

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10-Q**

**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 **001-12465**

**CTI BIOPHARMA CORP.**

(Exact name of registrant as specified in its charter)

**Washington**  
(State or other jurisdiction of  
incorporation or organization)

**91-1533912**  
(I.R.S. Employer  
Identification No.)

**3101 Western Avenue, Suite 600**  
**Seattle, Washington**  
(Address of principal executive offices)

**98121**  
(Zip Code)

**(206) 282-7100**  
(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 (§232.405 of this chapter) 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, or a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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.

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:

<u>Class</u>	<u>Outstanding at April 26, 2017</u>
Common Stock, no par value	28,214,847

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CTI BIOPHARMA CORP.

TABLE OF CONTENTS

	<u>PAGE</u>
<b><u>PART I - FINANCIAL INFORMATION</u></b>	
<u>ITEM 1: Financial Statements</u>	<u>4</u>
<u>Condensed Consolidated Balance Sheets at March 31, 2017 (unaudited) and December 31, 2016</u>	<u>4</u>
<u>Condensed Consolidated Statements of Operations – Three Months Ended March 31, 2017 and 2016 (unaudited)</u>	<u>5</u>
<u>Condensed Consolidated Statements of Comprehensive (Loss) Income – Three Months Ended March 31, 2017 and 2016 (unaudited)</u>	<u>6</u>
<u>Condensed Consolidated Statements of Cash Flows – Three Months Ended March 31, 2017 and 2016 (unaudited)</u>	<u>7</u>
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	<u>8</u>
<u>ITEM 2: Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>17</u>
<u>ITEM 3: Quantitative and Qualitative Disclosures about Market Risk</u>	<u>28</u>
<u>ITEM 4: Controls and Procedures</u>	<u>29</u>
<b><u>PART II - OTHER INFORMATION</u></b>	
<u>ITEM 1: Legal Proceedings</u>	<u>30</u>
<u>ITEM 1A: Risk Factors</u>	<u>32</u>
<u>ITEM 2: Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>49</u>
<u>ITEM 3: Defaults Upon Senior Securities</u>	<u>50</u>
<u>ITEM 4: Mine Safety Disclosures</u>	<u>50</u>
<u>ITEM 5: Other Information</u>	<u>50</u>
<u>ITEM 6: Exhibits</u>	<u>51</u>
<b><u>Signatures</u></b>	<b><u>53</u></b>

**PART I – FINANCIAL INFORMATION**  
**Item 1. Financial Statements.**

**CTI BIOPHARMA CORP.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(In thousands, except share amounts)

	<u>March 31, 2017</u>	<u>December 31, 2016</u>
	<u>(unaudited)</u>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 33,283	\$ 44,002
Accounts receivable	311	378
Receivables from collaborative arrangements	120	7,778
Inventory, net	1,502	1,525
Prepaid expenses and other current assets	1,554	2,141
Total current assets	36,770	55,824
Property and equipment, net	2,830	3,023
Other assets	5,060	4,996
Total assets	<u>\$ 44,660</u>	<u>\$ 63,843</u>
<b>LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 11,878	\$ 7,227
Accrued expenses	20,903	24,765
Current portion of deferred revenue	304	103
Current portion of long-term debt	8,170	7,949
Other current liabilities	619	602
Total current liabilities	41,874	40,646
Deferred revenue, less current portion	488	514
Long-term debt, less current portion	9,193	11,311
Other liabilities	3,478	3,615
Total liabilities	55,033	56,086
Commitments and contingencies		
Shareholders' (deficit) equity:		
Common stock, no par value:		
Authorized shares - 41,500,000		
Issued and outstanding shares - 28,224,447 and 28,228,602 at March 31, 2017 and December 31, 2016, respectively	2,172,061	2,170,300
Accumulated other comprehensive loss	(6,611)	(6,655)
Accumulated deficit	(2,170,154)	(2,150,326)
Total CTI shareholders' (deficit) equity	(4,704)	13,319
Noncontrolling interest	(5,669)	(5,562)
Total shareholders' (deficit) equity	(10,373)	7,757
Total liabilities and shareholders' (deficit) equity	<u>\$ 44,660</u>	<u>\$ 63,843</u>

See accompanying notes.

**CTI BIOPHARMA CORP.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except per share amounts)  
(unaudited)

	Three Months Ended March 31,	
	2017	2016
<b>Revenues:</b>		
Product sales, net	\$ 686	\$ 1,223
License and contract revenue	68	35,252
Total revenues	754	36,475
<b>Operating costs and expenses:</b>		
Cost of product sold	133	190
Research and development	9,253	20,846
Selling, general and administrative	10,688	11,312
Total operating costs and expenses	20,074	32,348
(Loss) income from operations	(19,320)	4,127
<b>Non-operating income (expense):</b>		
Interest expense	(534)	(714)
Amortization of debt discount and issuance costs	(38)	(101)
Foreign exchange (loss) gain	(43)	198
Other non-operating expense	—	(519)
Total non-operating expense, net	(615)	(1,136)
Net (loss) income before noncontrolling interest	(19,935)	2,991
Noncontrolling interest	107	321
Net (loss) income	\$ (19,828)	\$ 3,312
<b>Net (loss) income per common share:</b>		
Basic	\$ (0.71)	\$ 0.12
Diluted	\$ (0.71)	\$ 0.12
<b>Shares used in calculation of (loss) income per common share:</b>		
Basic	28,045	27,793
Diluted	28,045	27,816

See accompanying notes.

**CTI BIOPHARMA CORP.**  
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME**  
(In thousands)  
(unaudited)

	Three Months Ended March 31,	
	2017	2016
Net (loss) income before noncontrolling interest	\$ (19,935)	\$ 2,991
Other comprehensive income (loss):		
Foreign currency translation adjustments	(501)	(1,363)
Unrealized foreign exchange gain on intercompany balance	546	1,470
Other-than-temporary impairment on available-for-sale securities	—	519
Net unrealized (loss) gain on available-for-sale securities	(1)	1
Other comprehensive income	44	627
Comprehensive (loss) income	(19,891)	3,618
Comprehensive loss attributable to noncontrolling interest	107	321
Comprehensive (loss) income attributable to CTI	\$ (19,784)	\$ 3,939

See accompanying notes.

**CTI BIOPHARMA CORP.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)  
(unaudited)

	Three Months Ended March 31,	
	2017	2016
<b>Operating activities</b>		
Net (loss) income before noncontrolling interest	\$ (19,935)	\$ 2,991
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Baxalta milestone revenue	—	(32,000)
Share-based compensation expense	1,799	3,826
Depreciation and amortization	193	232
Provision for bad debt	—	321
Other-than-temporary impairment on available-for-sale securities	—	519
Noncash interest expense	38	101
Noncash rent benefit	(122)	(106)
Changes in operating assets and liabilities:		
Accounts receivable	73	(679)
Receivables from collaborative arrangements	7,660	—
Inventory	48	68
Prepaid expenses and other current assets	590	(2,004)
Other assets	15	(76)
Accounts payable	4,635	7,120
Accrued expenses	(3,870)	(3,265)
Deferred revenue	176	(108)
Total adjustments	11,235	(26,051)
Net cash used in operating activities	(8,700)	(23,060)
<b>Investing activities</b>		
Purchases of property and equipment	—	(29)
Net cash used in investing activities	—	(29)
<b>Financing activities</b>		
Repayment of Hercules debt	(1,934)	—
Payment of tax withholding obligations related to stock compensation	(2)	(113)
Cash paid for preferred stock issuance costs	—	(135)
Other	(36)	(1)
Net cash used in financing activities	(1,972)	(249)
Effect of exchange rate changes on cash and cash equivalents	(47)	(203)
Net decrease in cash and cash equivalents	(10,719)	(23,541)
Cash and cash equivalents at beginning of period	44,002	128,182
Cash and cash equivalents at end of period	\$ 33,283	\$ 104,641
<b>Supplemental disclosure of cash flow information</b>		
Cash paid during the period for interest	\$ 551	\$ 2,472
Cash paid during the period for taxes	\$ —	\$ —
<b>Supplemental disclosure of noncash financing and investing activities</b>		
Baxalta milestone advance - earned in lieu of repayment	\$ —	\$ 32,000

See accompanying notes.

**CTI BIOPHARMA CORP.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited)**

**1. Description of Business and Summary of Significant Accounting Policies**

CTI BioPharma Corp., together with its wholly-owned subsidiaries, also referred to collectively in this Quarterly Report on Form 10-Q as “we,” “us,” “our,” the “Company” and “CTI,” is a biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies covering a spectrum of blood-related cancers that offer a unique benefit to patients and health care providers. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with partners. We are currently concentrating our efforts on treatments that target blood-related cancers where there is an unmet medical need. In particular, we are primarily focused on evaluating pacritinib for the treatment of adult patients with myelofibrosis and the further development of PIXUVRI worldwide, for which our partner Les Laboratoires Servier and Institut de Recherches Internationales Servier, or collectively Servier, has commercialization rights outside the United States, or the U.S.

We operate in a highly regulated and competitive environment. The manufacturing and marketing of pharmaceutical products require approval from, and are subject to, ongoing oversight by the Food and Drug Administration, or the FDA, in the U.S., the European Medicines Agency, or the EMA, in the European Union, or the E.U., and comparable agencies in other countries. Obtaining approval for a new therapeutic product is never certain, may take many years and may involve expenditure of substantial resources.

*Basis of Presentation*

The accompanying unaudited financial information of CTI as of and for the three months ended March 31, 2017 and 2016 has been prepared in accordance with accounting principles generally accepted in the U.S. for interim financial information and with the instructions to Quarterly Report on Form 10-Q and Article 10 of Regulation S-X. In the opinion of management, such financial information includes all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of our financial position at such date and the operating results and cash flows for such periods. Operating results for the three months ended March 31, 2017 are not necessarily indicative of the results that may be expected for the entire year or for any other subsequent interim period.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted pursuant to the rules of the U.S. Securities and Exchange Commission, or the SEC. These unaudited financial statements and related notes should be read in conjunction with our audited financial statements for the year ended December 31, 2016 included in our Annual Report on Form 10-K filed with the SEC on March 2, 2017.

The condensed consolidated balance sheet at December 31, 2016 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by generally accepted accounting principles in the U.S. for complete financial statements.

*Principles of Consolidation*

The accompanying condensed consolidated financial statements include the accounts of CTI and its wholly-owned subsidiaries, which include Systems Medicine LLC and CTI Life Sciences Limited, or CTILS. We also retain ownership of our branch, CTI BioPharma Corp.– Sede Secondaria, or CTI (Europe); however, we ceased operations related to this branch in September 2009.

As of March 31, 2017, we also had an approximately 60% interest in our majority-owned subsidiary, Aequus Biopharma, Inc., or Aequus. The remaining interest in Aequus not held by CTI is reported as *noncontrolling interest* in the condensed consolidated financial statements.

All intercompany transactions and balances are eliminated in consolidation.

*Reverse Stock Split*

On January 1, 2017, we effected a one-for-ten reverse stock split, or the Stock Split. All impacted amounts included in the condensed consolidated financial statements and notes thereto have been retroactively adjusted for the Stock Split. Unless



otherwise noted, impacted amounts include shares of common stock authorized and outstanding, share issuances and cancellations, shares underlying warrants and stock options, shares reserved, conversion prices of convertible securities, exercise prices of warrants and options, and (loss) income per share. Additionally, the Stock Split impacted preferred stock authorized (but not outstanding because there were no shares of preferred stock outstanding as of the time of the Stock Split).

### *Liquidity*

The accompanying condensed consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business within one year after the date the condensed consolidated financial statements are issued. In accordance with Financial Accounting Standards Board, or the FASB, Accounting Standards Update No. 2014-15, *Presentation of Financial Statements - Going Concern (Subtopic 205-40)*, our management evaluates whether there are conditions or events, considered in aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued.

We will need to continue to conduct research, development, testing and regulatory compliance activities with respect to our compounds and ensure the procurement of manufacturing and drug supply services, the costs of which, together with projected general and administrative expenses, is expected to result in operating losses for the foreseeable future. Additionally, we have resumed primary responsibility for the development and commercialization of pacritinib as a result of the termination of the Pacritinib License Agreement in October 2016, and we will no longer be eligible to receive cost sharing or milestone payments for pacritinib's development from Baxalta Incorporated and its affiliates, or Baxalta, which is now part of Shire plc. We have incurred a net operating loss every year since our formation. As of March 31, 2017, we had an accumulated deficit of \$2.2 billion, and we expect to continue to incur net losses for the foreseeable future.

Our available *cash and cash equivalents* were \$33.3 million as of March 31, 2017. We believe that our present financial resources, together with payments projected to be received under certain contractual agreements and our ability to control costs, will only be sufficient to fund our operations into the third quarter of 2017. This raises substantial doubt about our ability to continue as a going concern.

Accordingly, we will need to raise additional funds to operate our business. We may seek to raise such capital through public or private equity financings, partnerships, collaborations, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources of financing. However, we have a limited number of authorized shares of common stock available for issuance and additional funding may not be available on favorable terms or at all. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. If we fail to obtain additional capital when needed, our ability to operate as a going concern will be harmed, and we may be required to delay, scale back or eliminate some or all of our research and development programs, reduce our selling, general and administrative expenses, be unable to attract and retain highly-qualified personnel, be unable to obtain and maintain contracts necessary to continue our operations and at affordable rates with competitive terms, refrain from making our contractually required payments when due (including debt payments) and/or may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. The accompanying condensed consolidated financial statements do not include adjustments, if any, that may result from the outcome of this uncertainty.

### *Accounts Receivable*

Our accounts receivable balance includes trade receivables related to PIXUVRI sales. We estimate an allowance for doubtful accounts based upon the age of outstanding receivables and our historical experience of collections, which includes adjustments for risk of loss for specific customer accounts. We periodically review the estimation process and make changes to our assumptions as necessary. When it is deemed probable that a customer account is uncollectible, the account balance is written off against the existing allowance. We also consider the customer's country of origin to determine if an allowance is required. We continue to monitor economic conditions, including the volatility associated with international economies and the sovereign debt crisis in certain European countries, and associated impacts on the financial markets and our business.

As of March 31, 2017 and December 31, 2016, our accounts receivable did not include any material balance from a customer in a country that has exhibited financial stress. We recorded no allowance for doubtful accounts as of March 31, 2017 and December 31, 2016.

### *Receivables from Collaborative Arrangements*

Our receivables from collaborative arrangements relate to amounts payable or reimbursable to us under the terms of collaborative arrangements with our partners. The receivable balance as of December 31, 2016 primarily relates to a milestone receivable from Servier for the attainment of a certain enrollment event in December 2016 in connection with our PIX306 study. When it is deemed probable that an amount is uncollectible, it is written off against the existing allowance. We had no allowance for doubtful accounts from collaborative arrangements as of March 31, 2017 or December 31, 2016.

#### *Value Added Tax Receivable*

Our European operations are subject to a value added tax, or VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable was approximately \$4.3 million and \$4.4 million as of March 31, 2017 and December 31, 2016, respectively, of which \$4.2 million and \$4.1 million, respectively, was included in *other assets* and \$0.1 million and \$0.3 million, respectively, was included in *prepaid expenses and other current assets*. The collection period of VAT receivable for our European operations ranges from approximately three months to five years. For our Italian VAT receivable, the collection period is approximately three to five years. As of March 31, 2017, the VAT receivable related to operations in Italy was approximately \$4.3 million. We review our VAT receivable balance for impairment whenever events or changes in circumstances indicate that the carrying amount might not be recoverable.

#### *Inventory*

We carry inventory at the lower of cost or net realizable value. The cost of finished goods and work in process is determined using the standard-cost method, which approximates actual cost based on a first-in, first-out method. Inventory includes the cost of materials, third-party contract manufacturing and overhead costs, quality control costs and shipping costs from the manufacturers to the final distribution warehouse associated with the distribution of PIXUVRI. Production costs for our other product candidates continue to be charged to research and development expense as incurred prior to regulatory approval or until our estimate for regulatory approval becomes probable. We review inventories on a quarterly basis for impairment and reserves are established when necessary. Estimates of excess inventory consider our projected sales of the product and the remaining shelf lives of product. In the event we identify excess, obsolete or unsalable inventory, the value is written down to the net realizable value. Based on assessment of shelf lives and net realizable value of the product, a reserve of \$1.5 million was recorded as of March 31, 2017 and December 31, 2016, for excess, obsolete or unsalable inventory.

#### *Revenue Recognition*

We currently have conditional marketing authorization for PIXUVRI in the E.U. Revenue is recognized when there is persuasive evidence of the existence of an agreement, delivery has occurred, prices are fixed or determinable, and collectability is assured. Where the revenue recognition criteria are not met, we defer the recognition of revenue by recording deferred revenue until such time that all criteria under the provision are met.

#### Product sales

We sell PIXUVRI primarily through a limited number of wholesale distributors. We generally record product sales upon receipt of the product by the health care providers and certain distributors at which time title and risk of loss pass. Product sales are recorded net of distributor discounts, estimated government-mandated rebates, trade discounts, and estimated product returns. Reserves are established for these deductions and actual amounts incurred are offset against the applicable reserves. We reflect these reserves as either a reduction in the related account receivable or as an accrued liability, depending on the nature of the sales deduction. These estimates are periodically reviewed and adjusted as necessary.

#### Collaboration Agreements

Milestone payments under collaboration agreements are generally aggregated into three categories for reporting purposes: (i) development milestones, (ii) regulatory milestones, and (iii) sales milestones. Development milestones are typically payable when a product candidate initiates or advances into different clinical trial phases. Regulatory milestones are typically payable upon submission for marketing approval with the FDA, or with the regulatory authorities of other countries, or on receipt of actual marketing approvals for the compound or for additional indications. Sales milestones are typically payable when annual sales reach certain levels.

At the inception of each agreement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the

enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We evaluate factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. Non-refundable development and regulatory milestones that are expected to be achieved as a result of our efforts during the period of substantial involvement are considered substantive and are recognized as revenue upon the achievement of the milestone, assuming all other revenue recognition criteria are met.

We follow Accounting Standard Codification, or ASC, 605-25, *Revenue Recognition – Multiple-Element Arrangements*, and ASC 808, *Collaborative Arrangements*, if applicable, to determine the accounting of reimbursement arrangements under collaborative research and development and commercialization agreements.

#### *Cost of Product Sold*

Cost of product sold includes third-party manufacturing costs, shipping costs, contractual royalties and other costs of PIXUVRI product sold. Cost of product sold also includes allowances, if any, for excess inventory that may expire and become unsalable.

#### *Foreign Currency Translation and Transaction Gains and Losses*

We record foreign currency translation adjustments and transaction gains and losses in accordance with ASC 830, *Foreign Currency Matters*. For our operations that have a functional currency other than the U.S. dollar, gains and losses resulting from the translation of the functional currency into U.S. dollars for financial statement presentation are not included in determining net loss, but are accumulated in the cumulative foreign currency translation adjustment account as a separate component of shareholders' (deficit) equity, except for intercompany transactions that are of a short-term nature with entities that are consolidated, combined or accounted for by the equity method in our condensed consolidated financial statements. We and our subsidiaries also have transactions in foreign currencies other than the functional currency. We record transaction gains and losses in our condensed consolidated statements of operations related to the recurring measurement and settlement of such transactions.

The intercompany balance due from CTILS is considered to be of a long-term nature. An unrealized foreign exchange gain of \$0.5 million and \$1.5 million was recorded in the cumulative foreign currency translation adjustment account for the three months ended March 31, 2017 and March 31, 2016, respectively. As of March 31, 2017, the intercompany balance due from CTILS was €29.1 million (or \$31.1 million upon conversion from euros as of March 31, 2017). As of December 31, 2016, the intercompany balance due from CTILS was €29.7 million (or \$31.2 million upon conversion from euros as of December 31, 2016).

#### *Net (Loss) Income Per Share*

Basic net (loss) income per share, or EPS, is calculated based on the net (loss) income attributable to common shareholders divided by the weighted average number of shares outstanding for the period excluding dilutive effects, if any, of options, warrants, unvested share awards and convertible securities. Diluted EPS assumes the conversion of all dilutive convertible securities, such as convertible debt and convertible preferred stock, using the if-converted method, and assumes the exercise or vesting of other dilutive securities, such as options, warrants and restricted stock, using the treasury stock method.

#### *Recently Adopted Accounting Standards*

In July 2015, the FASB issued new accounting guidance on simplifying the measurement of inventory which requires that inventory within the scope of the guidance be measured at the lower of cost and net realizable value. Prior to the issuance of the standard, inventory was measured at the lower of cost or market (where market was defined as replacement cost, with a ceiling of net realizable value and floor of net realizable value less a normal profit margin). The accounting guidance is effective for annual reporting periods (including interim periods within those periods) beginning after December 15, 2016. The adoption of this standard in the first quarter of 2017 did not have a material impact on our condensed consolidated financial statements.

In August 2014, the FASB issued a new accounting standard which requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern for each annual and interim reporting period and to provide related footnote disclosures in certain circumstances. The accounting standard is effective for annual reporting periods

ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016. The adoption of this standard in the fourth quarter of 2016 did not have a material impact on our condensed consolidated financial statements.

In March 2016, the FASB issued new accounting guidance for employee share-based payments accounting. The accounting standard primarily affects the accounting for forfeitures, minimum statutory tax withholding requirements, and income tax effects related to share-based payments at settlement (or expiration). The accounting guidance is effective for annual reporting periods beginning after December 15, 2016 (including interim periods within those periods). We have historically maintained a full valuation allowance against deferred tax assets. The adoption of this standard in the first quarter of 2017 did not have a material impact on our condensed consolidated financial statements, and we will continue to estimate expected forfeitures.

#### *Recently Issued Accounting Standards*

In May 2014, the FASB issued a new financial accounting standard which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and which supersedes current revenue recognition guidance. In March 2016, the FASB issued an amendment to clarify the implementation guidance around considerations of whether an entity is a principal or an agent, impacting whether an entity reports revenue on a gross or net basis. In April 2016, the FASB issued an amendment to clarify guidance on identifying performance obligations and the implementation guidance on licensing. In May 2016, the FASB issued amendments to certain aspects of the new revenue guidance (including transition, collectability, noncash consideration and the presentation of sales and other similar taxes) and provided certain practical expedients. The accounting standard is effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2017. Early adoption is permitted for annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. We are currently evaluating the impact of this accounting standard on our condensed consolidated financial statements.

In January 2016, the FASB issued a new accounting standard on recognition and measurement of financial assets and financial liabilities. The accounting standard primarily affects the accounting for equity investments and financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, it includes a clarification related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The accounting guidance is effective for annual reporting periods (including interim periods within those periods) beginning after December 15, 2017. Early adoption is permitted for the provision to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit risk in other comprehensive income. The adoption of this standard is not expected to have a material impact on our condensed consolidated financial statements.

In February 2016, the FASB issued new accounting guidance on accounting for leases which requires lessees to recognize virtually all of their leases (other than leases that meet the definition of a short-term lease) on the balance sheet. The accounting guidance is effective for annual reporting periods (including interim periods within those periods) beginning after December 15, 2018. Early adoption is permitted. We are currently evaluating the impact of this accounting standard on our condensed consolidated financial statements.

In August 2016, the FASB issued an amendment to add or clarify guidance on the classification of certain cash receipts and payments in the statement of cash flows with the objective of reducing diversity in practice regarding eight types of cash flows. The accounting guidance is effective for annual reporting periods (including interim periods within those periods) beginning after December 15, 2017. Early adoption is permitted. We do not expect the adoption of this standard to have a material impact on our statements of cash flows.

#### *Reclassifications*

Certain prior year items have been reclassified to conform to current year presentation.

## **2. Inventory**

The components of PIXUVRI inventory consisted of the following (in thousands):

	March 31, 2017	December 31, 2016
Finished goods	\$ 450	\$ 477
Work-in-process	2,576	2,558
Inventory, gross	3,026	3,035
Reserve for excess, obsolete or unsalable inventory	(1,524)	(1,510)
Inventory, net	<u>\$ 1,502</u>	<u>\$ 1,525</u>

### 3. Leases

Our deferred rent balance was \$3.4 million as of March 31, 2017, of which \$0.5 million was included in *other current liabilities* and \$2.9 million was included in *other liabilities*. As of December 31, 2016, our deferred rent balance was \$3.5 million, of which \$0.5 million was included in *other current liabilities* and \$3.0 million was included in *other liabilities*.

### 4. Share-based Compensation Expense

The following table summarizes share-based compensation expense, which was allocated as follows (in thousands):

	Three Months Ended March 31,	
	2017	2016
Research and development	\$ 32	\$ 786
Selling, general and administrative	1,767	3,040
Total share-based compensation expense	<u>\$ 1,799</u>	<u>\$ 3,826</u>

We incurred share-based compensation expense due to the following types of awards (in thousands):

	Three Months Ended March 31,	
	2017	2016
Performance rights	\$ —	\$ 360
Restricted stock	320	2,071
Options	1,479	1,395
Total share-based compensation expense	<u>\$ 1,799</u>	<u>\$ 3,826</u>

### 5. Earnings (Loss) Per Share

The numerator for both basic and diluted (loss) earnings per share, or EPS, is net (loss) income. The denominator for basic EPS (referred to as basic shares) is the weighted average number of common shares outstanding during the period, whereas the denominator for diluted EPS (referred to as diluted shares) also takes into account the dilutive effect of outstanding stock options and restricted stock awards using the treasury stock method. Basic and diluted shares were as follows (in thousands):

	Three Months Ended March 31,	
	2017	2016
Basic shares	28,045	27,793
Effect of dilutive securities	—	23
Diluted shares	<u>28,045</u>	<u>27,816</u>

The effect of dilutive securities included unexercised stock options and unvested restricted stock. Equity awards, warrants, and unvested share rights aggregating 3.5 million shares and 2.4 million shares for the three months ended March 31, 2017 and March 31, 2016, respectively, were excluded from the calculation of diluted EPS because they were anti-dilutive.

### 6. Other Comprehensive Loss

Total accumulated other comprehensive loss consisted of the following (in thousands):

	Net Unrealized Loss on Available-For- Sale Securities	Foreign Currency Translation Adjustments	Unrealized Foreign Exchange Gain (Loss) on Intercompany Balance	Accumulated Other Comprehensive Loss
December 31, 2016	\$ (6)	\$ (2,902)	\$ (3,747)	\$ (6,655)
Current period other comprehensive income (loss)	(1)	(501)	546	44
March 31, 2017	\$ (7)	\$ (3,403)	\$ (3,201)	\$ (6,611)

The value of available-for-sale securities of \$13,000 and \$13,500 as of March 31, 2017 and December 31, 2016, respectively, was included in *Prepaid expenses and other current assets*.

## 7. Legal Proceedings

In April 2009, December 2009 and June 2010, the Italian Tax Authority, or the ITA, issued notices of assessment to CTI (Europe) based on the ITA's audit of CTI (Europe)'s VAT returns for the years 2003, 2005, 2006 and 2007, or, collectively, the VAT Assessments. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We are defending ourselves against the assessments both on procedural grounds and on the merits of the case although we can make no assurances regarding the ultimate outcome of these cases. Following is a summary of the status of the legal proceedings surrounding each respective VAT year return at issue:

2003. In June 2013, the Regional Tax Court issued decision no. 119/50/13 in regards to the 2003 VAT assessment, which accepted the appeal of the ITA and reversed the previous decision of the Provincial Tax Court. In January 2014, we appealed such decision to the Italian Supreme Court both on procedural grounds and on the merits of the case. In March 2014, we paid a deposit in respect of the 2013 VAT matter of €0.4 million (or \$0.6 million upon conversion from euros as of the date of payment), following the ITA's request for such payment.

2005, 2006 and 2007. The ITA has appealed to the Italian Supreme Court the decisions of the respective appellate court with respect to each of the 2005, 2006 and 2007 VAT returns.

If the final decision of the Italian Supreme Court is unfavorable to us, or if, in the interim, the ITA were to make a demand for payment and we were to be unsuccessful in suspending collection efforts, we may be requested to pay the ITA an amount up to €9.4 million, or approximately \$10.1 million converted using the currency exchange rate as of March 31, 2017, plus collection fees, notification expenses and additional interest for the period lapsed between the date in which the assessments were issued and the date of effective payment. In January 2013, our then remaining deposit for the VAT Assessments was refunded to us.

### *Securities and Exchange Commission Subpoena*

We previously disclosed that we received a subpoena from the SEC in January 2016. The SEC's subpoena requested, among other things; internal and external communications related to pacritinib Phase 3 trials, including communications with the independent data monitoring committee, or IDMC, for pacritinib's Phase 3 trials, our steering committee, our board of directors, our audit committee, representatives of Baxter and Baxalta, and the FDA, and other documents related to pacritinib.

We believe that the SEC is seeking to determine whether there have been possible violations of the antifraud and certain other provisions of the federal securities laws related to the Company's disclosures concerning, among other things, the clinical test results of pacritinib. The SEC Staff's letter sent with the subpoena stated that the investigation is a fact-finding inquiry, and the investigation and subpoena do not mean that the SEC has concluded that we or anyone else has violated any law. We are cooperating with this investigation, which is ongoing.

### *In re CTI BioPharma Corp. Securities Litigation*

On February 10, 2016 and February 12, 2016, class action lawsuits entitled Ahrens v. CTI BioPharma Corp. et al., Case No. 1:16-cv-01044 and McGlothlin v. CTI BioPharma Corp. et al., Case No. C16-216, respectively, were filed in the United States District Court for the Southern District of New York and the United States District Court for the Western District of Washington, respectively, on behalf of shareholders that purchased or acquired the Company's securities pursuant to our

September 24, 2015 public offering and/or shareholders who otherwise acquired our stock between March 4, 2014 and February 9, 2016, inclusive. The complaints assert claims against the Company and certain of our current and former directors and officers for violations of the federal securities laws under Sections 11 and 15 of the Securities Act of 1933, as amended, or the Securities Act, and Sections 10 and 20 of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Plaintiffs' Securities Act claims allege that the Company's Registration Statement and Prospectus for the September 24, 2015 public offering contained materially false and misleading statements and failed to disclose certain material adverse facts about the Company's business, operations and prospects, including with respect to the clinical trials and prospects for pacritinib. Plaintiffs' Exchange Act claims allege that the Company's public disclosures were knowingly or recklessly false and misleading or omitted material adverse facts, again with a primary focus on the clinical trials and prospects for pacritinib. On May 2, 2016, the Company filed a motion to transfer the Ahrens case to the United States District Court for the Western District of Washington. The motion was unopposed and granted by the court on May 19, 2016. On June 3, 2016, the parties filed a joint motion to consolidate the McGlothlin case with the Ahrens case in order to proceed as a single consolidated proceeding. On June 13, 2016, the court granted the motion to consolidate with the action being captioned *In re CTI BioPharma Corp. Securities Litigation*, Master File No. 2:16-cv-00216-RSL. On September 2, 2016, the court appointed Lead Plaintiffs and Lead Counsel. On September 28, 2016, the court entered a scheduling order, as revised by order entered December 8, 2016, setting November 8, 2016 as the deadline to file a consolidated class action complaint and deadlines for briefing defendants' motion to dismiss. Briefing concluded on February 22, 2017. A hearing on the defendants' motion to dismiss has not been set. The consolidated class action complaint asserts claims similar to those asserted in the initial complaints, although it no longer asserts claims relating to the September 24, 2015 public offering, but adds claims relating to the Company's October 27, 2015 and December 4, 2015 public offerings. The lawsuit seeks damages in an unspecified amount. We believe that the allegations contained in the complaints are without merit and intend to vigorously defend ourselves against all claims asserted therein. A reasonable estimate of the amount of any possible loss or range of loss cannot be made at this time and, as such, we have not recorded an accrual for any possible loss.

*Wei v. James A. Bianco, et al.; England v. James A Bianco, et al; Nahar v. James A. Bianco, et al.; Hill v. James A. Bianco, et al.*

On March 14, 2016, a Company shareholder filed the first of four similar derivative lawsuits on behalf of the Company seeking damages for alleged harm to the Company caused by certain current and former officers and directors. The first suit, *Wei v. James A. Bianco, et al.*, 16-2-05818-3, was filed in King County Superior Court, Washington. A second suit, *England v. James A. Bianco, et al.*, 16-2-14422-5, was filed in King County Superior Court, Washington, on June 16, 2016. Two additional derivative suits, *Nahar v. James A. Bianco, et al.*, 2:16-cv-0756, and *Hill v. James A. Bianco, et al.*, 2:16-cv-1250, were filed in the United States District Court for the Western District of Washington on May 24, 2016 and August 9, 2016, respectively. The four suits raise similar allegations and seek similar relief against certain current and former officers and directors, including James A. Bianco, Louis A. Bianco, Jack W. Singer, Bruce J. Seeley, John H. Bauer, Phillip M. Nudelman, Reed V. Tuckson, Karen Ignagni, Richard L. Love, Mary O. Munding and Frederick W. Telling. Consistent with the requirements of a derivative action, the Company is named in each suit as a nominal defendant against which no monetary relief is sought. The complaints generally allege claims of: (1) breach of fiduciary duty; (2) abuse of control; (3) gross mismanagement; (4) waste of corporate assets and (5) unjust enrichment (receiving compensation that was unjust in light of the alleged conduct). Each is based on the assertion that the Company made materially false and misleading statements and omitted material information from its disclosures about pacritinib and its safety. Plaintiffs in none of the suits made a pre-suit demand on the current Board to investigate whether to pursue claims against officers or directors, instead claiming demand is excused because the named defendants lack independence, are not disinterested because they lack impartiality, received and want to continue to receive their compensation, have longstanding personal and business relationships, and cannot evaluate a demand since they are facing personal liability. Each of plaintiffs' suits requested the court to award the Company the damages allegedly sustained as a result of the conduct and to direct the Company and the individual defendants to reform and improve the Company's corporate governance to avoid future damages. On March 29, 2017 during mediation, the parties to the derivative suits reached an agreement in principle to settle all four suits subject to Board and court approvals. As part of the settlement, CTI has agreed to adopt certain corporate governance reforms and agreed not to object to an attorneys' fee application by plaintiffs' counsel of up to \$0.8 million collectively. There is no admission of liability or any wrongdoing by any of the individual defendants or CTI.

In connection with the four derivative lawsuits described above, after taking into account our existing insurance coverage, we accrued \$0.2 million of settlement expense as our reasonable estimate of liability, which is recorded in *Selling, general and administrative* expenses in our condensed consolidated statement of operations for the three months ended March 31, 2017.

In addition to the items discussed above, we are from time to time subject to legal proceedings and claims arising in the ordinary course of business.

## 8. Related Party Transaction

We have a majority ownership interest in Aequus. In May 2007, we entered into a license agreement with Aequus whereby Aequus gained rights to our Genetic Polymer™ technology. We also entered into an agreement to fund Aequus in exchange for a convertible promissory note.

In March 2017, we and Aequus entered into a License and Promissory Note Termination Agreement and a Note Cancellation Agreement, pursuant to which, (i) all of the then-outstanding principal, plus all accrued and unpaid interest, approximately \$13.7 million in total, was cancelled and terminated, (ii) our license agreement with Aequus was terminated, (iii) all obligations to Aequus were terminated with the exception of providing additional funding of up to \$347,500 to Aequus, and (iv) Aequus has agreed to pay us a) 20% of milestone and similar payments, up to a maximum amount of \$20.0 million, and b) royalties, on a product-by-product and county-by country basis, of 5% of net sales of certain ACTH Products being developed by Aequus. Payments from Aequus are due the later of (i) expiration of the last to expire valid patent claim that claims the ACTH Product, or (ii) ten years from the first commercial sale of the applicable ACTH Product. We have the right to terminate the License and Promissory Note Termination Agreement and require Aequus to assign all ACTH Product related assets to us if Aequus does not file an Investigational New Drug Application for an ACTH Product with the FDA by September 6, 2019.

## 9. Subsequent Event

In April 2017, we entered into an Amended and Restated Exclusive License and Collaboration Agreement (the "Restated Agreement") with Servier (together with the Company, the "Parties") pursuant to which the Parties amended and restated the Exclusive License and Collaboration Agreement entered into by the Parties on September 16, 2014 (the "Original Agreement") regarding the development and commercialization of PIXUVRI (to the extent incorporated in a pharmaceutical product, the "Licensed Product(s)"). The Restated Agreement replaces the Original Agreement in its entirety.

We have obtained conditional marketing authorization in the E.U. to market PIXUVRI for the treatment of adult patients with relapsed or refractory aggressive non-Hodgkin B-cell lymphomas. Under the Restated Agreement, we will transfer our European marketing authorization to Servier upon positive, statistically significant results in an ongoing post-authorization Phase III clinical trial, PIX306, unless Servier elects to terminate the Restatement Agreement within thirty (30) days after the positive results.

Under the Restated Agreement, we have granted to Servier an exclusive, sublicensable (subject to certain exceptions) license to manufacture the Licensed Products worldwide, and an exclusive, sublicenseable (subject to certain exceptions) license to develop and commercialize the Licensed Products worldwide, excluding the U.S. (the "Company Territory"). The Parties have agreed to enter into a commercialization transition plan by July 31, 2017 whereby we will transfer to Servier medical affairs and commercialization activities relating to the Licensed Products in Austria, Denmark, Finland, Germany, Israel, Norway, Sweden, Turkey and the United Kingdom (collectively, the "Transition Territory"). Upon the implementation of the commercialization transition plan, we will terminate or assign certain distributor and wholesaler contracts to Servier in the Transition Territory. Each party will be responsible for the manufacture and supply of drug products and substances in their respective territories.

We will receive payments of €12.0 million from Servier, which includes €2.0 million for a new milestone previously achieved, and Servier is obligated to purchase a certain amount of PIXUVRI drug product for an additional €0.9 million within 30 days of the Restated Agreement. Subject to the achievement of certain conditions, we are eligible to receive additional milestone payments from Servier in the aggregate amount of up to €76.0 million, which is comprised of the following: up to €36.0 million in potential regulatory milestone payments and up to €40.0 million in potential sales milestone payments. We are eligible to receive tiered royalty payments ranging from a low-double digit percentage up to a percentage in the low-twenties based on net sales of the Licensed Product, subject to certain reductions of up to mid-double digit percentages under certain circumstances. The Parties will no longer use a joint marketing plan, and marketing costs will no longer be shared equally between the Parties; instead Servier will be solely responsible for marketing costs within Europe. Mutually agreed upon development costs other than PIX306 will continue to be shared equally between the Parties, which represents no change to the development cost sharing.

The Restated Agreement also requires the Parties to amend the trademark license agreement entered into between the Parties on June 8, 2015 to provide for Servier's right to use of our trademark PIXUVRI in connection with Licensed Products worldwide, excluding the Company Territory.



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

*This Quarterly Report on Form 10-Q may contain, in addition to historical information, "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and should be read in conjunction with the Condensed Consolidated Financial Statements and the related Notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q. When used in this Quarterly Report on Form 10-Q, terms such as "anticipates," "believes," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," or "will" or the negative of those terms or other comparable terms are intended to identify such forward-looking statements. Such statements include statements concerning sufficiency of cash resources and other projections, product manufacturing and sales, research and development expenses, selling, general and administrative expenses, financings and additional losses. These statements are based on assumptions about many important factors and information currently available to us to the extent that we have thus far had an opportunity to fully and carefully evaluate such information in light of all surrounding facts, circumstances, recommendations and analyses. Additionally, these statements are subject to known and unknown risks and uncertainties, including, but not limited to, those discussed below and elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the fiscal year ending December 31, 2016, or the 2016 Form 10-K, particularly in "Factors Affecting Our Business, Financial Condition, Operating Results and Prospects," that could cause actual results, levels of activity, performance or achievements to differ significantly from those projected. Although we believe that expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We will not update any of the forward-looking statements after the date of this Quarterly Report on Form 10-Q to conform these statements to actual results or changes in our expectations. Readers are cautioned not to place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q.*

### OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies covering a spectrum of blood-related cancers that offer a unique benefit to patients and health care providers. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with partners. We are currently concentrating our efforts on treatments that target blood-related cancers where there is an unmet medical need. In particular, we are primarily focused on evaluating pacritinib for the treatment of adult patients with myelofibrosis and the further development of PIXUVRI worldwide, for which our partner, Les Laboratoires Servier and Institut de Recherches Internationales Servier, or collectively Servier, has commercialization rights outside the United States, or the U.S.

### PIXUVRI

PIXUVRI is a novel aza-anthracenedione with unique structural and physiochemical properties. In May 2012, the European Commission granted conditional marketing authorization in the European Union, or the E.U., for PIXUVRI as a monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive B-cell non-Hodgkin lymphoma, or NHL. PIXUVRI is the first approved treatment in the E.U. for patients with multiply relapsed or refractory aggressive B-cell NHL who have failed two or three prior lines of therapy. As a part of the conditional marketing authorization, we are required to conduct a post-authorization trial, which we refer to as PIX306, comparing PIXUVRI and rituximab with gemcitabine and rituximab in the setting of aggressive B-cell NHL. Although we do not have and are not currently pursuing regulatory approval of PIXUVRI in the U.S., we may reevaluate a possible submission strategy in the U.S. based on the data generated from the PIX306 study. Pursuant to our conditional marketing authorization in the E.U., and an extension granted in September 2016, we are required to submit the requisite clinical study report for PIX306 by December 2018.

