for a failure or delay in performance of any of the obligations hereunder due to any fire, flood, earthquake, explosion, storm, blockage, embargo, war, acts of war (whether war be declared or not), terrorism, insurrection, riot, civil commotion, strike, lockout or other labor disturbance, failure of public

utilities or common carriers, act of God or act, omission or delay in acting by any governmental authority (such events being defined as " **Force Majeure Event** "); provided , that the Party seeking relief from its obligations advises the other Party forthwith of the Force Majeure Event. A Party whose performance of obligations has been delayed by Force Majeure Event shall use commercially reasonable efforts to overcome the effect of the Force Majeure Event as soon as possible. If a Force Majeure Event delays Supplier's delivery of Product, Supplier shall be entitled to a day-for-day extension of any deadlines set forth in the applicable Purchase Order for so long as Supplier's performance or delivery is delayed. The other Party will have no right to demand indemnity for damage or assert a breach against such Party, provided , however , that if the event of Force Majeure Event preventing performance shall continue for more than six (6) months and such underlying cause would not also prevent other parties from performing such obligations, then the Party not subject to the event of Force Majeure Event may terminate this Agreement with a written notice to the other Party without any liability hereunder, except the obligation to make payments due to such date and any obligations surviving under Section 10.5 .

16.3 Severability . If any term or provision of this Agreement is for any reason held by a proper authority to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other term or provision hereof, and each such invalid, illegal or unenforceable term or provision will be changed and interpreted so as to be valid, legal and enforceable, and as similar in terms to such invalid, illegal or unenforceable provision as may be possible while giving effect to the benefits and burdens for which the Parties have bargained hereunder.

16.4 Entire Agreement; Amendments . This Agreement (together with all Purchase Orders and the Quality Agreement) constitutes the entire agreement between the Parties concerning the subject matter hereof and, as of the Effective Date, supersedes all written or oral prior agreements or understandings with respect thereto. No amendment or modification to this Agreement will be effective unless it is in writing and signed by authorized representatives of both Parties to this Agreement.

16.5 Waiver . No waiver by a Party of any right hereunder or failure to enforce a breach of any of the terms of this Agreement will be valid unless in writing and signed by an authorized representative of each Party hereto. Failure by either Party to enforce any rights under this Agreement will not be construed as a waiver of such rights, nor will a waiver by either Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

16.6 Appendices . All exhibits referenced herein are hereby made a part of this Agreement.

16.7 Counterparts . This Agreement may be executed in any number of separate counterparts, including .pdf versions, each of which will be deemed to be an original, but which together will constitute one and the same instrument.

16.8 Public Announcements. Except as otherwise set forth in Section 11.4, neither Party will issue or make any public announcement, press release or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, unless such disclosure is consistent with a disclosure previously approved by the other Party under this Section and such consent permitted such further disclosures without further review. In the event a Party is required to make a public disclosure by law or the rules of a stock exchange on which its securities are listed for which consent is necessary under the preceding sentence, if permitted by Applicable Law, such Party will use commercially reasonable efforts to submit the proposed disclosure in writing to the other Party for such Party's prior written consent which such consent shall not be unreasonable withheld, delayed or conditioned. In the event no objection is made to a required disclosure submitted by one Party to the other Party under the preceding sentence within five (5) business days of a written request and receipt of such request was acknowledged in writing by the other Party or confirmed in another manner, written consent will be deemed to have been given.

16.9 Relationships. The relationship between the Parties to this Agreement is that of independent contractors and nothing herein will be deemed to constitute the relationship of partners, joint ventures, nor of principal and agent between Supplier and TESARO. Neither Party will have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract or undertaking with any Third Party.

16.10 Headings. The headings in this Agreement are for convenience of reference only and will not affect its interpretation.

16.11 Definitional and Interpretative Provisions. Unless a clear contrary intention appears, (a) the words "hereof", "herein" and "hereunder" and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement (b) whenever the words "include", "includes" or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation", whether or not they are in fact followed by those words or words of like import, (c) the word "or" is used in the inclusive sense (and/or), (d) "writing", "written" and comparable terms refer to printing, typing and other means of reproducing words (including electronic media) in a visible form, (e) the singular includes the plural and vice versa, and (f) reference to any document, law, or policy means such document, law or policy as amended from time to time.

* * * * *

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives on the later day and year written below.

TESARO Bio GmbH Corden Pharma Colorado, Inc.

By: /s/ Orlando Oliveira By: /s/ Brian J. McCudden
Name: Orlando Oliveira Name: Brian J. McCudden
Title: SVP & GM, International Title: President and CEO

December 15, 2016

EXHIBIT A
to
Commercial Supply Agreement
dated December 15, 2016
between
Corden Pharma Colorado, Inc.
and
TESARO Bio GmbH

FACILITIES

EXHIBIT B
to
Commercial Supply Agreement
dated December 15, 2016
between
Corden Pharma Colorado, Inc.
and
TESARO Bio GmbH

PRODUCT

Niraparib API

[***] 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 C
to
Commercial Supply Agreement
dated December 15, 2016
between
Corden Pharma Colorado, Inc.
and
TESARO Bio GmbH

PRODUCT SPECIFICATIONS

Test Attribute	Method [1]	Acceptance Criteria
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
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[***]	[***]	[***]

[1] Metrics Contract Services method numbers

[***] 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
to
Commercial Supply Agreement
dated December 15, 2016
between
Corden Pharma Colorado, Inc.
and
TESARO Bio GmbH

TESARO-SUPPLIED COMPONENTS

[***]

[***] 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 E
to
Commercial Supply Agreement
dated December 15, 2016
between
Corden Pharma Colorado, Inc.
and
TESARO Bio GmbH

COMPONENTS

[***] 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
to
Commercial Supply Agreement
dated December 15, 2016
between
Corden Pharma Colorado, Inc.
and
TESARO Bio GmbH

SUPPLY PRICE

[***]	[***]
[***]	[***]

9123174_4

[***] 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 10.4

DRUG PRODUCT SUPPLY AGREEMENT

Between

TESARO Bio GmbH

And

Charles River Laboratories Contract Manufacturing PA, LLC

Dated

January 10, 2017

DRUG PRODUCT SUPPLY AGREEMENT

This DRUG PRODUCT SUPPLY AGREEMENT (this " Agreement "), made as of January 10, 2017 (the " Effective Date "), between TESARO Bio GmbH, having a principal place of business at Poststrasse 6, 6300 Zug, Switzerland, (together with its Affiliates, " Client "), and Charles River Laboratories Contract Manufacturing PA, LLC, a Delaware corporation having a principal place of business at 3 Chelsea Parkway, Boothwyn, PA 19061 (" CRL "). Client and CRL may be referred to as a " Party " or, together, the " Parties ".

RECITALS

WHEREAS, CRL has the capability to manufacture the Drug Product (as defined below); and

WHEREAS, the Parties desire that CRL supply Client with the Drug Product under this Agreement on the terms and subject to the conditions set forth below.

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

For purposes of this Agreement, the following initially capitalized terms, whether used in the singular or plural, shall have the following meanings:

1.1 " Act " means the U.S. Federal Food, Drug and Cosmetic Act as amended from time to time.

1.2 " Adverse Drug Experience " means any of: an "adverse drug experience," a "life threatening adverse drug experience," a "serious adverse drug experience," or an "unexpected adverse drug experience," as those terms are defined at either 21 C.F.R. § 312.32 or 21 C.F.R. § 314.80, or an "adverse event", "adverse reaction", "serious adverse event", "serious adverse reaction" or "unexpected adverse reaction" as those terms are defined at Article 2 of the Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the EU Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (the " Clinical Trials Directive ") or at Article 1 of Directive 2001/83/EC on the Community code relating to medicinal products for human use (the " Community Code ").

1.3 " Affiliate " of a Party means any Person which directly or indirectly controls, is controlled by, or is under common control with such Person for so long as such control exists, where "control" means the decision-making authority as to such Person and, further, where such control

shall be presumed to exist where a Person owns more than fifty percent (50%) of the equity (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) having the power to vote on or direct the affairs of the entity.

1.4 " Agreement " has the meaning set forth in the preamble hereof.

1.5 " Breaching Party " shall have the meaning set forth in Section 12.2.2 .

1.6 " Business Day " means any day on which banking institutions in New York, New York are open for business.

1.7 " Calendar Quarter " means each successive period of three calendar months commencing January 1, April 1, July 1 and October 1.

1.8 " Calendar Year " means, for the first calendar year, the period commencing on the Effective Date and ending on December 31of the calendar year during which the Effective Date occurs, and each successive period thereafter during the term of this Agreement beginning on January 1 and ending twelve (12) consecutive calendar months later on December 31.

1.9 " Certificate of Analysis " means a document identified as such and provided by CRL to Client or its designee that sets forth the analytical test results against the Specifications for a specified lot of Drug Product shipped to Client or its designee hereunder.

1.10 " Certificate of Compliance " means a document identified as such and provided by CRL to Client or its designee that certifies, warrants and reflects that each batch of Drug Product was produced and tested in compliance with the Specifications, cGMPs, the Master Batch Record and all other applicable regulatory documents.

1.11 " Claims " means all charges, complaints, actions, suits, proceedings, hearings, investigations, claims and demands.

1.12 " Client " has the meaning set forth in the preamble hereof.

1.13 " Committee " shall have the meaning set forth in Section 2.4.1 .

1.14 " Compound " means the active pharmaceutical ingredient for niraparib.

1.15 " Confidential Information " means all secret, confidential or proprietary information or data, whether provided in written, oral, graphic, video, computer or other form, whether or not marked as confidential, provided by one Party (the " Disclosing Party ") to the other Party (the " Receiving Party ") pursuant to this Agreement or generated pursuant to this Agreement, including but not limited to, information relating to the Disclosing Party's existing or proposed research, development efforts, patent applications, business or products, the terms of this Agreement and any other materials that have not been made available by the Disclosing Party to

the general public. Notwithstanding the foregoing sentence, Confidential Information shall not include any information or materials that:

1.15.1 were already known to the Receiving Party (other than under an obligation of confidentiality), at the time of disclosure by the Disclosing Party to the extent such Receiving Party has documentary evidence to that effect;

1.15.2 were generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

1.15.3 became generally available to the public or otherwise part of the public domain after its disclosure or development, as the case may be, and other than through any act or omission of a Party in breach of such Party's confidentiality obligations under this Agreement;

1.15.4 were disclosed to a Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or

1.15.5 were independently discovered or developed by or on behalf of the Receiving Party without the use of the Confidential Information belonging to the other Party and the Receiving Party has documentary evidence to that effect.

1.16 " Consent " means any consent, authorization, permit, certificate, license or approval of, exemption by, or filing or registration with, any Governmental Authority or other person.

1.17 " CRL " has the meaning set forth in the preamble hereof.

1.18 " Cost and Time Statement " shall have the meaning set forth in Section 3.2.2(b) .

1.19 " CRL Data " shall have the meaning set forth in Section 9.6.2(b) .

1.20 " CRL Invention " shall have the meaning set forth in Section 9.6.2(b) .