In April 2017, we entered into an Amended and Restated Exclusive License and Collaboration Agreement, or the Restated Agreement, with Servier. Under the Restated Agreement, Servier will have rights to PIXUVRI in all markets except in the U.S. where we will retain the commercialization rights. Previously Servier had rights to commercialize the drug globally except in Austria, Denmark, Finland, Germany, Israel, Norway, Sweden, Turkey, the United Kingdom, or the U.K., and the U.S. Servier will pay us €12.0 million and is obligated to purchase a certain amount of PIXUVRI drug product for an additional €0.9 million within 30 days of the Restated Agreement. We are eligible to receive up to €76.0 million in additional sales and regulatory milestone payments as well as royalties on net product sales.

For additional information on our collaboration with Servier, please see the discussion in Part I, Item 2, "License Agreements and Milestone Activities - Servier."

## **Pacritinib**

Our lead development candidate, pacritinib, is an investigational oral kinase inhibitor with specificity for JAK2, FLT3, IRAK1 and CSF1R. The JAK family of enzymes is a central component in signal transduction pathways, which are critical to normal blood cell growth and development, as well as inflammatory cytokine expression and immune responses. Mutations in these kinases have been shown to be directly related to the development of a variety of blood-related cancers, including myeloproliferative neoplasms, leukemia and lymphoma. In addition to myelofibrosis, the kinase profile of pacritinib suggests its potential therapeutic utility in conditions such as acute myeloid leukemia, or AML, myelodysplastic syndrome, or MDS, chronic myelomonocytic leukemia, or CMML, and chronic lymphocytic leukemia, or CLL, due to its inhibition of c-fms, IRAK1, JAK2 and FLT3. We believe pacritinib has the potential to be delivered as a single agent or in combination therapy regimens.

Pacritinib was evaluated in two Phase 3 clinical trials, known as the PERSIST program, for patients with myelofibrosis, with one trial in a broad set of patients without limitations on platelet counts, the PERSIST-1 trial; and the other in patients with low platelet counts, the PERSIST-2 trial. In August 2014, pacritinib was granted Fast Track designation by the Food and Drug Administration, or the FDA, for the treatment of intermediate and high risk myelofibrosis including, but not limited to, patients with disease-related thrombocytopenia (low platelet counts); patients experiencing treatment-emergent thrombocytopenia on other JAK2 inhibitor therapy; or patients who are intolerant of or whose symptoms are not well controlled (sub-optimally managed) on other JAK2 therapy.

In May 2015, we announced the final results from PERSIST-1, our Phase 3 trial evaluating the efficacy and safety of pacritinib compared to BAT (Best Available Therapy), excluding JAK2 inhibitors, which included a broad range of currently utilized treatments, in 327 patients with myelofibrosis regardless of the patients' platelet counts. The study included patients with severe or life-threatening thrombocytopenia. Patients were randomized to receive 400 mg pacritinib once daily or BAT, excluding JAK2 inhibitors. The trial met its primary endpoint of spleen volume reduction (SVR) (35 percent or greater from baseline to Week 24 by magnetic resonance imaging (MRI) or computerized tomography (CT)). The most common treatment-emergent adverse events (AEs), occurring in 20 percent or more of patients treated with pacritinib within 24 weeks, of any grade, were gastrointestinal (generally manageable diarrhea and nausea) and anemia.

In February 2016, clinical studies under the investigational new drug (IND) for pacritinib were subject to a full clinical hold issued by the FDA. A full clinical hold is a suspension of the clinical work requested under the IND application. Under the full clinical hold, all patients currently on pacritinib were required to discontinue pacritinib immediately and no patients could be enrolled or start pacritinib as initial or crossover treatment. In its written notification, the FDA cited the reasons for the full clinical hold were that it noted interim overall survival results from the PERSIST-2 Phase 3 trial showing a detrimental effect on survival consistent with the results from PERSIST-1.

In February 2016, prior to the clinical hold, we completed patient enrollment in the PERSIST-2 Phase 3 clinical trial. Under the full clinical hold, all patients participating in the PERSIST-2 clinical trial discontinued pacritinib treatment.

In August 2016, we announced the top-line results from PERSIST-2, our Phase 3 trial of pacritinib for the treatment of patients with myelofibrosis whose platelet counts are less than or equal to 100,000 per microliter. Three hundred eleven (311) patients were enrolled in the study, which formed the basis for the safety analysis. Two hundred twenty-one (221) patients had a chance to reach Week 24 (the primary analysis time point) at the time the clinical hold was imposed and constituted the intent-to-treat analysis population utilized for the evaluation of efficacy. Results demonstrated that the PERSIST-2 trial met one of the co-primary endpoints showing a statistically significant response rate in SVR in patients with myelofibrosis treated with pacritinib compared to BAT, including the approved JAK2 inhibitor ruxolitinib. The co-primary endpoint of reduction of Total Symptom Score (TSS) was not achieved but trended toward improvement in TSS. There was no significant difference in overall survival across treatment arms, censored at the time of clinical hold. The most common treatment-emergent AEs, occurring in 20 percent or more of patients treated with pacritinib within 24 weeks, of any grade, were gastrointestinal (generally manageable diarrhea, nausea and vomiting) and hematologic (anemia and thrombocytopenia) and were generally less frequent for twice-daily (BID) versus once-daily (QD) administration. Details of the trial were presented in a late-breaking oral session at the American Society of Hematology Annual Meeting in December 2016.

In January 2017, the FDA removed the full clinical hold following review of our complete response submission which included, among other items, final Clinical Study Reports for both PERSIST-1 and 2 trials and a dose-exploration clinical trial protocol that the FDA requested. At that time, we announced that we intend to conduct a new trial, PAC203, that plans to enroll up to approximately 105 patients with primary myelofibrosis who have failed prior ruxolitinib therapy to evaluate the dose response relationship for safety and efficacy (SVR at 12 and 24 weeks) of three dose regimens: 100 mg QD, 100 mg BID and

200 mg BID. The 200 mg BID dose regimen was used in PERSIST-2. The Company expects to initiate the trial in the second quarter of 2017.

The Marketing Authorization Application, or MAA, for pacritinib was submitted to the European Medicines Agency, or EMA, in February 2016 with an indication statement based on the PERSIST-1 trial data. In its initial assessment report, the Committee for Medicinal Products for Human Use (CHMP) determined that the current application is not approvable at this point in the review cycle because of major objections in the areas of efficacy, safety (hematological and cardiovascular toxicity) and the overall risk-benefit profile of pacritinib. Subsequent to the filing of the MAA, data from the second phase 3 trial of pacritinib, PERSIST-2, were reported. These data suggest that pacritinib may show clinical benefit in patients who have failed or are intolerant to ruxolitinib therapy, a population for which there is no approved therapy.

Following discussions with the EMA about how PERSIST-2 data might address the major objections and how to integrate the data into the current application, we have decided to withdraw the MAA. We are preparing a new MAA that seeks to address the major objections by including data from PERSIST-2 that will focus on patients with baseline platelet counts less than or equal to 100,000 per microliter, including patients with prior exposure to JAK2 inhibitor therapy. We plan to submit this application mid-year 2017.

#### **Other Pipeline Candidates**

Our earlier stage product candidate, tosedostat, is a novel oral, once-daily aminopeptidase inhibitor that has demonstrated significant responses in patients with AML. It is currently being evaluated in several Phase 2 cooperative group-sponsored trials and investigator-sponsored trials. These trials are evaluating tosedostat in combination with hypomethylating agents in AML and MDS, which are cancers of the blood and bone marrow. We anticipate data from these signal-finding trials may be used to determine an appropriate design for a Phase 3 trial.

#### **Management and Board of Directors**

In February 2017, we announced the appointment of Adam Craig, M.D., Ph.D., as President and Chief Executive Officer (CEO) and member of the Board of Directors effective March 20, 2017. Dr. Craig has over 20 years of experience in hematology, oncology and drug development in both the US and Europe. Dr. Craig worked as an independent consultant providing strategic and operational advice and support to CTI BioPharma and other hematology/oncology biotechnology companies. Prior to consulting, Dr. Craig was Chief Medical Officer (CMO) and Executive Vice President of Development at Sunesis Pharmaceuticals from 2012 to 2016. From 2008 to 2012, Dr. Craig was CMO and Senior Vice President of Chemgenex Pharmaceuticals Ltd. Dr. Craig is a Member of the Royal College of Physicians (UK) and undertook Post-Graduate Training in Pediatrics and Pediatric Oncology. Dr. Craig earned his Bachelor's and Medical degrees from Charing Cross and Westminster Medical School, University of London and holds a Ph.D. in Molecular Oncology from Leeds University in the U.K. and an MBA from the Open Business School, in the U.K. Dr. Craig recently served as a Product Development Reviewer for the Cancer Prevention Research Institute of Texas.

In January 2017, we announced that Michael A. Metzger was appointed a Director of CTI BioPharma. Mr. Metzger is currently president and chief operating officer of Syndax Pharmaceuticals, Inc., a publicly traded immuno-oncology biopharmaceutical company. Mr. Metzger served as president and chief executive officer of Regado Biosciences, Inc., a former publicly traded biotechnology company, from 2013 to 2015, where he oversaw the company's successful merger with Tobira Therapeutics, Inc. in 2015 and acted as an advisor to Tobira during its subsequent sale to Allergan in 2016. Previously, Mr. Metzger served as executive vice president and chief operating officer at Mersana Therapeutics, a privately held biotechnology company developing novel immunoconjugate therapies for cancer, from 2011 to 2013 and in senior business development positions including leading mergers and acquisitions at Forest Laboratories, Inc. from 2006 to 2011. Mr. Metzger served as vice president corporate development at Onconova Therapeutics, Inc., from 2001 until 2006, and was a managing director at MESA Partners, Inc., a venture capital firm, from 1997 to 2001.

#### **Financial Summary**

Our revenues are generated from a combination of PIXUVRI sales and collaboration and license agreements. Collaboration revenues reflect the earned amount of upfront payments and milestone payments under our product collaborations. Total revenues were \$0.8 million and \$36.5 million for the three months ended March 31, 2017 and 2016, respectively. Our loss from operations for the three months ended March 31, 2017 was \$19.3 million, compared to income from operations of \$4.1 million for the three months ended March 31, 2016. Our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, you should not rely on them as being indicative of our future performance.

As of March 31, 2017, cash and cash equivalents were \$33.3 million.

## RESULTS OF OPERATIONS

### Three months ended March 31, 2017 and 2016

**Product sales, net.** We sell PIXUVRI primarily through a limited number of wholesale distributors. Servier is responsible for distribution of PIXUVRI in the respective countries in its territory. We generally record product sales upon receipt of the product by the health care provider or distributor at which time title and risk of loss pass.

Product sales, net include royalty revenue as well as a provision for distributor discounts, estimated government-mandated discounts and rebates, trade discounts and estimated product returns. Product sales, net from PIXUVRI were \$0.7 million and \$1.2 million for the three months ended March 31, 2017 and 2016, respectively, and included royalty revenue of \$0.1 million for the three months ended March 31, 2017. No royalty revenue was recorded during the three months ended March 31, 2016. The decrease in product sales, net of \$0.5 million for the three months ended March 31, 2017 from the respective period in 2016 was primarily related to pricing and volume variances between the periods presented as well as the decline in average exchange rate of the euro for our euro-denominated sales and the average exchange rate of the British pound for our pound-denominated sales.

The provision for product returns relates to a limited right of return or replacement that we offer to certain customers. Distributor discounts, returns and rebates were \$0.1 million during the three months ended March 31, 2017 while no material amount was recorded for the same period in 2016. During the periods presented, there were no other material payments and credits applied towards provision for discounts, rebates and other for current or prior period sales.

Gross sales is defined as our contracted reimbursement price in each country. Gross sales from PIXUVRI were \$0.7 million and \$1.2 million for the three months ended March 31, 2017 and 2016, respectively.

Any expansion of our commercial operations in the E.U. (including with regard to sales of PIXUVRI) may increase our exposure to fluctuations in foreign currency exchange rates. Future revenues, if any, are dependent on market acceptance of PIXUVRI, the reimbursement decisions made by governmental authorities in each country where PIXUVRI is available for sale and other factors.

### License and Contract Revenues

License and contract revenues are summarized as follows (in thousands):

		Three Months Ended March 31,	
		2017	2016
Baxalta	Milestone and license revenue	\$ —	\$ 32,000
	Development services revenue	—	2,876
	<b>Total Baxalta revenue</b>	<b>—</b>	<b>34,876</b>
Servier	Milestone and license revenue	—	—
	Development services revenue	68	376
	<b>Total Servier revenue</b>	<b>68</b>	<b>376</b>
<b>Total license and contract revenue</b>		<b>\$ 68</b>	<b>\$ 35,252</b>

## Baxalta

In October 2016, we resumed primary responsibility for the development and commercialization of pacritinib as a result of the termination of the Pacritinib License Agreement with Baxalta Incorporated and its affiliates, or Baxalta, which is now part of Shire plc. As such, we will no longer be eligible to receive cost sharing or milestone payments for pacritinib's development from Baxalta.

During the three months ended March 31, 2016, we recorded milestone revenue of \$32.0 million. We received the cash advance for these milestone payments in the second quarter of 2015; it was accounted for as long-term debt until the achievement of the associated milestones in the first quarter of 2016. No such milestone payments were received during the three months ended March 31, 2017 due to the termination of the Pacritinib License Agreement as discussed above.

During the three months ended March 31, 2016, we recorded \$2.9 million of development services revenue, of which \$2.7 million was related to the reimbursable development costs from Baxalta under the terms of the Pacritinib License Agreement and \$0.2 million was related to the upfront payment we received in connection with the execution of the Pacritinib License Agreement in 2013. No such revenue was recorded during the same period in 2017 due to the termination of the Pacritinib License Agreement as discussed above.

For additional information relating to the Pacritinib License Agreement, see Part I, Item 2, "License Agreements and Milestone Activities - Baxalta".

## Servier

In February 2016, we entered into an agreement with one of Servier's affiliates whereby we are to conduct a pharmacokinetic sub-study on behalf of Servier in conjunction with our ongoing clinical trial, PIX-306. In relation to this study, we recorded \$42,000 and \$0.4 million of expense reimbursements as development services revenue during the three months ended March 31, 2017 and 2016, respectively.

We recognized \$26,000 of revenue for the three months ended March 31, 2017 and 2016, respectively, relating to development services allocated from the upfront payment we received in connection with the agreement in place with Servier. The remaining deferred revenue balance was \$0.6 million as of both March 31, 2017 and December 31, 2016. In addition, the deferred revenue balance as of March 31, 2017 included a \$0.2 million prepayment related to the pharmacokinetic sub-study. There was no such prepayment as of December 31, 2016.

For additional information on our collaboration with Servier, see Part I, Item 2, "License Agreements and Milestone Activities - Servier".

## Operating costs and expenses

**Cost of product sold.** Cost of product sold is related to sales of PIXUVRI. Cost of product sold for the three months ended March 31, 2017 and 2016 was \$0.1 million and \$0.2 million, respectively. The decrease in cost of product sold was primarily related to a decline in quantity of inventory sold between periods in addition to a decline in the euro between periods. This was partially offset by an increase in the per unit cost of product sold related to the product mix of the reduced-cost inventory.

We began capitalizing costs related to the production of PIXUVRI in February 2012 upon receiving a positive opinion for conditional marketing authorization by the EMA's CHMP. While we tracked the quantities of individual PIXUVRI product lots, we did not track manufacturing costs prior to capitalization and, therefore, the manufacturing cost of PIXUVRI produced prior to capitalization is not reasonably determinable. We expect approximately half of this reduced-cost inventory will be available for us to use commercially and to fulfill expected demand under the Restated Agreement with Servier. Accordingly, we have reserved \$1.5 million of existing inventory expected to be unsalable as of both March 31, 2017 and December 31, 2016. The timing of the sales of such reduced-cost inventory and its impact on gross margin is dependent on the level of PIXUVRI sales as well as our ability to utilize this inventory prior to its expiration date. We expect that our cost of product sold as a percentage of product sales may increase in future periods as PIXUVRI product manufactured and expensed prior to capitalization is sold; however, such future cost trend will ultimately depend on several factors in the near term, including, but not limited to, the consumption rate and availability of reduced cost inventory, the effect of expiring inventory and applicable manufacturing pricing structures (which will depend, in part, on the particular drug substance manufacturers we select.)

**Research and development expenses.** Our research and development expenses for compounds under development and preclinical development were as follows (in thousands):

	Three Months Ended March 31,	
	2017	2016
Compounds:		
PIXUVRI	\$ 2,065	\$ 3,503
Pacritinib	4,105	11,625
Opaxio	3	26
Tosedostat	106	377
Operating expenses	2,953	4,932
Research and preclinical development	21	383
Total research and development expenses	<u>\$ 9,253</u>	<u>\$ 20,846</u>

Costs for our compounds include external direct expenses such as principal investigator fees, charges from contract research organizations, or CROs, and contract manufacturing fees incurred for preclinical, clinical, manufacturing and regulatory activities associated with preparing the compounds for submissions of NDAs or similar regulatory filings to the FDA, the EMA or other regulatory agencies outside the U.S. and Europe, as well as upfront license fees for acquired technology. Subsequent to receiving a positive opinion for conditional approval of PIXUVRI in the E.U. from the EMA's CHMP, costs associated with commercial batch production, quality control, stability testing, and certain other manufacturing costs of PIXUVRI were capitalized as inventory. Operating expenses include our personnel and an allocation of occupancy, depreciation and amortization expenses associated with developing these compounds. Research and preclinical development costs primarily include costs associated with external laboratory services associated with the compound under development by Aequus Biopharma, Inc. We are not able to capture the total cost of each compound because we do not allocate operating expenses to all of our compounds. External direct costs incurred by us as of March 31, 2017 were \$122.5 million for PIXUVRI (excluding costs prior to our 2004 merger with Novuspharma S.p.A, formerly a public pharmaceutical company located in Italy), \$119.2 million for pacritinib (excluding costs for pacritinib prior to our acquisition of certain assets from S\*BIO, in May 2012 and \$29.1 million of in-process research and development expenses associated with the acquisition of certain assets from S\*BIO), \$228.0 million for Opaxio and \$14.0 million for tosedostat (excluding costs for tosedostat prior to our co-development and license agreement with Chroma Therapeutics Limited, or Chroma, in 2011 and \$21.9 million of in-process research and development expenses associated with the acquisition of certain assets from Chroma).

Research and development expenses decreased to \$9.3 million for the three months ended March 31, 2017 compared to \$20.8 million for the same period in 2016. The decrease was primarily attributed to a decrease in pacritinib development costs as a result of the full clinical hold, a decrease in operating expenses primarily attributed to personnel costs associated with a reduction in average headcount between periods, and a reduction in PIX306 comparator drug purchases between periods.

Regulatory agencies, including the FDA and EMA, regulate many aspects of a product candidate's life cycle, including research and development and preclinical and clinical testing. We will need to commit significant time and resources to develop our current and any future product candidates. Our product candidates pacritinib and tosedostat are currently in clinical development, and our product PIXUVRI, which is currently being commercialized in parts of Europe, is undergoing a post-authorization trial. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. We are unable to provide the nature, timing and estimated costs of the efforts necessary to complete the development of pacritinib and tosedostat, and to complete the post-authorization PIX306 trial of PIXUVRI, because, among other reasons, we cannot predict with any certainty the pace of patient enrollment of our clinical trials, which is a function of many factors, including the availability and proximity of patients with the relevant condition and the availability of the compounds for use in the applicable trials. We rely on third parties to conduct clinical trials, which may result in delays or failure to complete trials if the third parties fail to perform or meet applicable standards. Even after a clinical trial is enrolled, preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval and advancement of this compound through the development process. We or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks. For example, on February 8, 2016, the FDA placed a full clinical hold on pacritinib. Even if our drugs progress successfully through initial human testing in clinical trials, they may fail in later stages of development. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after reporting promising results in earlier trials. For these reasons, among others, we cannot estimate the date on which clinical development of our product candidates will be completed, if ever, or when we will generate material net cash inflows from PIXUVRI or be able to begin commercializing pacritinib or tosedostat to generate material net

cash inflows. In order to generate revenue from these compounds, our product candidates need to be developed to a stage that will enable us to commercialize, sell or license related marketing rights to third parties.

We also enter into collaboration agreements for the development and commercialization of our product candidates. We cannot control the amount and timing of resources our collaborators devote to product candidates, which may also result in delays in the development or marketing of products. Because of these risks and uncertainties, we cannot accurately predict when or whether we will successfully complete the development of our product candidates or the ultimate product development cost.

The risks and uncertainties associated with completing development on schedule and the consequences to operations, financial position and liquidity if the project is not timely completed are discussed in more detail in our risk factors, which can be found in Part II, Item 1A, "Risk Factors" of this Quarterly Report on Form 10-Q.

***Selling, general and administrative expenses.*** Selling, general and administrative expenses were \$10.7 million for the three months ended March 31, 2017 compared to \$11.3 million for the same period in 2016. This decrease was primarily attributable to a \$0.6 million decrease in personnel costs, a \$0.3 million decrease in bad debt expense, a \$0.3 million decrease in professional fees for marketing initiatives related to our drug candidate, pacritinib, a \$0.3 million decrease in pacritinib promotional costs previously shared with our collaboration partner, Baxalta, a \$0.3 million decrease in travel costs, and \$0.3 million decrease in other expense. Offsetting these decreases were a \$1.0 million increase to legal fees, a \$0.2 million increase in audit and tax related fees, a \$0.2 million increase in consulting and other professional service costs for PIXUVRI, and a \$0.1 million increase in general consulting fees.

#### **Non-operating income and expenses**

***Interest expense.*** Interest expense for the three months ended March 31, 2017 and 2016 was \$0.5 million and \$0.7 million, respectively. Interest expense was primarily related to our senior secured term loan.

***Amortization of debt discount and issuance costs.*** Amortization of debt discount and issuance costs for the three months ended March 31, 2017 and 2016 was \$38,000 and \$0.1 million, respectively, and was related to our senior secured term loan in 2017 and to the senior secured term loan and the Baxalta milestone advances in 2016.

***Foreign exchange (loss) gain.*** The foreign exchange loss for the three months ended March 31, 2017 and the gain for the three months ended March 31, 2016 were due to fluctuations in foreign currency exchange rates, primarily related to operations in our European branches and subsidiaries denominated in foreign currencies.

***Other non-operating expense.*** Other non-operating expense of \$0.5 million for the three months ended March 31, 2016 represents the other-than-temporary impairment recognized on our investment in equity securities.

## **LIQUIDITY AND CAPITAL RESOURCES**

### ***Overview***

***Cash and cash equivalents.*** As of March 31, 2017, we had \$33.3 million in cash and cash equivalents.

***Net cash used in operating activities.*** Net cash used in operating activities decreased to \$8.7 million during the three months ended March 31, 2017 compared to \$23.1 million for the same period in 2016. This decrease was primarily due to decreases in spending for research and development expenses for the three months ended March 31, 2017 compared to the same period in 2016, and the collection of \$7.7 million in receivables from collaborative arrangements in 2017, as well as timing of cash payments related to operating activities between the two periods.

***Net cash used in investing activities.*** There was no cash used in investing activities for the three months ended March 31, 2017. Net cash used in investing activities of \$29,000 for the same period in 2016 was due to purchases of property and equipment.

*Net cash used in financing activities.* Net cash used in financing activities was \$2.0 million and \$0.2 million for the three months ended March 31, 2017 and 2016, respectively. The increase was primarily due to repayment of our senior secured term loan.

In October 2016, we resumed primary responsibility for the development and commercialization of pacritinib as a result of the termination of the Pacritinib License Agreement. We currently have no commitments or arrangements for additional financing to fund the development and commercial launch of pacritinib, and we will need to seek additional funding. The development and commercialization of a major product candidate like pacritinib without a collaborative partner will require a substantial amount of our time and financial resources, and as a result, we will experience a decrease in our liquidity and a new demand on our capital resources. For additional information relating to the Pacritinib License Agreement, see Part I, Item 2, “License Agreements and Milestone Activities - Baxalta.”

### ***Capital Resources***

We have prepared our condensed consolidated financial statements assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. However, we believe that our present financial resources, together with payments projected to be received under certain contractual agreements and our ability to control costs, will only be sufficient to fund our operations into the third quarter of 2017. This raises substantial doubt about our ability to continue as a going concern. Further, we have incurred net losses since inception and expect to generate losses for the foreseeable future, primarily due to research and development costs for PIXUVRI, pacritinib, and tosedostat. Because of our reacquisition of worldwide rights for pacritinib, we will no longer be eligible to receive cost sharing or milestone payments for pacritinib’s development from Baxalta, and losses related to research and development for pacritinib will increase. We have historically funded our operations through equity financings, borrowings and funds obtained under product collaborations, any or all of which may not be available to us in the future. As of March 31, 2017, our available cash and cash equivalents totaled \$33.3 million. We had an outstanding principal balance under our senior secured term loan agreement of \$17.6 million.

Financial resource forecasts are subject to change as a result of a variety of risks and uncertainties. Changes in manufacturing, developments in and expenses associated with our clinical trials and the other factors identified under “*Capital Requirements*” below may consume capital resources earlier than planned. Additionally, we may not receive the anticipated milestone payments or achieve projected net sales from PIXUVRI. Due to these and other factors, the foregoing forecast for the period for which we will have sufficient resources to fund our operations may fail.

### ***Capital Requirements***

We will need to raise additional funds to operate our business. We may seek to raise such capital through public or private equity financings, partnerships, collaborations, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources of financing. However, we have a limited number of authorized shares of common stock available for issuance and additional funding may not be available on favorable terms or at all. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. If we fail to obtain additional capital when needed, our ability to operate as a going concern will be harmed, and we may be required to delay, scale back or eliminate some or all of our research and development programs, reduce our selling, general and administrative expenses, be unable to attract and retain highly qualified personnel, refrain from making our contractually required payments when due (including debt payments) and/or may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection.

Our future capital requirements will depend on many factors, including:

- developments in and expenses associated with our research and development activities;
- acquisitions of compounds or other assets;
- changes in manufacturing;
- ability to generate sales of PIXUVRI;
- regulatory approval developments;
- ability to execute appropriate collaborations for development and commercialization activities;



- ability to reach milestones triggering payments under certain of our contractual arrangements;
- litigation and other disputes;
- competitive market developments; and
- other unplanned business developments.

As of March 31, 2017, our contractual purchase obligations for which payments are due over the next 12 months, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016, decreased by approximately \$0.7 million.

## LICENSE AGREEMENTS AND MILESTONE ACTIVITIES

### *Servier*

In September 2014, we entered into an Exclusive License and Collaboration Agreement, or the Original Servier Agreement, pursuant to which we granted Servier an exclusive and sublicensable (subject to certain conditions) royalty-bearing license with respect to the development and commercialization of PIXUVRI for use in pharmaceutical products outside of Austria, Denmark, Finland, Germany, Israel, Norway, Sweden, Turkey, the U.K. and the U.S.

We received an upfront payment in October 2014 of €14.0 million (or \$17.8 million using the currency exchange rate as of the date we received the funds). In addition, subject to the achievement of certain conditions, the Original Servier Agreement provided for us to potentially receive milestone payments thereunder in the aggregate amount of up to €89.0 million, which was comprised of the following: up to €49.0 million in potential clinical and regulatory milestone payments (of which €9.5 million was payable upon occurrence of certain enrollment events in connection with the PIX306 study for PIXUVRI); and up to €40.0 million in potential sales-based milestone payments. As of March 31, 2017, of these potential milestone payments, we have received a €1.5 million (or \$1.7 million upon conversion from euros as of the date we received the funds) milestone payment relating to the attainment of reimbursement approval for PIXUVRI in Spain and a €7.5 million (or \$8.0 million upon conversion from euros as of the date we achieved the milestone in December 2016) milestone payment relating to the occurrence of a certain enrollment event in the PIX306 study.

In April 2017, we entered into an Amended and Restated Exclusive License and Collaboration Agreement (the "Restated Agreement") with Servier (together with the Company, the "Parties") pursuant to which the Parties amended and restated the Exclusive License and Collaboration Agreement entered into by the Parties on September 16, 2014 (the "Original Agreement") regarding the development and commercialization of PIXUVRI (to the extent incorporated in a pharmaceutical product, the "Licensed Product(s)"). The Restated Agreement replaces the Original Agreement in its entirety.

We have obtained conditional marketing authorization in the E.U. to market PIXUVRI for the treatment of adult patients with relapsed or refractory aggressive non-Hodgkin B-cell lymphomas. Under the Restated Agreement, we will transfer our European marketing authorization to Servier upon positive, statistically significant results in an ongoing post-authorization Phase III clinical trial, PIX306, unless Servier elects to terminate the Restatement Agreement within thirty (30) days after the positive results.

Under the Restated Agreement, we have granted to Servier an exclusive, sublicensable (subject to certain exceptions) license to manufacture the Licensed Products worldwide, and an exclusive, sublicensable (subject to certain exceptions) license to develop and commercialize the Licensed Products worldwide, excluding the U.S. (the "Company Territory"). The Parties have agreed to enter into a commercialization transition plan by July 31, 2017 whereby we will transfer to Servier medical affairs and commercialization activities relating to the Licensed Products in Austria, Denmark, Finland, Germany, Israel, Norway, Sweden, Turkey and the U.K. (collectively, the "Transition Territory"). Upon the implementation of the commercialization transition plan, we will terminate or assign certain distributor and wholesaler contracts to Servier in the Transition Territory. Each party will be responsible for the manufacture and supply of drug products and substances in their respective territories.

We will receive payments of €12.0 million from Servier, which includes €2.0 million for a new milestone previously achieved, and Servier is obligated to purchase a certain amount of PIXUVRI drug product for an additional €0.9 million within 30 days of the Restated Agreement. Subject to the achievement of certain conditions, we are eligible to receive additional milestone payments from Servier in the aggregate amount of up to €76.0 million, which is comprised of the following: up to €36.0 million in potential regulatory milestone payments and up to €40.0 million in potential sales milestone payments. We are eligible to receive tiered royalty payments ranging from a low-double digit percentage up to a percentage in the low-twenties

based on net sales of the Licensed Product, subject to certain reductions of up to mid-double digit percentages under certain circumstances. The Parties will no longer use a joint marketing plan, and marketing costs will no longer be shared equally between the Parties; instead Servier will be solely responsible for marketing costs within Europe. Mutually agreed upon development costs other than PIX306 will continue to be shared equally between the Parties, which represents no change to the development cost sharing.

The Restated Agreement also requires the Parties to amend the trademark license agreement entered into between the Parties on June 8, 2015 to provide for Servier's right to use of our trademark PIXUVRI in connection with Licensed Products worldwide, excluding the Company Territory.

#### *Baxalta*

In November 2013, we entered into a Development, Commercialization and License Agreement, dated as of November 14, 2013, with Baxter International Inc., or Baxter, for the development and commercialization of pacritinib for use in oncology and potentially additional therapeutic areas, or the Original Pacritinib License Agreement. The Original Pacritinib License Agreement, the rights and obligations to which Baxter had assigned to Baxalta, was amended by the License Amendment, effective June 8, 2015. The Original Pacritinib License Agreement, as amended by the License Amendment, is referred to herein as the "Pacritinib License Agreement." Under the Pacritinib License Agreement, Baxalta had an exclusive, worldwide (subject to co-promotion rights discussed below), royalty-bearing, non-transferable license (which was sub-licensable under certain circumstances) relating to pacritinib. Licensed products under the Pacritinib License Agreement consisted of products in which pacritinib is an ingredient.

We received an upfront payment of \$60.0 million under the Pacritinib License Agreement, which included a \$30.0 million investment in our equity. The Pacritinib License Agreement also provided for us to receive potential additional payments of up to \$302.0 million upon the successful achievement of certain development and commercialization milestones, comprised of \$112.0 million of potential clinical, regulatory and commercial launch milestone payments, and potential additional sales milestone payments of up to \$190.0 million. To date, we have received milestone payments of \$52.0 million.

In June 2015, we entered into the License Amendment. Pursuant to the License Amendment, two potential milestone payments in the aggregate amount of \$32.0 million from Baxalta to us were accelerated from the schedule contemplated by the original Pacritinib License Agreement relating to the PERSIST-2 Milestone and the MAA Milestone. In the first quarter of 2016, we recorded \$32.0 million in *license and contract revenue* upon attainment of the milestones.

In October 2016, we regained worldwide rights for the development and commercialization of pacritinib following termination of the Pacritinib License Agreement with Baxalta. Pursuant to the termination, Baxalta paid us a one-time cash payment in the amount of approximately \$10.3 million as reimbursement for certain expenses incurred or to be incurred. In exchange, we have agreed to provide a one-time payment to Baxalta, upon the first regulatory approval or any pricing and reimbursement approvals of a product containing pacritinib, in the amount of approximately \$10.3 million which represents certain amounts paid by Baxalta for the benefit of the pacritinib program manufacturing efforts. We have also agreed not to transfer, license, sublicense or otherwise grant rights with respect to intellectual property of pacritinib unless the transferee/licensee/sublicensee agrees to be bound by the terms of the Asset Return and Termination Agreement with Baxalta.

#### *University of Vermont*

We entered into an agreement with the University of Vermont, or UVM, in March 1995, as amended, or the UVM Agreement, which grants us an exclusive sublicensable license for the rights to PIXUVRI. Pursuant to the UVM Agreement, we acquired the rights to make, have made, sell and use PIXUVRI, and we are obligated to make royalty payments to UVM ranging from low single digits to mid-single digits as a percentage of net sales. The higher royalty rate is payable for net sales in countries where specified UVM licensed patents exist, or where we have obtained orphan drug protection, until such UVM patents or such protection no longer exists. For a period of ten years after first commercialization of PIXUVRI, the lower royalty rate is payable for net sales in such countries after expiration of the designated UVM patents or loss of orphan drug protection, and in all other countries without such specified UVM patents or orphan drug protection. Unless otherwise terminated, the term of the UVM Agreement continues for the life of the licensed patents in those countries in which a licensed patent exists, and continues for ten years after the first sale of PIXUVRI in those countries where no such patents exist. We may terminate the UVM Agreement, on a country-by-country basis or on a patent-by-patent basis, at any time upon advance written notice. UVM may terminate the UVM Agreement upon advance written notice in the event royalty payments are not made. In addition, either party may terminate the UVM Agreement in the event of an uncured material breach of the UVM Agreement by the other party or in the event of bankruptcy of the other party.

### *S\*BIO*

We acquired the compounds SB1518 (which is referred to as “pacritinib”) and SB1578, which inhibit JAK2 and FLT3, from S\*BIO in May 2012. Under our agreement with S\*BIO, we are required to make milestone payments to S\*BIO up to an aggregate amount of \$132.5 million if certain U.S., E.U. and Japanese regulatory approvals are obtained or if certain worldwide net sales thresholds are met in connection with any pharmaceutical product containing or comprising any compound that we acquired from S\*BIO for use for specific diseases, infections or other conditions. At our election, we may pay up to 50% of any milestone payments to S\*BIO through the issuance of shares of our common stock or shares of our preferred stock convertible into our common stock. In addition, S\*BIO will also be entitled to receive royalty payments from us at incremental rates in the low single-digits based on certain worldwide net sales thresholds on a product-by-product and country-by-country basis.

### *Vernalis*

We entered into an amended and restated exclusive license agreement with Vernalis (R&D) Limited, or Vernalis, in October 2014, or the Vernalis License Agreement, for the exclusive worldwide right to use certain patents and other intellectual property rights to develop, market and commercialize tosedostat and certain other compounds. Under the Vernalis License Agreement, we have agreed to make tiered royalty payments of no more than a high single-digit percentage of net sales of products containing licensed compounds, with such obligation to continue on a country-by-country basis for the longer of ten years following commercial launch or the expiry of relevant patent claims.

The Vernalis License Agreement will terminate when the royalty obligations expire, although the parties have early termination rights under certain circumstances, including the following: (i) we have the right to terminate, with three months’ notice, upon the belief that the continued development of tosedostat or any of the other licensed compounds is not commercially viable; (ii) Vernalis has the right to terminate in the event of our uncured failure to pay sums due; and (iii) either party has the right to terminate in the event of the other party’s uncured material breach or insolvency.

### *Gynecologic Oncology Group*

We entered into an agreement with the Gynecologic Oncology Group, now part of NRG Oncology, in March 2004, as amended, related to the GOG-0212 trial of Opaxio it is conducting in patients with ovarian cancer. Pursuant to the terms of such agreement, we paid an aggregate of \$1.2 million in milestone payments during 2014 based on certain enrollment milestones achieved. A milestone of \$0.5 million has been recorded in accounts payable as of March 31, 2017. We may be required to pay an additional \$0.5 million upon the attainment of a certain milestone. No further development of Opaxio is planned.

### *PG-TXL*

In November 1998, we entered into an agreement with PG-TXL, as amended in February 2006, or the PG-TXL Agreement, which granted us an exclusive worldwide license for the rights to Opaxio and to all potential uses of PG-TXL’s polymer technology. Pursuant to the PG-TXL Agreement, we acquired the rights to research, develop, manufacture, market and sell anti-cancer drugs developed using this polymer technology. Pursuant to the PG-TXL Agreement, we were obligated to make payments to PG-TXL upon the achievement of certain development and regulatory milestones of up to \$14.4 million. The timing of the remaining milestone payments under the PG-TXL Agreement was based on trial commencements and completions for compounds protected by PG-TXL license rights, and regulatory and marketing approval of those compounds by the FDA and the EMA. Additionally, we were required to make royalty payments to PG-TXL based on net sales. Our royalty obligations ranged from low to mid-single digits as a percentage of net sales. In February 2017, we terminated our agreement with PG-TXL and the exclusive worldwide license for rights to Opaxio and certain polymer technology under our agreement with PG-TXL.

### *Novartis*

In January 2014, we entered into a Termination Agreement, or the Novartis Termination Agreement, with Novartis, to reacquire the rights to PIXUVRI previously granted to Novartis under our agreement entered into in September 2006, as amended, or the Original Novartis Agreement. Pursuant to the Novartis Termination Agreement, the Original Novartis Agreement was terminated in its entirety, except for certain customary provisions, including those pertaining to confidentiality and indemnification, which survive termination.

Under the Novartis Termination Agreement, we agreed not to transfer, license, sublicense or otherwise grant rights with respect to intellectual property of PIXUVRI and Opaxio unless the recipient thereof agrees to be bound by the terms of the

Novartis Termination Agreement. We also agreed to provide potential payments to Novartis, including a percentage ranging from the low double-digits to the mid-teens, of any consideration received by us or our affiliates in connection with any transfer, license, sublicense or other grant of rights with respect to intellectual property of PIXUVRI or Opaxio; provided that such payments will not exceed certain prescribed ceilings in the low single-digit millions. Novartis is entitled to receive potential payments of up to \$16.6 million upon the successful achievement of certain sales milestones of PIXUVRI and Opaxio. We are also obligated to pay to Novartis tiered low single-digit percentage royalty payments for the first several hundred million dollars in annual net sales, and 10% royalty payments thereafter based on annual net sales of each of PIXUVRI and Opaxio, subject to reduction in the event generic drugs are introduced and sold by a third party, causing the sale of PIXUVRI to fall by a percentage in the high double digits. Royalty payments for PIXUVRI are subject to certain minimum floor percentages in the low single digits.

#### *Teva Pharmaceutical Industries Ltd.*

In June 2005, we entered into an acquisition agreement with Cephalon, Inc., or Cephalon, pursuant to which we divested the compound, TRISENOX. Cephalon was subsequently acquired by Teva Pharmaceutical Industries Ltd., or Teva. Under this agreement, we have the right to receive up to \$100 million in payments upon achievement by Teva of specified sales and development milestones related to TRISENOX. To date, we have received \$30.0 million of such potential milestone payments as a result of having achieved certain sales milestones.

#### *Other Agreements*

We have several agreements with CROs, third-party manufacturers and distributors that have durations of greater than one year for the development and distribution of certain of our compounds.

### **CRITICAL ACCOUNTING ESTIMATES**

We make certain judgments and use certain estimates and assumptions when applying accounting principles generally accepted in the U.S. in the preparation of our condensed consolidated financial statements. We evaluate our estimates and judgments on an on-going basis and base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Our experience and assumptions form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary materially from what we anticipate and different assumptions or estimates about the future could change our reported results. For a discussion of our critical accounting estimates, please see Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our 2016 Form 10-K. There have been no material changes to our critical accounting estimates discussed therein.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk.**

#### *Foreign Exchange Market Risk*

We are exposed to risks associated with the translation of euro-denominated financial results and accounts into U.S. dollars for financial reporting purposes. The carrying value of the assets and liabilities held in our European branches and subsidiaries will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. In addition, certain of our contractual arrangements, such as the Restated Agreement with Servier, denote monetary amounts in foreign currencies, and consequently, the ultimate financial impact to us from a U.S. dollar perspective is subject to significant uncertainty. Changes in the value of the U.S. dollar as compared to applicable foreign currencies (in particular, the euro) might have an adverse effect on our reported results of operations and financial condition. As the net positions of our unhedged foreign currency transactions fluctuate, our earnings might be negatively affected. As of March 31, 2017, we had a net asset balance, excluding intercompany payables and receivables, in our European branches and subsidiaries denominated in euros. If the euro were to weaken 20 percent against the dollar, our net asset balance would decrease by approximately \$1.3 million as of this date.

#### *Interest Rate Risk*

Our senior secured term loan bears interest at variable rates. Based on the outstanding principal balance under such loan at March 31, 2017 of \$17.6 million, a hypothetical increase of 1.0% in interest rates would result in additional interest expense of \$0.1 million over the next twelve months. For a detailed discussion of our senior secured term loan, including a discussion of the applicable interest rate, refer to Part II, Item 8, "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 8. Long-term Debt" in our 2016 Form 10-K.

#### **Item 4. Controls and Procedures.**

##### **(a) Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in U.S. Securities and Exchange Commission, or SEC, rules and forms, and that such information is accumulated and communicated to our management to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Our management, under the supervision and with the participation of our President and Chief Executive Officer and Executive Vice President, Chief Commercial and Administrative Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our President and Chief Executive Officer and Executive Vice President, Chief Commercial and Administrative Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective.

In connection with its review, our management noted that we are conducting an internal investigation whether certain expense reimbursements that we paid comported with our policy for the executive management team. We have not concluded our investigation and the outcome of the investigation may or may not result in the identification of significant deficiencies or material weaknesses in the design or operation of our internal control over financial reporting or the identification of deficiencies in our expense reimbursement procedures.

Our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, regardless of how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system will be met. These inherent limitations include the following:

- Judgments in decision-making can be faulty, and control and process breakdowns can occur because of simple errors or mistakes.
- Controls can be circumvented by individuals, acting alone or in collusion with each other, or by management override.
- The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.
- Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected.

##### **(b) Changes in Internal Control over Financial Reporting**

There have been no changes to our internal control over financial reporting that occurred during the first fiscal quarter ended March 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II – OTHER INFORMATION

### Item 1. Legal Proceedings

In April 2009, December 2009 and June 2010, the Italian Tax Authority, or the ITA, issued notices of assessment to CTI - Sede Secondaria, or CTI (Europe), based on the ITA's audit of CTI (Europe)'s value added tax, or VAT, returns for the years 2003, 2005, 2006 and 2007. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). The assessments, including interest and penalties, for the years 2003, 2005, 2006 and 2007 are €0.5 million, €5.5 million, €2.5 million and €0.8 million, respectively. We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We are defending ourselves against the assessments both on procedural grounds and on the merits of the case, although we can make no assurances regarding the ultimate outcome of these cases. If the final decision of the Italian Supreme Court is unfavorable to us, or if, in the interim, the ITA were to make a demand for payment and we were to be unsuccessful in suspending collection efforts, we may be requested to pay the ITA an amount up to €9.4 million, or approximately \$10.1 million converted using the currency exchange rate as of March 31, 2017, plus collection fees, notification expenses and additional interest for the period lapsed between the date in which the assessments were issued and the date of effective payment.

Following is a summary of the status of the legal proceedings surrounding each respective VAT year return at issue:

- 2003 VAT. In September 2011, the Provincial Tax Court issued decision no. 229/3/2011, which (i) fully accepted the merits of our appeal, (ii) declared that no penalties can be imposed against us, and (iii) found the ITA liable to pay us €10,000, as partial refund of the legal expenses we incurred for our appeal. In October 2012, the ITA appealed this decision. In June 2013, the Regional Tax Court issued decision no. 119/50/13, which accepted the appeal of the ITA and reversed the previous decision of the Provincial Tax Court. We believe that such decision has not carefully taken into account our arguments and the documentation we filed, and therefore appealed such decision in front of the Supreme Court both on procedural grounds and on the merits of the case in January 2014. In January 2014 the Company was provided a notice of payment with which the ITA requested the advance payment of €0.4 million of VAT, interest and penalties. We paid such amount in March 2014.
- 2005 VAT. In January 2011, the Provincial Tax Court issued decision No. 4/2010 which (i) partially accepted our appeal and declared that no penalties can be imposed against us, (ii) confirmed the right of the ITA to reassess the VAT (plus interest) in relation to the transactions identified in the 2005 notice of assessment and (iii) repealed the suspension of the notice of deposit payment. Both the ITA and the Company appealed to the higher court against the decision. In October 2012, the Regional Tax Court issued decision no. 127/31/2012, which (i) fully accepted the merits of our appeal and (ii) confirmed that no penalties can be imposed against us. In April 2013, the ITA appealed the decision to the Italian Supreme Court.
- 2006 VAT. In October 2011, the Provincial Tax Court issued decision no. 276/21/2011 (jointly with the 2007 VAT case) in which it (i) fully accepted the merits of our appeal, (ii) declared that no penalties can be imposed against us, and (iii) found that for the 2006 and 2007 VAT cases the ITA was liable to pay us €10,000 as partial refund of the legal expenses incurred for the appeal. In December 2011, the ITA appealed this decision to the Regional Tax Court. On April 16, 2013, the Regional Tax Court issued decision no. 57/35/13 (jointly with the 2007 VAT case) in which it fully rejected the merits of the ITA's appeal, declared that no penalties can be imposed against us, and found the ITA liable to pay us €12,000, as partial refund of the legal expenses we incurred for this appeal. In November 2013, the ITA appealed the decision to the Supreme Court.
- 2007 VAT. In October 2011, the Provincial Tax Court issued decision no. 276/21/2011 (jointly with the 2006 VAT case described above) in which the Provincial Tax Court (i) fully accepted the merits of our appeal, (ii) declared that no penalties can be imposed against us, and (iii) found that for the 2006 and 2007 VAT cases the ITA was liable to pay us €10,000 as partial refund of the legal expenses incurred for the appeal. In December 2011, the ITA appealed this decision to the Regional Tax Court. On April 16, 2013, the Regional Tax Court issued decision no. 57/35/13 (jointly with the 2006 VAT case) in which it fully rejected the merits of the ITA's appeal, declared that no penalties can be imposed against us, and found the ITA liable to pay us €12,000, as partial refund of the legal expenses we incurred for this appeal. In November 2013, the ITA appealed the decision to the Supreme Court.

#### *Securities and Exchange Commission Subpoena*

We previously disclosed that we had received a subpoena from the SEC in January 2016. We believe that the SEC is seeking to determine whether there have been possible violations of the antifraud and certain other provisions of the federal

securities laws related to the Company's disclosures concerning, among other things, the clinical test results of pacritinib. The SEC Staff's letter sent with the subpoena stated that the investigation is a fact-finding inquiry, and the investigation and subpoena do not mean that the SEC has concluded that we or anyone else has violated any law. We are cooperating with this investigation, which is ongoing.

*In re CTI BioPharma Corp. Securities Litigation*

On February 10, 2016 and February 12, 2016, class action lawsuits entitled *Ahrens v. CTI BioPharma Corp. et al.*, Case No. 1:16-cv-01044 and *McGlothlin v. CTI BioPharma Corp. et al.*, Case No. C16-216, respectively, were filed in the United States District Court for the Southern District of New York and the United States District Court for the Western District of Washington, respectively, on behalf of shareholders that purchased or acquired the Company's securities pursuant to our September 24, 2015 public offering and/or shareholders who otherwise acquired our stock between March 4, 2014 and February 9, 2016, inclusive. The complaints assert claims against the Company and certain of our current and former directors and officers for violations of the federal securities laws under Sections 11 and 15 of the Securities Act of 1933, as amended, or the Securities Act, and Sections 10 and 20 of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Plaintiffs' Securities Act claims allege that the Company's Registration Statement and Prospectus for the September 24, 2015 public offering contained materially false and misleading statements and failed to disclose certain material adverse facts about the Company's business, operations and prospects, including with respect to the clinical trials and prospects for pacritinib. Plaintiffs' Exchange Act claims allege that the Company's public disclosures were knowingly or recklessly false and misleading or omitted material adverse facts, again with a primary focus on the clinical trials and prospects for pacritinib. On May 2, 2016, the Company filed a motion to transfer the Ahrens case to the United States District Court for the Western District of Washington. The motion was unopposed and granted by the court on May 19, 2016. On June 3, 2016, the parties filed a joint motion to consolidate the McGlothlin case with the Ahrens case in order to proceed as a single consolidated proceeding. On June 13, 2016, the court granted the motion to consolidate with the action being captioned *In re CTI BioPharma Corp. Securities Litigation*, Master File No. 2:16-cv-00216-RSL. On September 2, 2016, the court appointed Lead Plaintiffs and Lead Counsel. On September 28, 2016, the court entered a scheduling order, as revised by order entered December 8, 2016, setting November 8, 2016 as the deadline to file a consolidated class action complaint and deadlines for briefing defendants' motion to dismiss. Briefing concluded on February 22, 2017. A hearing on the defendants' motion to dismiss has not been set. The consolidated class action complaint asserts claims similar to those asserted in the initial complaints, although it no longer asserts claims relating to the September 24, 2015 public offering, but adds claims relating to the Company's October 27, 2015 and December 4, 2015 public offerings. The lawsuit seeks damages in an unspecified amount. We believe that the allegations contained in the complaints are without merit and intend to vigorously defend ourselves against all claims asserted therein.

*Wei v. James A. Bianco, et al.; England v. James A. Bianco, et al.; Nahar v. James A. Bianco, et al.; Hill v. James A. Bianco, et al.*

On March 14, 2016, a Company shareholder filed the first of four similar derivative lawsuits on behalf of the Company seeking damages for alleged harm to the Company caused by certain current and former officers and directors. The first suit, *Wei v. James A. Bianco, et al.*, 16-2-05818-3, was filed in King County Superior Court, Washington. A second suit, *England v. James A. Bianco, et al.*, 16-2-14422-5, was filed in King County Superior Court, Washington, on June 16, 2016. Two additional derivative suits, *Nahar v. James A. Bianco, et al.*, 2:16-cv-0756, and *Hill v. James A. Bianco, et al.*, 2:16-cv-1250, were filed in the United States District Court for the Western District of Washington on May 24, 2016 and August 9, 2016, respectively. The four suits raise similar allegations and seek similar relief against certain current and former officers and directors, including James A. Bianco, Louis A. Bianco, Jack W. Singer, Bruce J. Seeley, John H. Bauer, Phillip M. Nudelman, Reed V. Tuckson, Karen Ignagni, Richard L. Love, Mary O. Munding and Frederick W. Telling. Consistent with the requirements of a derivative action, the Company is named in each suit as a nominal defendant against which no monetary relief is sought. The complaints generally allege claims of: (1) breach of fiduciary duty; (2) abuse of control; (3) gross mismanagement; and (4) waste of corporate assets and (5) unjust enrichment (receiving compensation that was unjust in light of the alleged conduct). Each is based on the assertion that the Company made materially false and misleading statements and omitted material information from its disclosures about pacritinib and its safety. Plaintiffs in none of the suits made a pre-suit demand on the current Board to investigate whether to pursue claims against officers or directors, instead claiming demand is excused because the named defendants lack independence, are not disinterested because they lack impartiality, received and want to continue to receive their compensation, have longstanding personal and business relationships, and cannot evaluate a demand since they are facing personal liability. Each of plaintiffs' suits requested the court to award the Company the damages allegedly sustained as a result of the conduct and to direct the Company and the individual defendants to reform and improve the Company's corporate governance to avoid future damages. On March 29, 2017 during mediation, the parties to the derivative suits reached an agreement in principle to settle all four suits subject to Board and court approvals. As part of the settlement, CTI has agreed to adopt certain corporate governance reforms and agreed not to object to an attorneys' fee

application by plaintiffs' counsel of up to \$800,000 collectively. There is no admission of liability or any wrongdoing by any of the individual defendants or CTI.

In addition to the items discussed above, we are from time to time subject to legal proceedings and claims arising in the ordinary course of business.

#### **Item 1A. Risk Factors**

*This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. The occurrence of any of the risks described below and elsewhere in this document, including the risk that our actual results may differ materially from those anticipated in these forward-looking statements, could materially adversely affect our business, financial condition, liquidity, operating results or prospects and the trading price of our securities. Additional risks and uncertainties that we do not presently know or that we currently deem immaterial may also harm our business, financial condition, operating results and prospects and the trading price of our securities.*

#### **Factors Affecting Our Business, Financial Condition, Operating Results and Prospects**

*We will need to raise additional funds to operate our business, but additional funds may not be available on acceptable terms, or at all. Any inability to raise required capital when needed could harm our liquidity, financial condition, business, operating results and prospects.*

We have substantial operating expenses associated with the development of our compounds and the commercialization of PIXUVRI, and we have significant contractual payment obligations. Our available cash and cash equivalents were \$33.3 million as of March 31, 2017. We believe that our present financial resources, together with payments projected to be received under certain of our contractual agreements and our ability to control costs, will only be sufficient to fund our operations into the third quarter of 2017. Cash forecasts and capital requirements are subject to change as a result of a variety of risks and uncertainties. Developments in and expenses associated with our clinical trials and other research and development activities, including the resumption of primary responsibilities for the development and commercialization of pacritinib as a result of the termination of the Pacritinib License Agreement in October 2016, acquisitions of compounds or other assets, our ability to generate projected sales of PIXUVRI, any expansion of our sales and marketing organization for PIXUVRI, regulatory approval developments, our ability to consummate appropriate collaborations for development and commercialization activities, our ability to reach milestones triggering payments under applicable contractual arrangements, receive the associated payments, litigation and other disputes, competitive market developments and other unplanned expenses or business developments may consume capital resources earlier than planned. Due to these and other factors, any forecast for the period for which we will have sufficient resources to fund our operations, as well as any other operational or business projection we have disclosed, or may, from time to time, disclose, may fail.

As of March 31, 2017, we had an outstanding principal balance under our senior secured term loan agreement of \$17.6 million. We were required to make monthly interest-only payments in respect thereof in the approximate amount of \$0.2 million until March 31, 2016. Following March 31, 2016, we are required to make monthly interest plus principal payments through December 1, 2018 in the approximate amount of \$0.8 million, with the final principal payment of approximately \$3.3 million on December 1, 2018. These borrowings are secured by a first priority security interest on substantially all of our personal property except our intellectual property and subject to certain other exceptions. In addition, the senior secured term loan agreement requires us to comply with restrictive covenants, including those that limit our operating flexibility and ability to borrow additional funds. A failure to make a required loan payment or an uncured covenant breach could lead to an event of default, and in such case, all amounts then outstanding may become due and payable immediately.

We will need to raise additional funds to operate our business. We may seek to raise such capital through public or private equity financings, partnerships, collaborations, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources of financing. However, our ability to do so is subject to a number of risks, uncertainties, constraints and consequences, including, but not limited to, the following:

- our ability to raise capital through the issuance of additional shares of our common stock or convertible securities is restricted by the limited number of our residual authorized shares, the potential difficulty of obtaining shareholder approval to increase authorized shares and the restrictive covenants under our senior secured term loan agreement;



- issuance of equity-based securities will dilute the proportionate ownership of existing shareholders;
- our ability to obtain further funds from any potential loan arrangements is limited by our existing senior secured term loan agreement;
- certain financing arrangements may require us to relinquish rights to various assets and/or impose more restrictive terms than any of our existing or past arrangements; and
- we may be required to meet additional regulatory requirements, and we may be subject to certain contractual limitations, which may increase our costs and harm our ability to obtain funding.

For these and other reasons, additional funding may not be available on favorable terms or at all. If we fail to obtain additional capital when needed, we may be required to delay, scale back or eliminate some or all of our research and development programs, reduce our selling, general and administrative expenses, be unable to attract and retain highly qualified personnel, refrain from making our contractually required payments when due (including debt payments) and/or be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. Any of these consequences could harm our business, financial condition, operating results and prospects.

*Our audit report for the year ended December 31, 2016 contains an explanatory paragraph on our consolidated financial statements, and we may in the future, receive additional such reports.*

Our independent registered public accounting firm included an explanatory paragraph in its reports on our consolidated financial statements for the year ended December 31, 2016 regarding their substantial doubt as to our ability to continue as a going concern. We believe that our present financial resources, together with payments projected to be received under certain contractual agreements and our ability to control costs, will only be sufficient to fund our operations into the third quarter of 2017, which does raise substantial doubt about our ability to continue as a going concern. The inclusion of a going concern explanatory paragraph in our audit report for the year ended December 31, 2016 and for future years may negatively impact the trading price of our common stock and make it more difficult, time consuming or expensive to obtain necessary financing, and we cannot guarantee that we will not receive such an explanatory paragraph in the future.

*We expect to continue to incur net losses, and we may never achieve profitability.*

We were incorporated in 1991 and have incurred a net operating loss every year since our formation. As of March 31, 2017, we had an accumulated deficit of \$2.2 billion, and we expect to continue to incur net losses. As part of our business plan, we will need to continue to conduct research, development, testing and regulatory compliance activities with respect to our compounds and ensure the procurement of manufacturing and drug supply services, the costs of which, together with projected general and administrative expenses, is expected to result in operating losses for the foreseeable future. There can be no assurances that we will ever achieve profitability.

*In order to develop and commercialize pacritinib, we will need to raise additional financing or seek a new collaboration partner for pacritinib.*

We have resumed primary responsibility for the development and commercialization of pacritinib as a result of the termination of the Pacritinib License Agreement in October 2016, and we will no longer be eligible to receive cost sharing or milestone payments for pacritinib's development from Baxalta. Because obtaining regulatory approval requires substantial time, effort and financial resources, the termination of this collaborative partnership could negatively impact our ability to successfully develop and commercialize pacritinib. We currently have no commitments or arrangements for any additional financing to fund the development and commercial launch of pacritinib, and we will need to seek additional funding, which may not be available or may not be available on favorable terms. We could also seek another collaborative partnership for the development and commercialization of pacritinib, which may not be available on reasonable terms or at all.

*If our development and commercialization collaborations are not successful, or if we are unable to enter into additional collaborations, we may not be able to effectively develop and/or commercialize our compounds, which could have a material adverse effect on our business.*

Our business is heavily dependent on the success of our development and commercialization collaborations. In particular, under the Restated Agreement with Servier, we rely heavily on Servier to collaborate with us to develop and commercialize PIXUVRI. As a result of our dependence on our relationship with Servier, the success or commercial viability of PIXUVRI is, to a certain extent, beyond our control. We are subject to a number of specific risks associated with our

dependence on our collaborative relationship with Servier, including the following: possible disagreements as to the timing, nature and extent of development plans for the respective compound, including clinical trials or regulatory approval strategy; changes in their respective personnel who are key to the collaboration efforts; any changes in their respective business strategies adverse to our interests, whether in connection with a change of control or otherwise; possible disagreements regarding ownership of proprietary rights; the ability to meet our financial and other contractual obligations under the respective agreements; and the possibility that Servier could elect to terminate their agreement with us pursuant to “at-will” termination clauses or breach their agreement with us. Furthermore, the contingent financial returns under our collaboration with Servier depends in large part on the achievement of development and commercialization milestones and the ability to generate applicable product sales to trigger royalty payments. Therefore, our success, and any associated future financial returns to us and our investors, will depend in large part on the performance of Servier. If our existing collaborations fail, or if we do not successfully enter into additional collaborations when needed, we may be unable to further develop and commercialize the applicable compounds, generate revenues to sustain or grow our business or achieve profitability, which would harm our business, financial condition, operating results and prospects.

*The regulatory approval process for pacritinib has been subject to delay and uncertainty associated with clinical holds placed on pacritinib clinical trials in February 2016 and the planned withdrawal of the MAA in Europe. While the full clinical hold on pacritinib trials has been removed and we plan to submit a new MAA mid-year 2017, our planned dose-exploration trial for pacritinib and further clinical trials for pacritinib could be subject to further delay or we could be prevented from further studying pacritinib or seeking its commercialization.*

On February 8, 2016, the FDA notified us that a full clinical hold had been placed on pacritinib and we subsequently withdrew our NDA for pacritinib until we determine next steps. A full clinical hold is a suspension of the clinical work requested under an investigational new drug application. Under the full clinical hold, all patients currently on pacritinib were required to discontinue pacritinib, and we are not permitted to enroll any new patients or start pacritinib as initial or crossover treatment. In its written notification, the FDA noted interim overall survival results from PERSIST-2 showing a detrimental effect on survival consistent with the results from PERSIST-1, and that deaths in PERSIST-2 in pacritinib-treated patients include intracranial hemorrhage, cardiac failure and cardiac arrest. On January 3, 2017, the full clinical hold was removed. Our complete response submission included, among other items, final Clinical Study Reports for both PERSIST-1 and 2 trials and the dose-exploration clinical trial protocol requested by the FDA. We plan to start the new trial, PAC203, in the second quarter of 2017 and enroll up to approximately 105 patients with primary myelofibrosis who have failed prior ruxolitinib therapy to evaluate the dose response relationship for safety and efficacy (spleen volume reduction at 12 or 24 weeks) of three dose regimens: 100 mg once-daily, 100 mg twice-daily (BID) and 200 mg BID. The 200 mg BID dose regimen was used in PERSIST-2. The results of PAC203 may not address all of the FDA’s concerns regarding appropriate safe and efficacious dosage for pacritinib, and the FDA may again request additional information or require us to pursue new clinical safety trials with changes to, among other things, protocol, study design or sample size.

Further, in the EMA’s initial assessment report regarding our MAA, the CHMP determined that the current application is not approvable because of major objections in the areas of efficacy, safety (hematological and cardiovascular toxicity) and the overall risk-benefit profile of pacritinib. Subsequent to the filing of the MAA, data from the second phase 3 trial of pacritinib, PERSIST-2, were reported. These data suggest that pacritinib may show clinical benefit in patients who have failed or are intolerant to ruxolitinib therapy, a population for which there is no approved therapy. Following discussions with the EMA about how PERSIST-2 data might address the major objections and how to integrate the data into the current application, we have decided to withdraw the MAA. We are preparing a new MAA that seeks to address the major objections by including data from PERSIST-2. The new application will focus on patients who have failed or are intolerant to ruxolitinib. We plan to submit this new application mid-year 2017.

The submission of new marketing applications, complying with any additional requests for information from the FDA or EMA or making any changes to protocol, study design, or sample size may be time-consuming, expensive and delay or prevent our ability to continue to study pacritinib. If we are unable to address any further recommendations and requests or the EMA’s major objections in a manner satisfactory to the FDA or EMA, as applicable, in a timely manner, or at all, we could be delayed or prevented from seeking commercialization of pacritinib. Delays in the commercialization of pacritinib would prevent us from receiving future milestone or royalty payments, and otherwise significantly harm our business.

*Compounds that appear promising in research and development may fail to reach later stages of development for a number of reasons, including, among others, that clinical trials may take longer to complete than expected or may not be completed at all, and top-line or preliminary clinical trial data reports may ultimately differ from actual results once existing data are more fully evaluated.*

Successful development of anti-cancer and other pharmaceutical products is highly uncertain, and obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and speculative. Compounds that appear promising in research and development may fail to reach later stages of development for several reasons, including, but not limited to:

- delay or failure in obtaining necessary U.S. and international regulatory approvals, or the imposition of a partial or full regulatory hold on a clinical trial;
- difficulties in formulating a compound, scaling the manufacturing process, timely attaining process validation for particular drug products and obtaining manufacturing approval;
- pricing or reimbursement issues or other factors that may make the product uneconomical to commercialize;
- production problems, such as the inability to obtain raw materials or supplies satisfying acceptable standards for the manufacture of our products, equipment obsolescence, malfunctions or failures, product quality/contamination problems or changes in regulations requiring manufacturing modifications;
- inefficient cost structure of a compound compared to alternative treatments;
- obstacles resulting from proprietary rights held by others with respect to a compound, such as patent rights;
- lower than anticipated rates of patient enrollment as a result of factors, such as the number of patients with the relevant conditions, the proximity of patients to clinical testing centers, eligibility criteria for tests and competition with other clinical testing programs;
- preclinical or clinical testing requiring significantly more time than expected, resources or expertise than originally expected and inadequate financing, which could cause clinical trials to be delayed or terminated;
- failure of clinical testing to show potential products to be safe and efficacious, and failure to demonstrate desired safety and efficacy characteristics in human clinical trials;
- suspension of a clinical trial at any time by us, an applicable collaboration partner or a regulatory authority on the basis that the participants are being exposed to unacceptable health risks or for other reasons;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs, and trial sites; and
- failure of third parties, such as CROs, academic institutions, collaborators, cooperative groups and/or investigator sponsors, to conduct, oversee and monitor clinical trials and results.

In addition, from time to time we report top-line data for clinical trials. Such data are based on a preliminary analysis of then-available efficacy and safety data, and such findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. Top-line or preliminary data are based on important assumptions, estimations, calculations and information then available to us to the extent we have had, at the time of such reporting, an opportunity to fully and carefully evaluate such information in light of all surrounding facts, circumstances, recommendations and analyses. As a result, top-line results may differ from future results, or different conclusions or considerations may qualify such results once existing data have been more fully evaluated. In addition, third parties, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular compound and our business in general.

If the development of our compounds is delayed or fails, or if top-line or preliminary clinical trial data reported differ from actual results, our development costs may increase and the ability to commercialize our compounds may be harmed, which could harm our business, financial condition, operating results or prospects.

*We or our collaboration partners may not obtain or maintain the regulatory approvals required to develop or commercialize some or all of our compounds.*

We are subject to rigorous and extensive regulation by the FDA in the U.S. and by comparable agencies in other jurisdictions, including the EMA in the E.U. Some of our other product candidates are currently in research or development and, other than conditional marketing authorization for PIXUVRI in the E.U., we have not received marketing approval for our

compounds. Our products may not be marketed in the U.S. until they have been approved by the FDA and may not be marketed in other jurisdictions until they have received approval from the appropriate foreign regulatory agencies. Each product candidate requires significant research, development and preclinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval. Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our products on a timely basis, or at all. For instance, on February 8, 2016, the FDA placed pacritinib on full clinical hold and the clinical hold was not removed until January 3, 2017. The number, size, design and focus of preclinical and clinical trials that will be required for approval by the FDA, the EMA or any other foreign regulatory agency varies depending on the compound, the disease or condition that the compound is designed to address and the regulations applicable to any particular compound. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. The FDA, the EMA and other foreign regulatory agencies can delay, limit or deny approval of a compound for many reasons, including, but not limited to:

- a compound may not be shown to be safe or effective;
- the clinical and other benefits of a compound may not outweigh its safety risks;
- clinical trial results may be negative or inconclusive, or adverse medical events may occur during a clinical trial;
- the results of clinical trials may not meet the level of statistical significance required by regulatory agencies for approval;
- such regulatory agencies may interpret data from pre-clinical and clinical trials in different ways than we do;
- such regulatory agencies may not approve the manufacturing process of a compound or determine that a third party contract manufacturers manufactures a compound in accordance with current good manufacturing practices, or cGMPs;
- a compound may fail to comply with regulatory requirements; or
- such regulatory agencies might change their approval policies or adopt new regulations.

If our compounds are not approved at all or quickly enough to provide net revenues to defray our operating expenses, our business, financial condition, operating results and prospects could be harmed.

*In the event that we seek and the FDA does not grant accelerated approval or priority review for a drug candidate, we would experience a longer time to commercialization in the U.S., if commercialized at all, our development costs may increase and our competitive position may be harmed.*

We were seeking accelerated approval and requested Priority Review of our NDA for pacritinib. However, on February 8, 2016, the FDA notified us that a full clinical hold had been placed on pacritinib and we subsequently withdrew our NDA for pacritinib. On January 3, 2017, the full clinical hold was removed, and we now intend to conduct a new trial, PAC203, that plans to enroll up to approximately 105 patients with primary myelofibrosis who have failed prior ruxolitinib therapy to evaluate the dose response relationship for safety and efficacy (spleen volume reduction at 12 and 24 weeks) of three dose regimens: 100 mg once-daily, 100 mg twice-daily (BID) and 200 mg BID. The 200 mg BID dose regimen was used in PERSIST-2.

We may in the future decide to seek accelerated approval pathway for our compounds. The FDA may grant accelerated approval to a product designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. A surrogate endpoint under an accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. There can be no assurance that the FDA will agree that any endpoint we suggest with respect to any of our drug candidates is an appropriate surrogate endpoint. Furthermore, there can be no assurance that any application will be accepted or that approval will be granted. Even if a product candidate is granted accelerated approval, such accelerated approval is contingent on the sponsor's agreement to conduct one or more post-approval confirmatory trials. Such confirmatory trial(s) must be completed with due diligence and, in some cases, the FDA may require that the trial(s) be designed and/or initiated prior to approval. Moreover, the FDA may withdraw approval of a product candidate or indication approved under the accelerated approval pathway for a variety of reasons, including if the trial(s) required to verify the predicted clinical benefit of a product candidate fail to verify such benefit or do not demonstrate sufficient

clinical benefit to justify the risks associated with the drug, or if the sponsor fails to conduct any required post-approval trial(s) with due diligence.

In the event of priority review, the FDA has a goal to (but is not required to) take action on an application within a total of eight months (rather than a goal of twelve months for a standard review). The FDA grants priority review only if it determines that a product treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared to a standard application. The FDA has broad discretion whether to grant priority review, and, while the FDA has granted priority review to other oncology product candidates, our drug candidates may not receive similar designation. Moreover, receiving priority review from the FDA does not guarantee completion of review or approval within the targeted eight-month cycle or thereafter.

A failure to obtain accelerated approval or priority review would result in a longer time to commercialization of the applicable compound in the U.S., if commercialized at all, could increase the cost of development and could harm our competitive position in the marketplace.

*Even if our compounds are successful in clinical trials and receive regulatory approvals, we or our collaboration partners may not be able to successfully commercialize them.*

The development and ongoing clinical trials for our compounds may not be successful and, even if they are, the resulting products may never be successfully developed into commercial products. Even if we are successful in our clinical trials and in obtaining other regulatory approvals, the respective products may not reach or remain in the market for a number of reasons including:

- they may be found ineffective or cause harmful side effects;
- they may be difficult to manufacture on a scale necessary for commercialization;
- they may experience excessive product loss due to contamination, equipment failure, inadequate transportation or storage, improper installation or operation of equipment, vendor or operator error, inconsistency in yields or variability in product characteristics;
- they may be uneconomical to produce;
- political and legislative changes emerging after the recent election of the President of the United States may make the commercialization of our product candidates more difficult;
- we may fail to obtain reimbursement approvals or pricing that is cost effective for patients as compared to other available forms of treatment or that covers the cost of production and other expenses;
- they may not compete effectively with existing or future alternatives;
- we may be unable to develop commercial operations and to sell marketing rights;
- they may fail to achieve market acceptance; or
- we may be precluded from commercialization of a product due to proprietary rights of third parties.

In particular, with respect to the commercialization of PIXUVRI, we will be heavily dependent on our collaboration partner, Servier. The failure of Servier (or any other applicable collaboration partner) to fulfill its commercialization obligations with respect to a compound, or the occurrence of any of the events in the list above, could adversely affect the commercialization of our products. Additionally, uncertainty and speculation regarding the possible repeal of all or a portion of the Patient Protection and Affordable Care Act has emerged after the recent election of the President of the United States. Members of the Trump administration, including the President, have made statements suggesting the administration plans to seek repeal of all or portions of the Affordable Care Act, and have stated that they will ask Congress to replace the current legislation with new legislation. The uncertainty this causes for the healthcare industry could also adversely affect the commercialization of our products. If we fail to commercialize products or if our future products do not achieve significant market acceptance, we will not likely generate significant revenues or become profitable.

*The pharmaceutical business is subject to increasing government price controls and other restrictions on pricing, reimbursement and access to drugs, which could adversely affect our future revenues and profitability.*

To the extent our products are developed, commercialized and successfully introduced to market, they may not be considered cost-effective and third-party or government reimbursement might not be available or sufficient. Globally, governmental and other third-party payors are becoming increasingly aggressive in attempting to contain health care costs by strictly controlling, directly or indirectly, pricing and reimbursement and, in some cases, limiting or denying coverage altogether on the basis of a variety of justifications, and we expect pressures on pricing and reimbursement from both governments and private payors inside and outside the U.S. to continue. In the U.S., we are subject to substantial pricing, reimbursement and access pressures from state Medicaid programs, private insurance programs and pharmacy benefit managers, and implementation of U.S. health care reform legislation is increasing these pricing pressures. The Patient Protection and Affordable Care Act instituted comprehensive health care reform, which includes provisions that, among other things, reduce and/or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose new and/or increased taxes. In addition, members of the Trump administration, including the President, have made public statements criticizing pricing practices within the pharmaceutical industry, indicating that they may seek to increase pricing pressures on the pharmaceutical industry.

In almost all European markets, pricing and choice of prescription pharmaceuticals are subject to governmental control. Therefore, the price of our products and their reimbursement in Europe is and will be determined by national regulatory authorities. Reimbursement decisions from one or more of the European markets may impact reimbursement decisions in other European markets. A variety of factors are considered in making reimbursement decisions, including whether there is sufficient evidence to show that treatment with the product is more effective than current treatments, that the product represents good value for money for the health service it provides and that treatment with the product works at least as well as currently available treatments. The continuing efforts of government and insurance companies, health maintenance organizations and other payors of health care costs to contain or reduce costs of health care may affect our future revenues and profitability or those of our potential customers, suppliers and collaborative partners, as well as the availability of capital.

*We may never be able to generate significant product revenues from the sale of PIXUVRI.*

We anticipate that, for at least the next several years, our ability to generate revenues and become profitable will depend, in part, on our ability and that of our collaborator, Servier, to successfully commercialize our only currently marketed product, PIXUVRI. PIXUVRI is not approved for marketing in the U.S., is presently available only in a limited number of countries and is reimbursed in even fewer countries.

In addition, the successful commercialization of PIXUVRI depends heavily on the ability to obtain and maintain favorable reimbursement rates for users of PIXUVRI, as well as on various additional factors, including, without limitation, the ability to:

- obtain an annual renewal of our conditional marketing authorization for PIXUVRI;
- increase demand for and sales of PIXUVRI and obtain greater acceptance of PIXUVRI by physicians and patients;
- establish and maintain agreements with wholesalers and distributors on reasonable terms;
- maintain, and where necessary, enter into additional, commercial manufacturing arrangements with third parties, cost-effectively manufacture necessary quantities and secure distribution, managerial and other capabilities; and
- further develop and maintain a commercial organization to market PIXUVRI.

If we are unable to successfully commercialize PIXUVRI as planned, our business, financial condition, operating results and prospects could be harmed.

*Post-approval or authorization regulatory reviews and obligations often result in significant expense and marketing limitations, and any failure to satisfy such ongoing obligations, including, in particular, our post-authorization commitment trial for PIXUVRI, could negatively affect our business, financial condition, operating results or prospects.*

Even if a product receives regulatory approval or authorization, as applicable, we are and will continue to be subject to numerous regulations and statutes regulating the manner of obtaining reimbursement for and selling the product, including limitations on the indicated uses for which a product may be marketed. Approved or authorized products, including PIXUVRI,

are subject to extensive manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping regulations. These requirements include submissions of safety and other post-marketing information and reports. In addition, such products are subject to ongoing maintenance of product registration and continued compliance with cGMPs, good clinical practices, or GCPs, and good laboratory practices, or GLPs. Further, distribution of products must be conducted in accordance with good distribution practices, or GDPs. The distribution process and facilities of our third-party distributors are subject to, and our wholesale distribution authorization by the UK Medicines and Healthcare Products Regulatory Agency subjects us to, continuing regulation by applicable regulatory authorities with respect to the distribution and storage of products. Regulatory authorities may also impose new restrictions on continued product marketing or may require the withdrawal of a product from the market if adverse events of unanticipated severity or frequency are discovered following approval. In addition, regulatory agencies may impose post-approval/post-authorization clinical trials, such as our ongoing PIX306 trial of PIXUVRI required by the EMA. We cannot predict the outcome of PIX306 or whether we will be able to complete the associated requirements in a timely manner. If we are unable to submit the requisite PIX306 clinical study report by the due date in December 2018 and are unable to obtain an extension of such deadline, or if we are otherwise unable to satisfy all applicable requirements, our conditional marketing authorization for PIXUVRI may be revoked.

Any other failure to comply with applicable regulations could result in warning or untitled letters, product recalls, interruption of manufacturing and commercial supply processes, withdrawal or seizure of products, suspension of an applicable wholesale distribution authorization and/or distribution of products, operating restrictions, injunctions, suspension of licenses, revocation of the applicable product's approval or authorization, other administrative or judicial sanctions (including civil penalties and/or criminal prosecution) and/or unanticipated related expenditure to resolve shortcomings, which could negatively affect our business, financial condition, operating results or prospects.

*We may not be able to maintain our listings on The NASDAQ Capital Market and the Mercato Telematico Azionario, or MTA, in Italy, or trading on these exchanges may otherwise be halted or suspended, which may make it more difficult for investors to sell shares of our common stock and consequently may negatively impact the price of our common stock.*

We regained compliance in January 2017 with the minimum \$1.00 bid price requirement by effecting a 1-for-10 reverse stock split on January 1, 2017, after receiving notice of non-compliance from NASDAQ in March 2016.

We have in the past and may in the future fail to comply with the NASDAQ Stock Market LLC, or NASDAQ. If our common stock ceases to be listed for trading on The NASDAQ Capital Market for failure to comply with the minimum \$1.00 per share closing bid price requirement or for any other reason, it may harm our stock price, increase the volatility of our stock price, decrease the level of trading activity and make it more difficult for investors to buy or sell shares of our common stock. Our failure to maintain a listing on The NASDAQ Capital Market may constitute an event of default under our senior secured term loan and any future indebtedness, which would accelerate the maturity date of such debt or trigger other obligations. In addition, certain institutional investors that are not permitted to own securities of non-listed companies may be required to sell their shares adversely affecting the market price of our common stock. If we are not listed on The NASDAQ Capital Market or if our public float falls below \$75 million, we will be limited in our ability to file new shelf registration statements on SEC Form S-3 and/or to fully use one or more registration statements on SEC Form S-3. We have relied significantly on shelf registration statements on SEC Form S-3 for most of our financings in recent years, so any such limitations may harm our ability to raise the capital we need. Delisting from The NASDAQ Capital Market could also affect our ability to maintain our listing or trading on the MTA in Italy. Trading in our common stock has been halted or suspended on both The NASDAQ Capital Market and MTA in the past and may also be halted or suspended in the future due to market or trading conditions at the discretion of The NASDAQ Stock Market, CONSOB or the Borsa Italiana (which ensures the development of the managed markets in Italy). Any halt or suspension in the trading in our common stock may negatively impact the market price of our common stock.

*We may be unable to obtain a quorum for meetings of our shareholders or obtain requisite shareholder approval and, consequently, be unable to take certain corporate actions, including financing activities.*

Failure to meet the requisite quorum or obtain requisite shareholder approval can prevent us from raising capital through equity financing or otherwise taking certain actions that may be in our best interest and that of our shareholders. We have experienced such difficulties in the past.

We are required under the NASDAQ Marketplace Rules to obtain shareholder approval for any issuance of additional equity securities that would comprise more than 20% of the total shares of our common stock outstanding before the issuance of such securities sold at a discount to the greater of book or market value in an offering that is not deemed to be a "public offering" by the NASDAQ Marketplace Rules, as well as under certain other circumstances. We have in the past and may in the future issue additional equity securities that would comprise more than 20% of the total shares of our common stock

outstanding in order to fund our operations. However, we might not be successful in obtaining the required shareholder approval for any future issuance that requires shareholder approval pursuant to applicable rules and regulations, particularly in light of difficulties we have had in the past in obtaining a quorum and obtaining the requisite vote. If we are unable to obtain financing or our financing options are limited due to shareholder approval difficulties, such failure may harm our ability to continue operations.

Additionally, a portion of our common shares are held by Italian institutions and, under Italian laws and regulations, it is difficult to communicate with the beneficial holders of those shares to obtain votes. In recent years, certain depository banks in Italy holding shares of our common stock have facilitated book-entry transfers of their share positions at Monte Titoli, S.p.A., the Italian central clearing agency, to their U.S. correspondent bank, who would then transfer the shares to an account of the Italian bank at a U.S. broker-dealer that is an affiliate of that bank. Certain of the banks we contacted to facilitate these arrangements agreed to make the share transfers pursuant to these arrangements as of the record date of the shareholder meeting, subject to the relevant beneficial owner being given notice before such record date and taking no action to direct the voting of such shares. Obtaining a quorum and necessary shareholder approvals at shareholder meetings may depend in part upon the willingness of the Italian depository banks to continue participating in the custody transfer arrangements, and we cannot be assured that those banks that have participated in the past will continue to do so in the future.