1.21 " cGMPs " means all applicable standards relating to manufacturing practices for fine chemicals, active pharmaceutical ingredients, intermediates, bulk products or finished pharmaceutical products, including (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 210 and 211, as may be amended from time to time, (b) Laws promulgated by any Governmental Authority having jurisdiction over the manufacture of the Drug Product, including but not limited to the Clinical Trials Directive, the Community Code, the Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (the " GMP Directive ") and the related national implementing laws and regulations of the European Union (" EU ") Member States, as may be amended from time to time, and (c) guidance documents promulgated by any Governmental Authority having jurisdiction over the manufacture of the Drug Product, including but not limited to Volume 4 of

"The rules governing medicinal products in the European Union" published by the European Commission (the " Notice to Applicants "), advisory opinions, compliance policy guides and guidelines, which guidance documents are being implemented by CRL or within the pharmaceutical manufacturing industry for such Drug Product and specifically identified by Client to be applicable to this Agreement, subject to any arrangements, additions or clarifications agreed to from time to time by the Parties in the Quality Agreement.

1.22 " Data " shall have the meaning set forth in Section 9.6.2(a) .

1.23 " Disclosing Party " shall have the meaning set forth in the definition of Confidential Information.

1.24 "Discretionary Manufacturing Changes " shall have the meaning set forth in Section 3.2.2(b) .

1.25 " Drug Product " means a prescription pharmaceutical product that contains Compound as the sole active ingredient supplied in bulk tablets for final labeling and packaging by Client or its designee.

1.26 " Effective Date " has the meaning set forth in the preamble hereof.

1.27 " Executed Batch Record " means the executed and completed Master Batch Record for each batch of Drug Product manufactured pursuant to the terms of this Agreement.

1.28 " Facility " shall mean CRL's manufacturing facility located at 3 Chelsea Parkway, Boothwyn, PA.

1.29 " FDA " means the United States Food and Drug Administration and any successor thereto.

1.30 " File Retention Samples " shall have the meaning set forth in Section 6.5 .

1.31 " Force Majeure Event " shall have the meaning set forth in Section 14.4 .

1.32 " Forecast " shall have the meaning set forth in Section 5.1 .

1.33 " Governmental Authority " means (a) any court, tribunal, arbitrator, agency, legislative body, commission, official or other instrumentality of the United States or a federal, state, county, city or other political subdivision thereof and (b) any court, tribunal, arbitrator, agency, legislative body, commission, official or other instrumentality of any supra-national organization, nation, state, or other political subdivision having jurisdiction over the Drug Product.

1.34 " ICH " means the International Conference on Harmonization of Technical Requirements for Pharmaceuticals for Human Use.

1.35 " Indemnified Party " shall have the meaning set forth in Section 11.3.1 .

1.36 " Indemnifying Party " shall have the meaning set forth in Section 11.3.1 .

1.37 " Inspection Period " shall have the meaning set forth in Section 7.1.1 .

1.38 " Intellectual Property Rights " shall have the meaning set forth in Section 9.6.2(a) .

1.39 " Inventions " shall have the meaning set forth in Section 9.6.2(a) .

1.40 " Laws " means all applicable laws, statutes, rules, regulations, including, without limitation, cGMPs, ICH guidelines, Investigational New Drug regulations at 21 C.F.R. § 312, New Drug Application (NDA) regulations at 21 C.F.R. § 314 and other applicable laws promulgated by any Governmental Authority having jurisdiction over the Drug Product, including, but not limited to, the Clinical Trials Directive, the Community Code, the GMP Directive and the related national implementing laws and regulations of the EU Member States, as may be amended from time to time, regulations and guidelines of the FDA or other applicable Governmental Authority, and applicable ordinances and other pronouncements having the binding effect of law of any Governmental Authority.

1.41 " Litigation Condition " shall have the meaning set forth in Section 11.3.2.

1.42 " Losses of Client " shall have the meaning set forth in Section 11.1 .

1.43 " Losses of CRL " shall have the meaning set forth in Section 11.2 .

1.44 " Manufacturing Activities " shall mean the manufacturing, processing, testing, packaging, storing and other activities undertaken or required to be undertaken by CRL or its suppliers in order to manufacture and supply Client with the Drug Product.

1.45 " Marketing Authorization " means, with respect to a country, the regulatory authorization required to market and sell Product in such country as granted by the relevant Governmental Authority.

1.46 " Master Batch Record " shall mean the current version of the master batch record approved by the Parties, which may be amended in writing from time to time by mutual agreement of the Parties.

1.47 " Materials " means the raw materials, components and other ingredients required to manufacture the Drug Product.

1.48 " Materials Certification " shall have the meaning set forth in Section 3.4 .

1.49 " Nonconforming Drug Product " means any Drug Product supplied to Client by CRL under this Agreement that does not conform with the Specifications at the time that such Drug Product is delivered to Client or is damaged, does not meet the quantity requirements of the

applicable Purchase Order or has other defects discovered by Client. Each Nonconforming Drug Product shall be regarded as having a " Nonconformity ".

1.50 " Party " and " Parties " have the meanings set forth in the preamble hereof.

1.51 " PC " shall have the meaning set forth in Section 2.4.1 .

1.52 " Person " means any natural person, corporation, general partnership, limited partnership, joint venture, proprietorship or other business organization.

1.53 " Product " means a finished prescription pharmaceutical product that contains Compound as the sole active ingredient.

1.54 " Purchase Order " shall have the meaning set forth in Section 5.2.1(a) .

1.55 " Quality Agreement " shall have the meaning set forth in Section 3.2.1 .

1.56 " Recall " means any action (a) by Client to recover title to or possession of quantities of the Product sold or shipped to third parties (including, without limitation, the voluntary withdrawal of the Drug Product from the market), or (b) by any Governmental Authorities to seize or destroy the Product. A Recall shall also include any action by either Party to refrain from selling or shipping quantities of the Product to third parties which would be subject to a Recall if sold or shipped.

1.57 " Receiving Party " shall have the meaning set forth in the definition of Confidential Information.

1.58 " Records " shall have the meaning set forth in Section 3.3.1 .

1.59 " Required Manufacturing Changes " shall have the meaning set forth in Section 3.2.2(a) .

1.60 " Retention Period " shall have the meaning set forth in Section 3.3.1 .

1.61 " Shipping Costs " shall have the meaning set forth in Section 6.3 .

1.62 " Specifications " means all specifications for the Drug Product as set forth on Schedule 1.62, as may be amended by the Parties from time to time.

1.63 " Supply Price " shall have the meaning set forth in Section 8.1.1.

1.64 " Third Party " means a Person who is not a Party or an Affiliate of a Party.

1.65 " Third Party Claim " shall have the meaning set forth in Section 11.3.1

1.66 " Waste " shall mean any "Hazardous Substance" and/or "Hazardous Material" as provided under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), any "Hazardous Waste" as provided under the Resource Conservation and Recovery

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Act (RCRA), and/or any other waste material, pollutant and/or contaminant of any kind including any routine process waste or any by-product arising from manufacture of the Drug Product.

ARTICLE 2
SUPPLY BY CRL

2.1 Commitment to Supply. Upon the terms and subject to the conditions of this Agreement and pursuant to Purchase Orders delivered from time to time by Client to CRL in accordance with Section 5.2 , CRL shall manufacture, test, package in bulk, store, release and deliver and supply to Client or its designee the Drug Product in accordance with the Specifications, cGMPs, the Master Batch Record, the Quality Agreement and all applicable Laws. CRL acknowledges that time is of the essence in accordance with the terms of this Agreement.

2.2 Facilities, Equipment and Materials. Except for the equipment and facility construction provided to CRL by Client which is to be covered under a separate Equipment Agreement between the Parties, CRL agrees to provide, at its own cost and expense, all facilities, equipment, machinery and materials (other than as specifically set forth herein) in accordance with the Specifications and the Master Batch Records and labor necessary for the performance of the Manufacturing Activities. CRL will not use any facility in the manufacture of the Drug Product other than the Facility. CRL shall (a) ensure that the Facility and any other facilities or plants used by CRL to perform the Manufacturing Activities or to store the Drug Product is licensed by the FDA, and (b) [***]. In the event that Client determines during the assessment of the written notice that the change may require a regulatory filing, the Parties will work in good faith to discuss the change and determine an appropriate project plan. CRL shall delay the change as reasonably necessary to allow for sufficient time to file any regulatory filings and receive any approvals as required under applicable Laws.

2.3 Responsibility. Unless otherwise specified herein or expressly consented to in writing by Client, as between the Parties, CRL shall be solely responsible for performance of all activities necessary for Client to be supplied with Drug Product as contemplated hereunder. CRL shall not amend or modify the Specifications or Master Batch Record or any protocols, processes or procedures used to perform the Manufacturing Activities without the express prior written approval from Client. Unless otherwise expressly agreed in writing in advance by Client, CRL may not sublicense or subcontract the activities to be performed by CRL under this Agreement to an Affiliate, Third Party or other designee, except for the subcontractors of CRL as listed on Schedule 2.3 .

2.4 Governance Committee .

2.4.1 Composition . Within thirty (30) days of execution of the Agreement, the Parties will form a Governance Committee (the " Committee "). The Committee will consist of up to three (3) representatives from each Party, including the Primary Contact (" PC ") and quality representative from each Party. The Committee will provide a forum for routine communication and discussion of Agreement deliverables and responsibilities.

2.4.2 Meetings . During the term of this Agreement, the Committee will schedule and hold routine meetings, at defined intervals acceptable to the Committee, but no less frequently then quarterly, with a minimum of two (2) face-to-face meetings annually. The PCs at each Party will develop agendas as well as supporting material requirements, define required participation and generate meeting notes for distribution. Each Party will bear all expenses of its representatives relative to their participation both on the Committee, and in the meetings of the Committee. Nothing prevents the Committee, or its respective members, from meeting on an ad hoc basis, as required.

2.4.3 Responsibilities . The Committee shall undertake the following responsibilities:

(a) review the most current Forecast and the binding portion thereof to ensure alignment on Agreement deliverables;

(b) review current status of all applicable critical inventories, including packaging materials, Drug Product and packaged Drug Product, and any other items deemed appropriate by the Committee;

(c) act as a forum for discussion of operational, technical, and quality issues, and any and all other relationship-driven issues, as required;

(d) advise the Parties regarding activities involved in day-to-day, tactical operations, involving additional subject matter experts from each Party as required to address specific activities and decisions; and

(e) recommend creation and resourcing of sub-teams as required to address specific issues.

2.4.4 Committee Designation Contact List . The individual members of the Committee are set forth below. Each Party may change any of its representatives to the Committee upon prior written notice to the other Party.

	CRL	Client
Primary Contact	[***]	[***]
Quality Representative	[***]	[***]
Technical Representative	[***]	[***]

ARTICLE 3
STANDARD TERMS OF SUPPLY OF DRUG PRODUCT

3.1 Regulatory Matters.

3.1.1 Consents. CRL shall obtain all Consents for which it is responsible and are required by it as of the Effective Date pursuant to its performance of this Agreement. At all times, CRL shall maintain and comply with all the Consents required by any Governmental Authority having jurisdiction with respect to its manufacturing operations, the Manufacturing Activities and/or the Facility and that otherwise must be obtained by CRL to permit the performance of its then current obligations under this Agreement. Notwithstanding the foregoing, Client shall obtain, maintain and comply with all Marketing Authorizations required in connection with the sale of the Product. In the event any Consent held by CRL relating to the Facility or its ability to manufacture the Drug Product in accordance with this Agreement is suspended or revoked, or CRL has material restrictions imposed upon it by any Governmental Authority affecting the Drug Product or the Facility, CRL shall immediately notify Client and shall promptly provide a schedule of compliance and such other information related thereto as is reasonably requested by Client.