As a result of the foregoing or for other reasons, we may be unable to obtain a quorum at annual or special meetings of shareholders. Even if we are able to obtain a quorum at our shareholder meetings, we may not obtain enough votes to approve matters to be resolved upon at those meetings. Any failure to obtain a quorum or the requisite vote on a proposal in question could harm us.

*We are subject to Italian regulatory requirements, which limit our ability to issue additional shares of our common stock, could result in administrative and other challenges and additional expenses and/or could limit our ability to undertake other business initiatives.*

Because our common stock is traded on the MTA in Italy, we are required to also comply with the rules and regulations of the Commissione Nazionale per le Società e la Borsa, or CONSOB, and the Borsa Italiana S.p.A., or Borsa Italiana, which regulate companies listed on Italy's public markets. Compliance with Italian regulatory requirements may delay additional issuances of our common stock or other business initiatives. Under Italian law, we must publish a registration document, securities note and summary (which jointly compose a prospectus) that have to be approved by CONSOB prior to issuing common stock that is equal to or exceeds, in any twelve-month period, 10% of the number of shares of our common stock outstanding at the beginning of that period, subject to certain exceptions. If we are unable to obtain and maintain a registration document, securities note or summary to cover general financing efforts under Italian law, we may be required to raise money using alternative forms of securities. For example, we have issued convertible preferred stock in numerous prior offerings and may in the future issue convertible securities; the common stock resulting from the conversion of such securities, subject to current provisions of European Directive No. 71/2003 and according to the current interpretations of the Committee of European Securities Regulators, is not subject to the 10% limitation imposed by E.U. and Italian law. However, this exception to the prospectus requirement could change or cease to be available as a result of changes in regulations, interpretive positions, and policies or otherwise. Any such change may increase compliance costs or limit our ability to issue securities. Compliance with these regulations and responding to periodic information requests from Borsa Italiana and CONSOB requires us to devote additional time and resources to regulatory compliance matters and to incur additional expenses of engaging additional outside counsel, accountants and other professional advisors. Actual or alleged failure to comply with Italian regulators can also subject us to regulatory investigations and fines or other sanctions from time to time.

Any of such regulatory requirements of CONSOB and the Borsa Italiana could result in administrative and other challenges and additional expenses, limit our ability to undertake other business initiatives and negatively affect our business, financial condition, operating results and prospects.

*We will incur a variety of costs for, and may never realize the anticipated benefits of, acquisitions, collaborations or other strategic transactions.*

We evaluate and undertake acquisitions, collaborations and other strategic transactions from time to time. The process of negotiating these transactions, as well as integrating any acquisitions and implementing any strategic alliances, may result in operating difficulties and expenditures. In addition, these transactions may require significant management attention that would otherwise be available for ongoing development of our business, whether or not any such transaction is ever consummated. These undertakings could also result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to intangible assets, and we may never realize the anticipated benefits. In addition, following the consummation of a transaction, our results of operations and the market price of our common stock may



be affected by factors different from those that affected our results of operations and the market price of our common stock prior to such acquisition. Any of the foregoing consequences resulting from transactions of the type described above could harm our business, financial condition, operating results or prospects.

*We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our products for non-FDA-approved, or off-label, uses.*

Our business and future growth depend on the development, ultimate sale and use of products that are subject to FDA, EMA and or other regulatory agencies regulation, clearance and approval. Under the U.S. Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting our products for off-label uses. This means that in the U.S., we may not make claims about the safety or effectiveness of our products and may not proactively discuss or provide information on the use of our products, except as allowed by the FDA.

Government investigations concerning the promotion of off-label uses and related issues are typically expensive, disruptive and burdensome, generate negative publicity and may result in fines or payments of settlement awards. If our promotional activities are found to be in violation of applicable law or if we agree to a settlement in connection with an enforcement action, we would likely face significant fines and penalties and would likely be required to substantially change our sales, promotion, grant and educational activities.

*A failure to comply with the numerous laws and regulations that govern our business, including those related to cross-border conduct, health care fraud and abuse, anti-corruption and false claims and the protection of health information, could result in substantial penalties and prosecution.*

We are subject to risks associated with doing business outside of the U.S., which exposes us to complex foreign and U.S. regulations. For example, we are subject to regulations imposed by the Foreign Corrupt Practices Act, or the FCPA, the Bribery Act 2010 and other anti-corruption laws. These laws generally prohibit U.S. companies and their intermediaries from offering, promising, authorizing or making improper payments to foreign government officials for the purpose of obtaining or retaining business. The SEC and U.S. Department of Justice have increased their enforcement activities with respect to the FCPA. Internal control policies and procedures and employee training and compliance programs that we have implemented to deter prohibited practices may not be effective in prohibiting our employees, contractors or agents from violating or circumventing our policies and the law.

In addition, we are subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. There are similar laws in other countries. These laws may impact, among other things, the sales, marketing and education programs for our products. The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program. The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act can be brought by any individual on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in any amounts paid by the entity to the government in fines or settlement. Many states have also adopted laws similar to the federal Anti-Kickback Statute and False Claims Act.

We may also be subject to the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act and their respective implementing regulations, or HIPAA, which established uniform standards for certain “covered entities” (health care providers, health plans and health care clearinghouses) governing the conduct of certain electronic health care transactions and protecting the security and privacy of protected health information. Among other things, HIPAA’s privacy and security standards are directly applicable to “business associates” - independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. In addition to possible civil and criminal penalties for violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney’s fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

We are unable to predict whether we could be subject to actions under any of the foregoing or similar laws and regulations, or the impact of such actions. If we were to be found to be in violation of applicable laws or regulations, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government health care

reimbursement programs and the curtailment or restructuring of our operations, all of which could have a material adverse effect on our business and results of operations.

*We are dependent on third-party service providers for a number of critical operational activities including, in particular, for the manufacture, testing and distribution of our compounds and associated supply chain operations, as well as for clinical trial activities. Any failure or delay in these undertakings by third parties could harm our business.*

Our business is dependent on the performance by third parties of their responsibilities under contractual relationships. In particular, we rely heavily on third parties for the manufacture and testing of our compounds. We do not have internal analytical laboratory or manufacturing facilities to allow the testing or production of compounds in compliance with GLP and cGMP. As a result, we rely on third parties to supply us in a timely manner with manufactured products/product candidates. We may not be able to adequately manage and oversee the manufacturers we choose, they may not perform as agreed or they may terminate their agreements with us. In particular, we depend on third-party manufacturers to conduct their operations in compliance with GLP and cGMP or similar standards imposed by the U.S. and/or applicable foreign regulatory authorities, including the FDA and EMA. Any of these regulatory authorities may take action against a contract manufacturer who violates GLP and cGMP. Failure of our manufacturers to comply with FDA, EMA or other applicable regulations may cause us to curtail or stop the manufacture of such products until we obtain regulatory compliance.

We may not be able to obtain sufficient quantities of our compounds if we are unable to secure manufacturers when needed, or if our designated manufacturers do not have the capacity or otherwise fail to manufacture compounds according to our schedule and specifications or fail to comply with cGMP regulations. In particular, in connection with the transition of the manufacturing of PIXUVRI and pacritinib drug supply to successor vendors, respectively, we could face logistical, scaling or other challenges that may adversely affect supply. Furthermore, in order to ultimately obtain and maintain applicable regulatory approvals, any manufacturers we utilize are required to consistently produce the respective compounds in commercial quantities and of specified quality or execute fill-finish services on a repeated basis and document their ability to do so, which is referred to as process validation. In order to obtain and maintain regulatory approval of a compound, the applicable regulatory authority must consider the result of the applicable process validation to be satisfactory and must otherwise approve of the manufacturing process. Even if our compound manufacturing processes obtain regulatory approval and sufficient supply is available to complete clinical trials necessary for regulatory approval, there are no guarantees we will be able to supply the quantities necessary to effect a commercial launch of the applicable drug, or once launched, to satisfy ongoing demand. Any compound shortage could also impair our ability to deliver contractually required supply quantities to applicable collaborators, as well as to complete any additional planned clinical trials.

We also rely on third-party service providers for certain warehousing, transportation, sales, order processing, distribution and cash collection services. With regard to the distribution of our compounds, we depend on third-party distributors to act in accordance with GDP, and the distribution process and facilities are subject to continuing regulation by applicable regulatory authorities with respect to the distribution and storage of products.

In addition, we depend on medical institutions and CROs (together with their respective agents) to conduct clinical trials and associated activities in compliance with GCP and in accordance with our timelines, expectations and requirements. To the extent any such third parties are delayed in achieving or fail to meet our clinical trial enrollment expectations, fail to conduct our trials in accordance with GCP or study protocol or otherwise take actions outside of our control or without our consent, our business may be harmed. Furthermore, we conduct clinical trials in foreign countries, subjecting us to additional risks and challenges, including, in particular, as a result of the engagement of foreign medical institutions and foreign CROs, who may be less experienced with regard to regulatory matters applicable to us and may have different standards of medical care.

With regard to certain of the foregoing clinical trial operations and stages in the manufacturing and distribution chain of our compounds, we rely on single vendors. In particular, our current business structure contemplates, at least in the foreseeable future, use of a single commercial supplier for PIXUVRI drug substance. In addition, in the event pacritinib is approved, we are initially preparing to have only one commercial supplier for pacritinib. We may in the future seek to qualify an additional manufacturer of pacritinib, but the process for qualifying a manufacturer can be lengthy and may not occur on a timely basis or at all. The use of single vendors for core operational activities, such as clinical trial operations, manufacturing and distribution, and the resulting lack of diversification, expose us to the risk of a material interruption in service related to these single, outside vendors. As a result, our exposure to this concentration risk could harm our business.

Although we monitor the compliance of our third-party service providers performing the aforementioned services, we cannot be certain that such service providers will consistently comply with applicable regulatory requirements or that they will otherwise timely satisfy their obligations to us. Any such failure and/or any failure by us to monitor their services and to plan for and manage our short and long term requirements underlying such services could result in shortage of the compound, delays

in or cessation of clinical trials, failure to obtain or revocation of product approvals or authorizations, product recalls, withdrawal or seizure of products, suspension of an applicable wholesale distribution authorization and/or distribution of products, operating restrictions, injunctions, suspension of licenses, other administrative or judicial sanctions (including civil penalties and/or criminal prosecution) and/or unanticipated related expenditures to resolve shortcomings. Such consequences could have a significant impact on our business, financial condition, operating results or prospects.

*If we are unable to recruit, retain, integrate and motivate senior management, other key personnel and directors, or if such persons are unable to perform effectively, our business could suffer.*

Our future success depends, in part, on our ability to continue to attract and retain senior management, other key personnel and directors to enable the execution of our business plan and to identify and pursue new opportunities. Additionally, our productivity and the quality of our operations are dependent on our ability to integrate and train our new personnel quickly and effectively. In February 2017, we announced the appointment of Adam Craig, M.D., Ph.D., as President and Chief Executive Officer effective March 2017, and also in March 2017, we announced the appointment of Bruce J. Seeley as Executive Vice President, Chief Commercial and Administrative Officer and Secretary. Leadership transitions and management changes can be difficult to manage and may create uncertainty or disruption to our business or increase the likelihood of turnover in our other officers and employees. We may not be able to effectively manage our transition to a new president and chief executive officer.

Directors and management of publicly traded corporations are increasingly concerned with the extent of their personal exposure to lawsuits and shareholder claims, as well as governmental, creditor and other claims that may be made against them. Due to these and other reasons, such persons are also becoming increasingly concerned with the availability of directors and officers liability insurance to pay on a timely basis the costs incurred in defending such claims. We currently carry directors and officers liability insurance. However, directors and officers liability insurance is expensive and can be difficult to obtain. If we are unable to continue to provide directors and officers sufficient liability insurance at affordable rates or at all, or if directors and officers perceive our ability to do so in the future to be limited, it may become increasingly more difficult to attract and retain management and qualified directors to serve on our Board of Directors.

The loss of the services of senior management, other key personnel or directors and/or the inability to timely attract or integrate such persons could significantly delay or prevent the achievement of our development and strategic objectives and may adversely affect our business, financial condition and operating results.

*We face direct and intense competition from our competitors in the biotechnology and pharmaceutical industries, and we may not compete successfully against them.*

Competition in the oncology market is intense and is accentuated by the rapid pace of technological and product development. We anticipate that we will face increased competition in the future as new companies enter the market. Our competitors in the U.S. and elsewhere are numerous and include, among others, major multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. Specifically:

- In Europe, PIXUVRI faces competition from existing treatments for adults with multiply relapsed or refractory aggressive B-cell NHL. For example, patients are currently being treated with ibrutinib, idelalisib, lenolidimide, bendamustine, oxaliplatin and gemcitabine, although these particular agents do not have regulatory approval in Europe for the foregoing indication. If we were to pursue bringing PIXUVRI to market in the U.S. (which is not currently part of our near-term plan), PIXUVRI would face similar competition.
- If we are successful in bringing pacritinib to market, pacritinib will face competition from the currently approved JAK1/JAK2 inhibitor, Jakafi®.
- If we are successful in bringing tosedostat to market, we will face competition from currently marketed products, such as cytarabine, Dacogen®, Vidaza®, Clolar®, Revlimid® and Thalomid®.

In addition to the specific competitive factors discussed above, new anti-cancer drugs that may be under development or developed and marketed in the future could compete with our various compounds.

Many of our competitors, particularly multinational pharmaceutical companies, either alone or together with their collaborators, have substantially greater financial and technical resources and substantially larger development and marketing teams than us, as well as significantly greater experience than we do in developing, commercializing, manufacturing, marketing and selling products. As a result, products of our competitors might come to market sooner or might prove to be more effective,

less expensive, have fewer side effects or be easier to administer than ours. In any such case, sales of PIXUVRI or any potential future product would likely suffer and we might never recoup the significant investments we have made and will continue to make to develop and market these compounds.

*If any of our license agreements for intellectual property underlying our compounds are terminated, we may lose the right to develop or market that product.*

We have acquired or licensed intellectual property from third parties, including patent applications and patents relating to intellectual property for PIXUVRI, pacritinib and tosedostat. Some of our product development programs depend on our ability to maintain rights under these arrangements. Each licensor has the power to terminate its agreement with us if we fail to meet our obligations under these licenses. We may not be able to meet our obligations under these licenses. If we default under any license agreement, we may lose our right to market and sell any products based on the licensed technology and may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. Bankruptcy may result in the termination of agreements pursuant to which we license certain intellectual property rights.

*If we are unable to in-license or acquire additional product candidates, our future product portfolio and potential profitability could be harmed.*

One component of our business strategy is the in-licensing and acquisition of drug compounds developed by other pharmaceutical and biotechnology companies or academic research laboratories. PIXUVRI, pacritinib and tosedostat have all been in-licensed or acquired from third parties. Competition for new promising compounds and commercial products can be intense. If we are not able to identify future in-licensing or acquisition opportunities and enter into arrangements on acceptable terms, our future product portfolio and potential profitability could be harmed.

*We hold rights under numerous patents that we have acquired or licensed or that protect inventions originating from our research and development, and the expiration of any of these patents may allow our competitors to copy the inventions that are currently protected.*

We dedicate significant resources to protecting our intellectual property, which is important to our business. We have filed numerous patent applications in the U.S. and various other countries seeking protection of inventions originating from our research and development, and we have also obtained rights to various patents and patent applications under licenses with third parties and through acquisitions. Patents have been issued on many of these applications. We have pending patent applications or issued patents in the U.S. and foreign countries directed to PIXUVRI, pacritinib, tosedostat and other product candidates. However, the lives of these patents are limited. Patents for the individual products extend for varying periods according to the date of the patent filing or grant and the legal term of patents in the various countries where patent protection is obtained.

Our PIXUVRI-directed patents currently in force in Europe began to expire in late March 2015 and will continue to expire through a portion of 2023. Some of these European patents are also subject to Supplementary Protection Certificates such that the extended patents will expire from 2020 to 2027. In the United States, our PIXUVRI-directed U.S. patent will expire in 2024. Our PIXUVRI-directed patents outside of Europe and the U.S. began to expire in 2015 and will continue to expire through 2023.

Our U.S. and various foreign pacritinib-directed patents expire from 2026 through 2030. Our U.S. and various foreign tosedostat-directed patents expire from 2017 to 2018.

In the absence of a patent, we would, to the extent possible, need to rely on unpatented technology, know-how and confidential information. Ultimately, the lack or expiration at any given time of a patent to protect our compounds may allow our competitors to copy the underlying inventions and better compete with us.

*If we fail to adequately protect our intellectual property, our competitive position and the potential for long-term success could be harmed.*

Development and protection of our intellectual property are critical to our business. If we do not adequately protect our intellectual property, competitors may be able to practice our technologies. Our success depends in part on our ability to:

- obtain and maintain patent protection for our products or processes both in the U.S. and other countries;
- protect trade secrets; and

- prevent others from infringing on our proprietary rights.

The patent position of pharmaceutical and biotechnology firms, including ours, generally is highly uncertain and involves complex legal and factual questions. The U.S. Patent and Trademark Office has not established a consistent policy regarding the breadth of claims that it will allow in biotechnology patents. If it allows broad claims, the number and cost of patent interference proceedings in the U.S. and the risk of infringement litigation may increase. If it allows narrow claims, the risk of infringement may decrease, but the value of our rights under our patents, licenses and patent applications may also decrease. Patent applications in which we have rights may never issue as patents, and the claims of any issued patents may not afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors may be challenged and subsequently narrowed, invalidated or circumvented. Litigation, interference proceedings or other governmental proceedings that we may become involved in with respect to our proprietary technologies or the proprietary technology of others could result in substantial cost to us.

We also rely upon trade secrets, proprietary know-how and continuing technological innovation to remain competitive. Third parties may independently develop such know-how or otherwise obtain access to our technology. While we require our employees, consultants and corporate partners with access to proprietary information to enter into confidentiality agreements, these agreements may not be honored.

*Patent litigation is widespread in the biotechnology industry, and any patent litigation could harm our business.*

Costly litigation might be necessary to protect a patent position or to determine the scope and validity of third-party proprietary rights, and we may not have the required resources to pursue any such litigation or to protect our patent rights. Any adverse outcome in litigation with respect to the infringement or validity of any patents owned by third parties could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using a product or technology. With respect to our in-licensed patents, if we attempt to initiate a patent infringement suit against an alleged infringer, it is possible that our applicable licensor will not participate in or assist us with the suit and as a result we may not be able to effectively enforce the applicable patents against the alleged infringers.

*We may be unable to obtain or protect our intellectual property rights and we may be liable for infringing upon the intellectual property rights of others, which may cause us to engage in costly litigation and, if unsuccessful, could cause us to pay substantial damages and prohibit us from selling our products.*

At times, we may monitor patent filings for patents that might be relevant to some of our products and product candidates in an effort to guide the design and development of our products to avoid infringement, but may not have conducted an exhaustive search. We may not be able to successfully challenge the validity of third-party patents and could be required to pay substantial damages, possibly including treble damages, for past infringement and attorneys' fees if it is ultimately determined that our products infringe such patents. Further, we may be prohibited from selling our products before we obtain a license, which, if available at all, may require us to pay substantial royalties.

Moreover, third parties may challenge the patents that have been issued or licensed to us. We do not believe that PIXUVRI, pacritinib or any of the other compounds we are currently developing infringe upon the rights of any third parties nor are they materially infringed upon by third parties; however, there can be no assurance that our technology will not be found in the future to infringe upon the rights of others or be infringed upon by others. In such a case, others may assert infringement claims against us, and should we be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. In addition to any damages we might have to pay, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements or redesign our compounds so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Conversely, we may not always be able to successfully pursue our claims against others that infringe upon our technology and the technology exclusively licensed from any third parties. Thus, the proprietary nature of our technology or technology licensed by us may not provide adequate protection against competitors.

Even if infringement claims against us are without merit, or if we challenge the validity of issued patents, lawsuits take significant time, may, even if resolved in our favor, be expensive and divert management attention from other business concerns. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

*The illegal distribution and sale by third parties of counterfeit versions of a product or stolen product could have a negative impact on our reputation and business.*

Third parties might illegally distribute and sell counterfeit or unfit versions of a product that do not meet our rigorous manufacturing and testing standards. A patient who receives a counterfeit or unfit product may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit or unfit product sold under our brand name. In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

*We may owe additional amounts for VAT related to our operations in Europe.*

Our European operations are subject to the VAT which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable was \$4.3 million and \$4.4 million as of March 31, 2017 and December 31, 2016, respectively. On April 14, 2009, December 21, 2009 and June 25, 2010, the ITA issued notices of assessment to CTI (Europe) based on the ITA's audit of CTI (Europe)'s VAT returns for the years 2003, 2005, 2006 and 2007. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). The assessments, including interest and penalties, for the years 2003, 2005, 2006 and 2007 are €0.5 million, €5.5 million, €2.5 million and €0.8 million, respectively. While we are defending ourselves against the assessments both on procedural grounds and on the merits of the case, there can be no assurances that we will be successful in such defense. Further information pertaining to these cases can be found in Part II, Item 1, "Legal Proceedings," and is incorporated by reference herein. If the final decision of the Italian Supreme Court is unfavorable to us, or if, in the interim, the ITA were to make a demand for payment and we were to be unsuccessful in suspending collection efforts, we may be requested to pay to the ITA an amount up to €9.4 million (or approximately \$10.1 million upon conversion from euros as of March 31, 2017) plus collection fees, notification expenses and additional interest for the period lapsed between the date in which the assessments were issued and the date of effective payment.

*We are currently subject to certain regulatory and legal proceedings, and may in the future be subject to additional proceedings and/or allegations of wrong-doing, which could harm our financial condition and operating results.*

We are currently, and may in the future be, subject to regulatory matters and legal claims, including possible securities, derivative, consumer protection and other types of proceedings pursued by individuals, entities or regulatory bodies. As described in Part II, Item 1, "Legal Proceedings," we are currently engaged in certain pending legal proceedings, including the purported class action lawsuits filed against us and certain of our current and former directors and officers in February 2016 and the four derivative lawsuits filed against us in March, May, June and August 2016. In addition, we are in the process of supplying documents in response to a subpoena from the SEC in connection with an investigation into potential federal securities law violations as described in Part II, Item 1, "Legal Proceedings." Litigation is subject to inherent uncertainties, and we have had and may in the future have unfavorable rulings and settlements. Adverse outcomes may result in significant monetary damages or injunctive relief against us. It is possible that our financial condition and operating results could be harmed in any period in which the effect of an unfavorable final outcome becomes probable and reasonably estimable. If an unfavorable ruling were to occur in any of the legal proceedings we are or may be subject to, our business, financial condition, operating results and prospects could be harmed. The ultimate outcome of litigation and other claims is subject to inherent uncertainties, and our view of these matters may change in the future.

We cannot predict with certainty the eventual outcome of pending litigation. In addition, negative publicity resulting from any allegations of wrong-doing could harm our business, regardless of whether the allegations are valid or whether there is a finding of liability. Furthermore, we may have to incur substantial time and expense in connection with such lawsuits and management's attention and resources could be diverted from operating our business as we respond to the litigation. Our insurance is subject to high deductibles and there is no guarantee that the insurance will cover any specific claim that we currently face or may face in the future, or that it will be adequate to cover all potential liabilities and damages. In the event of negative publicity resulting from allegations of wrong-doing and/or an adverse outcome under any currently pending or future lawsuit, our business could be materially harmed.

*Our net operating losses may not be available to reduce future income tax liability.*

We have substantial tax loss carryforwards for U.S. federal income tax purposes, but our ability to use such carryforwards to offset future income or tax liability is limited under section 382 of the Internal Revenue Code of 1986, as amended, as a result of prior changes in the stock ownership of the Company. Moreover, future changes in the ownership of our stock, including those resulting from issuance of shares of our common stock upon exercise of outstanding warrants, may further limit our ability to use our net operating losses.

*Due to the fact that we have European branches and subsidiaries conducting operations, together with the fact that we are party to certain contractual arrangements denoting monetary amounts in foreign currencies, we are subject to risk regarding currency exchange rate fluctuations.*

We are exposed to risks associated with the translation of euro-denominated financial results and accounts into U.S. dollars for financial reporting purposes. The carrying value of the assets and liabilities, as well as the reported amounts of revenues and expenses, in our European branches and subsidiaries will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. Any expansion of our commercial operations in Europe (including with regard to sales of PIXUVRI) may increase our exposure to fluctuations in foreign currency exchange rates. In addition, certain of our contractual arrangements, such as the Restated Agreement with Servier, denote monetary amounts in foreign currencies, and consequently, the ultimate financial impact to us from a U.S. dollar perspective is subject to significant uncertainty. Furthermore, the referendum in the United Kingdom in June 2016, in which the majority of voters voted in favor of an exit from the European Union has resulted in increased volatility in the global financial markets and caused severe volatility in global currency exchange rate fluctuations that resulted in the strengthening of the U.S. dollar against the euro. Changes in the value of the U.S. dollar as compared to foreign currencies (in particular, the euro) might have an adverse effect on our reported operating results and financial condition.

*We may be unable to obtain the raw materials necessary to produce a particular product or product candidate.*

We may not be able to purchase the materials necessary to produce a particular product or product candidate in adequate volume and quality. If any raw material required to produce a product or product candidate is insufficient in quantity or quality, if a supplier fails to deliver in a timely fashion or at all or if these relationships terminate, we may not be able to qualify and obtain a sufficient supply from alternate sources on acceptable terms, or at all.

*Because there is a risk of product liability associated with our compounds, we face potential difficulties in obtaining insurance, and if product liability lawsuits were to be successfully brought against us, our business may be harmed.*

Our business exposes us to potential product liability risks inherent in the testing, manufacturing, marketing and sale of human pharmaceutical products. In particular, as a result of the commercialization of PIXUVRI, our risk with respect to potential product liability has increased. If our insurance covering a compound is not maintained on acceptable terms or at all, we might not have adequate coverage against potential liabilities. Our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or limit the commercialization of any products we develop. A successful product liability claim could also exceed our insurance coverage and could harm our financial condition and operating results.

*We may be subject to claims relating to improper handling, storage or disposal of hazardous materials.*

Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to federal, state and local laws and regulations, both internationally and domestically, governing the use, manufacture, storage, handlings, treatment, transportation and disposal of such materials and certain waste products and employee safety and health matters. Although we believe that our safety procedures for handling and disposing of such materials comply with applicable law and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated completely. In the event of such an accident, we could be held liable for any damages that result and any such liability not covered by insurance could exceed our resources. Compliance with environmental, safety and health laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

*We depend on sophisticated information technology systems to operate our business and a cyber-attack or other breach of these systems could have a material adverse effect on our business.*

We rely on information technology systems to process, transmit and store electronic information in our day-to-day operations. The size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption. Any such successful attacks could result in the theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyber-attacks are becoming more sophisticated and frequent. We have invested in our systems and the protection of our data to reduce the risk of an intrusion or interruption, and we monitor our systems on an ongoing basis for any current or potential threats. There can be no assurance that these measures and efforts will prevent future interruptions or breakdowns. If we fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to these systems, we could have difficulty preventing, detecting

and controlling fraud, have disputes with customers, physicians and other health care professionals, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues or suffer other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows.

### **Risks Related to the Securities Markets**

*Shares of our common stock are subordinate to existing and any future indebtedness and to any preferred stock we may issue.*

Shares of our common stock rank junior to our existing indebtedness, including under our senior secured term loan agreement and any future indebtedness we may incur, as well as to all creditor claims and other non-equity claims against us and our assets available to satisfy claims on us, including claims in a bankruptcy or similar proceeding. Our senior secured term loan agreement restricts, and any future indebtedness and preferred stock may restrict, payment of dividends on our common stock. Shares of our common stock will also rank junior to any shares of our preferred stock that we may issue in the future.

Additionally, unlike indebtedness, where principal and interest customarily are payable on specified due dates, in the case of our common stock, (i) dividends are payable only when and if declared by our Board of Directors or a duly authorized committee of our Board of Directors and (ii) as a corporation, we are restricted to making dividend payments and redemption payments out of legally available assets. We have never paid a dividend on our common stock and have no current intention to pay dividends in the future. Furthermore, our common stock places no restrictions on our business or operations or on our ability to incur indebtedness or engage in any transactions, subject only to the voting rights available to our shareholders generally.

*The market price of shares of our common stock is extremely volatile, which may affect our ability to raise capital in the future and may subject the value of your investment in our securities to sudden decreases.*

The market price for securities of biopharmaceutical and biotechnology companies, including ours, historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. For example, during the 12-month period ended April 26, 2017, our stock price ranged from a low of \$3.07 to a high of \$6.48. Fluctuations in the market price or liquidity of our common stock may harm the value of your investment in our common stock. Factors that may have an impact, which, depending on the circumstances, could be significant, on the market price and marketability of our securities include:

- announcements by us or others of results of clinical trials and regulatory actions, such as the imposition of a clinical trial hold;
- announcements by us or others of serious adverse events that have occurred during administration of our products to patients;
- announcements by us or others relating to our ongoing development and commercialization activities;
- halting or suspension of trading in our common stock on The NASDAQ Capital Market or on the MTA;
- announcements of technological innovations or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;
- our issuance of debt or equity securities, which we expect to pursue to generate additional funds to operate our business, or any perception from time to time that we will issue such securities;
- our quarterly operating results;
- liquidity, cash position or financing needs;
- developments or disputes concerning patent or other proprietary rights;
- developments in relationships with collaborative partners;
- acquisitions or divestitures;



- our ability to realize the anticipated benefits of our compounds;
- litigation and government proceedings;
- adverse legislation, including changes in governmental regulation;
- third party reimbursement policies;
- changes in securities analysts' recommendations;
- short selling of our securities;
- changes in health care policies and practices;
- a failure to achieve previously announced goals and objectives as or when projected; and
- general economic and market conditions.

*Anti-takeover provisions in our charter documents, in our shareholder rights agreement, or rights plan, under Washington law and in other applicable instruments could make removal of incumbent management or an acquisition of us, which may be beneficial to our shareholders, more difficult.*

Provisions of our articles of incorporation and bylaws may have the effect of deterring or delaying attempts by our shareholders to remove or replace management, to commence proxy contests or to effect changes in control. These provisions include:

- elimination of cumulative voting in the election of directors;
- procedures for advance notification of shareholder nominations and proposals;
- the ability of our Board of Directors to amend our bylaws without shareholder approval; and
- the ability of our Board of Directors to issue shares of preferred stock without shareholder approval upon the terms and conditions and with the rights, privileges and preferences as our Board of Directors may determine.

Pursuant to our rights plan, an acquisition of 20% or more of our common stock by a person or group, subject to certain exceptions, could result in the exercisability of the preferred stock purchase right accompanying each share of our common stock (except those held by a 20% shareholder, which become null and void), thereby entitling the holder to receive upon exercise, in lieu of a number of units of preferred stock, that number of shares of our common stock having a market value of two times the exercise price of the right. The existence of our rights plan could have the effect of delaying, deterring or preventing a third party from making an acquisition proposal for us and may inhibit a change in control that some, or a majority, of our shareholders might believe to be in their best interest or that could give our shareholders the opportunity to realize a premium over the then-prevailing market prices for their shares.

In addition, as a Washington corporation, we are subject to Washington's anti-takeover statute, which imposes restrictions on some transactions between a corporation and certain significant shareholders. Other existing provisions applicable to us that could have an anti-takeover effect include our executive employment agreements and certain provisions of our outstanding equity-based compensatory awards that allow for acceleration of vesting in the event of a change in control.

The foregoing provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

## **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

### *Stock Repurchases in the First Quarter*

The following table sets forth information with respect to purchases of our common stock during the three months ended March 31, 2017:

<u>Period</u>	<u>Total Number of Shares Purchased (1)</u>	<u>Average Price Paid per Share</u>	<u>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</u>	<u>Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs</u>
January 1 - January 31, 2017	88	\$ 4.87	—	—
February 1 - February 28, 2017	—	—	—	—
March 1 - March 31, 2017	456	4.25	—	—
Total	544	\$ 4.35	—	—

(1) Represents purchases of shares in connection with satisfying tax withholding obligations on the vesting of restricted stock awards to employees granted under our Equity Incentive Plans.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
3.1	Amended and Restated Articles of Incorporation.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on March 23, 2015.
3.2	Articles of Amendment to Amended and Restated Articles of Incorporation, dated October 29, 2015 (Series N Preferred Stock).	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on October 30, 2015.
3.3	Articles of Amendment to Amended and Restated Articles of Incorporation, dated October 29, 2015 (Series N-1 Preferred Stock).	Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on October 30, 2015.
3.4	Articles of Amendment to Amended and Restated Articles of Incorporation, dated December 8, 2015 (Series N-2 Preferred Stock).	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on December 9, 2015.
3.5	Articles of Amendment to Amended and Restated Articles of Incorporation, dated April 29, 2016.	Incorporated by reference to Exhibit 3.5 to the Registrant's Quarterly Report on Form 10-Q, filed on May 10, 2016.
3.6	Amendment to Amended and Restated Articles of Incorporation of CTI BioPharma Corp.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on December 21, 2016.
3.7	Amended and Restated Bylaws.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on December 3, 2015.
4.1	Shareholder Rights Agreement, dated December 28, 2009, between the Registrant and Computershare Trust Company, N.A.	Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form 8-A, filed on December 28, 2009.
4.2	First Amendment to Shareholder Rights Agreement, dated as of August 31, 2012, between the Registrant and Computershare Trust Company, N.A., as Rights Agent.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on September 4, 2012.
4.3	Second Amendment to Shareholder Rights Agreement, dated as of December 6, 2012, between the Registrant and Computershare Trust Company, N.A., as Rights Agent.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on December 7, 2012.
4.4	Third Amendment to Shareholder Rights Agreement, dated as of December 1, 2015, between the Registrant and Computershare Trust Company, N.A., as Rights Agent.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on December 1, 2015.
4.5	Specimen Common Stock Certificate.	Incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-3 (File No. 333-200452), filed on November 21, 2014.
4.6	Form of Common Stock Purchase Warrant, dated December 13, 2011.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on December 14, 2011.

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
4.7	Warrant Agreement, dated June 9, 2015, by and between Registrant and Hercules Technology Growth Capital, Inc.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on June 10, 2015.
10.1	Director Compensation Policy.	Filed herewith.
10.2	Employment Agreement, dated February 24, 2017, by and between the Company and Adam Craig.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on February 27, 2017.
10.3	Separation and Release Agreement, dated March 13, 2017, by and between the Company and Louis A. Bianco.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on March 13, 2017.
10.4†	Amended and Restated Exclusive License and Collaboration Agreement by and between the Company, CTI Life Sciences Limited, Laboratoires Servier and Institut de Recherches Internationales Servier dated as of April 21, 2017.	Filed herewith.
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
32	Certification of Principal Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith.
101. INS	XBRL Instance	Filed herewith.
101. SCH	XBRL Taxonomy Extension Schema	Filed herewith.
101. CAL	XBRL Taxonomy Extension Calculation	Filed herewith.
101. DEF	XBRL Taxonomy Extension Definition	Filed herewith.
101. LAB	XBRL Taxonomy Extension Labels	Filed herewith.
101. PRE	XBRL Taxonomy Extension Presentation	Filed herewith.

† Portions of this exhibit have been omitted pursuant to a request for confidential treatment.

**SIGNATURES**

Pursuant to the requirements 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:

**CTI BIOPHARMA CORP.**

(Registrant)

Dated: May 3, 2017

By: /s/ Adam R. Craig  
Adam R. Craig  
President and Chief Executive Officer

Dated: May 3, 2017

By: /s/ Bruce J. Seeley  
Bruce J. Seeley  
Executive Vice President,  
Chief Commercial and Administrative  
Officer

## CTI BIOPHARMA CORP.

## DIRECTOR COMPENSATION POLICY

*Effective February 23, 2017*

Directors of CTI BioPharma Corp., a Washington corporation (the “Company”), who are not employed by the Company or one of its subsidiaries (“non-employee directors”) shall be entitled to the compensation set forth below for their service as a member of the Board of Directors (the “Board”) of the Company. Except as provided in the next sentence, this policy supersedes all prior policies or provisions of any equity plans concerning compensation of the Company’s non-employee directors effective as of the date set forth above. This policy does not, however, modify the terms of any equity or incentive award granted by the Company prior to the date set forth above. The Board has the authority to amend this policy from time to time.

**Cash Compensation**Annual Retainer for Board Service

Each non-employee director shall be entitled to an annual cash retainer while serving on the Board in the amount of \$40,000 (the “Annual Retainer”). The Company shall pay the Annual Retainer on a semi-annual basis, with half of the Annual Retainer to be paid on each of the first business day of January and the first business day of July.

Annual Retainer for Chairman of the Board Service

A non-employee director who serves as the Chair of the Board shall be entitled to an annual cash retainer while serving in that position in the amount of \$75,000 (the “Chair of the Board Retainer”). The Company shall pay the Chair of the Board Retainer on a semi-annual basis, with half of the Chair of the Board Retainer to be paid on each of the first business day of January and the first business day of July.

Board Committee Chair Retainer

A non-employee director who serves as the chair of one of the following committees of the Board shall be entitled to an annual cash retainer while serving in that position in the corresponding amount set forth below (the “Chair Retainer”):

<u>Committee of the Board</u>	<u>Amount of Chair Retainer</u>
Audit Committee	\$15,000
Compensation Committee	\$12,500
Nominating and Corporate Governance Committee	\$7,500

The Company shall pay the Chair Retainer on a semi-annual basis, with half of the Chair Retainer to be paid on each of the first business day of January and the first business day of July.

Board Meeting Attendance Fee

A non-employee director who attends a Board meeting, whether in person or telephonic and regardless of length, will be entitled to a fee in the amount of \$2,750 (“Board Meeting Fee”) for each such meeting. The Company shall pay the Board Meeting Fee in cash on a quarterly basis in arrears, with payment for a particular quarter to be made no later than ten business days following the end of that quarter.

Board Committee Meeting Attendance Fee

A non-employee director who attends a Board committee meeting, whether in person or telephonic and regardless of length or whether a meeting is scheduled on the same day as a Board meeting, will be entitled to a fee in the amount of \$1,250 (“Committee Meeting Fee”) for each such meeting; provided that (unless otherwise approved by the Board) a Committee Meeting Fee will not be paid for any meeting of a Board committee that occurs as a joint meeting with the Board. The

Company shall pay the Committee Meeting Fee in cash on a quarterly basis in arrears, with payment for a particular quarter to be made no later than ten business days following the end of that quarter.

### **Equity Compensation**

#### *Initial Equity Award for New Directors*

A new non-employee director shall be granted a stock option to acquire shares of Company common stock in connection with joining the Board (an "Initial Award"). The number of shares of Company common stock covered by an Initial Award will be determined by the Board in connection with the grant of the award. An employee director who ceases to be an employee, but who remains a director, will not receive an Initial Award.

#### *Annual Equity Award for Continuing Board Members*

On an annual basis in connection with each annual meeting of the Company's shareholders, each non-employee director continuing on the Board after such meeting shall be granted a stock option to acquire shares of Company common stock (an "Annual Award"). The number of shares of Company common stock covered by an Annual Award will be determined by the Board in connection with the grant of the award.

#### *Provisions Applicable to All Non-Employee Director Stock Option Awards*

The date of grant of each Initial Award and each Annual Award (each, an "Award") shall be determined by the Board. Each Award shall be granted under the Company's 2015 Equity Incentive Plan or any successor equity compensation plan approved by the Company's stockholders and in effect at the time of grant (as applicable, the "Equity Plan"). Unless otherwise provided by the Board in connection with a particular Award, each Award will be evidenced by and subject to the terms and conditions of the Company's standard form of stock option award agreement for non-employee director stock option grants under the Equity Plan as in effect on the date of grant of the award.

The per share exercise price of each Award will equal the closing price of a share of Company common stock on the date of grant of the Award (or, if such date of grant is not a trading day, the closing price of a share of Company common stock on the last trading day immediately preceding the date of grant of the Award). Such exercise price and the number of shares subject to an Award will be subject to adjustment for stock splits and similar events as provided in the applicable stock option award agreement.

Each Award granted will be scheduled to vest on the date that is twelve months after the date of grant of the Award or, if earlier, immediately prior to the first annual meeting of the Company's shareholders at which one or more members of the Board are to be elected and that occurs in the calendar year after the calendar year in which the Award is granted. The maximum term of each Award is ten years from the date of grant of the Award, subject to earlier termination as provided in the applicable stock option award agreement.

In addition, the stock options subject to a particular Award (as well as any stock options, restricted stock awards, and restricted stock unit awards granted to the non-employee director under prior versions of this policy), to the extent then outstanding and unvested, shall become fully vested in the event of a Change in Control (as such term is defined in the applicable Equity Plan under which the award was granted or, if not so defined, as defined in the applicable award agreement) that occurs while such non-employee director is a member of the Board.