3.1.2 Notification of Potential Adverse Impact on Manufacturing Activities. CRL shall notify Client promptly of any information that to CRL's knowledge may have adverse regulatory compliance and/or reporting consequences concerning the Drug Product, Manufacturing Activities, or the Facility.

3.1.3 Governmental Authorities. CRL shall provide to Client any information reasonably requested by Client, and shall consult with Client before providing any information to any Governmental Authority, in connection with manufacture of Drug Product. CRL shall immediately advise Client of any requests by any Governmental Authority for inspections of the Facility that relate to the Drug Product or the Manufacturing Activities.

3.1.4 Inspection of Drug Product Suppliers by Governmental Authorities. In the event CRL is audited or inspected by a Governmental Authority relating to the Manufacturing Activities or the Drug Product, CRL shall promptly (but in any event, within one business day) notify Client of such audit or inspection as well as of any alleged violations or deficiencies relating to the Facility, process, and/or Drug Product, allow Client to be present during such audit or inspection, and shall promptly disclose to Client all relevant portions of any notice of observations or potential violations, as well as a copy of CRL's response thereto. In addition, CRL will provide Client with unredacted (subject to Third Party confidentiality obligations) copies of any FDA Form 483(s) and Establishment Inspection Reports (or their equivalents) issued as a result of said audit or inspection and any follow-up written communications between CRL and the Governmental Authority. CRL shall use its commercially reasonable best efforts to correct all identified deficiencies in a timely manner and advise Client periodically of progress being made, as well as when all deficiencies have been corrected.

3.1.5 Adverse Reaction Reporting . To the extent permitted under applicable Laws, including the Health Insurance Portability and Accountability Act of 1996 and Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and the related national implementing laws and regulations of individual EU Member States, each as amended, CRL shall promptly notify Client of all

information reported to it relating to any Adverse Drug Experience, whether expected or unexpected, relating to the use of the Product.

3.1.6 Notice of Changes to Marketing Authorization . Client shall provide CRL with sufficient advance notice of any changes to any Marketing Authorization that results in a change to the Materials or to CRL's obligations hereunder.

3.2 Manufacturing Matters.

3.2.1 Quality Agreement . Within 30 days of execution of this Agreement, Client and CRL shall enter into the Quality Agreement (the " Quality Agreement ") appended to this Agreement as Schedule 3.2 . To the extent there are any inconsistencies or conflicts between this Agreement and the Quality Agreement, the terms and conditions of this Agreement shall control unless the inconsistencies or conflicts directly relate to quality assurance or quality procedural aspects of the Manufacture Activities, in which case the Quality Agreement shall control. In the event that the Quality Agreement contains material provisions that substantially differ from applicable Laws, the applicable Laws shall control.

3.2.2 Specification Changes . Client shall be entitled to request changes to the Specifications from time to time. CRL shall endeavor to make all revisions to the Specifications requested by Client, in accordance with this Section 3.2.2 and all applicable Laws. Client retains the right and responsibility for final written approval of the Specifications prior to implementation by CRL.

(a) Required Manufacturing Changes . For changes to the Specifications that are required by a Governmental Authority, the Marketing Authorization or applicable Laws (collectively " Required Manufacturing Changes "), Client and CRL shall cooperate in making such changes and CRL shall implement such changes in compliance with such applicable Laws and as promptly as practicable.

(b) Discretionary Manufacturing Changes . For changes to the specifications that are not Required Manufacturing Changes (collectively " Discretionary Manufacturing Changes "), Client shall submit a request to CRL for any such Discretionary Manufacturing Changes. Upon receipt of such request from Client, CRL shall reasonably and in good faith determine (i) one time and/or ongoing costs that would be incurred resulting from the Discretionary Manufacturing Changes, (ii) any resulting planned changes in timing for the delivery of the Drug Product and (iii) the estimated time of implementing any such Discretionary Manufacturing Changes (the " Cost and Time Statement "). CRL shall provide the Cost and Time Statement to Client setting forth the terms on which CRL would be willing to make the Discretionary Manufacturing Changes and the Parties shall promptly discuss such Cost and Time Statement in good faith. Upon Client's written approval of the Cost and Time Statement (or any amended version thereof based upon the discussion between the Parties), the Parties shall cooperate in making such Discretionary Manufacturing Changes and CRL shall implement such Discretionary Manufacturing Changes.

(c) Cost and Payment for Changes to the Specifications.

(i) For all changes to the Specifications pursuant to Section 3.2.2(a) , Client shall be responsible for and pay CRL any and all amounts incurred in implementing a change to the Specifications. For all changes to the Specifications pursuant to Section 3.2.2(b) , Client shall be responsible for and pay CRL all amounts set forth in the Cost and Time Statement approved by Client in writing. CRL agrees to use commercially reasonable efforts to minimize its costs associated with any Specification change.

(ii) For all changes to the Specifications that are necessitated because a change is required to the Facility generally, CRL shall be responsible for the costs and expenses of such changes.

3.2.3 Accident Reports . Each Party shall promptly notify the other of all material accidents related to the manufacture, handling, use or storage of Drug Product, including: (a) accidents resulting in significant personal injury requiring more than first aid treatment, (b) accidents resulting in chronic illness or loss of consciousness, (c) accidents resulting in material property damage, (d) accidents resulting in material environmental release and (e) accidents that result in regulatory, safety, health or environmental audits.

3.2.4 Handling of Materials; Wastes . The generation, collection, storage, handling, transportation, movement and release of Waste generated by or on behalf of CRL in connection with the manufacture of the Drug Product will be the responsibility of CRL, at the cost and expense of CRL. CRL shall inform its employees, contractors and other personnel of any known or reasonably ascertainable chemical hazards associated with the Drug Product or any Wastes generated through performance of the Manufacturing Activities, and to provide such persons with reasonable training in the proper methods of handling and disposing of such items. In addition, CRL shall handle, accumulate, label, package, ship and dispose of all Wastes generated through performance of the Manufacturing Activities in accordance with all applicable Laws. In connection herewith, Client shall provide CRL with data on the chemical and physical properties, toxicity and handling, storing and shipping information for the Drug Product, including Material Safety Data Sheets (MSDS) or equivalent, and agree to provide updates to CRL as new related information becomes available to Client.

3.2.5 Information

(a) Documentation for Governmental Authority Requirements . CRL shall maintain complete and accurate documentation of all validation data, stability testing data, batch records, quality control and laboratory testing and any other data required under cGMPs and other requirements of any relevant Governmental Authority in connection with the performance of any Manufacturing Activities hereunder. CRL shall provide Client with such documentation promptly upon Client's request.

(b) Technical Information. As set forth in the Quality Agreement, CRL, at its sole cost and expense, shall, upon receiving a written request from Client, supply technical

information on the Drug Product and methods of manufacture and testing to the extent that such information is necessary both to enable Client to fulfill its obligations within this Agreement or in its agreements with its customers, including compliance with any statutory or regulatory requirements of, or a request by, any Governmental Authority. To the extent Client requests technical information that CRL has previously provided to Client or its designee, but nonetheless Client requests such information to be re-sent or re-delivered, CRL's standard hourly rates, shall supply such requests for information.

(c) Other Information . CRL will supply Client, for use by Client and its Affiliates and their respective licensees, sublicensees and/or contractors, such other data and information related to the Manufacturing Activities as Client may from time to time reasonably request. To the extent Client requests such other data or information that CRL has previously provided to Client or designee, but Client nonetheless requests such other data or information to be re-sent or re-delivered, CRL's standard hourly rates, shall supply such requests for data or information.

3.3 Storage Obligations, Containers and Inventories.

3.3.1 Records, Retained Samples and Storage . CRL shall retain all materials, data and documentation obtained or generated by CRL in the course of performing the Manufacturing Activities, including, without limitation, reference standards, retained samples of Drug Product and key intermediaries, computerized records and files and records from each batch of Drug Product (collectively, the " Records ") in a secure area reasonably protected from fire, theft and destruction for the longer of (a) five (5) years after completion of the applicable Purchase Order under which such Records were generated or (b) two (2) years past the last expiration date of Drug Product supplied under this Agreement, or, in each case, for such longer period as is required by applicable Laws for record keeping, testing and regulatory purposes or specified in the Quality Agreement (the " Retention Period "). At the end of the Retention Period, all Records will, at Client's option, either be (i) delivered to Client or to its designee in such form as is then currently in the possession of CRL at Client's cost, (ii) retained by CRL, at Client's cost, until further disposition instructions are received, or (iii) disposed of, at the direction and written request of Client at Client's cost. In no event will CRL dispose of any Records without first giving Client at least sixty (60) days' prior written notice of its intent to do so and an opportunity to have the Records transferred to Client. While in the possession and control of CRL, Records will be available during audits or at other mutually agreed to times for inspection, examination, review or copying by Client and its representatives; provided , however , that CRL may exclude or redact from such Records any confidential or proprietary information of Third Parties. Notwithstanding anything in this Section 3.3.1 to the contrary, CRL may retain copies of any Records as necessary to comply with applicable Law, regulatory requirements or its obligations under this Agreement, subject to the obligations of confidentiality of CRL under this Agreement.

3.3.2 Storage. When storing Drug Product, Compound, nonconforming Compound or Wastes, CRL shall comply with and maintain all storage facilities in compliance with Specifications and in accordance with cGMPs and applicable Laws.

3.3.3 Containers and Packaging . CRL shall supply the Drug Product in such containers and packaging and with such container closure systems and labeling as set forth in the Master Batch Record.

3.4 Materials Suppliers . Notwithstanding anything to the contrary contained herein, (a) CRL shall obtain Materials only from such suppliers named in the relevant Marketing Authorization, (b) CRL will perform paper audits of its Material suppliers as provided in the Quality Agreement, and (c) CRL shall prepare all certifications as to any Materials required by cGMPs or Laws, (each, a " Materials Certification "). Such Materials Certifications shall include, without limitation, all certifications required by Laws related to Materials derived from animal products.

3.5 Facility .

3.5.1 Sole Location . The Facility shall be the only location where CRL performs the Manufacturing Activities unless otherwise agreed to in writing by Client, in accordance with Section 2.2 .

3.5.2 Certain Prohibitions. CRL shall not manufacture, store or process any Drug Product in the same building in which CRL manufactures, stores or processes penicillins, genetically modified organisms, cephalosporins, and infectious agents (e.g., spore-bearing and live viruses).

3.5.3 Representatives . In connection with the monitoring of this Agreement, subject to reasonable advance notice and compliance with CRL's policies for visitors to the Facility, Client shall be allowed to have, at Client's cost, representatives on site at CRL, access to the portions of CRL's Facility used in the manufacture, generation, storage, testing, treatment, holding, transportation, distribution or other handling or receiving of the Compound and Drug Product and all associated records for the purpose of observing, reporting on, and consulting as to such activities, and adequate temporary desk space and other reasonable resources available to these representatives during the periods they are working at CRL. In addition, Client shall have the right, subject to any Third Party confidentiality obligations and prior advance notice of at least ten (10) Business Days and approval by CRL, not to be unreasonably withheld, refused, conditioned or delayed, and during normal business hours, to examine those technical records made by CRL that relate to the manufacture of Drug Product and CRL's operations generally.

3.6 Monitoring and Recordkeeping; Operating Procedures . Throughout the term of this Agreement, and for so long thereafter as is required by applicable Laws, CRL shall monitor and maintain reasonable records respecting its compliance with cGMPs, including through the establishment and implementation of such operating procedures as are reasonably necessary to assure such compliance. [***]

3.7 Inspection, Access and Documentation.

3.7.1 Audit Rights . For the purpose of permitting a routine quality and compliance audit, including to ascertain compliance with cGMPs, Specifications and applicable Laws, CRL

shall grant to authorized representatives of Client (or a Third Party hired on behalf of Client who is reasonably acceptable to CRL), upon reasonable notice, access to the Facility for one (1) two (2)-day period annually. Client shall provide CRL at least ten (10) Business Days' notice in writing of the desire to have such access; provided, however, that in the event of an Adverse Drug Experience, any proposed or actual inspection by a Governmental Authority, an emergency involving the Product, or for cause (determined in good faith), Client shall have the right at any time upon oral or written notice to CRL of one (1) Business Day to conduct an audit of the Facility without reference to the annual limitation described above. CRL shall promptly respond to Client's request and the Parties shall agree on the time, scope and manner of the audit.

3.7.2 cGMP Documentation . CRL shall maintain, in accordance with and for the period required under cGMPs and applicable Laws, complete and adequate records pertaining to the methods and facilities used for the manufacture, processing, testing, packing, labeling, holding and distribution of the Drug Product.

3.8 Compliance and Quality.

3.8.1 Compliance Standards . CRL is solely responsible for the safety and health of its employees, consultants and visitors and compliance with all Laws related to health, safety and the environment, including, without limitation, providing its employees, consultants and visitors with all required information and training concerning any potential hazards involved in the manufacture, packaging, storage and supply of the Drug Product and taking any precautionary measures to protect its employees from any such hazards. In connection herewith, Client shall provide CRL with data on the chemical and physical properties, toxicity and handling, storing and shipping information for the Drug Product, including Material Safety Data Sheets (MSDS) or equivalent, and agrees to provide updates to CRL as new related information becomes available to Client.

3.8.2 Quality Assurance; Quality Control . CRL shall implement and perform testing against the Specifications and such other quality assurance and quality control procedures as required by cGMPs and applicable Laws.

3.9 Provision of Information . CRL shall provide to Client copies (in electronic or hard-copy form, as requested by Client) of all data generated during the term of this Agreement as may be reasonably requested from time to time by Client.

ARTICLE 4
SUPPLY OF COMPOUND

4.1 Supply . At least thirty (30) business days prior to the start of Manufacturing Activities, Client will provide CRL with Compound, at no cost to CRL, in sufficient quantity to enable CRL to perform the Manufacturing Activities and supply Drug Product to Client. Upon receipt of the Compound by CRL, CRL shall test the API against the Specifications as indicated on Schedule 1.62 .

4.2 Consignment Stock . All Compound supplied to CRL by Client is supplied as consignment stock and shall at all times remain the property of Client. All Compound shall be kept segregated and clearly identified as the property of Client at the Facility, stored in accordance with Client's instructions. Title to the Compound will at all times be and remain with Client. Upon expiration or termination of this Agreement, CRL shall, at the election of Client, return to Client, or dispose of, all unused Compound supplied by Client in accordance with Client's instructions and at Client's cost.

4.3 Use of the Compound . CRL shall use the Compound only to perform the Manufacturing Activities to produce and supply the Drug Product to Client.

4.4 Representations and Warranties of CRL for Compound . CRL represents, warrants and covenants that Compound will be held at the Facility only, unless otherwise consented by Client in writing (which consent shall not be unreasonably withheld), and that such Facility, at CRL's sole cost and expense, has and will, for such time as such Compound will be maintained meet the requirements established by applicable Governmental Authorities, and that the Compound will always be maintained in accordance with cGMPs, the Quality Agreement (including storage conditions specified therein), the Specifications and all applicable Laws (including, without limitation, the receipt and possession of all applicable permits and authorizations), as well as Client's reasonable written instructions.

4.5 Inspection . At no additional cost to Client, Client shall be entitled to inspect the Compound and its related records during normal business hours upon reasonable request and prior written notice, it being understood that Client shall make reasonable efforts to minimize interference with CRL's ordinary course of business.

4.6 Risk of Loss . The risks of loss, damage or destruction of the Compound delivered to CRL shall be borne by CRL from the date of delivery to the Facility until delivery in accordance with Section 6.2 below.

4.7 Withdrawals of Stock.

4.7.1 Withdrawal . CRL shall be entitled to withdraw Compound for the performance of the Manufacturing Activities according to the terms and conditions of this Agreement and respecting the procedure of first expiry/first out, except for Compound that is beyond re-test.

4.7.2 Statement of Use . Within seven (7) days after the end of each quarter during the term of this Agreement, CRL shall send Client a statement of usage and inventory showing the following items: (a) the quantities of Compound supplied by Client; (b) the quantities of Compound in CRL's inventory at the beginning of the calendar quarter; (c) the quantities of Compound withdrawn by CRL; (d) the quantities of Compound used by CRL in performing the Manufacturing Activities; (e) any quantities of Compound lost or destroyed while held as consignment stock or following withdrawal from consignment stock; (f) any quantities of Compound for which CRL is unable to account; (g) Compound that is no longer useable because of degradation due to stability or that is beyond re-test; and (h) the quantities of Compound in

CRL's inventory at the end of the month. If, based upon its inspections of the Compound pursuant to Section 4.5 , Client disputes any of the items on the statement of usage and inventory, the Parties will promptly meet to attempt to resolve such disagreement.

4.7.3 Responsibility for Compound Lost or Destroyed . In addition to any other remedies available to Client at law or in equity, CRL shall be entirely responsible for Compound lost or destroyed for reasons other than nonconformance of Compound with the Specifications or used by CRL in the Manufacturing Activities.

4.7.4 Late Delivery of Compound. If Client's delivery of the Compound to CRL is late, Client acknowledges that CRL shall have no liability to the extent that such late delivery of the Drug Product precludes or otherwise limits CRL's performance as agreed between the Parties in writing.

ARTICLE 5
FORECASTING AND ORDERING

5.1 Forecast . Within ten (10) business days of the Effective Date, and on or prior to the first business day of each Calendar Quarter thereafter during the term of this Agreement, Client shall provide CRL with a rolling six (6) Calendar Quarter non-binding, good faith estimate of the quantities of Drug Product that Client foresees it will order from CRL during such six (6) Calendar Quarter period, including any validation batches (each, a " Forecast "), with quarterly updates. The volume requirements for Drug Product as set forth for the [***] of each Forecast will be a binding commitment to purchase the specified volumes of Drug Product for such Calendar Quarter. The binding portion of each Forecast may be changed by the mutual written agreement of the Parties.

5.2 Ordering Under the Forecast.

5.2.1 Purchase Orders.

(a) Delivery of Purchase Order . Client may from time to time place purchase orders with CRL for quantities of Drug Product at least ninety (90) days prior to the delivery date specified in each respective purchase order (each, a " Purchase Order "). On each Purchase Order submitted by Client, Client shall specify the requested quantity, delivery date(s), shipment method and destination(s) of Drug Product being ordered. Each Purchase Order corresponding with the binding portion of each Forecast must be consistent therewith, provided that Client may order a larger quantity of Drug Product than specified in the binding portion, subject to Section 5.2 . CRL shall deliver Drug Product against each Purchase Order in accordance with this Article 5 . Client shall purchase all such Drug Product ordered and delivered by the delivery date specified in a Purchase Order, and CRL shall use commercially reasonable efforts to supply any quantity of Drug Product ordered in the aggregate that exceeds [***] percent ([***]%) the quantity in the Forecast. All Purchase Orders shall be for full batch quantities of Drug Product or integral multiples thereof.

(b) Acceptance of Purchase Order . All Purchase Orders shall be deemed accepted by CRL upon receipt; provided, that CRL may reject any portion of a Purchase Order that exceeds [***] percent ([***]%) of the projections set forth in the most recent Forecast if CRL provides written notice to Client of such rejection within fourteen (14) days of CRL's receipt of the applicable Purchase Order. Once accepted, a Purchase Order becomes part of this Agreement and no changes may be made without mutual written agreement of CRL and Client.

(c) Integration; Conflicting Terms . This Agreement sets forth the exclusive contract terms between the Parties with respect to, and shall apply to, all orders for the Drug Product. Any terms in a Purchase Order, sales order, invoice or other notice submitted by either Party to the other Party that are different from or additional to the provisions hereof shall be null and void notwithstanding CRL's delivery of, and Client's acceptance of, the Drug Product under any Purchase Order, sales order, invoice or other notice containing such terms.

5.3 Addressees for Correspondence . All Forecasts, Purchase Orders, written acceptances of Purchase Orders and other notices contemplated under this Article 5 shall be sent to the attention of such persons as each Party may identify to the other in writing from time to time.

ARTICLE 6
SHIPPING AND DELIVERY; STORAGE

6.1 Shipping and Delivery Dates . CRL shall arrange for the shipment of Drug Product to Client's (or its designee's) designated facilities as stated on the Purchase Order and in a manner consistent with good commercial practices, and in accordance with any agreed-upon shipping specifications, this Agreement and Client's or its designee's reasonable instructions. CRL shall not ship any Drug Product until CRL receives a written release from Client as provided in the Quality Agreement.

6.2 Terms of Delivery . Once Client has released the Drug Product in accordance with Section 6.4 , CRL shall deliver the Drug Product FCA the Facility (Incoterms 2010), in accordance with Client's instructions.

6.3 Shipping Costs . Client shall pay all costs, expenses, taxes, levies, tariffs, brokerage fees, insurance premiums and other costs and charges assessed or levied in connection with the transportation of Drug Product from CRL's Facility to Client pursuant to Section 6.1 (the " Shipping Costs "). If CRL pays any of the Shipping Costs on behalf of Client, then CRL shall invoice such Shipping Costs to Client and Client shall pay such costs.

6.4 Documentation and Release . Prior to each shipment of Drug Product, CRL shall provide Client with a Certificate of Analysis and a Certificate of Compliance, as required by the Quality Agreement, and, at Client's request, CRL shall provide Client with reasonable access to any applicable supporting data. Prior to release of the Drug Product, CRL shall test the Drug Product in accordance with the testing procedures described in Schedule 1.62 and against the Specifications, and shall provide Client with a copy of the applicable Executed Batch Record for each batch shipped and a copy of the applicable deviation or other investigatory report, if any.

Client shall review the Certificate of Analysis and the Certificate of Compliance and indicate to CRL within [***] ([***]) days after receipt of such certificates, whether to release each batch of Drug Product for shipment in accordance with the Quality Agreement. If Client does not provide notice to CRL within such [***] ([***]) day period, CRL shall store the Drug Product pursuant to Section 6.6.2 or until such time as the Drug Product is released . With each shipment of Drug Product, CRL shall provide Client with commercially appropriate shipping documentation, including bills of lading.

6.5 Retention of Samples . CRL shall properly store and retain appropriate samples (identified by batch number) of Drug Product that it supplies to Client in conditions and for times consistent with all applicable Laws and to permit appropriate or required internal and regulatory checks and references (collectively, the " File Retention Samples "). CRL shall provide Client with reasonable access to and portions of the File Retention Samples for testing and other purposes upon Client's request.