### **Expense Reimbursement**

All non-employee directors shall be entitled to reimbursement from the Company for their reasonable travel (including airfare and ground transportation), lodging and meal expenses incident to meetings of the Board or committees thereof or in connection with other Board related business. The Company shall also reimburse directors for attendance at director continuing education programs that are relevant to their service on the Board and which attendance is pre-approved by the Chair of the Nominating and Corporate Governance Committee or Chair of the Board. The Company shall make reimbursement to a non-employee director within a reasonable amount of time following submission by the non-employee director of reasonable written substantiation for the expenses (and in all events not later than the end of the year following the year in which the related expense was incurred).

Amended and Restated Exclusive License and Collaboration Agreement

**LES LABORATOIRES SERVIER**, a company duly organized and existing under the laws of France, having offices and principal place of business at 50 Rue Carnot, 92284 Suresnes Cedex, France

and

**INSTITUT DE RECHERCHES INTERNATIONALES SERVIER**, a company duly organized and existing under the laws of France, having offices and principal place of business at 50 Rue Carnot, 92284 Suresnes Cedex, France

AND

**CTI BIOPHARMA CORP.**, a corporation organized and existing under the laws of Washington, having offices and principal place of business at 3101 Western Ave., Suite 600, Seattle, WA 98121, United States of America

and

**CTI LIFE SCIENCES LIMITED**, a company duly organized and existing under the laws of England, having offices and principal place of business at Highlands House, Basingstoke Road, Spencers Wood, Reading, Berkshire RG7 1NT, United Kingdom

\*\* Indicates that certain information contained herein has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

\*\*\*\* Indicates that the amount of information omitted was a page or more in length, and such information has been filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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ARTICLE 1 DEFINITIONS	7
ARTICLE 2 LICENSE	26
2.1 License Grant	26
2.2 License to CTI	26
2.3 Sublicensing	27
2.4 Performance by Affiliates	27
2.5 Generic Arms	27
ARTICLE 3 GOVERNANCE	27
3.1 Joint Executive Committee	27
3.2 Joint Steering Committee	28
3.3 General Rules	29
3.4 Decision Making	30
3.5 Additional Committees	31
3.6 Interactions between the Committees and the Additional Committees	32
3.7 Day-to-Day Decision-Making Authority	32
3.8 Alliance Managers	32
3.9 Cost of Governance	33
ARTICLE 4 PROVISION OF DATA AND KNOW-HOW	33
4.1 Know-How Transfer	33
4.2 Rights of Reference; Use of Data; Format of Reports	33
4.3 Disclaimer	35
ARTICLE 5 RESEARCH & DEVELOPMENT	35
5.1 Development	35
5.2 Development Plan	36
5.3 Responsibilities under the Development Plan	38
5.4 Development Costs	38
5.5 Estimates, Accruals, Reconciliation and Reimbursement	39
5.6 Additional Studies	40
5.7 Clinical Studies in the Other Party's Respective Territory	41
5.8 Development in CTI Territory	41
5.9 Development Records	41
5.10 Subcontracts	42
5.11 Personnel	42
ARTICLE 6 DATA; REGULATORY MATTERS	42
6.1 General	42
6.2 Prior to the European MA Transfer	43
6.3 After the European MA Transfer	44
6.4 Outside the European Union	44
6.5 Recalls and Complaints	45
6.6 Pharmacovigilance Agreement	46
6.7 No Use of Debarred Person	47
6.8 Notice of Investigation or Inquiry	47
ARTICLE 7 COMMERCIALIZATION	48
7.1 Transition Territory	48
7.2 Servier Territory other than Transition Territory	49
7.3 Updates	50

7.4	Termination of Sharing	50
ARTICLE 8 COMMERCIAL COVENANTS		51
8.1	Competing Products	51
8.2	Competing Product Affiliation Transaction	52
8.3	Remedies	53
8.4	Exportation/Importation of Licensed Product	54
ARTICLE 9 MANUFACTURING AND SUPPLY		54
9.1	Manufacturing Responsibilities	54
9.2	Supply	54
9.3	Quality Agreement	56
9.4	Technology Transfer	56
9.5	Assistance in Technology Transfer	56
9.6	Audit	57
ARTICLE 10 FINANCIAL TERMS		57
10.1	License Fee	57
10.2	Regulatory Milestones	57
10.3	Sales Milestones	59
10.4	Royalties	59
10.5	Estimates, Payments and Reports	59
10.6	Adjustments to Royalties	60
10.7	Payments and Reporting Generally	61
10.8	Interest	61
10.9	Taxes	61
10.10	Audit Rights	62
10.11	Records	62
ARTICLE 11 INTELLECTUAL PROPERTY		63
11.1	Joint Ownership	63
11.2	Sole Inventions	63
11.3	Inventorship	63
11.4	Intellectual Property Litigation	63
11.5	Drug Price Competition and Patent Rights Term Extensions	65
11.6	Patent Prosecution, Maintenance and Ownership	65
11.7	Product Trademarks, Corporate Names and Domain Names	66
ARTICLE 12 PUBLICATION; CONFIDENTIALITY		67
12.1	Confidentiality Obligations of Servier	67
12.2	Confidentiality Obligations of CTI; Confidentiality Obligations of each Party	68
12.3	Publicity; Required Disclosures	70
12.4	Scientific Papers, Abstracts and Posters	71
12.5	Registries	73
12.6	Timeline Extension or Deferral of Disclosures	73
12.7	Failure to Object to Disclosure	73
12.8	Authorized Disclosure	73
ARTICLE 13 REPRESENTATIONS, WARRANTIES AND COVENANTS		74
13.1	By each Party	74
13.2	By CTI	75
13.3	CTI Covenants	78

13.4	Mutual Covenant	79
13.5	Disclaimer	79
ARTICLE 14 TERM AND TERMINATION		80
14.1	Term Expiration	80
14.2	Unilateral Termination by Servier	80
14.3	Termination for Safety Reasons	80
14.4	Termination for Regulatory Reasons	81
14.5	Termination for Repudiatory Breach	81
14.6	Effects of Termination of the Agreement	81
14.7	Accrued Rights	84
14.8	Rights in Bankruptcy	84
14.9	Data and Information Transfer	84
ARTICLE 15 DISPUTE RESOLUTION		85
15.1	Arbitration	85
15.2	Accelerated Arbitration Procedure	86
15.3	Confidential	86
15.4	Communications with Internal Counsel	86
ARTICLE 16 INDEMNIFICATION		86
16.1	Indemnification by CTI in the CTI Territory	86
16.2	Indemnification by Servier in the Servier Territory	87
16.3	Right of Contractual Actions	87
16.4	Indemnification and Defense Procedures	87
16.5	Insurance	89
16.6	Disclaimer of Liability for Consequential Damages	89
ARTICLE 17 MISCELLANEOUS		89
17.1	Assignment	89
17.2	Governing Law; Jurisdiction	90
17.3	Severability	90
17.4	Notices	90
17.5	No Waiver	91
17.6	Further Assurances	91
17.7	No Third Party Beneficiaries	91
17.8	Relationship of the Parties	91
17.9	Entire Agreement	92
17.10	Counterparts	92
17.11	Compliance with Applicable Law	92
17.12	Force Majeure	92
17.13	English Language	92
17.14	Expenses	93
17.15	Exit of the United Kingdom or other country from European Union	93
17.16	Interpretation	93

## AMENDED AND RESTATED EXCLUSIVE LICENSE AND COLLABORATION AGREEMENT

This Amended and Restated Exclusive License and Collaboration Agreement (this “*Agreement*”) is entered into as of April 21, 2017 (the “*Restatement Date*”) by and between Les Laboratoires Servier, a company organized and existing under the laws of France, having offices and principal place of business at 50 Rue Carnot, 92284 Suresnes Cedex, France (“*LLS*”), and Institut de Recherches Internationales Servier, a company organized and existing under the laws of France, having offices and principal place of business at 50 Rue Carnot, 92284 Suresnes Cedex, France (“*IRIS*” and together with LLS, “*Servier*”) and CTI BioPharma Corp., a corporation organized and existing under the laws of Washington, having offices and principal place of business at 3101 Western Ave., Suite 600 Seattle, WA 98121, United States (“*CTI US*”), and CTI Life Sciences Limited, Highlands House, Basingstoke Road, Spencers Wood, Reading, Berkshire RG7 1NT, United Kingdom (“*CTILS*”) (together with CTI US, “*CTP*”). Servier and CTI are each referred to herein by name or individually as a “*Party*” or collectively as the “*Parties*.”

### BACKGROUND

**WHEREAS**, CTILS is a wholly owned subsidiary of CTI US, which has been granted conditional marketing authorization for the Licensed Product (as defined below) in the European Union for patients with aggressive B-cell non-Hodgkin lymphoma (“*NHL*”) who failed prior line(s) of therapy, subject to the post-marketing commitment to conduct the PIX306 trial with respect to the 2nd-4th line treatment of aggressive B-cell NHL (the “*PIX306 Trial*”);

**WHEREAS**, CTI has other oncology products in development and does not intend to allocate the resources to further develop and commercialize the Licensed Product in certain territories;

**WHEREAS**, CTI is seeking a development and commercialization partner for the Licensed Product in such territories;

**WHEREAS**, Servier is a pharmaceutical company developing and commercializing medicinal products and wishes to progressively build its commercial capabilities in the oncology field;

**WHEREAS**, Servier and CTI entered into that certain Exclusive License and Collaboration Agreement, effective September 16, 2014 (the “*Original Agreement*”), whereby the Parties established a collaboration for the Development, Manufacturing, and Commercialization of Licensed Product(s);

**WHEREAS**, the Parties wish to amend the Original Agreement, subject to the following recitals, to reflect the transfer of commercial rights to Servier in all countries of the world except for the United States;

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**WHEREAS**, the Parties wish to amend the Original Agreement to effect the transfer of marketing authorization for the Licensed Compound in the European Union upon the PIX306 Positive Outcome;

**WHEREAS**, the Parties wish to amend the Original Agreement to transfer manufacturing rights to Servier for the Servier Territory;

**NOW, THEREFORE**, in consideration of the promises and mutual covenants herein below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

## **ARTICLE 1**

### **DEFINITIONS**

**Defined Terms.** As used in this Agreement, the following terms shall have the meanings indicated:

**“Accounting Standards”** means with respect to Servier, the International Financial Reporting Standards (“**IFRS**”), and with respect to CTI, US GAAP.

**“Affiliate”** means, with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party, other than any Generics Affiliate (as defined below). For the purpose of this definition, “control” shall mean, direct or indirect, ownership of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interest in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby the entity or Person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity, or the ability to cause the direction of the management or policies of a corporation or other entity. In the case of entities organized under the laws of certain countries, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and in such case, such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. Notwithstanding the foregoing, the Parties agree that any Person that controls, is controlled by, or is under common control with a Party and is engaged primarily in the development, manufacture and/or commercialization of generic pharmaceutical or biopharmaceutical products (such Persons, “**Generics Affiliates**”) shall be deemed to be Third Parties and not Affiliates for purposes of this Agreement.

**“Applicable Law”** means any applicable national, supranational, federal, state, local or foreign law, statute, ordinance, principle of common law, or any rule, regulation, standard, judgment, order, writ, injunction, decree, arbitration award, agency requirement, license or permit of any Governmental Authority, including any rules, regulations, guidelines, directives or other requirements of Regulatory Authorities, and including all laws pertaining

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to the pharmaceutical industry or the healthcare industry and all anti-bribery or anti-corruption laws, as applicable.

“**Arbitrable Matter**” means, subject to Sections 3.4 and 3.7, any dispute or claim concerning the validity, interpretation or construction of, compliance with, inducement of, or breach of, this Agreement, any dispute with respect to whether either Party is entitled to terminate this Agreement, and any dispute concerning a Party’s indemnification obligations hereunder (including allocation of liability or Losses between the Parties with respect to an indemnification matter set forth in Article 16 and excluding only Litigable Matters).

“**Business Day**” means a day that is not a Saturday, Sunday or a day on which banking institutions in Paris, France or Seattle, Washington, United States are authorized by Applicable Law to remain closed.

“**Calendar Quarter**” means each three (3) consecutive calendar months ending on each March 31, June 30, September 30 and December 31.

“**Calendar Year**” means any period of time commencing on January 1 and ending on the next December 31 unless otherwise noted.

“**GMP**” means current Good Manufacturing Practices as specified in the United States Code of Federal Regulations, MHLW regulations, ICH Guidelines Q7A to Q11, US Pharmacopoeia/National Formulary, European Pharmacopoeia, Q7A, and equivalent laws, rules, or regulations of an applicable Regulatory Authority applicable to the Manufacture of any of Licensed Compounds and/or Licensed Product at the time of Manufacture.

“**Change of Control Transaction**” means, with respect to a Party, any of the following events:

(a) any Third Party or group of Third Parties acting in concert becomes the beneficial owners, directly or indirectly, of fifty percent (50%) or more of the combined voting power of the then outstanding voting securities or equity interest entitled to vote generally in the election of directors (or similar body) of such Party or any of its direct or indirect parent companies (the “**Outstanding Voting Securities**”);

(b) the consummation of any acquisition, merger or consolidation involving any Third Party or group of Third Parties acting in concert and a Party (a “**Business Combination Transaction**”), in which (i) more than fifty percent (50%) of the total voting power of the stock outstanding of the surviving entity normally entitled to vote in elections of members of the board of directors (or similar body) is not held by the parties holding at least fifty percent (50%) of the Outstanding Voting Securities of such Party preceding the execution of the initial agreement providing for such Business Combination Transaction, or (ii) less than fifty percent (50%) of the members of the board of directors (or similar body) of the surviving entity were members of the board of directors of such Party at the

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time of the execution of the initial agreement providing for such Business Combination Transaction; or

(c) a Party or any of its Affiliates sells, transfers or leases, in one or more related transactions, all or substantially all of its assets to any Third Party(ies) or group of Third Parties acting in concert.

“**Clinical Study(ies)**” means any experiment in which a drug or therapy is administered or dispensed to, or used involving, one or more human subjects.

“**CMC**” means the chemistry, manufacturing and controls section(s) in the IND/IMPd or NDA/EU CTD, including but not limited to registration batches/process validation, engineering studies qualification and validation, process validation, characterization and stability, scale and technology transfer to CMOs, qualification and validation activities, and quality assurance/quality control development.

“**CMO**” means a contract manufacturing organization.

“**Combination Product**” means any pharmaceutical preparations, in any dosage strengths, formulations and methods of administration, that combine the Licensed Compound and one or more other active ingredients in fixed dose combination, whether co-formulated or co-packaged.

“**Commercially Reasonable Efforts**” means, the use of efforts and resources consistent with the efforts \*\*, typically devotes with respect to a compound or product with similar market or commercial prospects at a similar stage in the product life cycle, taking into account the stage and risk of Development or Commercialization of the Licensed Compound or Licensed Product, the cost effectiveness of efforts or resources while optimizing profitability, the competitiveness of alternative compounds, products or \*\* that are or are expected to be in the marketplace, the scope and duration of Patents or other property rights related to the compound or product (including any regulatory exclusivity), the profitability of the Licensed Compound or Licensed Product and alternative products (including pricing and reimbursement status achieved or likely to be achieved) or other relevant commercial factors, \*\*. For the avoidance of doubt, it is understood and agreed that \*\*.

“**Commercialization**” means, with respect to a Licensed Product, any and all processes and activities directed to selling, offering for sale (including any application for pricing and reimbursement approvals and more generally, any pricing, reimbursement and market access activities), detailing, marketing, advertising, promoting, storing, transporting, distributing, importing, and other commercial exploitation activities; provided, however, that Commercialization shall exclude Development and Manufacturing activities (including Manufacturing activities related to Commercialization) and Medical Affairs Activities. “**Commercialize**” and “**Commercializing**” shall have their correlative meanings.

“**Competing Compound**” means any \*\* other than the Licensed Compound.

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“**Competing Product(s)**” means a pharmaceutical product containing a Competing Compound as an active ingredient (alone or in combination with other active ingredient(s)) \*\*. Competing Products include \*\* but shall not include \*\*.

“**Conditional MA**” means that certain conditional MA \*\* granted by the EMA for the Licensed Compound and the Licensed Product prior to and in effect on the Restatement Date, and each annual renewal thereof, \*\*.

“**Confidential Information**” means any and all information, Data, Know-How and other proprietary information and data of a confidential nature (including Licensed Know-How and Joint Know-How), whether financial, business, legal, technical or non-technical, oral, written, or in electronic form, including information and data related to the Licensed Compound, the Licensed Product, a Party, or any concepts, discoveries, inventions, data, designs or formulae in relation to this Agreement, that is disclosed, supplied or otherwise made available by one Party or any of its Affiliates or Sublicensees (“**Disclosing Party**”) to the other Party or any of its Affiliates or Sublicensees (“**Receiving Party**”). All Confidential Information disclosed by a Party pursuant to the Mutual Confidential Disclosure Agreement between CTI US and Les Laboratoires Servier dated January 15, 2014 (the “**Prior CDA**”) shall be deemed to be Confidential Information of such Party pursuant to this Agreement (with the mutual understanding and agreement that any use and disclosure thereof that is authorized under Article 12 shall not be restricted by, or be deemed a violation of, such Prior CDA).

“**Control**” and “**Controlled by**” means, with respect to any material, information, or intellectual property right, that a Party or its Affiliates (a) owns, or (b) has a license or right to use, in the case of each of (a) or (b) with the ability to grant to the other Party access, a right to use, a license, or a sublicense (as applicable) on the terms and conditions set forth herein, without violating the terms of any agreement or other arrangement with any Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such (sub)license, right to use or access.

“**Cover,**” “**Covered**” or “**Covering**” means, with respect to a product and a Patent in a given country, that, in the absence of a (sub)license under, or ownership of, such Patent, the making, using, offering for sale, selling or importing of such product with respect to a given country would infringe a Valid Claim of such Patent in such country.

“**CTD**” means the Common Technical Document for the Registration of Pharmaceuticals for Human Use, intended for submission to the FDA or the EMA.

“**CTI Group**” means CTI and its Affiliates.

“**CTI Territory**” means the United States of America, including its territories, possessions and Puerto Rico.

“**Data**” means any and all research, pharmacology, pre-clinical, clinical, commercial, marketing, process development, manufacturing and other data or information, including

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investigator reports (both preliminary and final), statistical analyses, expert opinions and reports, and safety data, in each case generated from Clinical Studies or non-clinical studies, research or testing specifically related or directed to the Licensed Compound(s) and/or the Licensed Product.

**“Development”** means those activities required and/or useful to obtain and maintain Regulatory Approval, including research, pre-clinical/non-clinical studies and Clinical Studies, toxicology studies, CMC activities, formulation, pharmacodynamics, pharmacokinetics, quality assurance/quality control, regulatory affairs (including submission of Data or other materials to a Governmental Authority to obtain, maintain and/or expand Regulatory Approval of the Licensed Product), biomarker strategy and development, report writing and statistical analysis, with respect to any Licensed Compound and/or Licensed Product, including such activities as are set forth in the Development Plan; provided, however, that Development shall exclude Commercialization and Manufacturing activities and Medical Affairs Activities and Non-Development Studies. **“Develop”** and **“Developing”** shall have their correlative meanings.

**“Development Costs”** means \*\* Development Costs exclude \*\*.

**“Development Studies”** means any Clinical Studies that are necessary to obtain or maintain a Regulatory Approval other than Territory Specific Studies and Investigator Sponsored Studies.

**“DMF”** means a drug master file and all equivalents, and related proprietary dossiers, in any country or jurisdiction (including any active substance master file in the EMA) for the Licensed Compound and/or the Licensed Product submitted or to be submitted by a Party to Regulatory Authorities.

**“Drug Product”** means bulk drug product containing the Licensed Compound that is in glass vials, but excluding any final packaging, finishing and labeling.

**“Drug Substance”** means bulk drug product containing the Licensed Compound.

**“EMA”** means the European Medicines Agency or any successor agency thereto.

**“European Union”** or **“EU”** means the member states of the European Union as of the Restatement Date and such other countries as may become part of the European Union after the Restatement Date. The term **“European Union”** or **“EU”** as used herein shall cease to cover those member states of the European Union which are no longer part of the European Union as from the date on which the Applicable Laws of the European Union are no longer applicable to those countries. Notwithstanding the foregoing, for purposes of this Agreement, the term **“European Union”** or **“EU”** shall include Norway and Iceland.

**“FD&C Act”** or **“Act”** means the United States Federal Food, Drug, and Cosmetic Act, as amended, and all rules and regulations promulgated thereunder.

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“**FDA**” means the United States Food and Drug Administration or any successor entity thereto.

“**Field**” means any and all uses for the treatment, diagnostic, prevention, or prophylaxis of any disease or condition in humans or animals.

“**Finished Product**” means Drug Product that has undergone final packaging, finishing and labeling activities (such as country-specific labelling and package inserts).

“**Firewall**” means \*\*.

“**First Commercial Sale**” means the first sale of a Licensed Product by a Party or an Affiliate or Sublicensee of a Party to a Third Party in a country following Regulatory Approval or any pricing and reimbursement approvals of such Licensed Product in that country or, if no such Regulatory Approval, pricing and reimbursement approvals or similar approval is required, the date of the first bona fide commercial sale of such Licensed Product in such country in ordinary trade channels and not for the purpose of advancing the date of a First Commercial Sale. \*\*.

“**FTE**” means a full-time equivalent person year (consisting of \*\* hours per year) of work performing activities hereunder. For clarity, indirect personnel (including support functions such as managerial, legal or business development) shall not constitute FTEs.

“**FTE Costs**” for a given period means the product of (a) the total FTEs (proportionately, on a per-FTE basis) dedicated by a Party or its Affiliates in the particular period to the direct performance of the activities allocated to such Party hereunder and (b) the FTE Rate.

“**FTE Rate**” means, unless otherwise agreed between the Parties, a rate per FTE equal to \*\* for CTI and \*\* for Servier per annum (which may be prorated on a daily or hourly basis as necessary) with respect to Development activities conducted pursuant to this Agreement. The FTE Rate will increase at the beginning of each subsequent Calendar Year over the prior year amount by: (i) the increase of the Consumer Price Index-All Urban Consumers during the prior year for CTI and (ii) the average increase of the monthly salary index applicable to the pharmaceutical industry as published by the LEEM (“*Les Entreprises du Médicament*”) during the prior year for Servier. The FTE Rate is “fully burdened” and \*\*.

“**GAAP**” or “**US GAAP**” means Generally Accepted Accounting Principles.

“**GDP**” means current Good Distribution Practice and indicates the guidelines and requirements for the proper distribution of medicinal products for human use. The GDP requirements are specified in the United States Code of Federal Regulations, USP 1079, and EU Directive 92/25/EEC regarding the wholesale distribution of drugs for human consumption. GDP is a quality warranty system, which includes requirements for purchase, receiving, storage and export of drugs intended for human consumption. GDP regulates the

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division and movement of pharmaceutical products from the premises of the manufacturer of medicinal products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health establishments.

“**Generic Equivalent**” means, \*\*.

“**Generics Firewall**” means \*\*.

“**GLP**” or “**Good Laboratory Practice**” means the quality systems concerned with the organizational process and the conditions under which laboratory studies are planned, performed, monitored, recorded and reported in a given country or group of countries, including in relation to such laboratory studies in the EU, Directive 2004/9/EC and Directive 2004/10/EC, as may be amended or replaced from time to time as well as any “*Rules Governing Medicinal Products in the European Community Vol. 3, ISBN 92.825 9619-2 (ex OECD principles of GLP)*” as amended and applicable from time to time and (ii) the equivalent requirements in any other jurisdiction in the countries in which the Licensed Product(s) is Developed from time to time.

“**Governmental Authority**” means any domestic or foreign entity exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to government, including any governmental authority, agency, department, board, commission, court, tribunal, judicial body or instrumentality of any union of nations, federation, nation, state, municipality, county, locality or other political subdivision thereof.

“**HealthCare Practitioners**” includes treatment decision makers, patient care providers and prescribers.

“**Hercules Loan and Security Agreement**” means that certain loan and security agreement dated March 26, 2013, as amended, between CTI US, Systems Medicine LLC and Hercules Technology Growth Capital Inc.

“**ICH**” means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for human use.

“**IFRS**” means International Financial Reporting Standards.

“**IND/IMP**” means (a) an Investigational New Drug Application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA, (b) the Investigational Medicinal Product Dossier in the European Union, or (c) the equivalent application to the applicable Regulatory Authority in any other regulatory jurisdiction, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

“**Investigator Sponsored Study**” means any Clinical Study with respect to a Licensed Compound or Licensed Product where the sponsor of the study is a physician or group of

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physicians acting as sponsor-investigator(s) and neither of the Parties nor any of their Affiliates accept the role of sponsor or co-sponsor of such study.

**“Joint Intellectual Property”** means all intellectual property rights in Joint Inventions (which for the avoidance of doubt shall include Joint Know-How and Joint Patent Rights).

**“Joint Invention”** means an invention arising during the term of this Agreement or the Original Agreement that is either: (a) jointly created by one or more employees, consultants, or contractors of a Party or of any Affiliate or Sublicensee of such Party in the course of performing activities under this Agreement or the Original Agreement, or (b) jointly funded by the Parties under the Development Plan.

**“Joint Know-How”** means all Know-How arising during the term of this Agreement or the Original Agreement that is either: (a) jointly created by one or more employees, consultants, or contractors of each Party or of any Affiliate of such Party in the course of performing activities under this Agreement or the Original Agreement, or (b) jointly funded by the Parties under the Development Plan.

**“Joint Patent Right”** means a Patent that claims a Joint Invention and/or any Joint Know-How.

**“Know-How”** means all scientific and technical information and know-how, trade secrets, Data and technology, including inventions (whether patentable or not), discoveries, trade secrets, specifications, instructions, processes, formulae, materials, expertise and other technology applicable to compounds, formulations, compositions, products or to their Manufacture, Development, registration, use or Commercialization or methods of assaying or testing them or processes for their Manufacture, formulations containing them, compositions incorporating or comprising them and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data, instructions, processes, formulae, expertise and information, regulatory filings and copies thereof, that relate to or are directed to the Licensed Compound and/or the Licensed Product in the Field (including (i) medical, clinical, toxicological or other scientific Data and (ii) processes and analytical methodology) that is now, or is hereafter during the term of the Agreement or the Original Agreement, useful for the Development, formulation, registration, testing, analysis, Manufacturing, use, Medical Affairs Activities, or Commercialization of and/or which may be useful in studying, testing, Development, production or formulation of the Licensed Compound and/or the Licensed Product, or intermediates for the synthesis thereof. Know-How does not include Patents or inventions claimed thereby.

**“Knowledge”** means the knowledge of CTI’s officers or Servier’s officers as applicable, after reasonable inquiry.

**“Licensed Compound”** means pixantrone dimaleate which has received a conditional MA in the European Union under the trademark PIXUVRI®, as well as \*\*.

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**“Licensed Intellectual Property”** means Licensed Know-How and Licensed Patents.

**“Licensed Know-How”** means all Know-How that is developed or Controlled by CTI (other than as part of a Competing Product Affiliation Transaction), prior to the Restatement Date (whether or not pursuant to the Original Agreement) and thereafter during the term of this Agreement that is necessary or useful for the Development, Medical Affairs Activities, Manufacture, and/or Commercialization relating to the Licensed Compound or a Licensed Product (including any Data resulting from the pediatric investigation plans). Licensed Know-How shall include CTI’s interest in Joint Know-How that meets the above requirements.

**“Licensed Patents”** means all Patents that are Controlled by CTI (other than as part of a Competing Product Affiliation Transaction), prior to the Restatement Date (whether or not pursuant to the Original Agreement) and thereafter during the term of this Agreement that are necessary or useful for the Development, Medical Affairs Activities, Manufacture, and/or Commercialization relating to the Licensed Compound or a Licensed Product (including any such Patents claiming its composition, formulation, combination, product by process, or method of use, Manufacture, preparation or administration) including those Patents set forth on Exhibit A. Licensed Patents shall include CTI’s interest in Joint Patent Rights that meet the above requirements.

**“Licensed Product”** means any pharmaceutical product containing any Licensed Compound as its sole active ingredient or in combination with other active ingredients, in any form or formulation, but shall not include any Generic Equivalent.

**“Litigable Matter”** means any dispute between the Parties concerning the validity, scope, enforceability, inventorship, or ownership of a Patent, without prejudice to the provisions of the penultimate sentence of Section 15.1.

**“Local Representative”** shall have the meaning \*\*.

**“Loss of Market Exclusivity”** means, \*\*.

**“Losses”** means any and all losses, liabilities, costs and expenses (including reasonable attorneys’ fees and expenses), debts and other obligations arising out of or resulting from claims, judgments, damages of any kind whatsoever, arbitral awards, and amounts paid in settlement of claims, judgments, legal (including but not limited to judicial, arbitral and administrative) proceedings and the like.

**“MA”** means the approval (either conditional or not) of an MAA by the European Commission or any competent Regulatory Authorities.

**“MAA”** means any Marketing Authorization Application filed with the EMA pursuant to the centralised procedure or with any competent Regulatory Authorities.

**“MAH”** means the marketing authorization holder of an MA.

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“**Manufacture**” means, with respect to any Licensed Compound and Licensed Product, any and all processes and activities conducted to manufacture preclinical, clinical and commercial quantities of Licensed Compound or Licensed Product, the production, manufacture, processing, filling, finishing, packaging, labeling, inspection, receiving, holding and shipping of Licensed Compound or Licensed Product, or any raw materials or packaging materials with respect thereto, or any intermediate of any of the foregoing, including process and cost optimization, process qualification and validation, commercial manufacture, stability and release testing, quality assurance and quality control. Manufacture excludes \*\*. For clarity, “**Manufacturing**” has a correlative meaning.

“**Manufacturing Costs**” means the actual, fully-burdened cost of all Manufacturing activities, including raw materials, transportation, testing, unrecoverable taxes, direct labor and benefits, and the proportionate share (as determined pursuant to the subsequent sentence) of indirect Manufacturing costs, including Third Party Manufacturing costs. For clarity, such fully-burdened cost shall be calculated (i) on a normal full-capacity basis (with reasonable deductions for changeover and maintenance downtime) with the percentage allocable to Manufacturing Costs representing the number of units or runs of, respectively, Licensed Compound or Licensed Product, as applicable, produced or performed as a percentage of the total number of units or runs, including those of other products, that could be Manufactured in such facility during a Calendar Year and (ii) in accordance with Accounting Standards, consistently applied. \*\*, shall not be included in the determination of Manufacturing Costs. Unless otherwise agreed in writing between the Parties, Manufacturing Costs shall exclude any Development Costs. For the avoidance of doubt, \*\*.

“**Medical Affairs Activities**” means design, strategies, oversight and implementation of activities designed to ensure or improve appropriate medical use of, conduct medical education of, or further research regarding, the Licensed Product, including by way of example: (i) activities of Medical Liaisons, (ii) grants to support continuing independent medical education (including independent symposia and congresses), (iii) Non-Development Studies and medical studies, (iv) activities such as booths and other presence at international congresses such as EHA, ASH and ICML, and (v) Development, publication and dissemination of publications in support of an approved indication for the Licensed Product, as well as medical information services (and the content thereof) provided in response to inquiries communicated via the sales representatives or received by letter, phone call or email.

“**Medical Liaisons**” means those healthcare professionals employed or engaged by a Party with sufficient healthcare experience to engage in in-depth dialogues with HealthCare Practitioners regarding exchange on critical scientific, technical and Development issues associated with Licensed Product and the diseases they address, and are not sales representatives or otherwise engaged in direct selling or promotion of Licensed Product. Medical Liaisons are field-based and report directly to the medical department.

“**MHLW**” means the Ministry of Health, Labour and Welfare of Japan.

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“**MHRA**” means the Medicines and Healthcare products Regulatory Agency of the United Kingdom.

“**Mutual Consent Matters**” means:

- (a) any matter relating to the Development Plan, including but not limited to the Development Budget, and any change(s) to any Development Budget for a given Calendar Year which, alone or together with other changes to the Development Budget for such Calendar Year, represent an \*\* for such Calendar Year, provided that the \*\* the Development Costs for any given Development Study \*\* the initial Development Budget for such Development Study;
- (b) the submission of any Regulatory Materials to the EMA pursuant to Section 6.2.3;
- (c) such matters as may be designated as Mutual Consent Matters hereunder.

“**NDA**” means a New Drug Application, including all supplements and amendments thereto, for the approval of the Licensed Product as a new drug by the FDA.

“**Net Sales**” means, in the case of sales by or for the benefit of Servier, its Affiliates and its Sublicensees (the “**Seller**”) to independent, unrelated persons in bona fide arm’s length transactions (except as provided below with respect to clinical trial samples), the gross amount billed or invoiced by Seller with respect to the Licensed Product, during the Royalty Term, less the following deductions (“**Permitted Deductions**”):

- (a) trade, cash, promotional and quantity discounts consistent with Servier’s practices in the relevant country;
  - (b) taxes on sales (such as excise, sales or use taxes or value added tax), to the extent added to the sales price;
  - (c) taxes on sales of pharmaceutical specialties reimbursed pursuant to a government health service, health insurance, social insurance or similar social services program, to the extent added to the sales price;
  - (d) freight, insurance, packing costs and other transportation charges to the extent added to the sales price;
  - (e) amounts repaid or credits taken by reason of rejections, defects or returns or because of retroactive price reductions, or due to recalls or Applicable Laws requiring rebates;
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(f) free goods;

(g) rebates taken by or fees paid to distributor, warehousing, pick, pack general distribution costs, wholesaler management fees in total not to \*\* of the aforesaid gross amounts;

(h) chargeback payments and rebates and/or discounts on sales of Licensed Products given to health insurance and other types of payers in any given country of the Servier Territory due to specific agreement (“*claw-back*” type of agreements) involving the Licensed Products consistent with Servier’s practices in the relevant country;

(i) the actual amount of any write-offs for bad debt; provided with respect to such write-off that an amount subsequently recovered or reversed with respect to such write-off will be treated as Net Sales in the quarter in which it is recovered or reversed; and

(j) any other specifically identifiable amounts included in gross amounts invoiced for the Licensed Products, to the extent such amounts become customary deductions from net sales calculations in the pharmaceutical or biotechnology industries in the applicable country for reasons substantially equivalent to those listed above, after the Restatement Date.

For the purposes hereof, “*Net Sales*” shall not include any consideration received with respect to a sale, use or other disposition of any Licensed Product in a country for \*\* consistent with practices in the industry in the relevant country. Notwithstanding the foregoing, amounts invoiced by Servier, its Affiliates, or their Sublicensees for the sale of Product among Servier, its Affiliates or their respective Sublicensees for resale shall not be included in the computation of Net Sales hereunder and Net Sales shall be the gross invoice or contract price charged to the Third Party customer for that Product, less the Permitted Deductions.

In the event that the Licensed Product is sold as a Combination Product, the Net Sales will be calculated by \*\* containing the \*\* containing the \*\*. Regarding prices \*\*, if these are \*\* that are included in the \*\*, then the applicable Party shall be entitled to make a proportional adjustment to such prices in calculating the royalty-bearing Net Sales of the \*\*. If the \*\* cannot be determined for the \*\* containing the \*\*, the calculation of \*\* will be agreed by the Parties based on the relative value contributed by each component (each Party’s agreement not to be unreasonably withheld or delayed).

“*Non-Development Studies*” means any Clinical Studies other than Development Studies, including any Territory Specific Studies and Investigator Sponsored Studies.

“*Novartis Agreements*” means (i) the license and co-development agreement dated September 15, 2006, between Cell Therapeutics, Inc., Cell Therapeutics Europe S.r.l, and Novartis International Pharmaceutical Ltd. (“*Novartis*”) and (ii) the termination agreement dated January 3, 2014 between Cell Therapeutics, Inc. and Novartis.

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**“Out-of-Pocket Costs”** means all direct project expenses incurred in respect of Third Parties after the Restatement Date, which are specifically identifiable and incurred for services or materials provided by them directly in their performance of the Development in accordance with the Development Plan and Development Budget, or Medical Affairs Activities and Commercialization expenses incurred in the performance of the Commercialization Transition Plan, as appropriate; such expenses to have been recorded as income statement items in accordance with Accounting Standards and for the avoidance of doubt, not including pre-paid amounts (until expensed in accordance with applicable Accounting Standards) or recoverable taxes. For clarity, Out-of-Pocket Costs do not include capital expenditures, FTE travel expenses or items intended to be covered by FTE costs.

**“Patent”** means any of the following, whether existing now or in the future, anywhere in the world: (i) any patents and patent applications (including provisional applications), (ii) any patent applications filed either from such patents or patent applications (including all provisional applications, divisionals, continuations, substitutions, continuations-in-part, re-examinations, reissues, additions, renewals, extensions, registrations, and supplemental protection certificates and the like of any of the foregoing) or from an application claiming priority from either of these, including continuations, continuations-in-part, divisionals, converted provisionals, continued prosecution applications, and substitute applications, (iii) any patents issued based on or claiming priority to any such patent applications in (i) and (ii), (iv) any and all extensions or restorations by existing or future extension or restoration mechanisms, including adjustments, revalidations, renewals, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications in (i), (ii) and (iii), and (v) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patents of addition to any of such foregoing patents or patent applications.

**“Person”** means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, Governmental Authority, association or other entity.

**“PIX Positive Outcome”** means the time-point at which the results of the \*\*.

**“PIX Protocol”** means the protocol for the PIX306 Trial, as may be amended from time to time in accordance with the terms hereof.

**“PIX306 Trial”** has the meaning set forth in the preamble.

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**“Product Liability Claims”** means any product liability claims asserted or filed by Third Parties (without regard to their merit or lack thereof), seeking damages or equitable relief of any kind, relating to personal injury, wrongful death, medical expenses, an alleged

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need for medical monitoring, consumer fraud or other alleged economic losses, allegedly caused by the Licensed Product, and including claims by or on behalf of users of the Licensed Product (including spouses, family members and personal representatives of such users) relating to the use, sale, distribution or purchase of the Licensed Product sold by or on behalf of a Party or such Party's Affiliates or Sublicensees, including, but not limited to, claims by Third Party payers, such as insurance carriers and unions.

**“Regulatory Approval”** means, with respect to a Licensed Product in any country or jurisdiction, any and all approvals (including any NDA and MAA approvals but excluding any pricing and reimbursement approvals), licenses, permits, certifications, registrations or authorizations of any Regulatory Authority necessary under Applicable Law in a country or other jurisdiction in order to commercially distribute, Manufacture and have Manufactured, sell or market the Licensed Product (or new indication for such Licensed Product ) in such country or jurisdiction.

**“Regulatory Authority”** means any Governmental Authority or other authority responsible for reviewing Regulatory Materials and/or granting Regulatory Approvals for Licensed Product, including the FDA, EMA and any corresponding national or regional regulatory authorities.

**“Regulatory Exclusivity Rights”** means, with respect to the Licensed Product and a particular country or regulatory jurisdiction, the exclusive legal right granted by the relevant Regulatory Authority either to market and sell such Licensed Product in that country or regulatory jurisdiction or the exclusive right to the use of or reference to clinical Data in relation to such Licensed Product in that country or regulatory jurisdiction.

**“Regulatory Materials”** means regulatory applications, submissions, dossiers, notifications, registrations, case reports forms, common technical documents, question and answers with Regulatory Authorities, Regulatory Approvals and/or other filings made to or with, or other approvals granted by, a Regulatory Authority that are necessary or reasonably desirable in order to Develop, Manufacture, conduct Medical Affairs Activities regarding, or Commercialize the Licensed Product in a particular country or regulatory jurisdiction (but excluding any pricing and reimbursement approvals). Regulatory Materials include IND/IMPDs, MAAs, MAs and DMFs and any foreign country equivalents of the foregoing.

**“Respective Territory”** means with respect to Servier, the Servier Territory, and with respect to CTI, the CTI Territory.

**“Royalty Term”** means, on a country-by-country basis, the period commencing on the First Commercial Sale of a Licensed Product in a country and ending on the latest of (a) \*\* thereafter, (b) expiration of the last-to-expire Valid Claim of a Licensed Patent that Covers the composition of matter of the Licensed Product in the country in which it is sold, or (c) the expiration of all Regulatory Exclusivity Rights with respect to such Licensed Product in the country in which it is sold.

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“**Safety Reason**” means Servier’s reasonable belief, that, based upon scientific data, there are safety and public health issues relating to the Licensed Product such that the medical benefit/risk ratio of such Licensed Product is sufficiently unfavorable as to materially compromise the welfare of patients to Develop or Commercialize or to continue to Develop or Commercialize it.

“**Senior Officers**” means the senior officers designated by each Party for the purposes hereof.

“**Servier EU Territory**” means the European Union.

“**Servier Ex-EU Key Markets**” means \*\*.

“**Servier Ex-EU Territory**” means the countries of the Servier Territory other than the countries of the Servier EU Territory.

“**Servier Key Markets**” means (i) \*\* and (ii) the Servier Ex-EU Key Markets.

“**Servier Territory**” means the entire world, but excluding the CTI Territory.

“**Standard MA**” means the granting of an MA (other than a conditional MA) by the EMA, as the result of a positive decision of the European Commission, consistent with the Conditional MA granted by the European Commission for the Licensed Compound and the Licensed Product.

“**Sublicensee**” means a Third Party which is a sublicensee of either Party’s rights hereunder in accordance with the terms and conditions of this Agreement. For sake of clarity, Sublicensees do not include subcontractors, contract sales forces, CROs, CMOs, wholesalers, distributors or the like, even if they are granted a limited right to resell the Licensed Product sold to any of them, and, further, Sublicensees do not include such Party’s Affiliates.

“**Territory Specific Study**” means any Clinical Study or non-clinical study that is required only by Regulatory Authorities in any given jurisdiction (or group of jurisdictions) in order to obtain or maintain Regulatory Approval for the Licensed Product in such jurisdiction (or group of jurisdictions) but not by the EMA or by the Regulatory Authorities in other jurisdictions (or group of jurisdictions).

“**Third Party**” means any entity other than CTI or Servier, and their respective Affiliates; provided, however, that, for clarity, it is agreed that the Parties’ respective Generics Affiliates shall be deemed to be “**Third Parties**” and not “**Affiliates**” for purposes of this Agreement.

“**Third Party Claim**” means any and all claims of Losses that are asserted by a Third Party (other than any Generic Affiliate), including any Product Liability Claims.

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“*Transition Territory*” means Israel, Turkey, Germany, Austria, United Kingdom, Denmark, Finland, Norway and Sweden.

“*University of Vermont Agreement*” means that certain license agreement dated March 8, 1995, as amended, between Boehringer Mannheim Italy and the University of Vermont (the “*University of Vermont*”).

“*Valid Claim*” means any claim of a Patent (other than a Joint Patent) that is issued and unexpired and has not been revoked or held unenforceable or invalid by a final, nonappealable decision of a court or other Governmental Authority of competent jurisdiction or a final decision of a court or other Governmental Authority of competent jurisdiction that has not been appealed within the time allowed. Notwithstanding the foregoing, if a claim of a pending patent application has not issued as a claim of a patent within \*\* after the filing date from which such claim takes priority, such claim shall not be a Valid Claim for the purposes of this Agreement, unless and until such claim issues as a claim of any issued patent (from and after which time the same would be deemed a Valid Claim subject to the first sentence of the definition above).

*Additional Definitions.* Each defined term used in this Agreement but not set forth above is defined in the body of this Agreement as indicated below.

<i>Term</i>	<i>Section</i>
“ <i>Accelerated Arbitration Procedure</i> ”	15.2
“ <i>Additional Committee</i> ”	3.5
“ <i>Additional Study</i> ”	5.6.1.2(ii)
“ <i>Agreement</i> ”	Preamble
“ <i>Alliance Manager</i> ”	3.8
“ <i>Annual Sales</i> ”	10.3
“ <i>Arbitration</i> ”	15.1
“ <i>Arbitration Request</i> ”	15.1
“ <i>Auditor</i> ”	10.10.1
“**”	9.2.2.1
“ <i>Business Combination Transaction</i> ”	Definition of “Change of Control Transaction”
“ <i>Claim Notice</i> ”	16.4.1
“ <i>Co-Chair</i> ”	3.3.3
“ <i>Commercialization Transition Date</i> ”	7.1.2
“ <i>Commercialization Transition Plan</i> ”	7.1.2
“ <i>Committee</i> ”	3.3.1
“ <i>Competing Product Affiliation Transaction</i> ”	8.2.1
“ <i>Corrective Action</i> ”	6.5.1
“ <i>Cost Report</i> ”	5.5.3
“ <i>CTF</i> ”	Preamble
“ <i>CTI Indemnitee</i> ”	16.2

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<i>Term</i>	<i>Section</i>
<i>“CTI Trademark”</i>	11.7.1
<i>“CTI US “</i>	Preamble
<i>“CTILS”</i>	Preamble
<i>“Development Budget”</i>	5.2
<i>“Development Plan”</i>	5.2
<i>“Disclosing Party”</i>	Definition of “Confidential Information”
<i>“Dispute”</i>	15.1
<i>“Electing Party”</i>	8.2.1
<i>“European MA Transfer”</i>	6.2.1
<i>“Generics Affiliates”</i>	Definition of “Affiliate”
<i>“Head Licenses”</i>	10.6.4(A)
<i>“IFRS”</i>	Definition of “Accounting Standards”
<i>“Indemnified Party”</i>	16.4.2.2
<i>“Indemnifying Party”</i>	16.4.2.1
<i>“IRIS”</i>	Preamble
<i>“Joint Executive Committee” or “JEC”</i>	3.1.1
<i>“Joint Steering Committee” or “JSC”</i>	3.2.1
<i>“Licensed IP Claims”</i>	11.4.1
<i>“LLS”</i>	Preamble
<i>“Manufacturing Know-How”</i>	9.4
<i>“Medical Journals”</i>	12.4.1
<i>“NHL”</i>	Recitals
<i>“Non-Proposing Party”</i>	5.6.1
<i>“Novartis”</i>	Definition of “Novartis Agreements”
<i>“Opt-In Right”</i>	5.6.2
<i>“Outstanding Voting Securities”</i>	Definition of “Change of Control Transaction”
<i>“Party” or “Parties”</i>	Preamble
<i>“Paying Party”</i>	10.7
<i>“Permitted Deductions”</i>	Definition of “Net Sales”
<i>“PIX306 Triggering Event”</i>	6.2.1
<i>“Prior CDA”</i>	Definition of “Confidential Information”
<i>“Proposing Party”</i>	5.6.1
<i>“Quality Agreement”</i>	9.3
<i>“Raw Data”</i>	4.2.5
<i>“Receiving Party”</i>	Definition of “Confidential Information”
<i>“Recipient Party”</i>	10.9
<i>“Reconciliation Report”</i>	5.5.4
<i>“Regulatory Milestone Payment”</i>	10.2
<i>“Restatement Date”</i>	Preamble
<i>“Royalties”</i>	10.4
<i>“Royalty Report”</i>	10.5.2

<i>Term</i>	<i>Section</i>
<i>“Rules”</i>	15.1
<i>“Sale Milestone Payment”</i>	10.3
<i>“Scientific Meeting”</i>	12.4.2
<i>“Scientific Paper”</i>	12.4.1
<i>“Seller”</i>	Definition of “Net Sales”
<i>“Servier”</i>	Preamble
<i>“Servier Indemnitee”</i>	16.1
<i>“Servier Product Trademarks”</i>	11.7.2
<i>“Sole Invention”</i>	11.2
<i>“Sole Invention Patents”</i>	11.2
<i>“Supply Agreement”</i>	9.2
<i>“**”</i>	5.2.3
<i>“Third Party IP Claims”</i>	11.4.1
<i>“Transfer”</i>	17.1
<i>“University of Vermont”</i>	Definition of “University of Vermont Agreement”
<i>“Withholding Taxes”</i>	10.9

## ARTICLE 2

### LICENSE

2.1 **License Grant.** In accordance with the terms and conditions of this Agreement, CTI hereby grants to Servier:

2.1.1 an exclusive (even as to CTI) and sublicensable (subject to Section 2.3), royalty-bearing right and license under the Licensed Intellectual Property to Develop, have Developed, Commercialize, have Commercialized, and conduct and have conducted Medical Affairs Activities regarding the Licensed Compound and the Licensed Product(s) in the Field in the Servier Territory, provided that CTI shall be entitled to conduct or have conducted Development activities with respect to the Licensed Compound and/or Licensed Product(s) in the Servier Territory pursuant to the Development Plan;

2.1.2 a sublicensable (subject to Section 2.3) exclusive (even as to CTI subject to the right for CTI to have Manufactured the Licensed Product(s) in the Servier Territory for Commercialization in the CTI Territory), royalty-bearing right and license under the Licensed Intellectual Property to Manufacture, have Manufactured, import and have imported, anywhere in the world the Licensed Compound and Licensed Product(s) for use, Development, Medical Affairs Activities and Commercialization in the Field in the Servier Territory; and

2.1.3 a sublicensable (subject to Section 2.3), non-exclusive, royalty-bearing right and license under the Licensed Intellectual Property to conduct or have conducted Development activities with respect to Licensed Compounds and/or Licensed Product in the CTI Territory pursuant to the Development Plan and/or solely in support of Development, Medical Affairs Activities and Commercialization of Licensed Product in the Field in the Servier Territory.

2.2 **License to CTI.** Subject to the terms and conditions of this Agreement, Servier hereby grants to CTI a non-exclusive, royalty-free, sublicensable right only with the prior written consent of Servier, such consent not to be unreasonably withheld or delayed, and license under the Know-How generated by Servier under the Original Agreement and after the Restatement Date pursuant to this Agreement and any Sole Inventions and Sole Invention Patents of Servier to: (a) conduct or have conducted Development activities with respect to the Licensed Compound and/or Licensed Product(s), (b) Manufacture and have Manufactured the Licensed Compound and/or Licensed Product(s) anywhere in the world for use, Development, Medical Affairs Activities and Commercialization in the Field in the CTI Territory and (c) conduct or have conducted Medical Affairs Activities and Commercialization with respect to the Licensed Product(s) in the Field in the CTI Territory.

2.3 **Sublicensing.** Each Party shall have the right, in its sole and absolute discretion, to sublicense the rights granted to it under this Agreement to any Third Parties or to disclose and provide to them any of the Know-How licensed to it in connection therewith, subject to Section 2.2 with respect to CTI and provided that, in the case of Servier, Servier shall provide CTI with written notice as set forth below in this Section 2.3 of any Sublicense of the right to Commercialize the Licensed Product in \*\*. The grant of any such sublicense shall not relieve the relevant Party of its obligations under this Agreement, and each such sublicense shall include restrictions on the Sublicensee preventing it from further sublicensing the granted rights and shall contain terms, including obligations of confidentiality and restrictions on use, at least as restrictive as those contained in this Agreement. Each Party shall be responsible for the performance of its Sublicensees and the compliance of each such Sublicensee with the terms and conditions of this Agreement. Each Party shall notify the other within fifteen (15) days of entering into any such sublicense and, at the request of the other Party, provide a copy thereof which may be redacted to omit confidential financial information.

2.4 **Performance by Affiliates.** Subject to the terms and conditions of this Agreement, each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. All applicable terms and provisions of this Agreement shall apply to any such Affiliate to which this Agreement has been extended to the same extent

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as such terms and provisions apply to the Party granting such extension, which Party shall cause such Affiliate to comply with such applicable terms and provisions. Each Party shall remain primarily liable for any acts or omissions of its Affiliates.

2.5 **Generic Arms.** Each Party shall put in place a Generics Firewall between, on the one hand, itself and all of its Affiliates involved in the collaboration contemplated by this Agreement, and, on the other hand, its Generics Affiliates.

### **ARTICLE 3**

#### **GOVERNANCE**

##### **3.1 Joint Executive Committee.**

3.1.1 The Parties have established a joint executive committee (the “*Joint Executive Committee*” or “*JEC*”), all in accordance with this Section 3.1 and the Original Agreement. The JEC membership and procedures are further described in Section 3.3.

3.1.2 The JEC shall in particular, in accordance with the decision-making principles set forth in Section 3.4, manage \*\*.

3.1.3 Unless otherwise agreed upon between the Parties, the JEC shall be comprised of an equal number of representatives from each of Servier and CTI, which unless otherwise agreed upon between the Parties, shall be of \*\* members of each Party and shall be in accordance with Sections 3.3.2 and 3.3.3.

3.1.4 The JEC will meet in accordance with Section 3.3.4 at least \*\* (or more if agreed upon), with the Co-Chairs (as defined in Section 3.3.3 below) attending in person. The location of the meetings of the JEC \*\* the place \*\* and the place \*\*, with the intent that each such meeting shall be held at the \*\*.

##### **3.2 Joint Steering Committee.**

3.2.1 The Parties have established a joint steering committee (the “*Joint Steering Committee*” or “*JSC*”) to assume a general role of leadership in the collaboration, to oversee and \*\* of the project and the alliance, facilitate communication and provide a forum to review any Development, regulatory, Manufacturing, quality and compliance, product distribution, financial, medical affairs and commercial matters pertaining to the Licensed Product, all in accordance with this Section 3.2 and the Original Agreement.

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3.2.2 The JSC shall in particular, in accordance with the decision-making principles set forth in Section 3.4:

3.2.2.1 coordinate the activities of the Parties under this Agreement, including \*\* with respect to the \*\* of the \*\*;

3.2.2.2 provide \*\* of the Licensed Product;

3.2.2.3 review and approve \*\* updates and proposed amendments thereto;

3.2.2.4 perform such other duties as are expressly assigned to the JSC in this Agreement, and perform such other functions as appropriate to further the purposes of this Agreement as may be allocated to it by written agreement of the Parties;

3.2.2.5 review any proposed Territory Specific Studies and Additional Studies;

3.2.2.6 review and approve any Mutual Consent Matters;

3.2.2.7 establish Additional Committees as set forth in Section 3.5 below;

3.2.2.8 attempt to resolve issues presented to it by, and disputes within, the Additional Committees, in accordance with Section 3.4;

3.2.2.9 inform the other Party regarding any Investigator Sponsored Studies that are planned or, as of the Restatement Date, are ongoing; and

3.2.2.10 make such determinations as are expressly delegated to it under the terms of this Agreement.

3.2.3 Unless otherwise agreed upon between the Parties, the JSC shall be comprised of \*\* unless otherwise agreed upon between the Parties, shall be comprised of \*\* and shall be in accordance to Sections 3.3.2 and 3.3.3.

3.2.4 The JSC will meet \*\* (or more if agreed upon), with the Co-Chairs attending in person \*\*, in accordance with Section 3.3.4.

**3.3 General Rules.** The following are general rules applicable to Committees:

3.3.1 Each of the Joint Executive Committee and the Joint Steering Committee (each, a “*Committee*”) will have solely the roles and responsibilities assigned

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to it in this Article 3 and as otherwise expressly set forth in this Agreement. The Committees will have no authority to amend, modify or waive compliance with this Agreement, to make decisions that conflict with the terms and conditions of this Agreement, or to create new obligations for a Party not specified in this Agreement. Neither the Committees, the Senior Officers, nor either Party exercising its final decision-making power pursuant to Sections 3.4 and 3.7, shall have authority to alter, increase, expand, modify or otherwise amend, or to waive compliance with, this Agreement.

3.3.2 **Committee Membership.** Either Party may replace its respective committee representatives at any time upon prior written notice to the other Party. In the event a Committee member from either Party is unable to attend or participate in a Committee meeting, the Party who designated such representative may designate a substitute representative for the meeting in its sole discretion. The Alliance Managers appointed by Servier and CTI are ex officio members of each of the Committees and the Additional Committees.

3.3.3 **Committee Co-Chairs.** Each Party shall appoint one of its members in each Committee to co-chair such Committee's meetings (each, a "**Co-Chair**"). The Co-Chairs shall (a) ensure the orderly conduct of the Committee's meetings, (b) attend each Committee meeting (either in-person, by videoconference or telephonically, unless otherwise expressly provided herein), and (c) prepare and issue written minutes of each meeting within \*\* thereafter accurately reflecting the discussions and decisions of such meeting. Unless otherwise agreed, the Committee shall have at least one (1) representative with relevant decision-making authority from each Party such that the Committee, subject to Sections 3.4 and 3.7, is able to effectuate all of its decisions within the scope of its responsibilities. In the event the Co-Chair from either Party is unable to attend or participate in a Committee meeting, the Party who designated such Co-Chair may designate a substitute Co-Chair for the meeting in its sole discretion.

3.3.4 **Committee Meetings.** All meetings will be conducted in English and may be conducted by telephone, videoconference or in person as determined by the Co-Chairs, as appropriate; provided that not less than \*\* prior written notice has been given to the other Party, and subject to such other Party's approval (not to be unreasonably withheld, delayed or retained), other employees of the Parties may attend Committee meetings as observers. Either Party may also call a special meeting of a Committee (by videoconference or teleconference) by at least \*\* prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting, and no later than \*\* prior to the special meeting, such Party shall provide the Committee with materials reasonably adequate to enable an informed decision. The Co-Chair representing the host Party for each meeting will be

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responsible for (a) providing an agenda to all participants in draft form at least \*\* in advance of the meeting and in final form at least \*\* in advance of the meeting, (b) recording the minutes for each meeting and (c) distributing such minutes to the participants no later than \*\* after the meeting. In the event a Party fails to attend a duly called meeting, and as a result no consensus can be reached, the matter shall be deemed disputed and shall be escalated or decided as set forth in this Article 3.

3.4 **Decision Making.** Other than as set forth herein, in order to make any decision required of it hereunder with respect to any approval, a Committee must have present (in person, by videoconference or telephonically) at least the Co-Chair of each Party (or his/her designee for such meeting). The Parties will endeavor to make decisions where required with respect to any approval of a Committee by consensus of the Co-Chairs. If a dispute or failure to agree arises which cannot be resolved, the Co-Chairs of either Party may cause such dispute or failure to agree to be referred to the Joint Steering Committee for resolution. If a dispute or failure to agree arises which cannot be resolved within the Joint Steering Committee, the Co-Chairs of either Party may cause such dispute or failure to agree to be referred to the JEC. The JEC shall attempt in good faith to resolve such dispute or failure to agree by unanimous consent (with the Co-Chairs each having one vote). If the JEC cannot resolve such dispute or failure to agree within \*\* of the matter being referred to it, then either Party may cause such dispute or failure to agree to be referred to the Senior Officers for resolution. The Senior Officers shall attempt in good faith to resolve such dispute or failure to agree by unanimous consent (with the CTI Senior Officer having one vote and the Servier Senior Officer having one vote). If the Senior Officers cannot resolve such dispute or failure to agree within \*\* of the matter being referred to them, then the resolution and/or course of conduct shall be determined as follows:

3.4.1 the matter would be finally decided solely by CTI with respect to matters related to \*\*, and solely by Servier with respect to matters related to \*\*, provided that in each case, the matter \*\*; and

3.4.2 with respect to the Mutual Consent Matters, all disputes or failures to agree shall be resolved only by unanimous consent of the Senior Officers (with the CTI Senior Officer having one vote and the Servier Senior Officer having one vote). For the avoidance of doubt, \*\*.

3.4.3 For the avoidance of doubt, each Party shall have the final decision making authority with respect to \*\*, in each case to the extent related to \*\*, the activities to be conducted \*\* in connection therewith, the cessation or suspension of any \*\*.

3.4.4 If a matter relating to \*\* is escalated pursuant to this Section 3.4 or Section 15.1 but requires urgent action (including any matter involving the safety of

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patients in \*\*), such Party shall be entitled to take all precautionary actions pending such escalation without prejudice to the other Party's right to seek damages or an injunction or other equitable relief with respect to any actual or threatened breach of this Agreement or otherwise to prevent or avoid irreparable harm.

3.5 **Additional Committees.** From time to time, the JSC may establish or dissolve permanent or ad hoc committees to oversee particular projects or activities within the scope of its responsibilities hereunder, and such committees will be constituted as the JSC determines (each, an "**Additional Committee**"). If any Additional Committee is unable to reach a decision on any matter after endeavoring in good faith to do so, such matter shall be referred to the JSC for resolution as provided in Section 3.4.

3.6 **Interactions between the Committees and the Additional Committees.** The Parties recognize that while they will establish the Committees and Additional Committees for the purposes hereof, each Party may maintain such internal structures (including its own committees, teams and review boards) as it deems appropriate, which structures to be involved in administering such Party's activities under this Agreement. The Parties shall establish procedures to facilitate communications between each Committee and Additional Committee hereunder and the relevant internal committees, teams or boards within each Party in order to maximize the efficiency of the Parties' activities pursuant to this Agreement.

3.7 **Day-to-Day Decision-Making Authority.** Each Party shall have day-to-day decision-making authority with respect to the Development, Manufacturing, Medical Affairs Activities and Commercialization of Licensed Product in its Respective Territory, provided that such decisions are not inconsistent with the then-current Development Plan, Development Budget, other decisions of the Committees within the scope of their authority specified therein, or the terms and conditions of this Agreement.

3.8 **Alliance Managers.** Each of Servier and CTI shall appoint one senior representative who possesses a general understanding of development, regulatory, manufacturing and commercialization matters to act as its respective alliance manager for this relationship (each, an "**Alliance Manager**"). Each Party may replace its respective Alliance Manager at any time upon written notice to the other in accordance with this Agreement. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within and among the Committees. Each Alliance Manager will also be responsible for:

3.8.1 coordinating the relevant functional representatives of the Parties in Developing and executing key strategies and plans for the Licensed Product in an

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effort to ensure consistency and efficiency within the CTI Territory and in the Servier Territory;

3.8.2 providing a primary point of communication responsible for facilitating the flow of information and for seeking consensus both within the respective Party's organization and together regarding key strategy and plan issues;

3.8.3 ensuring that the governance procedures and the rules set forth herein are complied with;

3.8.4 identifying and raising disputes to the relevant Committee for discussion in a timely manner; and

3.8.5 planning and coordinating internal and external communications in accordance with the terms of this Agreement.

3.8.6 The Alliance Managers shall be entitled to attend all Committee and Additional Committee meetings. Each Alliance Manager may bring any matter to the attention of the Committees and Additional Committees where such Alliance Manager reasonably believes that such matter requires attention of the Committees and Additional Committees.

3.9 **Cost of Governance.** The Parties agree that the costs incurred by each Party in connection with its participation at any meetings under this Article 3 shall be borne solely by such Party.

#### ARTICLE 4

##### PROVISION OF DATA AND KNOW-HOW

###### 4.1 Know-How Transfer.

4.1.1 Promptly after the Restatement Date but not later than \*\* after such date, CTI shall transfer to Servier, to the extent not already transferred pursuant to the Original Agreement, the Licensed Know-How, as well as any Regulatory Materials and Regulatory Approvals (subject to Section 6.2.1) and any pricing and reimbursement approvals obtained prior to the Restatement Date in the Servier Territory (other than \*\*, and the Know-How related to Manufacturing, which is covered by Article 9). Such transfer shall occur in a manner and following a reasonable schedule to be established by the JSC and a list that sets forth the specific Licensed Know-How to be provided to Servier.

4.1.2 Thereafter on a continuing basis for the duration of this Agreement, CTI shall promptly make available to Servier all additional Licensed Know-

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How which comes into existence from time to time and Servier shall promptly make available to CTI all Know-How licensed to CTI pursuant to Section 2.2, which comes into existence from time to time (other than the CTI Know-How related to Manufacturing, which is covered by Article 9 with respect to transfers by CTI to Servier), including all Data generated under any Development Plan or Territory Specific Study (for purposes of Section 5.6.3) or under any Additional Study in accordance with Section 5.6.

#### 4.2 Rights of Reference; Use of Data; Format of Reports

4.2.1 Each Party shall have the right to \*\*, file or incorporate by reference in its Respective Territory any Regulatory Materials (and any Data contained therein) filed by the other Party or the other Party's Affiliates for the Licensed Product in order to enable the applicable Party (and its Affiliates and Sublicensees) to Develop, Manufacture, conduct Medical Affairs Activities and Commercialize the Licensed Product in accordance with this Agreement, subject to the provisions of Section 5.6 with respect to Additional Studies.

4.2.2 Each Party will provide, and cause its Affiliates to provide, reasonable cooperation to the other Party to effect the foregoing (including permitting the other Party and/or any relevant Regulatory Authority to inspect any such Regulatory Materials upon reasonable notice). Each Party shall, on written request by the other Party, provide to such requesting Party and to any specified Regulatory Authority a letter, in the form reasonably required by such requesting Party, acknowledging that such requesting Party (or its Affiliates and Sublicensees) has the above right of reference to any such Regulatory Materials.

4.2.3 In the event that the Regulatory Materials to be cross-referenced, filed or incorporated by reference include any DMF of a Third Party manufacturer, such rights of cross-reference, filing or incorporation by reference shall be subject to such obligations and restrictions as the applicable Party may have to such Third Party manufacturer with respect to the use or disclosure of its DMF.

4.2.4 Notwithstanding any provision herein, no Party shall be entitled to, nor shall it allow any of its Affiliates or Sublicensees to nor grant any Third Party any right to, directly or indirectly \*\* in order to \*\*; provided, however, that nothing in this Section is intended to \*\* in any manner the \*\* in the same way as \*\* would be able to \*\*; provided, further, \*\* in connection with any \*\*.

4.2.5 Either Party shall have the right to request primary source data ("**Raw Data**") for any Data filed by or received from the other Party in respect of the studies conducted by CTI in relation with the Licensed Product and intended for submission to any

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Regulatory Authority, such right to be exercised in good faith. The Parties agree to conduct appropriate quality control and verification procedures and such other processes as may be required to confirm that the Data accurately describes the experimental methods and results of any study. Such quality control and verification procedures shall include verification against Raw Data to ensure that supporting statements and conclusions embodied in any documents submitted by Servier or CTI to any Regulatory Authority are accurately represented. The Parties will ensure that quality control and verification procedures are conducted by individuals and entities with the appropriate technical expertise and experience, and that quality control and verification procedures are documented appropriately in compliance with the industry standard operating procedures and all Applicable Laws. \*\* for all Out-of-Pocket Costs incurred in the performance of \*\*.

4.2.6 All CMC, non-clinical and clinical study reports shall be in \*\*. The costs and expenses relating to the preparation of \*\* shall be borne by t\*\*. The costs and expenses relating to the preparation of all other study reports in \*\* shall be borne by \*\*.

4.3 **Disclaimer.** Other than as expressly set forth in this Agreement, any Data disclosed by a Party to the other Party under this Agreement is provided on an “as is” basis, without any warranty (express or implied) of any kind, and the Disclosing Party expressly disclaims all such warranties to the maximum extent permitted under Applicable Law. The Receiving Party on behalf of itself and its Affiliates and Sublicensees accepts all risk and liability in relation to the use of the Data received from the Disclosing Party under this Agreement and shall indemnify and hold harmless the Disclosing Party from any Third Party’s claim(s) based upon such Data as provided in Article 16.

## ARTICLE 5

### RESEARCH & DEVELOPMENT

5.1 **Development.** The Parties will collaborate in the Development of the Licensed Product pursuant to the Development Plan as described below. Except as expressly provided for herein, \*\*.

5.1.1 Notwithstanding the foregoing, \*\* shall remain solely responsible for \*\* necessary to \*\*. CTI shall use Commercially Reasonable Efforts in connection with its Development activities, including its activities pursuant to any Development Plan, provided that given the value of the \*\* for the Development and Commercialization of the Licensed Product, with respect to the \*\*, CTI shall:

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5.1.1.1 conduct all \*\*, and failure to achieve any of the results referred to in this Section 5.1.1.1 and in Section 5.1.1.2 \*\*, provided that CTI has exercised diligent efforts with respect thereto;

5.1.1.2 keep Servier promptly updated on the progress and/or any difficulties with respect to the \*\*;

5.1.1.3 send regular updates to the \*\* and \*\* on an annual basis until the completion of the European MA Transfer, provided that all such communications shall be submitted to Servier for timely review and approval in accordance with Section 6.1 below;

5.1.1.4 collaborate with Servier on statistical analysis and clinical study report writing with respect to the \*\* (including in connection with \*\*). Subject to Servier's confirmation, Servier will \*\*, and CTI will \*\*. For the purposes of this Section, the \*\* will include \*\*. Servier will confirm such responsibility for \*\*. The Parties shall \*\*; and

5.1.1.5 transfer a full and complete copy of \*\* to Servier (i) \*\* prior to the date of \*\* as determined \*\* and (ii) \*\*. Data transfer under this Section shall take full account of all data integrity issues including but not limited to \*\*. In connection with the foregoing, the Parties shall closely collaborate with each other through regular data review meetings and \*\*.

**5.2 Development Plan.** The activities of the Parties with respect to the Development of the Licensed Product shall be conducted in accordance with one or more written development plans, which shall set forth the specific activities to be conducted by each Party for each such Licensed Product and the estimated timelines (either the Initial Development Plan or Subsequent Development Plan(s), as applicable, together, the “*Development Plan*”) and the associated budgets (together, the “*Development Budget*”).

**5.2.1 Initial Development Plan.** The Parties shall continue to follow the development plan agreed to by the Parties in the Original Agreement (“*Initial Development Plan*”) and any additional development plans (“*Subsequent Development Plans*”) to the extent such plans are agreed to by the Parties and are still in effect. An updated version of the Initial Development Plan is attached hereto as Schedule 5.2.1.

**5.2.2 Subsequent Development Plans.** \*\*, additional subsequent versions of the Development Plan (each, a “*Subsequent Development Plan*”) may be agreed upon between the Parties to include:

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5.2.2.1 \*\* for a new indication; provided that the return on investment for such \*\*, taking into account in particular the scope and duration of the underlying Regulatory Exclusivity Rights, is acceptable to the Parties, it being understood that \*\*;

5.2.2.2 any other Clinical Studies that the Parties agree to include in the Subsequent Development Plan,

in each case, subject to the Parties' agreement as to a Development Plan and budget as well as any other specific terms and conditions to which the Parties may agree.

5.2.3 \*\*. CTI may decide to start a Development Study of the Licensed Product in \*\* patients in the \*\* and with respect to the dose determination portion of such study, in the \*\*, subject to Servier's reasonable approval of the study protocol, centers and principal investigator(s) in \*\*, prior to the \*\* and the Parties' agreement as to a Subsequent Development Plan, subject to the provisions of the last sentence of Section 5.6.1.2. If CTI does so, such Development Study shall be regarded as an Additional Study for purposes of Section 5.6.1.2, provided that the percentage of Development Costs to be paid by Servier to use the related Data pursuant to Section 5.6.2 shall be \*\* equal to \*\* at any time before the later to occur of \*\*.

5.2.4 **Development Budget.** The JSC shall adopt and approve the Development Budget, which shall encompass the activities contemplated in any Subsequent Development Plan and any other matter agreed to by the JSC.

5.2.5 **Reports.** Each Party shall provide the other Party and the JSC with regular reports detailing its Development activities, and Development Costs under the Development Plan and the results of such activities at each regularly scheduled JSC meeting. Each Party shall also include in the regular reports a forecast of the amount by which the Party is above or below the Development Budget promptly after the end of each Calendar Quarter. The frequency, distribution list and format of all such reports shall be determined by the JSC; provided that: (a) all Clinical Study reports shall be in \*\*; (b) reports for all non-clinical studies with a GLP status, shall be in \*\*; and (c) for non-GLP non-clinical studies, \*\*.

5.2.6 **Amendments.** \*\* (no later than respectively \*\* and \*\*), commencing November 30, 2017, or more often as the JSC deems appropriate, the JSC shall review and, as required, prepare an update and amendment to the Development Plan and Development Budget (including activities and costs on a study-by-study basis by \*\*) for approval by the JSC. Each such updated and amended Development Plan shall reflect any changes, additions, re-prioritization of the studies and/or indications within, and/or

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reallocation of resources with respect to, the Development of the Licensed Product. Once approved by the JSC, an amended Development Plan and Development Budget shall become effective and supersede the previous Development Plan and Development Budget as of the date of such approval.

**5.3 Responsibilities under the Development Plan.** The Parties agree that to the extent appropriate, \*\*. Each Party's responsibilities under the Development Plan are apportioned as follows:

5.3.1 Servier shall be \*\*, and CTI shall \*\*, provided that if Clinical Studies pursuant to the \*\*.

5.3.2 Before commencement of each Clinical Study pursuant to \*\*.

**5.4 Development Costs.**

5.4.1 Unless otherwise agreed by the Parties, the Development Costs incurred by the Parties \*\*, provided that \*\* during the term of this Agreement. Notwithstanding the foregoing, as from \*\* (a) \*\* of the Development Costs related to \*\*, and (b) \*\* shall \*\*, including without limitation \*\* and \*\* for the \*\*, as from \*\*. A good-faith estimate of the Development Costs related to \*\* has been prepared by \*\*.

5.4.2 For the avoidance of doubt, other than as provided in Section 5.4.1 with respect to Development Costs, \*\* of the Development Costs incurred by \*\* for the Licensed Product (including \*\*) and \*\* of the Development Costs incurred by \*\* for the Licensed Product (including \*\*).

**5.5 Estimates, Accruals, Reconciliation and Reimbursement.**

5.5.1 Upon initiation of Development activities by Servier, the Parties shall negotiate in good faith a provision with respect to the reporting of the monthly estimated Development Costs incurred in material excess of the amount allocated for such month in the Development Budget.

5.5.2 Within \*\* following the last day of each Calendar Quarter, during such time as it is conducting Development activities, each Party shall provide to the other its good faith estimate of its Development Costs incurred with respect to the immediately prior quarter pursuant to Section 5.4.1. The Parties acknowledge that the above reporting terms have been negotiated in order to enable CTI to comply with the requirements of the Italian Financial Market Authority and the United States Securities and Exchange Commission (together, the "**Financial Authorities**"), and to enable prompt quarterly closing. Should the requirements imposed by the Financial Authorities on CTI to make such quarterly

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closing change over time, the Parties agree to discuss in good faith an extension of the time period for providing the information to CTI pursuant to this Section 5.5.2.

5.5.3 Within \*\* after the end of each Calendar Quarter, each Party shall provide the other Party with a detailed statement of the Development Costs (i.e., Out-of-Pocket Costs invoiced by vendor pursuant to Section 5.4.1 and FTE Costs incurred by such Party pursuant to Section 5.4.1) in a format to be agreed upon by the Parties (the “**Cost Report**”).

5.5.4 Within \*\* after the end of each Calendar Quarter, Servier shall provide CTI with a written report (the “**Reconciliation Report**”) setting forth in a format to be agreed upon by the Parties, the calculations of each Party’s share of such Development Costs for the previous Calendar Quarter. Such Reconciliation Report shall include for such Calendar Quarter (i) the Cost Report in accordance with Section 5.5.2, and each Party’s respective share thereof, and (ii) the net payment due from one Party to the other Party in accordance with this Section 5.5.

5.5.5 Any net payment owed from one Party to the other Party shall be paid within \*\* following such reconciliation, provided that if a Party disputes an amount provided in such Reconciliation Report then such disputed amount shall be reviewed by the JSC, and any net payment owed with respect to the undisputed amounts shall be paid within the above-set-forth timeline. If requested by a Party, any invoices or other supporting documentation for any payments to a Third Party shall be promptly provided.

## 5.6 Additional Studies.

5.6.1 If a Party (including through its Affiliates or Sublicensees) wishes to conduct one or more additional Development Studies which Data could be used in the other Party’s Respective Territory (beyond what is then included in an applicable Development Plan or any Territory Specific Studies) in the Field for Development of the Licensed Product, such Party (the “**Proposing Party**”) shall notify the other Party (the “**Non-Proposing Party**”) of such proposed studies and provide the Non-Proposing Party with any supporting Data or publications supporting any such proposal. In such event, the JSC shall consider such proposal and evaluate the supporting Data and information in good faith. If:

5.6.1.1 the Parties both wish to collaborate in the conduct of such proposed Development, the Proposing Party shall prepare an amendment to the applicable Development Plan to include the proposed additional Development Study(ies) and related budget for review and approval by the JSC; or

5.6.1.2 the Non-Proposing Party is not interested in pursuing any such proposed additional Development Study(ies) pursuant to a

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Development Plan, then, the Non-Proposing Party shall promptly so inform the Proposing Party, and the Proposing Party (i) shall not perform such Development Study(ies) with respect to the Non-Proposing Party's Respective Territory and (ii) shall have the right to perform the proposed Development Study(ies) with respect to its Respective Territory (the "***Additional Study***") at its own expense. The Proposing Party shall deliver to the JSC regular updates on such Additional Study, and promptly following completion of the Additional Study, a top-line summary of all Data resulting from such Additional Study. Notwithstanding the foregoing, the Proposing Party shall not conduct the Additional Study if the Non-Proposing Party (a) expresses concerns related to patient safety in the Additional Study and such concerns are supported or can be verified with scientific data or (b) provides commercial or scientific data that the Additional Study will adversely affect the Development or Commercialization of Licensed Product(s) in the Non-Proposing Party's Respective Territory or the overall marketing or branding strategy with respect to the Licensed Product.

5.6.2 If the Non-Proposing Party wishes to obtain access to and have the right to use the Data resulting from any Additional Study(ies) in its Regulatory Materials to support any NDA or MAA filings or extension of a Regulatory Approval or any pricing and reimbursement applications, or to otherwise use or disclose such Data, including without limitation for any commercial or medical education purpose (the "***Opt-In Right***") in its Respective Territory (other than pursuant to Section 5.6.3 below), it may do so by notice in writing to the Proposing Party at any time, provided that upon the exercise of its Opt-In Right, the Non-Proposing Party shall reimburse the Proposing Party for \*\* of its Development Costs for such Additional Study(ies). Following such payment, the Data resulting from the Additional Study will be treated for purposes of this Agreement as Data resulting from the Development Plan.

5.6.3 Notwithstanding anything to the contrary in this Agreement, each Party shall have access to and the right to use at no cost to such Party all Data resulting from Additional Studies and Non Development Studies conducted by or on behalf of the other Party, its Affiliates and its Sublicensees solely as necessary to comply with safety reporting or other similar regulatory requirements in its Respective Territory, and provided that such Party's license rights and rights of reference to such Data shall be limited solely to such purpose or to other purposes to the extent that such other purposes are necessary to comply with mandatory regulatory requirements.

5.6.4 Notwithstanding anything to the contrary in this Agreement, each Party shall have access to and the right to use at no cost to such Party all Data resulting from Clinical Studies that are Non-Development Studies conducted or funded by or on

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behalf of the other Party, its Affiliates and its Sublicensees, provided that in each case, such Party's license rights and rights of reference to such Data shall not include commercially sensitive information regarding Medical Affairs Activities and Commercialization activities in the other Party's Respective Territory.

#### **5.7 Clinical Studies in the Other Party's Respective Territory.**

5.7.1 In the event that, in furtherance of its Development activities for Licensed Product(s) in its Respective Territory, a Party believes it needs to conduct Clinical Studies which include one or more sites in the other Party's Respective Territory (outside of the Development Plan), then the requesting Party shall provide written notice to the JSC of the \*\* (including the \*\* involved in the \*\*, and seek the other Party's consent to conduct such study using sites in such other Party's Respective Territory.

5.7.2 For the avoidance of doubt, either Party may conduct Non-Development Studies within its own Respective Territory subject to the review by the JSC of those Non-Development Studies referred to in Section 3.2.2.5, and neither Party shall conduct Non-Development Studies (or other Medical Affairs Activities) within the Respective Territory of the other Party, except as provided in Section 5.7 or otherwise approved in writing by the other Party.

5.8 **Development in CTI Territory.** Notwithstanding anything to the contrary in this Agreement, and further notwithstanding any Data disclosed by Servier under this Agreement, the Parties agree and acknowledge that Servier shall have no involvement whatsoever in, and shall not be obligated to participate in, the Development, Commercialization, Medical Affairs Activities and/or Manufacture of Licensed Product in or for the CTI Territory other than to the extent expressly set forth in the Development Plan and such other obligations as are expressly provided herein.

5.9 **Development Records.** Each Party shall (and shall cause its Sublicensees to) maintain complete and accurate records (in the form of technical notebooks and/or electronic files where appropriate) of all work conducted by it or on its behalf (including by Sublicensees) under the Development Plan. Such records, including any electronic files where such Data may also be contained, shall fully and properly reflect all work done and results achieved in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. Each Party shall have the right to review and receive a copy of such records (including a copy of the databases) maintained by the other Party (including its Sublicensees) at reasonable times, but no more than \*\* in any \*\*, and to obtain access to source documents to the extent needed for patent or regulatory purposes or for other legal proceedings. The Parties may agree to set up an electronic data room in order to manage the exchange of information in a secure manner.

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5.10 **Subcontracts.** Each Party may perform any of its obligations under this Agreement through one or more subcontractors and consultants and shall provide information in that regard to the JSC, provided that:

5.10.1.1 such Party remains responsible for the work allocated to, and payment to, such subcontractors and consultants as it selects to the same extent it would if it had done such work itself;

5.10.1.2 the subcontractors and consultants undertake in writing obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties pursuant to Article 12 hereof; and

5.10.1.3 such Party retains Control of all intellectual property developed by the subcontractors and consultants in the course of performing any such work under the Development Plan or in connection with Territory Specific Studies for any Regulatory Authorities in the European Union.

5.11 **Personnel.** Each Party shall cause its employees, agents and subcontractors and its Affiliates conducting activities under this Agreement to, prior to commencing any such activities, have executed an agreement assigning or transferring Control to any inventions and related intellectual property rights to the Party by whom they are employed or for whom they are providing services (or its designated Affiliate).