6.6 Storage of Drug Product .

6.6.1 Prior to delivery, all Drug Product at the Facility will be stored in a clean secured and segregated area and otherwise in accordance with cGMPs, the Quality Agreement (including storage conditions specified therein), the Specifications and all applicable Laws, as well as Client's reasonable prior written instructions.

6.6.2 Notwithstanding anything to the contrary contained herein, Client may request that CRL, rather than ship Drug Product upon completion to a designated location, store the Drug Product at the Facility until such time as Client requests that the Drug Product be shipped to a designated location. In the event that Client requests that the Drug Product be stored at the Facility, (a) the provisions of Section 6.6.1 shall be applicable to any such Drug Product, (b) the risk of loss, damage or destruction of the Drug Product shall be borne by CRL until it is delivered to the stipulated Carrier pursuant to Section 6.2 , (c) Client shall pay the storage cost (including insurance) mutually agreed upon by the Parties in connection with the storage, and (d) the amount of Drug Product stored shall be limited to an amount as reasonably agreed to by the Parties.

ARTICLE 7
INSPECTION AND DEFECTIVE DRUG PRODUCT; RECALL

7.1 Inspection by Client.

7.1.1 Inspection of Drug Product . All Drug Product shall be received subject to Client's right of inspection and rejection. Within [***] ([***]) days following its receipt of a shipment of Drug Product (the " Inspection Period "), Client or its designee may inspect such shipment and reject all or any part of such shipment that contains Nonconforming Drug Product, as determined by reasonable and customary visual inspection. Upon detection of any Nonconformity prior to the expiration of the Inspection Period, Client shall promptly notify CRL of any Nonconformity and the nature and type of the alleged Nonconformity.

7.1.2 Acceptance of Drug Product. If notice is not given by Client or its designee pursuant to Section 7.1.1 during the Inspection Period, then the shipment shall be deemed accepted by Client for purposes of this Article 7 and, except as provided in Section 7.2, may not be rejected pursuant to Section 7.3 or Section 7.4.

7.2 Latent Defects. In the case of Drug Product with defects not discoverable through the use of reasonable and customary visual inspection, each Party shall notify the other Party of any such defects discovered by such Party promptly following such Party's discovery thereof. Notwithstanding anything to the contrary contained herein, in the case of such latent defects, Client shall have [***] ([***]) days from the earlier of (a) date of discovery of such latent defect, or (b) expiration of the shelf life of the Drug Product, to notify CRL of such latent defect.

7.3 Nonconforming Drug Product.

7.3.1 Nonconforming Drug Product. In any case where Client or its designee expects to reject or otherwise make a claim against CRL with respect to Nonconforming Drug Product, CRL shall be offered a reasonable opportunity to offer proof or evidence as to why such alleged Nonconforming Drug Product should not be rejected and to inspect and/or test such Drug Product. Client shall supply CRL with any evidence it or its designee has that relates to Nonconforming Drug Product.

7.3.2 Testing of File Retention Samples. In the event of any dispute as to whether Drug Product may be rightfully rejected by Client or its designee for failure to conform to the Specifications or to be manufactured in accordance with cGMPs, such Drug Product shall be tested, using the File Retention Samples, for conformity with the applicable Specifications and cGMPs and acceptance criteria by an independent testing organization mutually acceptable to both Parties, which analysis shall be binding on CRL and Client solely for the purpose of determining whether such Drug Product may be rightfully rejected as having a Nonconformity, damaged or otherwise defective. The fees and expenses charged by such independent testing organization shall be paid by the Party in error.

7.3.3 Rejection by Client. Subject to the provisions of this Article 7, Client has the right to reject and return, at the expense of CRL, any portion of any shipment of Drug Product as to which (a) CRL has not responded to a notice of Nonconformity within [***] ([***]) days of receipt thereof, (b) an independent expert engaged under Section 7.3.2 has found is Nonconforming, or (c) the Parties agree is Nonconforming, without invalidating any remainder of such shipment.

7.3.4 Disposal of Rejected Drug Product. All or part of any shipment of Nonconforming Drug Product rejected by Client in accordance with Section 7.3.3 shall be held by Client or its designee for a period of [***] ([***]) days following notice to CRL for proper disposal by CRL, at CRL's expense. If CRL does not provide instructions for disposal of the Drug Product within such period, then Client or its designee may dispose of such Drug Product and CRL shall either pay or reimburse Client or its designee for all costs and expenses incurred by Client or its designee in connection with the disposal of such Drug Product. All or part of any

shipment of Drug Product determined to have a Nonconformity prior to its release for shipment to Client or its designee shall be properly disposed of by CRL, at CRL's expense.

7.4 Remedies . In the event Client or its designee rejects any or all of a shipment for Nonconformity resulting from CRL's breach of this Agreement, or its negligence or willful misconduct in performance of its obligations, then CRL will promptly, at Client's option, (a) replace the Nonconforming Drug Product with Drug Product that meets the Specifications, the Purchase Order and the other requirements set forth under this Agreement, at CRL's cost, or (b) refund Client for the invoice price of any amounts paid in respect of the Nonconforming Drug Product.

7.5 Product Recall.

7.5.1 Recalls .

(a) Client and CRL will each maintain records necessary to permit a Recall of the Drug Product delivered to Client or the Product delivered to customers of Client. Each Party will promptly notify the other Party of any information which might affect the marketability, safety or effectiveness of the Product or to its knowledge may reasonably result in the Recall or seizure of the Drug Product or the Product. Upon receipt of such information, each Party will stop making any further shipments of the Drug Product in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. Client, in its sole responsibility and discretion, shall be entitled to make all decisions with respect to any recall, market withdrawals or other corrective action related to the Product.

(b) If (i) any Governmental Authority issues a directive, order or written request that the Product be Recalled, (ii) a court of competent jurisdiction orders a Recall, or (iii) Client determines that the Product should be Recalled or that a "Dear Doctor" letter is required for the Product, CRL shall provide all reasonable assistance requested by Client with respect thereto.

7.5.2 Costs Associated with Product Recall .

(a) The out-of-pocket costs associated with any Recall, including the cost of replacement Compound, shall be borne by the Parties in proportion to which any such Recall is required as a result of CRL's (or its suppliers', permitted subcontractors' or Affiliates') or Client's (or its designees', subcontractors' or Affiliates') breach of their respective obligations or representations or warranties under this Agreement, including the Quality Agreement. If neither Party is in breach, Client shall be responsible for such costs.

(b) If a Recall or return results from, or arises out of, a failure by CRL to manufacture the Drug Product in accordance with the Specifications or cGMPs, then CRL shall be responsible for Client's documented expenses of the Recall or return and CRL shall promptly, at Client's option, (i) replace the Nonconforming Drug Product with Drug Product that meets the Specifications and cGMPs, at CRL's own cost, or (ii) refund Client for the invoice price of any amounts paid in respect of the Nonconforming Drug Product. In either case, CRL shall be

responsible for reimbursing Client for the cost of any lost Compound. Additionally, CRL shall bear the cost of disposition for any damaged, defective, returned or Recalled Drug Product for which it bears responsibility under this Section 7.5.2. Client will give CRL prompt written notice of any Recalls for which Client believes CRL has responsibility under this Section 7.5.2. In all other circumstances, Recalls, returns or other corrective actions will be made at Client's cost and expense.

7.6 Inability to Supply.

7.6.1 Notice of Inability to Supply. CRL shall notify Client within five (5) days of (a) any damage to the Facility or other issue relating to the Facility that will or may affect or delay CRL's ability to manufacture Drug Product under this Agreement, or (b) the occurrence of any other event that may or will impact CRL's ability to fill an accepted Purchase Order by the requested delivery date or otherwise meet its obligations under this Agreement. The foregoing will not be deemed a limitation on CRL's obligations or the rights of Client under this Agreement.

7.6.2 Costs Incurred as a Result of CRL's Failure to Supply. To the extent Client incurs any additional costs or expenses as a result of a delay in or failure by CRL to supply, CRL shall promptly reimburse Client for such additional costs and expenses upon written invoice therefore with reasonable supporting documentation; provided, however, if Client is required to obtain Drug Product from an alternate source, CRL shall not be required to reimburse Client for more than [***] percent ([***]%) of the supply price charged by CRL pursuant to Section 8.1 for such alternate supply of Drug Product.

ARTICLE 8
FINANCIAL PROVISIONS

8.1 Supply Price.

8.1.1 Initial Supply Price. CRL shall supply Drug Product to Client at the price per batch as set forth in Schedule 8.1 (the "Supply Price").

8.1.2 Changes to Supply Price. The Supply Price will not be increased during the first year following the Effective Date. Thereafter, the Parties will review the Supply Price on an annual basis. At least thirty (30) days prior to each anniversary of the Effective Date, CRL shall submit to Client a revised Supply Price reflecting increases or decreases in the costs of materials, supplies, utilities or labor used to manufacture the Drug Product for the upcoming year and any documentation reasonably requested by Client supporting such revised Supply Price. Client and CRL will negotiate in good faith to agree on an amended Supply Price; provided, that the annual increase to the Supply Price, shall not exceed the lesser of (a) the percentage increase over the relevant period in the Producer Price Index Pharmaceutical Commodity Index or (b) [***] percent ([***]%). Notwithstanding the foregoing, if the Specifications or Purchase Order are revised, the Parties shall promptly negotiate in good faith any amendments to the Supply Price necessary to reflect such revisions.

8.2 Process Improvements and Sharing of Cost Efficiencies . CRL shall be committed to developing and implementing, continuous cost, quality and customer service improvement programs by seeking productivity improvements, by minimizing waste and improving yields, by purchasing quality materials at lower cost, by improving manufacturing processes, by streamlining organizational processes, by reducing cycle times and lead times and the like. In each December during the term of this Agreement, the Parties shall meet to discuss and set targets and goals of cost reductions and quality and customer service improvements for the following twelve (12)-month period, and to discuss the impact of any cost saving achieved during the previous twelve (12)-month period on the Drug Product pricing. The Parties agree to negotiate in good faith changes to Drug Product pricing to share equitably in any such cost savings so achieved.

8.3 Manner of Payments . All sums due to either Party under this Agreement shall be payable in United States Dollars by bank wire transfer in immediately available funds to such bank account(s) as each of CRL and Client shall from time to time designate, unless otherwise agreed by the Parties in writing.

8.4 Invoices; Timing of Payments . CRL shall invoice Client for all Drug Product supplied hereunder on the completion date of manufacturing, and for all other amounts due to CRL, if any, hereunder monthly in arrears . Each invoice shall specify the Purchase Order number to which it corresponds and contain an itemized breakdown of all fees and expenses (and be accompanied by reasonable and relevant supporting documentation upon Client's written request). Invoices will be sent electronically via e-mail to [***]. Unless otherwise specified in this Agreement, all amounts due to CRL hereunder shall be paid by Client within thirty (30) days following the invoice date; provided, that the invoice shall be sent upon the earlier of (i) the date of shipment of the Drug Product or (ii) three (3) days after Client's release of the Drug Product in accordance with the Quality Agreement; provided, that Client may reasonably dispute any invoice or portion thereof to the extent that it reasonably believes that the charges reflected therein are inappropriate or lack a clear basis. Once such dispute is resolved, Client shall pay any remaining undisputed charges within thirty (3) days of the date that such resolution occurs. Each CRL invoice or portion thereof that is not the subject of a bona fide dispute shall be payable within such time period described in the preceding sentence and thereafter unpaid balances shall bear interest at a rate equal to the lesser of [***] per annum or the highest rate allowed by Law, unless determined not to be properly payable hereunder.

ARTICLE 9

9.1 Confidential Information . Each of CRL and Client shall maintain all Confidential Information received from the other Party with the same degree of care it maintains the confidentiality of its own Confidential Information, but in no event less than a reasonable degree of care. Neither Party shall use such Confidential Information for any purpose other than in performance of this Agreement or disclose the same to any other Person other than to such of its agents who have a need to know such Confidential Information to implement the terms of this Agreement or enforce its rights under this Agreement and who are subject to restrictions on use and nondisclosure obligations at least as stringent as those obligations set forth in this Agreement. A Receiving Party shall advise any agent who receives such Confidential Information of the confidential nature thereof and of the obligations contained in this Agreement relating thereto and the Receiving Party shall ensure that all such agents comply with such obligations as if they had been a party hereto.

9.2 Permitted Disclosures .

9.2.1 Required Disclosures . Notwithstanding anything to the contrary in this Agreement, the Receiving Party shall have the right to disclose any Confidential Information provided hereunder if, in the reasonable opinion of the Receiving Party's legal counsel, such disclosure is required by court order, legal process or applicable Law. Where practicable, the Receiving Party shall (a) promptly notify the Disclosing Party of the Receiving Party's intent to make such disclosure of Confidential Information pursuant to the provision of the preceding sentence sufficiently prior to making such disclosure to allow the Disclosing Party adequate time to take whatever action the Disclosing Party may deem to be appropriate to protect the confidentiality of the information, and (b) thereafter disclose only the minimum information required to be disclosed in order to comply with such order, legal process or applicable Law.

9.2.2 Regulatory Filings . Notwithstanding anything in this Agreement to the contrary, Client and its Affiliates, licensees and sublicensees may use Confidential Information of CRL in connection with regulatory filings related to the Product. To the extent consistent with the foregoing sentence, Client may disclose Confidential Information of CRL (a) to any Governmental Authority, and (b) to any Affiliate of Client or to any licensee or sublicense or other Third Party who is manufacturing Drug Product, Product or providing related services to Client or any of its Affiliates, licensees or sublicensees; provided, that each such Third Party other than a Governmental Authority is under an obligation of confidentiality and restrictions on use with respect to such information that are at least as restrictive as those applicable to Client under this Article 9 .

9.3 Return of Confidential Information . Upon termination of this Agreement, the Receiving Party shall return or destroy all documents, tapes or other media containing Confidential Information of the Disclosing Party that remain in the Receiving Party's or its agents' possession, except that the Receiving Party may keep one copy of the Confidential Information in the legal department files of the Receiving Party, solely for archival purposes and/or

compliance with applicable Laws. Such copy shall be deemed to be the property of the Disclosing Party, and shall continue to be subject to the provisions of this Article 9 . Notwithstanding anything to the contrary in this Agreement, the Receiving Party shall have the right to disclose any Confidential Information provided hereunder if, in the reasonable opinion of the Receiving Party's legal counsel, such disclosure is necessary to comply with the terms of this Agreement or the requirements of any Law. Where possible, the Receiving Party shall notify the Disclosing Party of the Receiving Party's intent to make such disclosure of Confidential Information pursuant to the provision of the preceding sentence sufficiently prior to making such disclosure so as to allow the Disclosing Party adequate time to take whatever action the Disclosing Party may deem to be appropriate to protect the confidentiality of the information.

9.4 Public Announcements . Except as may be required by applicable Laws, neither Party will make any public announcement of any information regarding this Agreement or any agreement related hereto without the prior written approval of the other Party. Once any written statement is approved for disclosure by the Parties or information is otherwise made public in accordance with the preceding sentence, either Party may make a subsequent public disclosure of the contents of such statement without further approval of the other Party.

9.5 Confidentiality of this Agreement . The terms of this Agreement shall be Confidential Information of each Party and, as such, shall be subject to the provisions of this Article 9 .

9.6 Inventions .

9.6.1 Materials . All documentation, information, and biological, chemical or other materials controlled by Client and furnished to CRL, including without limitation the Compound and all associated Intellectual Property Rights, will remain the exclusive property of Client. CRL will use such materials provided by Client only as necessary to perform the Manufacturing Activities hereunder.

9.6.2 Data and Inventions .

(a) All data, information, reports and any and all related documentation, which are developed, generated or derived, directly or indirectly, by CRL (or by any subcontractor of agent of CRL) for Client during the term of this Agreement (the " Data "), and all inventions, discoveries, formulae, procedures, any other intellectual property, and any improvements thereto, whether patentable or not, which result or evolve directly or as a result of the services provided hereunder by CRL (or by any subcontractor or agent of CRL) (the " Inventions ") shall be and remain the sole and exclusive property of Client. CRL hereby assigns to Client all of the right, title and interest of CRL in and to all Data and Inventions and all intellectual property rights therein, including, without limitation, patents, copyrights, trademarks, applications, service marks, trade names, applications for any of the foregoing, firmware, trade secrets, mask works, industrial design rights, rights of priority, know-how, concepts, processes, data rights, design flows, methodologies, and any and all other legal rights protecting proprietary intangible property (collectively, " Intellectual Property Rights ") therein. CRL agrees to promptly notify Client upon its knowledge of the creation and/or existence of all such Inventions and Intellectual

Property Rights and reasonably cooperate with and assist Client, at Client's expense, to apply for, and to execute any applications and/or assignments reasonably necessary to obtain any patent, copyright or other statutory protections for Inventions in Client's name as Client deems appropriate. All work product resulting from the Manufacturing Activities that are " Works Made for Hire " as defined in the U.S. Copyright Act and other copyrightable works will be deemed, upon creation, to be assigned to Client. Client will be free to use Data for any and all purposes.

(b) Notwithstanding the foregoing, any present and future documentation, testing methods, practices, procedures, techniques, tests, test apparatus, equipment, materials, control data, or any inventions, improvements or developments or intellectual property relating to the conduct of CRL's business, drug delivery technology, formulation, analysis or manufacturing process of pharmaceutical products generally, or other information related thereto, owned or licensed by CRL (or by any subcontractor or agent of CRL), and not resulting from CRL's performance of its obligations herein (" CRL Invention ", with Data relating thereto, " CRL Data "), shall be and remain the property of CRL. CRL hereby grants to Client a worldwide, royalty-free, exclusive license, with right to sublicense, upon written notice to CRL, to develop, use, manufacture and sell such CRL Invention and CRL Data in connection with the development, use, manufacture, offer for sale, import and sale of the Drug Product.

(c) During the term of this Agreement, Client hereby grants to CRL a non-exclusive, fully paid-up, royalty-free license under any Intellectual Property Rights owned or controlled by Client to perform the Manufacturing Activities in accordance with the terms and conditions of this Agreement. CRL acknowledges and agrees that (i) it shall have no right or license to use any Intellectual Property Rights owned or controlled by Client except to perform the Manufacturing Activities in accordance with the terms and conditions of this Agreement, and (ii) it shall not manufacture or supply Drug Product for any Third Party.

(d) In the event CRL conceives or reduces to practice an invention related to the Compound, Data, Materials or Client Confidential Information in breach of its obligations under this Agreement, CRL agrees that Client shall be the sole and exclusive owner such invention and of any intellectual property rights therein. CRL shall execute and deliver any documents of assignment and conveyance to effectuate the ownership of Client therein.

9.7 Survival . The obligations and prohibitions contained in this Article 9 shall survive the expiration or termination of this Agreement.

ARTICLE 10
REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1 Representations of CRL . CRL represents, warrants and covenants to Client that:

10.1.1 all Drug Product shall be packaged and shipped in accordance with Client's labeling instructions and shall not be adulterated or misbranded within the meaning of the Act, and is not an article which may not, under the Act, be introduced into interstate commerce;

10.1.2 all Drug Product shall be manufactured, generated, processed, packaged, transported, treated, stored, disposed and handled by CRL in accordance with and conform to the Specifications, cGMPs, the Master Batch Record, all applicable Laws, the Quality Agreement and any further formulating, manufacturing, packaging or other standards agreed in writing by the Parties;

10.1.3 all Drug Product so sold and shipped shall be manufactured in accordance with all applicable Laws in effect at the time and place of manufacture of such Drug Product, and all Waste, including but not limited to all hazardous waste, generated at the time of manufacture of Drug Product shall be disposed by it in accordance with all applicable Laws;

10.1.4 all records as are necessary and appropriate to demonstrate compliance with applicable Laws shall be maintained by CRL and such manufacture of Drug Product shall be performed in a facility maintaining a current drug establishment registration with the FDA as set forth in 21 C.F.R. Part 207 and the necessary authorisation delivered by a Governmental Authority having jurisdiction over the manufacture of the Drug Product, including the competent authorities of the individual EU Member States;

10.1.5 the ownership and operation of the Facilities shall be in material compliance with cGMPs, all applicable Laws (including the receipt and possession of all applicable permits and authorizations, including a current drug establishment registration with the FDA as set forth in 21 C.F.R. Part 207, if applicable), no suspension, revocation, or cancellation of such permits and authorizations is pending or threatened, and there is no basis for believing such permits and authorizations will not be renewable upon expiration;

10.1.6 neither it nor any of its officers or employees has received any notice or communication from the FDA or other Governmental Authority requiring, recommending, threatening, or initiating any action alleging noncompliance with applicable Laws, that would materially impact CRL's ability to deliver Drug Product pursuant to this Agreement;

10.1.7 there have not been and are not now any FDA Form 483 observations, civil, criminal or administrative actions, suits, demands, claims, complaints, hearings, investigations, demand letters, warning or untitled letters, proceedings or requests for information pending or in effect against CRL or any of its officers and employees for alleged noncompliance with applicable Laws, that would (in each case) materially impact CRL's ability to deliver Drug Product pursuant to this Agreement;

10.1.8 neither it nor any person who will perform any of the Manufacturing Activities for Client (a) has been debarred or subject to temporary denial of approval pursuant to 21 U.S.C. § 335a, or excluded, suspended, declared ineligible under other Applicable Laws, including, but not limited to, 42 U.S.C. § 1320a-7, and (b) to its knowledge, is not under consideration to be excluded, suspended, declared ineligible, or debarred or subject to temporary denial of approval, and CRL will not utilize any debarred individual or debarred entity in the performance of any Manufacturing Activities at any time during the term of this Agreement;

10.1.9 (a) CRL has and shall maintain all federal, state and local licenses or registrations necessary to the manufacture and supply of the Drug Product (including, but not limited to the lawful handling, storage, dispensing and shipping of pharmaceutical products),(b) each such license or registration is valid and in full force and effect, (c) there is no pending or threatened suspension, revocation or cancellation of any such license or registration, and (d) there is no basis for believing any such license or registration will not be renewable upon expiration;

10.1.10 the Drug Product delivered to Client will be free and clear of all liens and encumbrances; and

10.1.11 CRL shall notify Client promptly of any breach of the representations, warranties or covenants set forth in this Section 9.1 , including without limitation, of any denial, revocation or suspension of, or any adverse action taken against, any required license or registration, or any material changes in such license or registration, that would limit the ability of CRL to perform its obligations under this Agreement.