## ARTICLE 6

### DATA; REGULATORY MATTERS

#### 6.1 General.

6.1.1 The Parties shall each use Commercially Reasonable Efforts to prepare and file all necessary Regulatory Materials for the Licensed Product with Regulatory Authorities in accordance with the respective responsibilities of the Parties as set forth in the Development Plan and in this Agreement. Notwithstanding Section 4.2.6, and except as provided under Section 6.2.5, \*\* shall reimburse \*\* for all \*\* associated with supporting any Regulatory Materials in \*\* incurred after \*\*.

6.1.2 Each Party shall, unless prohibited by law, keep the other Party informed of regulatory developments and quality and compliance matters relating to the Licensed Product in the European Union, including through regular reports at the JSC meetings.

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6.1.3 Each Party may conduct compassionate use programs and Investigator Sponsored Studies in its own Respective Territory, at its own costs, but not in the other Party's Respective Territory.

## 6.2 Prior to the European MA Transfer

6.2.1 The Parties acknowledge that CTI has obtained a Conditional MA for the Licensed Product in the European Union. As soon as practicable under Applicable Law after (i) the occurrence of the PIX Positive Outcome and (ii) the disclosure by CTI to Servier of \*\* ((i) and (ii), the "*PIX306 Triggering Event*"), CTI shall transfer and assign, and does hereby assign to Servier subject to the last sentence of this subsection, free from encumbrances, all of CTI's right, title and interest in and to such MA and \*\* and establish Servier as the sole MAH under such MA (the "*European MA Transfer*"), and Servier agrees to thereafter assume all responsibilities and obligations as the MAH thereunder. The obligations of Servier in this Section and the above assignment shall not apply if Servier elects to terminate this Agreement with respect to \*\* within thirty (30) days after the PIX306 Triggering Event.

6.2.2 After the Restatement Date and until the completion of the European MA Transfer, CTI shall timely file any further Regulatory Materials, MAA, MA and other Regulatory Approval applications (including \*\*) necessary for obtaining approval of the Standard MA regarding the Licensed Product in the European Union and shall be responsible for maintaining the MA in the European Union, subject to Section 6.2.3 and Section 11.1 with respect to the ownership of Data.

6.2.3 Through the JSC, the Parties shall collaborate in the preparation and agree on the form and content of Regulatory Materials to be submitted to the EMA which shall be a Mutual Consent Matter. CTI shall notify Servier of any Regulatory Materials submitted to or received from the EMA and shall provide Servier with copies thereof. Further, CTI shall to the extent possible provide Servier with reasonable advance notice of all substantive meetings, conferences, and discussions scheduled with the EMA concerning \*\* or the Licensed Product, and the Parties shall to the extent possible attend together such meetings, conferences or discussion and shall to the extent possible agree in advance on a common position to be presented by the Parties in this respect. CTI shall provide Servier with reasonable advance notice (at least \*\*) with all Regulatory Materials requiring review pursuant to this Section 6.2.3.

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6.2.4 To the extent not already designated, Servier shall be designated as the sole Party responsible for Medical Affairs Activities and Commercialization of the Licensed Product in Servier EU Territory. In addition, CTI shall take all actions necessary for (i) the timely designation of Servier as \*\* in the Servier EU Territory, and (ii) the identification as such on the package leaflet and label of the Licensed Product in the Servier EU Territory, subject to the availability of such updated labeling, which the Parties shall cooperate to make available in a timely fashion, such updated labeling at \*\* sole cost and expense.

6.2.5 \*\* shall bear any fees due to a Regulatory Authority in connection with the filing and maintenance for any Regulatory Approval relating to the Licensed Product \*\* until European MA Transfer. \*\* shall bear \*\* incurred to prepare and make any filing for Regulatory Approval for the Licensed Product \*\* only until European MA Transfer, after which \*\* will be solely responsible for such costs and expenses.

### **6.3 After the European MA Transfer.**

Upon and after the completion of the European MA Transfer, \*\* shall be \*\* for filing all further Regulatory Materials and for obtaining all further Regulatory Approvals for all Licensed Product in \*\* and for all costs and expenses related to the foregoing. In addition, after the European MA Transfer, \*\* shall be \*\* for the preparation, content and submission of all Regulatory Materials to the EMA regarding \*\*. \*\* shall send to \*\* copies of all Regulatory Materials submitted to or received from the Regulatory Authorities in Europe.

### **6.4 Outside the European Union.**

6.4.1 Unless otherwise provided in the Development Plan, (i) Servier shall be solely responsible and have the final authority with respect to regulatory activities (including preparing and filing all Regulatory Materials and Regulatory Approval applications) regarding the Licensed Product in the Servier ex-EU Territory in the Field and (ii) CTI shall be responsible and have the final authority with respect to all regulatory activities (including preparing and filing all Regulatory Materials and other Regulatory Approval applications) regarding the Licensed Product in the \*\* in the Field. \*\* shall be responsible for all costs and expenses related to \*\*, and \*\* shall be responsible for all costs and expenses related to \*\*.

6.4.2 Each Party shall send to the other Party copies of all Regulatory Materials submitted to or received from the Regulatory Authorities, with respect to CTI, in the \*\*, and with respect to Servier, in the \*\*.

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6.4.3 Each Party shall notify the other Party of any Regulatory Materials (other than routine correspondence) submitted to or received from the Regulatory Authorities, with respect to CTI, in the \*\*, and with respect to Servier, in \*\*, and shall provide the other Party with copies thereof.

6.4.4 Each Party shall, unless prohibited by law, keep the other Party informed of material regulatory developments and quality and compliance matters relating to each Licensed Product in the \*\* with respect to CTI and in the \*\* with respect to Servier, including through regular reports at the JSC meetings.

## 6.5 Recalls and Complaints.

6.5.1 Each Party shall notify the other Party as promptly as practicable following the discovery of any issue regarding the Licensed Product that would be relevant for purposes of determining whether any corrective action (e.g., complaints, recall, market withdrawal, or other corrective action) (“*Corrective Action*”) is required with respect to the Licensed Product. Notification of complaints and the associated Corrective Actions will follow the country and regional regulatory compliance requirements for notification timing, investigation and Corrective Action. [Further details for complaint management will be included in the Quality Agreement]. As promptly as possible following the issuance of any such notice, the JSC shall meet and discuss in good faith whether any Corrective Action is required with respect to the Licensed Product. In the event that the JSC is unable to timely meet or the Parties are unable to timely agree pursuant to the JSC on any such recall, market withdrawal, or other Corrective Action:

6.5.1.1 **Servier Ex-EU Territory.** Servier, in its sole responsibility and discretion, shall be entitled to make all decisions with respect to any such Corrective Action in the Servier Territory; provided, however, that if CTI has provided notice in writing to Servier requesting Corrective Action with respect to Licensed Product in the Servier Territory and Servier declines to implement any such Corrective Action, Servier shall, at its sole expense, indemnify, and hold harmless the CTI Indemnitees from and against any and all Third Party Claims that are connected or related in any way whatsoever to such failure to implement a Corrective Action in the Servier Territory.

6.5.1.2 **CTI Territory.** CTI, in its sole responsibility and discretion, shall be entitled to make all decisions with respect to any such Corrective Action in the CTI Territory; provided, however, that if Servier has provided notice in writing to CTI requesting Corrective Action with respect to Licensed Product in the CTI Territory and CTI declines to implement any such Corrective Action, CTI shall, at its sole expense, indemnify, and hold harmless the Servier Indemnitees from

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and against any and all Third Party Claims that are connected or related in any way whatsoever to such failure to implement a Corrective Action in the CTI Territory.

#### 6.5.1.3 **European Union.**

(a) **Prior to the European MA Transfer.** CTI shall be free to initiate any such Corrective Action with respect to the Licensed Product in the European Union that CTI deems necessary or appropriate, after reasonable consultation with Servier. In addition, Servier shall have the right to request CTI to undertake any such Corrective Action with respect to the applicable Licensed Product in the European Union it deems necessary or appropriate, in its sole responsibility and discretion, such cooperation not to be unreasonably withheld.

(b) **After the European MA Transfer.** \*\* shall be free to initiate any such Corrective Action with respect to the Licensed Product in the European Union that \*\* deems necessary or appropriate in accordance with the terms set out in \*\*.

6.5.2 In each case, the holder of the Regulatory Approval in the applicable country shall be responsible for the actual implementation of any Corrective Action with respect to the Licensed Product and shall be entitled to make all decisions with respect to the implementation of any such Corrective Action with respect to the Licensed Product. At such implementing Party's request, the other Party shall reasonably assist the implementing Party with any such Corrective Action.

6.5.3 All documented and reasonable costs associated with any Corrective Action (but excluding all Losses associated with any Third Party Claims, which shall be subject to the provisions of Article 16) shall be borne by the manufacturing Party in the event that the Corrective Action is required as a result of any failure of the Licensed Product to meet the quality requirements set forth in any Supply Agreement between the Parties governing the manufacture and supply of such Licensed Product. In all other cases, all documented and reasonable costs associated with such Corrective Action with respect to the Licensed Product will be: (i) borne by Servier, with respect to Corrective Actions in the Servier Territory, and (ii) borne by CTI, with respect to Corrective Actions in the CTI Territory.

#### 6.6 **Pharmacovigilance Agreement.**

(a) As soon as practicable after the Restatement Date, the Parties shall agree on an amendment (the "**PV Amendment**") to the pharmacovigilance agreement entered into between the Parties dated October 18, 2016 which details all pharmacovigilance activities to be conducted by the Parties with respect to the Licensed Product (the "**Pharmacovigilance Agreement**"). Unless otherwise agreed between the Parties, the Pharmacovigilance Agreement as amended by the PV Amendment shall remain in effect until completion of

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the European MA Transfer. In the event of a conflict between the Pharmacovigilance Agreement (as may be amended by the PV Amendment) and this Agreement, this Agreement shall prevail. Upon the European MA Transfer, \*\* shall be responsible for all Out-of-Pocket Costs incurred for pharmacovigilance activities in \*\*, and \*\* shall be responsible for all such Out-of-Pocket Costs in \*\*.

(b) Until the occurrence of the European MA Transfer, \*\* shall reimburse \*\* for pharmacovigilance activities conducted by or on behalf of \*\* in the European Union from \*\* until the occurrence of the European MA Transfer. The first and last \*\* amounts due and payable hereunder will be adjusted \*\* to reflect the actual number of days in the \*\* and \*\*. For clarity and notwithstanding anything to the contrary contained herein or in the Pharmacovigilance Agreement, the foregoing payment set forth in this Section 6.6(b) is \*\* sole and exclusive obligation to reimburse \*\* for such pharmacovigilance activities.

**6.7 No Use of Debarred Person.** For the duration of this Agreement, each Party agrees that it will not use any employee, agent, consultant or contractor that is debarred by any Regulatory Authority or, to such Party's Knowledge, is the subject of debarment proceedings by any Regulatory Authority. If either Party learns that any employee, agent, consultant or contractor performing on its behalf under this Agreement has been debarred by any Regulatory Authority, or has become the subject of debarment proceedings by any Regulatory Authority, it will promptly notify the other Party and will prohibit such employee, agent, consultant or contractor from further performing on its behalf under this Agreement.

**6.8 Notice of Investigation or Inquiry.** If any Regulatory Authority (i) contacts a Party with respect to the alleged improper Development, Manufacture, Medical Affairs Activities or Commercialization of Licensed Product (anywhere in the world), (ii) conducts, or gives notice of its intent to conduct, an inspection at such Party's facilities to the extent related to any Licensed Compound or the Licensed Product (anywhere in the world), or (iii) takes, or gives notice of its intent to take, any other regulatory action with respect to any activity of such Party that could reasonably be expected to materially adversely affect any Development, Manufacturing, Medical Affairs Activities or Commercialization activities with respect to the Licensed Product for use or sale anywhere in the world, then such Party shall promptly notify the other Party of such contact, inspection or notice. The inspected Party shall provide such other Party with copies of all pertinent information and documentation issued by any such Regulatory Authority as soon as reasonably practicable after receipt, and the JSC (or such employees of a Party or its Affiliates as a Party's JSC Co-Chair may designate) shall have the right to review and provide comment in advance, where feasible, of any responses that pertain thereto.

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## ARTICLE 7

### COMMERCIALIZATION

#### 7.1 Transition Territory.

7.1.1 **Exclusivity.** CTI shall transfer exclusive Commercialization rights for the Licensed Products in the Transition Territory to Servier as of the Restatement Date. Upon registration of Servier as \*\* or MAH, as applicable, Servier will have the exclusive right and will use Commercially Reasonable Efforts to conduct Medical Affairs Activities and Commercialize Licensed Product in countries in the Transition Territory and will be solely responsible for all aspects of the Medical Affairs Activities and Commercialization of the Licensed Product in the Transition Territory, including planning and implementation, distribution, booking of sales, pricing and reimbursement. In addition, CTI shall use Commercially Reasonable Efforts to have Servier appointed as \*\* in those Transition Territory countries where such appointment is necessary for Servier to Commercialize the Licensed Products prior to the European MA Transfer. Reflecting Servier's exclusive Commercialization rights across the European Union, Servier shall pay \*\* of the expenses for Medical Affairs Activities such as \*\*.

7.1.2 **Commercialization Transition Plan.** As soon as practicable after the Restatement Date, the Parties shall use commercially reasonable efforts to agree on a transition plan whereby all rights granted by CTI to Servier under this Agreement to conduct Medical Affairs Activities and to Commercialize Licensed Product in the Transition Territory are transitioned from CTI to Servier (the "**Commercialization Transition Plan**"). The Parties shall use Commercially Reasonable Efforts to execute all activities in the Commercialization Transition Plan. The Commercialization Transition Plan shall include \*\*, and also include the estimate of all costs and expenses expected to be incurred in implementing the Commercialization Transition Plan, a copy of which is attached as Exhibit 7.1.2. The Parties agree that by no later than July 31, 2017 (the "**Commercialization Transition Date**"), the Commercialization Transition Plan shall be complete and all Medical Affairs Activities and Commercialization with regard to Licensed Products will have been transitioned to Servier. For avoidance of doubt, any failure by the Parties to agree upon a Commercialization Transition Plan as contemplated above will not relieve either Party of its obligations under Section 7.1.1, and in such event, each Party shall use commercially reasonable efforts to take those actions and undertake those activities necessary to ensure a smooth transition by the Commercialization Transition Date. Prior to the Commercialization Transition Date, CTI shall act in its own name and responsibility to fulfill orders for Licensed Products arising out of any country within the Transition Territory as applicable. CTI shall promptly inform Servier of any such orders and follow Servier's reasonable instructions as to the negotiations with Third Party customers. The Parties shall cooperate in order to

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implement the Commercialization Transition Plan so that Servier may achieve full capacity to Commercialize the Licensed Product in the Transition Territory no later than the Commercialization Transition Date. Prior to the Commercialization Transition Date, \*\*. Within \*\* after the end of \*\* until the completion of the Commercialization Transition Plan, CTI will provide to Servier a written report showing \*\* on a country-by-country basis. Promptly upon the completion of the Commercialization Transition Plan, CTI shall provide Servier with a complete accounting of all costs and expenses actually incurred in implementing the Commercialization Transition Plan, and \*\*.

**7.1.3 Commercially Reasonable Efforts.** Upon registration of Servier \*\* or MAH, as applicable, and \*\* where applicable for the Licensed Product, Servier shall itself, or through its Affiliates or Sublicensees (if permitted), use Commercially Reasonable Efforts, on a country-by-country basis, to Commercialize the Licensed Product in the applicable Transition Territory country in the Servier Key Markets within the Servier Territory. Subject to compliance with the foregoing, Servier's decision-making and activities with respect to Medical Affairs Activities and Commercialization of the Licensed Product in the Transition Territory shall be in Servier's sole discretion.

**7.1.4 Distributors and Wholesalers.** Upon implementation of the Commercialization Transition Plan, upon Servier's request in its sole discretion, CTI shall terminate or assign, \*\*, the distributor and/or wholesaler contracts in effect as of the Restatement Date, as listed in Exhibit 7.1.4. \*\*, any termination costs associated with the termination or assignment of such distributor and/or wholesaler contracts, unless \*\* elects, and notifies \*\* in writing of that election, to \*\*. Agreements with such distributors and wholesalers shall contain confidentiality restrictions at least as restrictive as those contained herein.

**7.1.5 Quintiles.** Servier hereby acknowledges that CTILS is a party to certain Third Party services agreements covering certain existing Commercialization activities with Quintiles Commercial Europe Limited and its Affiliates. CTILS hereby agrees that it shall \*\*.

## **7.2 Servier Territory other than Transition Territory.**

**7.2.1 Exclusivity.** Except with regard to the Transition Territory, which is addressed in Section 7.1 above, Servier will have the exclusive right to conduct Medical Affairs Activities and Commercialize Licensed Product in countries in the Servier Territory and will be solely responsible for all aspects of the Medical Affairs Activities and Commercialization of the Licensed Product in the Servier Territory, including planning and implementation, distribution, booking of sales, pricing and reimbursement. Except with regard to the Transition Territory, which is addressed in Section 7.1.1 above, CTI will have

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the exclusive right to conduct Medical Affairs Activities and Commercialize Licensed Product in countries in the CTI Territory and will be solely responsible for all aspects of the Medical Affairs Activities and Commercialization of the Licensed Product in the CTI Territory, including planning and implementation, distribution, booking of sales, pricing and reimbursement.

7.2.2 **Commercially Reasonable Efforts.** Except with respect to the Transition Territory as set forth in Section 7.1.2, Servier shall itself, or through its Affiliates or Sublicensees, use Commercially Reasonable Efforts to Commercialize the Licensed Product in \*\*, commencing, on a country-by-country basis, upon receipt of Regulatory Approval \*\* where applicable for the Licensed Product in the applicable country \*\*, and in each case continuing thereafter until the end of the Royalty Term in such country. Subject to compliance with the foregoing with respect to such \*\* other than the Transition Territory, Servier's decision-making and activities with respect to Medical Affairs Activities and Commercialization of the Licensed Product in the Servier Territory shall be in Servier's sole discretion.

### 7.3 Updates.

7.3.1 Servier shall provide CTI and the JSC with \*\* updates with respect to Medical Affairs Activities and Commercialization activities of the Licensed Product in countries in the Servier Territory, including \*\*.

7.3.2 CTI shall assign or transfer to Servier all Investigator Sponsored Studies that are still open and/or ongoing in the Transition Territory as of the Restatement Date, provided that, \*\*.

7.4 **Termination of Sharing.** Neither Party shall have an obligation to share or provide any information that such Party's counsel has advised the Party would violate Applicable Law. Without prejudice to any other remedies, if either Party breaches its obligations under Section 7.1.1 and 8.2, then the other Party shall have no obligation thereafter to share or provide any Commercialization plans or to discuss at the JSC its Medical Affairs Activities and Commercialization activities. In the event of a Change of Control Transaction involving CTI, Servier shall have no obligation thereafter to share or provide any Commercialization plans or to discuss at the JSC its Medical Affairs Activities and Commercialization activities.

7.5 **Acknowledgement.** Servier shall use, in connection with all packaging, literature, labels and other printed matters, to the extent required by Law, and where reasonably practicable in light of space limitations, an expression to the effect that the Licensed Product(s) were developed under license from CTI, together with the CTI logo. The provisions of this Section 7.5 shall not apply to packaging that is in direct contact with

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a Licensed Product or the Licensed Product(s) themselves, including vials, blister packs, tablets and capsules.

## Article 8

### COMMERCIAL COVENANTS

#### 8.1 Competing Products.

8.1.1 As partial consideration for CTI's rights and Servier's obligations set forth herein, CTI covenants and agrees that:

8.1.1.1 for the period commencing on \*\* and ending at \*\* (the "*Non-Compete Term*") \*\*, it shall not, and it shall cause its Affiliates not to, directly or indirectly, through assisting a Third Party or otherwise, develop, manufacture, have manufactured, market, distribute, sell, promote or otherwise Commercialize any Competing Products within the field of oncology, \*\* without the prior written consent of Servier; and

8.1.1.2 it shall (i) include enforceable provisions in any license agreement prohibiting its licensees for the Non-Compete Term on a country-by-country and activity-by-activity basis from, directly or indirectly, through assisting a Third Party or otherwise, developing, manufacturing, marketing, distributing, selling, promoting or otherwise Commercializing any Competing Products, without the prior written consent of Servier, with the right to terminate the License in case of breach of this provision, provided, however, that this requirement shall not extend to wholesalers, distributors and other counterparties that market, distribute, sell, promote or Commercialize multiple products that may include Competing Products, and (ii) use commercially reasonable efforts to enforce the provisions and the termination rights set forth in subclause (i).

8.1.2 As partial consideration for CTI's obligations and Servier's rights set forth herein, Servier covenants and agrees that:

8.1.2.1 for the Non-Compete Term \*\* and activity-by-activity basis, it shall not, and it shall cause its Affiliates not to, directly or indirectly, through assisting a Third Party or otherwise, develop, manufacture, market, distribute, sell, promote or otherwise commercialize any Competing Products within the field of oncology, in \*\* without the prior written consent of CTI; and

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8.1.2.2 it shall (i) include enforceable provisions in any Sublicense prohibiting its Sublicensees for the Non-Compete Term on a country-by-country and activity-by-activity basis, from, directly or indirectly, through assisting a Third Party or otherwise, developing, manufacturing, marketing, distributing, selling, promoting or otherwise commercializing any Competing Products, without the prior written consent of CTI, with the right to terminate the Sublicense in case of breach of this provision, provided, however, that this requirement shall not extend to wholesalers, distributors and other counterparties that market, distribute, sell, promote or Commercialize multiple products that may include Competing Products, and (ii) use commercially reasonable efforts to enforce the provisions and the termination rights set forth in subclause (i).

## 8.2 Competing Product Affiliation Transaction.

8.2.1 If, at any time during the Non-Compete Term on a country-by-country and activity-by-activity basis, either Party merges or consolidates with, is otherwise acquired by, or acquires, a Third Party (including through a Change of Control Transaction), and if such Third Party (or any of its Affiliates) is as of the effective date of such transaction engaged in the development, manufacture or sale of a Competing Product during the Non-Compete Term, as applicable on an activity-by-activity basis (a “*Competing Product Affiliation Transaction*”), then, within \*\* after the effective date (e.g., after any pre-clearance or similar regulatory approval periods have expired or official approval for the transaction is otherwise obtained) of such Competing Product Affiliation Transaction, such Party or its relevant Affiliate shall make one of the elections set forth below in Sections 8.2.1.1 through 8.2.1.3, and upon such election such Party (the “*Electing Party*”) shall notify the other Party in writing as to such election, and thereafter, if the Electing Party complies with the provisions below relevant to such election, such Competing Product Affiliation Transaction shall be deemed not to result in a breach of such Party’s obligations pursuant to Section 8.1 above:

8.2.1.1 \*\* with respect to such Competing Product (subject to any regulatory requirements to complete ongoing clinical studies) and notify the other Party in \*\*, provided that if the Electing Party demonstrates to the other Party that it is \*\* from the closing date of such Competing Product Affiliation Transaction (it being understood that \*\*; or

8.2.1.2 \*\*, and, if the other Party is interested in \*\*, provided that, unless otherwise agreed by the Parties, \*\* after the closing date of such Competing Product Affiliation Transaction; or

8.2.1.3 \*\*.

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If CTI makes the election set forth in Section 8.2.1.3, \*\*, subject to \*\*, provided that \*\*. If Servier makes the election set forth in Section 8.2.1.3, \*\*.

8.2.2 Until the \*\* or this Agreement is terminated pursuant to Section 8.2.1.3, the Electing Party shall put in place a Firewall.

8.2.3 The remedies set forth in Sections 8.2.1 and 8.2.2 will be \*\*.

### 8.3 Remedies.

8.3.1 In case of a breach by either Party of Sections 8.1.1 or 8.1.2 or failure to comply with Section 8.2.1 and/or 8.2.2 and such breach or failure is not cured within \*\* after the breaching Party's receipt of written notice from the non-breaching Party labeled as a "notice of non-compete breach" that describes such breach or failure in reasonable detail and requires such breach or failure to be remedied, the non-breaching \*\*; provided, however, that if the breaching Party notifies to the non-breaching Party within such \*\* period that it disagrees in good faith with such asserted breach or failure, \*\*.

8.3.2 If the non-breaching Party elects the remedies under Section 8.2.1.3 and \*\*, the following shall apply:

8.3.2.1 If the non-breaching Party is \*\*, provided that \*\*.

8.3.2.2 If the non-breaching Party is \*\*.

8.3.3 The remedies under Section 8.3 \*\*, provided that if the breaching Party challenges the assertion of breach, the non-breaching Party shall be entitled \*\*.

8.4 **Exportation/Importation of Licensed Product.** For the period commencing on the Restatement Date and ending upon the expiry of the Royalty Term on a country-by-country basis, where and to the extent permitted under Applicable Law, each Party, its Affiliates and Sublicensees shall not Commercialize the Licensed Product in the other Party's Respective Territory. In addition, where and to the extent permitted under Applicable Law, each Party shall use Commercially Reasonable Efforts to restrict and prevent the export to any country in the other Party's Respective Territory, the Licensed Product that has been packaged and sold by such Party, its Affiliates and Sublicensees for use inside its Respective Territory.

## ARTICLE 9

### MANUFACTURING AND SUPPLY

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## 9.1 Manufacturing Responsibilities.

Servier and CTI will each be solely responsible, by itself or through one or more CMOs for the manufacture and supply of Drug Substance, Drug Product and Finished Product from Drug Product for each such Party's Respective Territories; provided, however, that until the completion of the European MA Transfer, \*\* will remain solely responsible for the manufacture and supply of Drug Substance, Drug Product and Finished Product from Drug Product in the European Union according to the terms of the Supply Agreement.

## 9.2 Supply.

9.2.1 Unless otherwise agreed by the Parties, that certain Supply Agreement by and between Servier and CTILS dated as of September 26, 2014 (the "**Supply Agreement**") through any Third Party contract manufacturer approved by Servier shall remain in effect until the completion of the European MA Transfer.

9.2.2 Effective Upon the Restatement Date:

9.2.2.1 CTI and Servier shall use Commercially Reasonable Efforts to \*\*.

9.2.2.2 Notwithstanding the foregoing, within thirty (30) days of the Restatement Date, Servier shall issue a purchase order to purchase from CTI, and CTI will supply to Servier \*\* vials of \*\* produced by \*\* at the price set forth in, and in accordance with the terms of, the Supply Agreement\*\*.

9.2.3 In case of a worldwide shortage \*\* available \*\* to CTI \*\* (other than the Servier safety stock, which shall be allocated solely to Servier), CTI and Servier agree that the \*\*, if any, shall be allocated between Servier and CTI \*\* of the Licensed Product over the \*\* period preceding the shortage.

9.2.4 Within the European Union and until the completion of the European MA Transfer, (a) CTI, with respect to all countries comprising the EU, shall have the marketing authorization responsibilities relating to the Manufacturing of the Licensed Product(s) until the European MA Transfer, and (b) CTI, with respect to all such countries, shall have responsibility for quality oversight of all Third Party manufacturers for the Licensed Product that are engaged by CTI or Servier for the manufacture and supply of Drug Product or Finished Product to Servier (including, as applicable, any Third Party vendors). Within the European Union and until the completion of the European MA Transfer, Servier shall \*\*, and CTI shall\*\*.

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### 9.3 Quality Agreement.

Unless otherwise agreed to by the Parties, the Quality Agreement between Servier and CTI dated as of September 29, 2014 (the “*Quality Agreement*”) shall remain in effect until CTI’s supply obligations, as provided in the Supply Agreement, have expired. For the avoidance of doubt, the quality provisions set out in the Quality Agreement with respect to Drug Product and Finished Product Manufactured by or on behalf of Servier prior to the termination or expiration of the Supply Agreement, including those purchased from CTI pursuant to Section 9.2.2.2, shall survive the termination or expiration of the Supply Agreement for any reason, in accordance with their respective terms and conditions, and for the respective duration stated therein, and where no duration is stated, will survive for a period of \*\*, except for provisions which, by their nature, are intended to survive.

### 9.4 Technology Transfer.

To facilitate Servier’s Manufacturing of \*\* in the Servier Territory, CTI shall upon the Restatement Date promptly disclose to Servier, its Affiliate or Third Party manufacturer selected by Servier, subject to obligations of confidentiality at least as restrictive as those contained herein, all Know-How necessary or useful to enable Servier, its Affiliate or Third Party manufacturer (as appropriate) to Manufacture \*\* in and for the Servier Territory (the “*Manufacturing Know-How*”).

### 9.5 Assistance in Technology Transfer.

Subject to Servier’s confidentiality obligations, CTI shall use reasonable efforts to cooperate with and provide technical assistance (including on-site assistance) and consultation as reasonably requested by Servier in connection with the transfer and implementation of the Manufacturing Know-How, to Servier, and to enable Servier to use such manufacturing technology to Manufacture \*\*, as applicable, and to obtain Regulatory Approval for (including \*\*) the process for the Manufacture of the \*\*, as applicable. All such documentation shall be in the English language and, if required by Applicable Law, an authenticated translation shall be provided by CTI. If available in electronic form, all such documentation shall be provided in electronic format. The costs of such technology transfer shall be borne by Servier.

### 9.6 Audit

Each Party shall have the right, at its own expense, no more than \*\* per Calendar Year (except in case of deficiencies or inspection by any Regulatory Authorities, in which case there could be more than \*\*), to allow the persons designated by each Party to carry out quality audits, provided that reasonable advance notice of any such audit shall be given. Any quality audits shall be led by the party holding the Marketing Authorization for the territory supplied by such CMO, with the other party holding “piggyback” audit rights. Such quality audits shall be limited in scope to the areas and systems directly related to the Licensed Product, responsibilities for GMP and GDP based on the named company

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on the product labels, boxes and packaging. Key quality and compliance documents for each Party required for such quality audits will be provided in English. The Quality Agreement will provide additional details for quality audits and the responsibilities for quality and compliance matters. Notwithstanding the foregoing, any and all audits of CMOs or Third Party manufacturers shall be done by the Parties simultaneously at a mutually agreeable time and date. In the event a Party elects to conduct any additional audit of any CMO or Third Party manufacturers, such audit costs and expenses shall be borne solely by such Party, and to be held in accord with the “piggyback” provision above.

## ARTICLE 10

### FINANCIAL TERMS

10.1 **License Fee.** As partial consideration for the rights granted hereunder, within \*\* following receipt by LLS of an invoice from CTI, which shall be issued no earlier than on the Restatement Date, Servier shall pay or cause to be paid either to CTI US or CTILS as designated in writing by both CTI US and CTILS a non-refundable, non-creditable cash payment in the amount of Ten Million Euros (€10,000,000), provided that the designated CTI entity shall receive such payment for itself and as an agent for the other entity, as applicable, and shall defend, indemnify and hold harmless Servier for any claims arising out of such payment to the designated CTI entity or lack of payment to the other CTI entity. Such payment shall be in addition to the original license fee of Fourteen Million Euros (€14,000,000) that the Parties acknowledge was previously paid by Servier to CTI under the Original Agreement.

10.2 **Regulatory Milestones.** As partial consideration for the rights granted hereunder, Servier shall make non-refundable, non-creditable, one-time milestone payments to CTI based on the regulatory achievements as set forth below (each, a “*Regulatory Milestone Payment*”). The Party responsible for achieving the milestone event shall notify the other Party in writing within \*\* of the first achievement of each of the milestone events in the table below. The corresponding Regulatory Milestone Payment shall be due \*\*.

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Milestone	Payment
Clinical:	
In Europe:	
▪ **	**
▪ **	**
▪ **	**
▪ Successful EMA approval of a Type II Variation	€2M
▪ **	**
**	
▪ **	**
▪ **	**

Each milestone payment is to be paid only one time regardless of how many times a Licensed Product achieves such milestone, and no payment is to be due for any milestone that is not achieved. \*\*.

10.3 **Sales Milestones.** As partial consideration for the rights granted hereunder, Servier shall make non-refundable, non-creditable, one-time milestone payments to CTI based on the sale achievements as set forth below (each, a “*Sale Milestone Payment*”). Servier shall notify CTI in writing \*\*. The corresponding Sale Milestone Payment shall be due \*\*.

**	
▪ **	**
▪ **	**
▪ **	**

Each milestone payment would be paid only one time regardless of how many times a Product achieves such milestone, and no payment would be due for any milestone which is not achieved. For clarity, and by way of example, \*\* in Annual Sales is achieved in \*\*, then milestone payments equal to €40M, representing all three performance milestones, shall be paid by Servier to CTI and no further performance milestone shall be due. If there is more than one Licensed Product, Net Sales shall be aggregated for purposes of this Section 10.3 and Section 10.4.

10.4 **Royalties.** As partial consideration for the rights granted hereunder in and to the Licensed Patents and Licensed Know-How, during the Royalty Term, on a

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country-by-country basis, Servier shall pay to CTI royalties (“*Royalties*”) at the rate set forth below, subject to adjustment as set forth in Section 10.6.

<b>On Net Sales of Licensed Product **</b>	<b>Royalty Rate</b>
**	**
**	**
**	**

#### 10.5 Estimates, Payments and Reports.

Payments of Royalties shall be paid as follows:

10.5.1 Within \*\* following the last day of each calendar month, Servier shall provide to CTI a good faith estimate of its Net Sales of Licensed Product(s) with respect to the immediately prior month in the Servier Territory.

10.5.2 Within \*\* after the end of each Calendar Quarter during the term of this Agreement following the First Commercial Sale of the first Licensed Product, Servier will provide to CTI a written report (each, a “*Royalty Report*”), showing Net Sales on a country-by-country basis.

10.5.3 Royalty Report also to include: line item detail including country by country of the quantity of Licensed Product sold, gross amount billed or invoiced with respect to sales which are included in “*Net Sales*,” detail of deductions taken in arriving at royalty due CTI and the Royalty rate applied and, if applicable, the exchange rate applied. CTI shall also provide an invoice to Servier for the Royalties due as specified in the Royalty Report. Payments of Royalties due shall be due \*\* on a calendar basis, in arrears, and shall be payable no later than \*\* after the date on which LLS received the invoice.

10.5.4 **Transition Payments.** Payment of \*\*.

10.6 **Adjustments to Royalties.** The Royalties shall be subject to adjustment as set forth in this Section 10.6.

10.6.1 **Loss of Patent Protection.** For any period during the Royalty Term in which the sale of the Licensed Product in any country is not covered by a Valid Claim of a Licensed Patent or any other Regulatory Exclusivity Rights, the Royalty rate applicable to Net Sales of the Licensed Product in such country during such period shall be \*\* of the weighted average royalty rates otherwise applicable to Net Sales of the Licensed Product set forth in Section 10.4.

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10.6.2 **Loss of Market Exclusivity.** In the event of a Loss of Market Exclusivity in any country, then from the date of such event the Royalties applicable to Net Sales of such Licensed Product in such country shall be reduced by \*\* of the amount otherwise due, as adjusted pursuant to Sections 10.6.1 and 10.6.3 as applicable.

10.6.3 **Third Party Licenses.** If Servier or any of its Affiliates or Sublicensees (i) determines in its good faith judgment with advice from independent legal counsel that it is necessary or advisable to obtain a license from any Third Party in order to make, have made, use, sell, offer for sale or import the Licensed Product for any given country of the Servier Territory, or (ii) is required by any court of competent jurisdiction to pay damages and/or such license fees to such a Third Party in any given country of its Respective Territory, Servier may deduct up to \*\* of any payments under subclauses (i) and/or (ii) to the Third Party from the Royalties; provided, however, that in no event shall the aggregate Royalties, payable to CTI be reduced pursuant to this Section 10.6.3 to less than \*\* of the amounts otherwise payable under Sections 10.4 and 10.6.

10.6.4 **Third Party Payments.** CTI shall solely bear, and shall indemnify Servier, its Affiliates and Sublicensees against, all Third Party license payments, milestones and royalties owed with respect to Licensed Compound or the Licensed Product, on intellectual property that: (A) is owned or licensed by CTI on or prior to the Restatement Date (including pursuant to the University of Vermont Agreement and the Novartis Agreements, together the “**Head Licenses**”); or (B) is intellectual property that CTI received notice of potential infringement from a Third Party prior to the Restatement Date and did not disclose same to Servier in writing prior to the Restatement Date.

10.7 **Payments and Reporting Generally.** All payments made by Servier pursuant to this Article 10 shall be made subject to receipt by LLS of an invoice from CTI in immediately available funds by wire transfer to such bank and account of CTI as may be designated from time to time by CTI. All payments under this Agreement shall be made in Euros. For any payment to be made hereunder, when conversion of payments from any foreign currency is required to be undertaken, the Euro equivalent shall be calculated by the applicable paying Party under this Agreement (“**Paying Party**”) using the average standard exchange rates published by the European Central Bank over the period corresponding to the payment (e.g., if the payment relates to the Development Costs over a Calendar Quarter, the exchange rate will be equal to the average exchange rates published by the European Central Bank over such Calendar Quarter).

10.8 **Interest.** Any payments or portions thereof due hereunder which are not paid when due shall bear interest equal to \*\*, calculated on the number of days such payment is delinquent.

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10.9 **Taxes.** All payments under this Agreement shall be made without any deduction or withholding for or on account of any tax, except as set forth in this Section 10.9. The Parties agree to cooperate and will each use reasonable efforts to minimize under Applicable Law obligations for any and all income or other taxes required by Applicable Law to be withheld or deducted from any of the Royalty and other payments made by or on behalf of a Party hereunder (“**Withholding Taxes**”). The applicable Paying Party shall, if required by Applicable Law, deduct from any amounts that it is required to pay to the other Party hereunder (the “**Recipient Party**”) an amount equal to such Withholding Taxes; provided that such Paying Party shall give the Recipient Party reasonable advance notice prior to paying any such Withholding Taxes. Such Withholding Taxes shall be paid to the proper Governmental Authority for the Recipient Party’s account and, if available, evidence of such payment shall be secured and sent to such Recipient Party as soon as such evidence, if any, is received by the Paying Party from the competent tax authority. The Paying Party shall, at the Recipient Party’s cost and expense, as mutually agreed by the Parties, do all such lawful acts and things and sign all such lawful deeds and documents as such other Party may reasonably request to enable the Paying Party to avail itself of any applicable legal provision or any double taxation treaties with the goal of paying the sums due to the Recipient Party hereunder without deducting any Withholding Taxes.

10.10 **Audit Rights.**

10.10.1 Each Party (the “**Auditing Party**”) shall have the right, at its own expense, no more than \*\* per Calendar Year and not more frequently than \*\* with respect to books and records covering any specific period of time, to inspect the other Party’s (the “**Inspected Party**”) relevant financial books and records with respect to Development Costs or other costs reimbursable hereunder, as well as Net Sales and Royalty determination, as applicable, for the \*\* Calendar Years through an independent internationally recognized auditor (“**Auditor**”) designated by the Auditing Party and approved by the Inspected Party, such approval not to be unreasonably withheld, conditioned or delayed. Before beginning its audit, the Auditor shall execute an undertaking acceptable to the Inspected Party by which the Auditor agrees to keep confidential all information reviewed during the audit. The Auditor shall have the right to disclose to the Auditing Party only its conclusions regarding any payments owed under this Agreement or the Supply Agreement.

10.10.2 The Inspected Party shall make such books and records available for inspection by such Auditor, during regular business hours at such place or places where such records are customarily kept and upon at least \*\* advance written notice, for the purpose of such Auditor confirming the correctness or completeness of any calculations or payments to be made pursuant to this Agreement or the Supply Agreement.

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10.10.3 The Auditor shall provide its audit report and basis for any determination to the Inspected Party at the time such report is provided to the Auditing Party and in any event before it is considered final.

10.10.4 In the event that the final result of such an audit reveals an underpayment by the Inspected Party, then unless disputed, the Inspected Party shall remit payment to the Auditing Party of the amount of the underpayment plus interest as set forth in Section 10.9. Any overpayments shall promptly be refunded to the Inspected Party. In the event that the underpayment or overpayment for any given audit period \*\* of the amount paid by the Inspected Party for such audit period, then the cost of the Auditor shall be borne by the Inspected Party and otherwise, it shall be borne by the Auditing Party.

10.11 **Records.** Each Party shall, and shall cause its Affiliates and permitted Sublicensees to, keep and maintain for \*\*, complete and accurate books and records in accordance with Accounting Standards in sufficient detail so that Development Costs, Net Sales, Royalties, Manufacturing Costs or other amounts payable hereunder, or under the Supply Agreement, may be reconciled and properly verified.

## ARTICLE 11

### INTELLECTUAL PROPERTY

11.1 **Joint Ownership.** CTI and Servier shall jointly and equally (50/50) own any Joint Intellectual Property. The Parties agree that during the Royalty Term: (a) the Parties may use or sublicense the Joint Intellectual Property without accounting to the other Party; provided, however, that neither Party may sublicense or assign its share in the Joint Intellectual Property for the purpose of enabling a Third Party to engage in the research, Development, Manufacture or Commercialization of the Licensed Product or any Competing Product, without the prior written consent of the other Party, such consent not to be unreasonably withheld; and (b) all enforcement of the Joint Intellectual Property shall be as contemplated in Section 11.4.