10.2 Mutual Representations and Warranties . Client and CRL each represents and warrants to the other as of the Effective Date that:

10.2.1 it has full corporate right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement;

10.2.2 the execution and delivery of this Agreement by such Party and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of applicable laws or regulations existing as of the Effective Date and applicable to such Party and (b) do not conflict with, violate, breach or constitute a default under, and are not prohibited or materially restricted by, any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date; and

10.2.3 such Party is duly authorized, by all requisite corporate action, to execute and deliver this Agreement and the execution, delivery and performance of this Agreement by such Party does not require any shareholder action or approval or the approval or consent of any Third Party, and the Person executing this Agreement on behalf of such Party is duly authorized to do so by all requisite corporate action.

9.2.4 neither Party's performance of its obligations under this Agreement and the use of any Intellectual Property Rights, Materials, or Compound owned or controlled by it in the performance of this Agreement will not infringe or misappropriate any patent, trade secret or other proprietary or Intellectual Property Right or other proprietary right of any Third Party, and that at the time of its execution of this Agreement there is no threatened litigation with respect to any of the foregoing and each Party shall promptly notify the other Party should it become aware of any claims alleging such infringement or misappropriation of any Third Party.

10.3 Disclaimer of Warranty . EXCEPT AS SPECIFICALLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY EXPRESS OR IMPLIED WARRANTIES

OR COVENANTS, STATUTORY OR OTHERWISE, CONCERNING THE DRUG PRODUCT. WITHOUT LIMITING THE FOREGOING, NEITHER PARTY MAKES ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE REGARDING THE DRUG PRODUCT. IN NO EVENT WILL CRL BE RESPONSIBLE FOR STABILITY OF THE DRUG PRODUCT MANUFACTURED IN ACCORDANCE WITH THE SPECIFICATIONS.

ARTICLE 11
INDEMNIFICATION AND INSURANCE

11.1 Indemnification by CRL . CRL hereby agrees to defend Client and their respective Affiliates, directors, officers, employees, agents, successors and assigns from and against any and all Claims of a Third Party and to indemnify and hold Client and their respective Affiliates, directors, officers, employees, agents, successors and assigns, harmless from and against any and all losses, damages, costs, penalties, liabilities (including strict liabilities), judgments, amounts paid in settlement, fines and expenses (including court costs and reasonable fees of attorneys and other professionals) (individually and collectively, the " Losses of Client ") arising out of or in connection with: (a) the negligence or willful misconduct of CRL or any Person for whose actions or omissions CRL is legally liable; (b) a breach by CRL of its representations, warranties and/or covenants hereunder; or (c) any claim asserted by a Third Party that CRL, in performing the services hereunder, has infringed or misappropriated any proprietary or confidential information or intellectual property rights of such Third Party, except as relate to any materials, specifications or instructions provided to CRL by Client or its affiliates; provided, however, that in all cases referred to in this Section 10.1 , CRL shall have no liability to Client for any Losses of Client to the extent that such Losses of Client were caused by any item for which Client is required to indemnify CRL pursuant to Section 10.2 .

11.2 Indemnification by Client . Client hereby agrees to defend CRL and its Affiliates and their respective directors, officers, employees, agents, successors and assigns from and against any and all Claims of a Third Party and to indemnify and hold CRL and its Affiliates and their respective directors, officers, employees, agents, successors and assigns, harmless from and against any and all losses, damages, costs, penalties, liabilities (including strict liabilities), judgments, amounts paid in settlement, fines and expenses (including court costs and reasonable fees of attorneys and other professionals) (individually and collectively, the " Losses of CRL ") arising out of or in connection with: (a) the negligence or willful misconduct of Client or any Person for whose actions or omissions Client is legally liable; (b) a breach by Client of its representations, warranties and/or covenants hereunder; (c) injuries and/or death to humans resulting from the use of Compound provided by Client to CRL for use in manufacturing the Drug Product; (d) the research, development, manufacture, distribution, use, sales or other disposition by Client, or any distributor, collaborator, customer, sublicensee, contractor, subcontractor, representative or agent of Client, of the Drug Product, Product, Compound or Client Confidential Information; or (e) patent infringement relating to the Compound; provided, however, that in all cases referred to in this Section 10.2 , Client shall have no liability to CRL for

any Losses of CRL to the extent that such Losses of CRL were caused by any item for which CRL is required to indemnify Client pursuant to Section 10.1 .

11.3 Indemnification Procedure.

11.3.1 Notice . Each Party will notify promptly the other if it becomes aware of a Claim (actual or potential) by any Third Party (a " Third Party Claim ") for which indemnification may be sought by that Party and will give such information with respect thereto as the other Party shall reasonably request. If any proceeding (including any governmental investigation) is instituted involving any Party for which such Party may seek an indemnity under Section 10.1 or 10.2 , as the case may be (the " Indemnified Party "), the Indemnified Party shall not make any admission or statement concerning such Third Party Claim, but shall promptly notify the other Party (the " Indemnifying Party ") orally and in writing and the Indemnifying Party and Indemnified Party shall meet to discuss how to respond to any Third Party Claims that are the subject matter of such proceeding. The Indemnifying Party shall not be obligated to indemnify the Indemnified Party to the extent any admission or statement made by the Indemnified Party or any failure by such Party to notify the Indemnifying Party of the claim materially prejudices the defense of such claim.

11.3.2 Defense of Claim . If the Indemnifying Party elects to defend or, if local procedural rules or laws do not permit the same, elects to control the defense of a Third Party Claim, it shall be entitled to do so provided it gives notice to the Indemnified Party of its intention to do so within thirty (30) days after the receipt of the written notice from the Indemnified Party of the potentially indemnifiable Third Party Claim (the " Litigation Condition "); provided, that the Indemnifying Party expressly agrees the Indemnifying Party shall be responsible for satisfying and discharging any award made to the Third Party as a result of such proceedings or settlement amount agreed with the Third Party in respect of the Third Party Claim without prejudice to any provision in this Agreement or right at law which will allow the Indemnifying Party subsequently to recover any amount from the Indemnified Party to the extent the liability under such settlement or award was attributable to the Indemnified Party. Subject to compliance with the Litigation Condition, the Indemnifying Party shall retain counsel reasonably acceptable to the Indemnified Party (such acceptance not to be unreasonably withheld, refused, conditioned or delayed) to represent the Indemnified Party and shall pay the fees and expenses of such counsel related to such proceeding. In any such proceeding, the Indemnified Party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of the Indemnified Party. The Indemnified Party shall not settle any claim for which it is seeking indemnification without the prior consent of the Indemnifying Party which consent shall not be unreasonably withheld, refused, conditioned or delayed. The Indemnified Party shall, if requested by the Indemnifying Party, cooperate in all reasonable respects in the defense of such claim that is being managed and/or controlled by the Indemnifying Party. The Indemnifying Party shall not, without the written consent of the Indemnified Party (which consent shall not be unreasonably withheld, refused, conditioned or delayed), effect any settlement of any pending or threatened proceeding in which the Indemnified Party is, or based on the same set of facts could have been, a party and indemnity could have been sought hereunder by the Indemnified Party,

unless such settlement includes an unconditional release of the Indemnified Party from all liability on claims that are the subject matter of such proceeding. If the Litigation Condition is not met, then neither Party shall have the right to control the defense of such Third Party Claim and the Parties shall cooperate in and be consulted on the material aspects of such defense at the each Party's own expense; provided that if the Indemnifying Party does not satisfy the Litigation Condition, the Indemnifying Party may at any subsequent time during the pendency of the relevant Third Party Claim irrevocably elect, if permitted by local procedural rules or laws, to defend and/or to control the defense of the relevant Third Party Claim so long as the Indemnifying Party also agrees to pay the reasonable fees and costs incurred by the Indemnified Party in relation to the defense of such Third Party Claim from the inception of the Third Party Claim until the date the Indemnifying Party assumes the defense or control thereof.

11.4 Assumption of Defense . Notwithstanding anything to the contrary contained herein, an Indemnified Party shall be entitled to assume the defense of any Third Party Claim with respect to the Indemnified Party, upon written notice to the Indemnifying Party pursuant to this Section 10.4 , in which case the Indemnifying Party shall be relieved of liability under Section 10.1 or 10.2 , as applicable, solely for such Third Party Claim and related Losses of Client or Losses of CRL, as applicable.

11.5 Limitation of Liability . IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER OR ANY OF ITS AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, WITHOUT LIMITATION, LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES, AND ANY PERSON IN PRIVITY WITH ANY OF THE FOREGOING, IN CONNECTION WITH A BREACH OR ALLEGED BREACH OF THIS AGREEMENT. CRL'S LIABILITY UNDER THIS AGREEMENT, REGARDLESS OF THE FORM OF ACTION, SHALL NOT EXCEED [***], PROVIDED THAT THE FOREGOING SHALL NOT LIMIT THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY UNDER THIS ARTICLE 10 FROM AND AGAINST CLAIMS OF THIRD PARTIES, OTHER THAN ANY PERSON IN PRIVITY WITH ANY PARTY OR CRL'S OBLIGATIONS OF CONFIDENTIALTY AND INTELLECTUAL PROPERTY CONTAINED IN SECTION 8.

11.6 Insurance . During the term of this Agreement and for a period of five (5) years after its termination, each Party shall obtain and/or maintain, respectively, at its sole cost and expense, liability insurance in amounts, respectively, required by applicable Laws, but in no event less than [***]. Such liability insurance shall insure against all liability, including personal injury, physical injury, or property damage arising out of the manufacture, sale, distribution, or marketing of the Drug Product. Each Party shall provide written proof of the existence of such insurance to the other Party upon request.

ARTICLE 12
TERM AND TERMINATION

12.1 Term . Unless terminated sooner as permitted hereunder, this Agreement shall commence on the Effective Date and shall expire on the third (3rd) anniversary of the launch date of the Product, provided that unless Client gives written notice at least six (6) months prior to the expiration of the initial term or any renewal term, this Agreement shall continue for successive two (2) year terms.

12.2 Termination . This Agreement may be terminated by Client upon six (6) months prior written notice to CRL in the event Client withdraws the Drug Product from the market. In addition, this Agreement may be terminated upon the written consent of both Parties, or upon the happening of one of the following events:

12.2.1 Termination by Client . Following the initial three year term provided for in Section 11.1, Client shall have the right to terminate this Agreement or any Purchase Order hereunder for convenience upon one hundred eighty (180) days' prior written notice.

12.2.2 Termination for Breach . Either Party may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement in the event that the other Party (as used in this subsection, the " Breaching Party ") shall have materially breached or defaulted in the performance of any of its obligations. The Breaching Party shall have sixty (60) days (thirty (30) days if solely monetary defaults) after written notice thereof was provided to the Breaching Party by the non-breaching Party to remedy such default. Any such termination shall become effective at the end of such sixty (60)-day period (ten (10) business day period if solely monetary defaults) unless the Breaching Party has cured any such breach or default prior to the expiration of such sixty (60)-day period (ten (10) business day period if solely monetary defaults).

12.2.3 Termination for Force Majeure Event . Notwithstanding anything to the contrary contained in this Agreement, in the event a Force Majeure Event shall have occurred and be continuing for ninety (90) consecutive days, either Party shall be entitled to terminate this Agreement effective immediately upon written notice to the Party suffering such Force Majeure Event; provided, that such termination shall not be deemed a breach by the Party suffering such Force Majeure Event.

12.3 Termination for Reasons of Insolvency or Termination of Business Activities . Either Party shall be entitled to terminate this Agreement if the other Party becomes insolvent or is the subject of a petition in bankruptcy whether voluntary or involuntary or of any other proceeding under bankruptcy, insolvency or similar laws, makes an assignment for the benefit of creditors, is named in such a petition, or its property is subject to a suit for the appointment of a receiver, or is dissolved or liquidated. Such termination right may be exercised without the need for written notice within thirty (30) days following the date as of which the Party entitled to terminate receives knowledge of such insolvency or termination of business activities by the other Party.

ARTICLE 13
RIGHTS AND DUTIES UPON TERMINATION

13.1 Pending Purchase Orders . Except in cases of the termination of this Agreement for a Force Majeure Event or as otherwise expressly set forth in this Agreement, the termination of this Agreement shall not affect Purchase Orders placed by Client and accepted by CRL at the time notice of termination is given and until the time any such termination becomes effective.

13.2 Outstanding Payment . Payments of amounts owing to either Party under this Agreement as of its expiration or termination shall be due and payable within the later of (a) to the extent such amounts can be calculated and a fixed sum determined at the time of expiration or termination of this Agreement, forty-five (45) days after the date of such expiration or termination or (b) ten (10) days after the date in which such amounts can be calculated and a fixed sum determined. Notwithstanding anything to the contrary contained in this Agreement, except when Client has terminated this Agreement as the result of CRL's breach pursuant to Section 12.2.1 , Client shall (a) compensate CRL for all services actually performed hereunder prior to termination of this Agreement or any Purchase Order(s) and (b) reimburse CRL for all expenses reimbursable in a Purchase Order actually incurred and any reimbursable commitments made by CRL in connection with such Purchase Order that are not cancelable.

13.2.1 Return of Materials . Within thirty (30) days following the expiration or termination of this Agreement, each Party shall destroy or return to the other Party all tangible items bearing, containing or contained in any of the Confidential Information of the other Party, and shall provide the other Party written certification of such destruction or return. CRL shall also promptly (a) return to Client or destroy, at Client's election, all unused quantities of Compound being held by CRL, and (b) transfer to Client or its designee all materials ordered by CRL for Client and all Drug Product (including any work-in-process), in each case at Client's cost.

13.3 Accrued Rights; Surviving Obligations . Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination or expiration. Such termination or expiration shall not relieve any Party from obligations which are expressly or by implication intended to survive termination or expiration of this Agreement and shall not affect or prejudice any provision of this Agreement which is expressly or by implication provided to come into effect on, or continue in effect after, such termination or expiration. Further, Sections 1, 3, 7, 9 (Confidentiality, IP), 10, 11, 12, 13, 14 will survive expiration or termination of this Agreement.

ARTICLE 14
GENERAL PROVISIONS

14.1 Relationship of the Parties . Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee benefits of such

employee. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without such Party's approval. For all purposes and notwithstanding any other provision of this Agreement to the contrary, CRL's legal relationship under this Agreement to Client shall be that of independent contractor. This Agreement is not a partnership agreement and nothing in this Agreement shall be construed to establish a relationship of co-partners or joint ventures between the Parties.

14.2 Covenant Not to Compete . CRL agrees that during the term of this Agreement (whether on its own behalf or with or on behalf of any Person), and shall not permit any of its Affiliates to, directly or indirectly:

14.2.1 carry on or be engaged, concerned, interested or in any way assist in the development or manufacture of, consulting, validation, contract manufacturing or any other services with respect to (a) any prescription or over the counter formulation of the Drug Product, Compound or Product, or (b) any generic, copycat versions, including Compounds or Products in the PARP inhibitor class, of the Drug Product, Compound or Product, including any salts, hydrates, polymorphs or anhydrous form thereof; or

14.2.2 sell, market, distribute or seek customers for or advertise any prescription or over the counter formulation of Drug Product, Compound or Product.

14.3 Force Majeure . The occurrence of an event which materially interferes with the ability of a Party to perform its obligations or duties hereunder which is not within the reasonable control of the Party affected or any of its Affiliates, not due to malfeasance by such Party or its Affiliates, and which could not with the exercise of due diligence have been avoided (each, a " Force Majeure Event "), including an injunction, order or action by a Governmental Authority, fire, strike, riot, civil commotion, act of God, or change in applicable Laws, shall not excuse such Party from the performance of its obligations or duties under this Agreement, but shall merely suspend such performance during the continuation of the Force Majeure Event. The Party prevented from performing its obligations or duties because of a Force Majeure Event shall promptly notify the other Party of the occurrence and particulars of such Force Majeure Event and shall provide the other Party, from time to time, with its best estimate of the duration of such Force Majeure Event and with notice of the termination thereof. The Party so affected shall use commercially reasonable efforts to avoid or remove such causes of nonperformance as soon as is reasonably practicable. Upon termination of the Force Majeure Event, the performance of any suspended obligation or duty shall promptly recommence. The Party subject to the Force Majeure Event shall not be liable to the other Party or any Third Party for any direct, indirect, consequential, incidental, special, punitive, exemplary or other damages arising out of or relating to the suspension or termination of any of its obligations or duties under this Agreement by reason of the occurrence of a Force Majeure Event, provided such Party complies in all material respects with its obligations under this Section 13.4 .

14.4 Governing Law . This Agreement shall be construed, and the respective rights of the Parties determined, according to the substantive Law of the State of Delaware notwithstanding

the provisions governing conflict of Laws to the contrary, except matters of intellectual property Law which shall be determined in accordance with the intellectual property Laws relevant to the intellectual property in question. The UNCITRAL Convention for the International Sale of Goods, as well as any other unified Law relating to the conclusion and implementation of contracts for the international sale of goods, shall not apply.

14.5 Jurisdiction. Any legal action or proceeding with respect to this Agreement shall be brought in the courts of the State of Delaware or of the United States District Court for District of Delaware, and, by execution and delivery of this Agreement; each Party hereby irrevocably accepts the exclusive jurisdiction of the aforesaid courts. Each Party hereby further irrevocably waives any claim that any such court lacks jurisdiction over it or to the laying of venue, and agrees not to plead or claim, in any legal action or proceeding with respect to this Agreement brought in any of the aforesaid courts, that any such court lacks jurisdiction over it or any such action or proceeding has been brought in an inconvenient forum.

14.6 Assignment. This Agreement may not be assigned by either Party without the prior written consent of the other Party; provided, however, that either Party may assign this Agreement, in whole or in part, to any of its Affiliates and such Party remains responsible for the performance of such Affiliate; and provided further, that either Party may assign this Agreement to a successor to all or substantially all of the assets or line of business to which this Agreement relates whether by merger, sale of stock, sale of assets or other similar transaction. No assignment will relieve either Party of the performance of any accrued obligation that such Party may then have under this Agreement. This Agreement shall be binding upon, and subject to the terms of the foregoing sentence, inure to the benefit of the Parties hereto, their permitted successors, legal representatives and assigns.

14.7 Notices. All notices hereunder must be in writing and will be deemed to have been duly given only if delivered personally, by facsimile with confirmation of receipt, by mail (first class, postage prepaid), or by overnight delivery using a globally-recognized carrier, to the Parties at the following addresses:

Client: TESARO Bio GmbH
Poststrasse 6
6300 Zug, Switzerland
Attention: Legal

With copy to:
TESARO, Inc.
1000 Winter Street, #3300
Waltham, MA 02451
Attention: General Counsel

CRL: Charles River Laboratories Contract Manufacturing PA, LLC
3 Chelsea Parkway
Boothwyn, PA 19061
Facsimile: 610-485-5933
Attn: Nutan Gangrade, Managing Director

or to such other address as the addressee shall have last furnished in writing in accord with this provision to the addressor. All notices shall be deemed effective upon receipt by the addressee.

14.8 Severability . In the event of the invalidity of any provisions of this Agreement or if this Agreement contains any gaps, the Parties agree that such invalidity or gap shall not affect the validity of the remaining provisions of this Agreement. The Parties will replace an invalid provision or fill any gap with valid provisions which most closely approximate the purpose and economic effect of the invalid provision or, in case of a gap, the Parties' presumed intentions. In the event that the terms and conditions of this Agreement are materially altered as a result of the preceding sentences, the Parties shall renegotiate the terms and conditions of this Agreement in order to resolve any inequities. Nothing in this Agreement shall be interpreted so as to require either Party to violate any applicable Laws.

14.9 Headings . The headings used in this Agreement have been inserted for convenience of reference only and do not define or limit the provisions hereof.

14.10 Certain Conventions . Unless the context of this Agreement otherwise requires: (a) words of any gender include each other gender, (b) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa, and (d) the words "include," "includes" and "including" shall be deemed to be followed by the phrase "but not limited to", "without limitation", "interalia", "among other things" or words of similar import.

14.11 Waiver; Remedies . Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by Law or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party. The Parties acknowledge that monetary damages may not be sufficient to remedy a breach by either Party of this Agreement and agree that the non-breaching Party will be entitled to seek specific performance, injunctive and/or other

equitable relief to prevent breaches of this Agreement and to specifically enforce the provisions hereof in addition to any other remedies available at law or in equity.

14.12 Entire Agreement . This Agreement (including the exhibits and schedules hereto) constitute the entire agreement between the Parties, and supersede all previous agreements and understandings between the Parties, whether written or oral, with respect to the within subject matter. This Agreement may be altered, amended or changed only by a writing making specific reference to this Agreement and signed by duly authorized representatives of Client and CRL.

14.13 No License . Nothing in this Agreement shall be deemed to constitute the grant of any license or other right in either Party, to or in respect of any Drug Product, patent, trademark, Confidential Information, trade secret or other data or any other intellectual property of the other Party, except as expressly set forth herein.

14.14 Third Party Beneficiaries . None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of either Party. No such Third Party shall obtain any right under any provision of this Agreement or shall by reasons of any such provision make any Claim in respect of any debt, liability or obligation (or otherwise) against either Party.

14.15 Counterparts . This Agreement may be executed in any two counterparts, each of which, when executed, shall be deemed to be an original and both of which together shall constitute one and the same document; and such counterparts may be delivered to the other Party by facsimile.

[*Signature page follows*]

IN WITNESS WHEREOF, Client and CRL, by their duly authorized officers, have executed this Agreement as of the Effective Date.

CLIENT:
TESARO Bio GmbH

By: _ /s/ Orlando Oliveira_____
Name: Orlando Oliveira
Title: SVP & General Manager International

CRL:
Charles River Laboratories Contract Manufacturing PA, LLC

By: _ /s/ Nutan Gangrade_____
Name: Nutan Gangrade, PhD
Title: Managing Director

Storage: [***]

Test Attribute	Method	Acceptance Criteria
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]		[***]
[***]	[***]	[***]

Schedule 2.3
CURRENT APPROVED SUBCONTRACTORS
[***]

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[***] 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.

Schedule 3.2
QUALITY AGREEMENT

See attached.

Schedule 8.1
SUPPLY PRICE

Batches/year	[***] capsules
[***]	[***]
[***]	[***]
[***]	[***]

Assumptions:
[***]

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: May 9, 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: May 9, 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 March 31, 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

May 9, 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 March 31, 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

May 9, 2017