11.2 **Sole Inventions.** Other than Joint Intellectual Property, each Party shall own all inventions, Know-How and other intellectual property, whether or not patentable, conceived and made solely by its or its Affiliates' own employees, agents, or independent contractors in the course of conducting its or its Affiliates' activities under this Agreement or the Original Agreement, together with all intellectual property rights therein ("**Sole Inventions**"). All Patents claiming patentable Sole Inventions (but not Joint Inventions) shall be referred to herein as "**Sole Invention Patents**."

11.3 **Inventorship.** For purposes of this Agreement, all determinations of inventorship shall be made in accordance with the United Kingdom patent laws.

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#### 11.4 Intellectual Property Litigation.

11.4.1 **Notice and Cooperation.** Other than with respect to claims involving a Generic Affiliate of either Party, each Party shall promptly notify the other, to the extent such Party becomes aware (i) of any suspected or threatened infringement of any Licensed Intellectual Property (including any “patent certification” filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) or similar provisions in other jurisdictions and/or of any declaratory judgment, or similar action alleging the invalidity, unenforceability or non-infringement of any Licensed Intellectual Property or any administrative challenge to Licensed Intellectual Property filed by Third Parties under Chapters 31 and 32 of Title 35, USC or similar provisions in other jurisdictions alleging the unpatentability of any Licensed Intellectual Property), (ii) of any claim that the exercise of the rights granted hereunder under the Licensed Intellectual Property infringes any rights or patents of a Third Party, (iii) of any claims of alleged patent infringement by CTI or Servier with respect to the Development, Manufacture, Medical Affairs Activities or Commercialization of the Licensed Compound or the Licensed Product and (iv) of any suspected or actual misappropriation of Licensed Know-How ((i) and (ii) together, “*Licensed IP Claims*,” and (iii) and (iv) together, “*Third Party IP Claims*,” it being agreed that Licensed IP Claims and Third Party IP Claims shall exclude claims involving Generic Affiliates).

#### 11.4.2 Right to Assert Claims/Defend Claims.

11.4.2.1 CTI may in its sole discretion, but shall not be required to, bring legal action against any Licensed IP Claims in the CTI Territory, or defend against any Third Party IP Claims in the CTI Territory.

11.4.2.2 Servier may in its sole discretion, but shall not be required to, bring legal action against any Licensed IP Claims in the Servier Territory, or defend against any Third Party IP Claims in the Servier Territory.

11.4.2.3 Prior to bringing or defending a legal action pursuant to this Section 11.4.2, the Party responsible for taking action shall discuss its intention with the other Party (subject to the other Party entering into a common interest agreement if requested by the responsible Party, and without disclosing any information that would compromise attorney-client privilege or similar privileges), and shall take commercially reasonable efforts to consider the other Party’s input in good faith. In the event the responsible Party brings or defends against any such action, it shall be at its own cost and expense. During the pendency of such action, at the other Party’s request, the responsible Party shall provide the other Party with all information reasonably requested regarding the status of such action (subject to

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the other Party entering into a common interest agreement if requested by the responsible Party, and without disclosing any information that would compromise attorney-client privilege or similar privileges). All materials provided by the responsible Party to the other Party under this Section 11.4.2 shall be treated as the responsible Party's Confidential Information. In any action or defense initiated by the responsible Party under this Section 11.4.2, the other Party shall be entitled to, and if legally required shall, join the action so long as the responsible Party retains at all times the sole right to direct and control the action (including the choice of its own counsel). The other Party is entitled to be independently represented by counsel of its choice, at its expense.

11.4.2.4 If Servier decides that it will not bring legal action or defend under Section 11.4.2 with respect to any Licensed Intellectual Property in the Servier Territory or CTI decides that it will not bring legal action or defend under Section 11.4.2 with respect to any Licensed Intellectual Property in the CTI Territory, then it shall promptly notify the other Party, and in any event, said notice shall be provided by the earlier of (A) \*\* from the date \*\* and (B) \*\* before the \*\*, if any, set forth in the appropriate laws and regulations for the filing of such actions or defense. Upon receipt of such notice of intent to decline action, the other Party may (to the extent permitted by Applicable Law), but shall not be required to, bring legal action or defend against any claim identified in Section 11.4.1 with respect to Licensed Intellectual Property in the Servier Territory if the other Party is CTI, and with respect to Licensed Intellectual Property in the CTI Territory if the other Party is Servier, in which event the Party taking action shall act in its own name (to the extent permitted by Applicable Law) and at its own cost and the provisions of Section 11.4.2.3 shall apply with respect to any such action.

11.4.2.5 For the avoidance of doubt, either Party shall be entitled, in its sole discretion, to bring or to defend against any legal action involving any Generic Affiliate of the other Party in any country.

11.4.3 **Cooperation.** When either Party is bringing or defending an action of the type described in this Section 11.4, then (i) upon request by a Party defending or enforcing any such action, the other Party will assist in the defense against or enforcement of such action at the other Party's expense, including if required or desirable to bring, maintain or prove damages in such action, furnishing a power of attorney, furnishing documents and information, cooperating in discovery, providing access to witnesses (including inventors) and executing all necessary documents as such Party may request, and (ii) neither Party shall settle, consent to judgment or otherwise voluntarily dispose of the suit or action without the prior written consent of the other Party, which consent shall not

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be unreasonably delayed, conditioned, or withheld if such settlement, consent to judgment or other voluntary disposition does not impose any liability on the other Party (other than liability that is fully satisfied by the settling Party on behalf of the other Party), does not impose any restrictions on the other Party and does not admit the invalidity or unenforceability of any Patent owned or controlled by the other Party.

11.4.4 **Allocation of Proceeds.** The proceeds recovered from any action described in Section 11.4.2 with respect to the Servier Territory with respect to the Licensed Intellectual Property shall be first allocated to the reimbursement of the reasonable attorneys' fees and Out-of-Pocket Costs incurred by each Party in connection with such action pursuant to the Agreement. If such recovery is insufficient to cover all such costs and expenses of both Parties, it shall be \*\*. The remaining portion of proceeds shall be allocated at a rate of \*\* to CTI and \*\* to Servier.

11.5 **Drug Price Competition and Patent Rights Term Extensions.** CTI shall discuss with Servier all actions necessary to obtain the patent extensions for Licensed Patents Covering the Licensed Compound and Licensed Product in the Servier Territory, including applications for regulatory exclusivities, including new chemical entity, pediatric, and orphan drug exclusivities as may now or hereafter apply with respect to obtaining patent extensions for Licensed Patents in the European Union and the Servier Territory. After discussion between the Parties, CTI agrees to execute such further authorization and instruments, make such filings, and take such further actions as may be requested by Servier to implement and obtain the foregoing. CTI shall be responsible for all costs and expenses incurred in connection with such filings and actions in the Servier Territory. The Parties agree to cooperate in an effort to avoid loss of any rights which may otherwise be available to the Parties hereto with respect to obtaining patent extensions for Licensed Patents in the Servier Territory.

#### 11.6 **Patent Prosecution, Maintenance and Ownership.**

11.6.1 CTI shall (i) prepare, file, prosecute and maintain the Licensed Patents in the Servier Territory, and (ii) use commercially reasonable efforts to prepare, file, prosecute and maintain the Licensed Patents in all other countries in the world, each \*\*. CTI shall be responsible for \*\*. CTI shall be responsible for \*\*.

11.6.2 CTI shall give Servier reasonable access to the files and other materials in the possession of CTI included in all proceedings and actions related to the preparation, filing, prosecution and maintenance of all Licensed Patents in the Servier Territory, as well as all pending applications of such Licensed Patents. CTI shall keep Servier reasonably informed with respect to the prosecution thereof including providing CTI with copies of each office action with enough lead time to enable Servier to review and comment

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on such action. CTI, its agents and attorneys, will give due consideration to all reasonable suggestions and comments of Servier regarding any aspect of such patent prosecution or proceeding. If CTI determines not to continue the prosecution of, or not to continue to maintain or defend, any Licensed Patent in any country of the Servier Territory, or if CTI otherwise determines to abandon any such Licensed Patent, CTI shall promptly notify Servier of such determination sufficiently in advance to permit Servier to undertake the continued prosecution, maintenance or defense of such Licensed Patent without a loss of rights, and Servier shall have the right to undertake such continued prosecution, maintenance or defense at its sole cost and expense, as the sole owner of such Licensed Patent.

**11.7 Product Trademarks, Corporate Names and Domain Names.** Each Party and its Affiliates shall retain all right, title and interest in and to its and their respective corporate logos and associated trademarks.

11.7.1 The Licensed Product has been approved in the European Union under the verbal and figurative trademark Pixuvri® (the “**CTI Trademark**”). CTI (or its local Affiliates, as appropriate) shall own and retain all rights to the CTI Trademark, together with all goodwill associated therewith, worldwide, and all e-brands, trade dress, service marks and copyrights for the Licensed Product. CTI shall establish, file, maintain and defend the CTI Trademark in the Servier Territory to the extent that Servier has elected to use such CTI Trademark in the Servier Territory pursuant to Section 11.7.3, in each case, in consultation with Servier. If the CTI Trademark has not been filed in one or more countries of the Servier Territory where there is a reasonable business reason for such a filing, then CTI undertakes to promptly conduct priority searches and proceed with any such filings at Servier’s cost and expense after Servier’s election to use the CTI Trademark pursuant to Section 11.7.3. Notwithstanding the foregoing and subject to Section 14.6.7, (i) Servier may elect to take over the preparation, filing, prosecution and maintenance of the CTI Trademarks in all or part of Servier Territory in Servier’s name and at Servier’s costs and in such case, CTI shall assign to Servier or its designated Affiliate, for no additional consideration than that set forth in Article 10, the trademarks and any corresponding domain names already filed by CTI in such part of the Servier Territory and (ii) CTI hereby authorizes Servier or its designated Affiliate, at Servier’s election, to file a duplicate of the CTI Trademark in the Servier EU Territory in Servier’s name and at Servier’s costs (the “**Second EU Trademark**”).

11.7.2 Servier shall select one or more Product trademarks (including backup trademarks) for the Licensed Product for use by Servier in the Servier Territory (where such Product trademark (including backup trademarks) may be the CTI Trademark or a different trademark of Servier’s choice, with the different trademark of Servier’s choice being referred to as the “**Servier Product Trademarks**”). Servier (or its

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local Affiliates, as appropriate) shall own and retain all rights to the Servier Product Trademark(s), together with all goodwill associated therewith, worldwide, and all e-brands, trade dress, service marks and copyrights for the Servier Product Trademark(s) used for the Licensed Product in the Servier Territory.

11.7.3 CTI hereby grants Servier and its Affiliates a sublicensable (subject to Section 2.3), fully paid-up, royalty-free right and license to use the CTI Trademark as well as any corresponding domain names, in connection with the Development, Commercialization and conduct of Medical Affairs Activities regarding the Licensed Compounds and the Licensed Product in the Field in the Servier Territory.

11.7.4 Within \*\* after \*\*, the Parties (and/or their Affiliates) will amend the trademark license agreement entered into between the Parties on June 8, 2015 with respect to the CTI Trademark and any corresponding domain names in accordance with Sections 11.7.1 and 11.7.3, which will also provide for Servier's right to enforce the CTI Trademark in the Servier Territory in case of suspected or threatened infringement.

11.7.5 Upon request by Servier, CTI shall (or shall cause its Affiliates, as appropriate, to) execute such documents and provide such assistance as may reasonably be required by Servier or its Affiliates for the purpose of recording the licenses or assignments described in Sections 11.7.3-11.7.5 and 11.7.1 with any Governmental Authority or obtaining a Second EU Trademark.

11.7.6 Each Party agrees that it will not use the CTI Trademark, for any product other than the Licensed Product, and shall not use any such trademark with respect to any Generic Equivalent in any country in the world.

## ARTICLE 12

### PUBLICATION; CONFIDENTIALITY

#### 12.1 Confidentiality Obligations of Servier.

12.1.1 For the \*\*, Servier:

12.1.1.1 shall hold in strict confidence any and all Confidential Information disclosed to it by or on behalf of CTI (together "***CTI Confidential Information***"), and shall not use, nor disclose or supply to any Third Party, nor permit any Third Party, to have access to the CTI Confidential Information, without first obtaining the written consent of CTI, except as expressly permitted in this Agreement; and

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12.1.1.2 shall take all reasonable precautions necessary or prudent to prevent material in its possession or control that contains or refers to CTI Confidential Information from being destroyed or lost, or discovered, received, used, intercepted or copied by any Third Party.

12.1.2 Servier's obligations of confidentiality and non-use under this Section 12.1 shall not apply, and Servier shall have no further obligations with respect to any of the CTI Confidential Information, to the extent that such CTI Confidential Information:

12.1.2.1 is or becomes part of the public domain after its disclosure without breach by Servier of this Agreement;

12.1.2.2 was rightfully in Servier's possession before disclosure by CTI and was not acquired directly or indirectly from CTI;

12.1.2.3 is obtained from a Third Party with no obligation of confidentiality to CTI, who has a right to disclose it to Servier;

12.1.2.4 is developed independently by Servier or any of its Affiliates without reference to or use of the CTI Confidential Information, as evidenced by Servier's written records; or

12.1.2.5 subject to Section 12.3.2, is required to be revealed in response to a court decision or administrative order, or to comply with Applicable Law or rules of a securities exchange (as established by an opinion of an outside legal counsel), in which case Servier shall inform CTI immediately by written notice and cooperate with CTI using its commercially reasonable efforts either to seek protective measures for such CTI Confidential Information, or to seek confidential treatment of such CTI Confidential Information, and in any case, Servier shall disclose only such portion of the CTI Confidential Information which is so required to be disclosed; provided, further, that, notwithstanding this Section 12.1.2.5, such information that is disclosed pursuant to such requirement shall continue to constitute CTI Confidential Information for purposes other than the required disclosure until an exception in Sections 12.1.2.1 through 12.1.2.4 above shall apply.

## 12.2 Confidentiality Obligations of CTI; Confidentiality Obligations of each Party.

12.2.1 For the \*\*, CTI:

12.2.1.1 shall hold in strict confidence any and all Confidential Information disclosed to it by or on behalf of Servier ("**Servier**

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*Confidential Information*”), and shall not use, nor disclose or supply to any Third Party nor permit any Third Party to have access to the Servier Confidential Information, without first obtaining the written consent of Servier, except as expressly permitted in this Agreement; and

12.2.1.2 shall take all reasonable precautions necessary or prudent to prevent material in its possession or control that contains or refers to Servier Confidential Information from being destroyed or lost, or discovered, received, used, intercepted or copied by any Third Party.

12.2.2 CTI’s obligations of confidentiality and non-use under this Section 12.2 shall not apply, and CTI shall have no further obligations with respect to any of the Servier Confidential Information to the extent that such Servier Confidential Information:

12.2.2.1 is or becomes part of the public domain after its disclosure without breach by CTI of this Agreement;

12.2.2.2 was rightfully in CTI’s possession before disclosure by Servier to CTI and was not acquired directly or indirectly from Servier;

12.2.2.3 is obtained from a Third Party with no obligation of confidentiality to Servier, who has a right to disclose it to CTI;

12.2.2.4 is developed independently by CTI or any of its Affiliates without reference to or use of the Servier Confidential Information, as evidenced by CTI’s written records; or

12.2.2.5 is required to be revealed in response to a court decision or administrative order, or to comply with Applicable Law or rules of a securities exchange (as established by an opinion of an outside legal counsel), in which case CTI shall inform Servier immediately by written notice and cooperate with Servier using its commercially reasonable efforts either to seek protective measures for such Servier Confidential Information, or to seek confidential treatment of such Servier Confidential Information to the extent practicable in light of CTI’s time constraints under Applicable Law or rules of a securities exchange as justified by such opinion of outside legal counsel, and in any case, CTI shall disclose only such portion of the Servier Confidential Information which is so required to be disclosed; provided, further, that, notwithstanding this Section 12.2.2.5, such information that is disclosed pursuant to such requirement shall continue to constitute Servier Confidential Information for purposes other than the required disclosure

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until an exception in Sections above 12.2.2.1 through 12.2.2.4 above or Section 12.3.5 below shall apply.

12.2.3 Data generated pursuant to a Development Plan or for which a Party has exercised its Opt-In Right shall be deemed to be both CTI Confidential Information and Servier Confidential Information, and each Party shall have the right to use and disclose such Data for any purpose, subject to the provisions of Article 9 and this Article 12.

12.2.4 All of the provisions of this Article 12 are subject to the provisions of Sections 12.1.2.5 or 12.2.2.5, as applicable, and Section 12.3.4.

12.2.5 Notwithstanding the respective introductory paragraphs of Sections 12.1.1 and 12.2.1, the obligation to keep a Party's trade secrets (which trade secrets shall be identified in writing by mutual reasonable agreement of the Parties within thirty (30) days after the expiration or termination of this Agreement) confidential, shall survive for such time as such information remains a protected trade secret under Applicable Law.

### **12.3 Publicity; Required Disclosures.**

12.3.1 Except with respect to the press release to be mutually agreed by the Parties announcing the entering into of this Agreement, or any other press release, public disclosure or any other disclosure to a Third Party with substance substantially similar to such mutually agreed press release which may be issued by either or both of the Parties upon execution of this Agreement, no disclosure shall be made by either Party concerning the execution of this Agreement or the terms and conditions hereof without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed.

12.3.2 Without prejudice to Section 12.2.2.5, each Party may issue a press release or public announcement if required to be revealed in response to a court decision or administrative order, if required under Applicable Law or rules of a securities exchange or if relating to such Party's Development, regulatory or commercial activities under this Agreement, provided that such Party shall use commercially reasonable efforts to provide the other Party with a copy of such press release or public announcement at least \*\* in advance of its intended publication or release thereof and shall consider in good faith the comments of the other Party, which comments shall be provided as promptly as reasonably practicable following receipt of the press release or public announcement from the Party desiring to make the disclosure.

12.3.3 Notwithstanding Section 12.3.1 and subject to the other provisions of this Article 12:

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12.3.3.1 no Party shall make any publication or disclosure of Data generated by or on behalf of the other Party (other than any such Data as is generated pursuant to the Development Plan) without the prior written approval of the other Party and through a procedure to be established by the JSC or its designee;

12.3.3.2 neither Party shall use the name of the other Party in any publicity or advertising without the prior written consent of the other Party; and

12.3.3.3 either Party may disclose the existence of this Agreement and the terms and conditions hereof in connection with a due diligence process associated with any future financing by either Party or the negotiation or exploration of a possible strategic corporate transaction involving such Party, provided that such disclosure is limited to information that is relevant to the contemplated transaction and is made in the course of such diligence, negotiation or exploration, and pursuant to confidentiality obligations consistent with those set forth in this Agreement.

12.3.4 Each Party agrees that it shall cooperate fully and in a timely manner with the other Party with respect to all disclosures required by the Securities and Exchange Commission and any other Governmental Authority or Regulatory Authority or recognized stock exchange or quotation system, including requests for confidential treatment of Confidential Information of either Party included in any such disclosure. Each Party shall consult with the other Party on the provisions of this Agreement, together with exhibits or other attachments attached hereto, to be filed with the Securities and Exchange Commission and/or for either Party as otherwise required by Applicable Law and shall use commercially reasonable efforts to limit the disclosure to those provisions required to be disclosed by Applicable Laws. A draft of the filing shall be provided to the other Party at least \*\* in advance of its intended publication or release thereof, and the disclosing Party shall consider in good faith the comments of the other Party, which comments shall be provided as promptly as reasonably practicable following timely receipt of the proposal from the disclosing Party.

12.3.5 Once a disclosure is publicly disclosed in accordance with the terms of this Agreement, the substance of such disclosure (or any portion thereof) may be repeated in a subsequent public disclosure by either Party without regard to the notification or other requirements of this Article 12.

#### **12.4 Scientific Papers, Abstracts and Posters.**

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12.4.1 **Scientific Papers.** Each Party through the JSC or its designee shall provide to the other, prior to submission for publication, a draft of any articles and papers containing Confidential Information or concerning the Licensed Compound or Licensed Product which have been prepared by or on behalf of such Party or under the Development Plan (each a “*Scientific Paper*”) to be published in indexed medical and scientific journals and similar publications (“*Medical Journals*”). Commencing with the receipt of such draft Scientific Paper, the Receiving Party shall have \*\* to notify the sending Party of its observations and suggestions with respect thereto (it being understood that, during such \*\* period, no submission for publication thereof shall take place), and the Parties shall discuss these observations and suggestions. The Party proposing to publish such Scientific Paper shall, in good faith, consider the comments made by the other Party, particularly if disclosure may be prejudicial to the other Party’s opportunity to obtain any Patent. Neither Party will publish or present any Confidential Information of the other Party without such other Party’s prior written consent. The sending Party shall provide to the Receiving Party copies of any final Scientific Paper accepted by a Medical Journal, within \*\* after the approval thereof (upon availability and distribution of such information assuming that providing such information is acceptable taking into consideration the publishers’ need to comply with any healthcare compliance guidelines). To enable free exchange of copyrighted material between the Parties, each Party agrees that it has or shall (i) obtain and maintain, at its own expense, an Annual Copyright License or equivalent license from the Copyright Clearance Center and (ii) list the other Party as a collaborator in an agreement with the Copyright Clearance Center if required by such agreement.

12.4.2 **Abstracts and Posters.** If a Party intends to present findings with respect to any Licensed Compound or Licensed Product at symposia or other meetings of healthcare professionals, or international and/or US or European congresses, conferences or meetings organized by a professional society or organization (any such occasion, a “*Scientific Meeting*”), to the extent permitted by Applicable Laws, such Party through the JSC or its designee shall provide to the other, prior to submission or presentation, as the case may be, copies of (i) all abstracts that will be submitted for publication in connection with (a) any international Scientific Meeting, in any Scientific Meeting in the European Union or in the United States (b) with respect to CTI, any Scientific Meeting in the Servier Territory and any major Scientific Meetings in the CTI Territory and (c) with respect to Servier, any Scientific Meeting in the CTI Territory and any Scientific Meeting \*\* (a list of which Scientific Meetings will be established and updated from time to time by a publication Additional Committee) and (ii) all posters that will be presented at such Scientific Meeting, in each case, concerning the Licensed Compound or Licensed Product which have been prepared by or on behalf of one of the Parties, for submission or presentation. Commencing with the receipt of any such abstract or poster, the Receiving Party shall have \*\* in the case

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of an abstract, or \*\* in the case of a poster, to inform the sending Party of its observations and suggestions with respect thereto (it being understood that, during such review period, as applicable, no submission or presentation thereof shall take place), and the Parties shall discuss these observations and suggestions. The Party proposing to publish such an abstract or make such a presentation shall, in good faith, consider the comments made by the other Party, particularly if disclosure may be prejudicial to the other Party's opportunity to obtain any patent rights. A Party will not publish or present any Confidential Information of the other Party without such other Party's prior written consent. The sending Party shall provide to the Receiving Party copies of (i) all final abstracts as soon \*\* after the approval of the Scientific Meeting, and (ii) all final posters accepted for publication or to be presented \*\* prior to the planned publication or presentation thereof (upon availability and distribution of such information assuming that providing such information is acceptable taking into consideration the publishers' need to comply with any healthcare compliance guidelines). The Parties shall use good faith and Commercially Reasonable Efforts to provide the other Party with draft slide presentations in accordance with the foregoing time periods.

12.5 **Registries.** Each Party shall be free to disclose any clinical trial Data generated by such Party concerning the Licensed Product as required by Applicable Law in clinical trial registries; provided, however, that the Party proposing to make such disclosure shall have provided the other Party at least \*\* prior to such disclosure (to the extent practicable), a detailed description of the proposed disclosure and shall have, in good faith, considered the comments made by the other Party.

#### 12.6 **Timeline Extension or Deferral of Disclosures.**

12.6.1 Each Party agrees that it will not unreasonably withhold, condition or delay its consent to requests for extensions of the above timelines in this Article 12 in the event that material late-breaking Data becomes available.

12.6.2 If either Party believes that any proposed press release or other public statement, or any publication, presentation or other disclosure would be prejudicial to its opportunity to obtain any Patent, then the affected Party shall notify the publishing Party within the timeframe provided for in this Article 12 as applicable, or if not applicable, as soon as practicable after receipt of the proposed press release or other public statement, publication, presentation or other disclosure, and the publishing Party shall refrain from making such press release, other public statement, publication, presentation or other disclosure for an additional \*\* from the last day of the period otherwise provided for herein to enable the preparation and filing of any necessary patent applications.

12.7 **Failure to Object to Disclosure.** If the Party proposing any press release or other public statement, or any publication, presentation or other disclosure referred

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to in this Article 12 (excluding for the avoidance of doubt any promotional materials) receives no objection from the other Party within the timeframes set forth in the corresponding Section, then, the Party proposing such press release, other public statement, publication, presentation, or other disclosure shall be free to proceed with the same without further reference to or agreement from the other Party; provided, however, that any such publication, presentation or other disclosure shall acknowledge the other Party's contribution to any Data included therein if requested by such other Party.

#### 12.8 Authorized Disclosure.

12.8.1 Except as expressly provided otherwise in this Agreement, each Party may use and disclose Confidential Information of the other Party as follows: (i) under appropriate written confidentiality provisions substantially equivalent to those in this Agreement, in connection with the performance of its obligations (e.g., in sublicense agreements), or as reasonably necessary in the exercise of its rights, under this Agreement, or in furtherance of the Development, Manufacture, use, Medical Affairs Activities or Commercialization of the Licensed Product, or in complying with the terms of the University of Vermont Agreement or the Novartis Agreements subject to the prior approval by Servier of a redacted version of this Agreement if required to be provided; (ii) to the extent such disclosure is reasonably necessary in filing or prosecuting patent applications in accordance with this Agreement, prosecuting or defending litigation, complying with applicable governmental regulations or the rules of any national securities exchange, obtaining Regulatory Approvals for Licensed Product, fulfilling post-approval regulatory obligations, or as otherwise required by Applicable Law; provided, however, that if a Party intends to rely on clause (i) or (ii) to make any such disclosure of the other Party's Confidential Information, it will, except to the extent inappropriate in the case of patent applications or as required by Applicable Law, use commercially reasonable efforts to secure confidential treatment of such Confidential Information so disclosed; (iii) in communication with advisors, including lawyers and accountants, on a need-to-know basis, in each case under appropriate confidentiality provisions substantially equivalent to those of this Agreement; (iv) to actual or potential Sublicensees; or (v) to the extent mutually agreed to in writing by the Parties.

12.8.2 Notwithstanding the foregoing, the Parties recognize that independent investigators, academic centers and cooperative groups have been engaged, and will be engaged in the future, to conduct clinical and non-clinical studies of the Licensed Compound and of the Licensed Product. The Parties recognize that such investigators, academic centers and cooperative groups operate in an academic environment and may publish and release information regarding such studies in a manner consistent with academic standards; provided that each Party will use reasonable efforts to prevent publications prior

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to the filing of relevant patent applications and to seek confidential treatment for any Confidential Information of either Party that is disclosed to such academic centers, cooperative groups or investigators.

### ARTICLE 13

#### REPRESENTATIONS, WARRANTIES AND COVENANTS

13.1 **By each Party.** Each Party, on behalf of itself and its Affiliates, hereby represents and warrants as of the Restatement Date to, and covenants with, the other Party as follows:

13.1.1 the Party is duly organized and validly existing under the laws of its jurisdiction of incorporation;

13.1.2 the Party has full corporate power and authority, and has taken all corporate action necessary, to enter into and perform its obligations under this Agreement;

13.1.3 this Agreement is legal, valid and binding on the Party and enforceable against it in accordance with its terms;

13.1.4 neither the execution and delivery of this Agreement by the Party, nor the performance by the Party of its obligations hereunder, conflicts with any agreement, instrument or understanding, oral or written, by which such Party is bound;

13.1.5 no authorization, consent, approval, license, exemption of or filing or registration with any Governmental Authority, under any Applicable Law currently in effect, is required in connection with the execution and delivery of this Agreement by such Party, or the performance by such Party of its obligations under this Agreement; and

13.1.6 the Party is not the agent of the other Party and represents and warrants that it will not directly or indirectly offer, give, promise to give or authorize the giving of any money or other thing of value to induce any Person to do or to refrain from doing any act in violation of such Person's lawful duty, to obtain any improper advantage, or to induce any person to use his or her influence improperly to affect or influence any act or decision in connection with the activities under this Agreement, and the Party has not done any of the foregoing.

13.2 **By CTI.** CTI, on behalf of the CTI Group, hereby represents and warrants, as of the Restatement Date, as follows: \*\*:

13.2.1 the Licensed Patents in the Servier Territory listed on Exhibit A constitute a true, accurate and complete list of (i) all Patents in existence as of the

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Restatement Date Controlled by CTI in the Servier Territory relating to the Licensed Compound or the Licensed Product in the Servier Territory, indicating the owner, licensor and/or co-owner(s) thereof if any such Licensed Patent is not solely owned by CTI, and (ii) all license, assignment or similar agreements relating to any such Licensed Patents other than routine agreements such as clinical trial agreements, consulting agreements, service agreements, material transfer and other similar agreements that may contain licensing terms (solely for purposes of the subject matter of the agreement) and assignment terms to the benefit of CTI;

13.2.2 CTI is the sole and exclusive owner, or exclusive licensee of all of the Licensed Intellectual Property existing as of the Restatement Date free from encumbrances (other than those resulting from the Head Licenses) and is listed in the records of the appropriate Governmental Authorities as the sole and exclusive owner or licensee of the Licensed Patents, provided that with respect to certain Licensed Patents, the name change and the transfer from Novuspharma to CTI has not been recorded;

13.2.3 CTI has obtained from all individuals who participated in the invention of any Licensed Intellectual Property existing as of the Restatement Date effective assignments of all ownership rights either pursuant to written agreement or by operation of law;

13.2.4 CTI is the sole and exclusive owner of the CTI Trademark free from encumbrances and, when appropriate, is listed in the records of the appropriate Governmental Authorities as the sole and exclusive owner of the CTI Trademark;

13.2.5 CTI has the right to grant the rights granted to Servier under this Agreement;

13.2.6 CTI has the right to use and disclose and to enable Servier to use and disclose (in each case under appropriate conditions of confidentiality) the Licensed Intellectual Property and the CTI Trademark free from encumbrances (other than those resulting from the Head Licenses);

13.2.7 patent applications within the Licensed Patents have been filed and prosecuted in good faith and all duties of disclosure with respect thereto and all Applicable Laws with respect thereto have been complied with;

13.2.8 all application and registration fees in respect of the Licensed Patents and the CTI Trademark as of the Restatement Date have been paid and all necessary documents and certificates have been filed with the relevant agencies for the purpose of registering the Licensed Patents and the CTI Trademark;

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13.2.9 CTI has not granted to any Third Party, including any academic organization or agency, any rights to Develop or Manufacture the Licensed Compounds or Licensed Product(s) that are conflicting with this Agreement or any rights to Commercialize the Licensed Compounds or Licensed Product(s) in the Servier Territory<sup>4</sup>;

13.2.10 to CTI's knowledge after due inquiry, the Licensed Intellectual Property comprises all of the intellectual property rights used by CTI and its Affiliates in the Development and Manufacture of the Licensed Compound and Licensed Product(s) prior to the Restatement Date and material to the Development and Manufacture of the Licensed Compound and Licensed Product(s);

13.2.11 CTI has not received any written notice and does not otherwise have Knowledge that the Development, registration, Manufacture, use or Commercialization of the Licensed Compounds and Licensed Product would infringe the patent rights or misappropriate the Know-How of any Third Party;

13.2.12 CTI has not initiated or been involved in any proceedings or claims in which it alleges that any Third Party is or was infringing or misappropriating any Licensed Intellectual Property or the CTI Trademark, nor have any such proceedings been threatened by CTI;

13.2.13 no officer or employee of CTI is subject to any agreement with any Third Party which requires such officer or employee to assign any interest in any Licensed Intellectual Property relating to the Licensed Compounds or Licensed Product to any Third Party;

13.2.14 CTI has taken reasonable precautions to preserve the confidentiality of the Licensed Know-How;

13.2.15 CTI has not granted any Third Party rights that would otherwise interfere or be inconsistent with the rights granted to Servier hereunder, and there are no agreements or arrangements to which CTI or any of its Affiliates is a party relating to the Licensed Product, Licensed Compounds, Licensed Patents, or Licensed Know-How that would limit the rights granted to Servier under this Agreement or that restrict or will result in a restriction on Servier's ability to Develop, Manufacture, register, use or Commercialize the Licensed Compounds and the Licensed Product(s) in the Servier Territory, and no rights granted to Servier pursuant to this Agreement are in violation of any agreement between CTI or any of its Affiliates and any Third Party;

13.2.16 neither CTI nor any of its Affiliates has committed any act which amounts to a material breach of any of CTI's obligations under the University of Vermont Agreement or the Novartis Agreements entitling the University of Vermont or

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Novartis, as the case may be, to terminate or modify the parties' rights under the University of Vermont Agreement or the Novartis Agreements, respectively;

13.2.17 CTI has timely made all filings required prior to the Restatement Date to maintain the MA in the European Union, including the renewal of the MA, which was obtained on April 11, 2014 and the status update on the PIX306 Trial which was submitted as part of the annual MA renewal in December 2013 on which CTI has received no negative comment or other feedback from the EMA;

13.2.18 CTI has disclosed or made available to Servier in writing, complete and correct copies of (i) any and all study reports and Data relating to the Licensed Compound or Licensed Product in its Control or that have been provided to any Regulatory Authority, (ii) all filings and correspondence between CTI and its Affiliates and any Regulatory Authority relating to the Licensed Compound or Licensed Product. In the course of the development of Licensed Product, CTI has not used any employee or consultant who has been debarred by any Regulatory Authority, or was the subject of debarment proceedings by a Regulatory Authority. All studies conducted with respect to the Licensed Compound have been conducted by CTI, and in accordance with Applicable Laws by persons with appropriate education, knowledge and experience;

13.2.19 the documents containing Data and Know-How disclosed or made available to Servier prior to the Restatement Date are true and accurate copies of what they purport to be. CTI has made available to Servier all relevant and material Data and Know-How and other relevant and material information relating to the Licensed Compound and the Development, Manufacture and Commercialization of the Licensed Compound or the Licensed Product. Without limiting the foregoing, CTI has disclosed to Servier any relevant and material information known to CTI with respect to (i) the safety of the Licensed Compound, (ii) the efficacy of such Licensed Compound, and (iii) any circumstance existing as of the Restatement Date which would be reasonably likely to prevent or restrict the Development, Manufacturing and/or Commercialization of the Licensed Compound in the Servier Territory;

13.2.20 no representations and warranties of CTI contained in this Agreement or materials provided by CTI to Servier (whether prepared by CTI or any Third Party) contain any untrue statement of a material fact or to CTI's knowledge omit a material fact;

13.2.1 \*\*

13.2.2 \*\*

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13.3 **CTI Covenants.** CTI, on behalf of the CTI Group, hereby covenants with Servier as follows.

13.3.1 CTI will not amend or modify the terms of the Head Licenses without the prior written consent of Servier; and

13.3.2 CTI and its Affiliates will comply with, perform and observe all obligations under the Head Licenses, and will not commit any act or fail to perform any obligation which would amount to a default or event of default or which, with the giving of notice, the lapse of time or the happening of any other event or condition would become a default or event of default thereunder or give rise to any right to terminate any such agreement or any part thereof. CTI and its Affiliates shall be solely responsible for any and all payments that become due under the Head Licenses, and CTI and its Affiliates promptly shall make all such payments.

13.3.3 CTI shall take such actions as are necessary in order for it to be the recorded owner of the Licensed Patents and CTI Trademark within a reasonable period following the Restatement Date.

13.3.4 CTI is committed to \*\*.

13.3.5 \*\*

13.4 **Mutual Covenant.** Each Party, on behalf of it and its Affiliates, hereby covenants that it has or will cause all employees, officers and consultants of such Party and its Affiliates to execute agreements under Applicable Laws requiring assignment to such Party of all inventions made during the course of and as the result of their association with such Party and obligating the individual to maintain as confidential such Party's Confidential Information as well as confidential information of other parties (including the other Party and its Affiliates) which such individual may receive, to the extent required to support such Party's obligations under this Agreement.

13.5 **Disclaimer.** EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT OR IN THE SUPPLY AGREEMENT, ALL INFORMATION, DATA AND INTELLECTUAL PROPERTY RIGHTS AND ALL LICENSED COMPOUNDS PROVIDED HEREUNDER ARE PROVIDED AS-IS. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT OR IN THE SUPPLY AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY WITH REGARD TO ANY PATENTS, KNOW-HOW, INTELLECTUAL PROPERTY RIGHTS, DATA, LICENSED COMPOUNDS OR LICENSED PRODUCT, OR OTHERWISE IN CONNECTION WITH THIS AGREEMENT OR THE SUPPLY AGREEMENT EXCEPT AS SPECIFICALLY SET FORTH IN THIS AGREEMENT OR IN THE SUPPLY AGREEMENT. EXCEPT AS

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EXPRESSLY PROVIDED IN THIS AGREEMENT OR IN THE SUPPLY AGREEMENT, EACH PARTY DISCLAIMS, AND WAIVES ALL WARRANTIES, EXPRESS OR IMPLIED, ARISING BY LAW OR OTHERWISE, WITH RESPECT TO ANY DATA, LICENSED COMPOUNDS OR LICENSED PRODUCT OR OTHERWISE IN CONNECTION WITH THIS AGREEMENT OR THE SUPPLY AGREEMENT, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTY WITH RESPECT TO THE APPROPRIATENESS OF ANY STUDY DESIGN OR ANY REGULATORY LABEL, OR ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IMPLIED WARRANTY ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE OF TRADE, AND ANY IMPLIED WARRANTY OF NON INFRINGEMENT.

## ARTICLE 14

### TERM AND TERMINATION

14.1 **Term Expiration.** The term of this Agreement shall commence on the Restatement Date and shall continue in effect, unless otherwise terminated pursuant to the provisions of Sections 14.2 through 14.6, until expiration of the Royalty Term on a country-by-country basis, upon expiration of the Royalty Term in the relevant country. Upon expiration of this Agreement, on a country-by-country basis:

14.1.1 the licenses granted by CTI to Servier with respect to Know-How, the CTI Trademark and the right to reference Regulatory Materials under this Agreement with respect to such Licensed Product in such country shall remain in effect on an exclusive basis (even as to CTI) as granted in accordance with this Agreement but become fully paid-up. CTI shall not be entitled to, nor shall it allow any of its Affiliates or Sublicensees to grant any Third Party any right to, directly or indirectly cross-reference, file or incorporate by reference in countries in the Servier Territory any Regulatory Approval for the applicable Licensed Product (or any related Regulatory Materials or Data contained therein) in order to enable CTI (and its Affiliates and Sublicensees) to Develop, Manufacture and Commercialize a Generic Equivalent version of such Licensed Product in such country); provided, however, that nothing in this Section is intended to limit in any manner the rights of any Generics Affiliate of CTI from applying for approval of a Generic Equivalent in the same manner as a Third Party would be able to apply for approval of a Generic Equivalent;

14.1.2 The following provisions shall survive expiration or termination of this Agreement: Section 6.5 (Recalls and Complaints), Section 6.6 (Pharmacovigilance Agreement), Sections 10.10 (Audit Rights) and 10.11 (Records), Section 11.4 (with respect to Joint Patent Rights), Sections 12.1, 12.2, 12.3 and 12.8 (Confidentiality), Section 13.5 (Disclaimer), Sections 14.1 (Term Expiration); 14.6 (Effects

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of Termination of the Agreement); Section 14.7 (Accrued Rights), Article 15 (Dispute Resolution), Article 16 (Indemnification) and Article 17 (Miscellaneous).

14.1.3 Other than as set forth in Section 14.1.2 and in Section 14.6, the provisions of this Agreement shall be of no further force or effect.

14.2 **Unilateral Termination by Servier.** Servier shall be permitted to terminate the Agreement on a country-by-country basis, without cause and without damages due by Servier to CTI, its Affiliates, licensees or sub-licensees on account of such termination, upon \*\* prior written notice to CTI.

14.3 **Termination for Safety Reasons.** Notwithstanding Section 14.2, Servier shall be permitted to terminate the Agreement on thirty (30) days' notice or within a shorter period if required under Applicable Law, on a country-by-country basis, promptly, for Safety Reasons.

14.4 **Termination for Regulatory Reasons.** Servier will be permitted to terminate the Agreement on \*\* notice or within a shorter period if required under Applicable Law, in its entirety or with respect to the countries in the Servier EU Territory, in the event of suspension or withdrawal of the MA; however, in the event the MA is suspended or withdrawn based on lack of clinically meaningful results despite PIX Positive Outcome, such notice period for termination shall be extended to \*\*. Servier will be permitted to terminate the Agreement promptly on a country-by-country basis in the Servier ex-EU Territory in the event of suspension or withdrawal of a Regulatory Approval in such country. Notwithstanding the foregoing, if such suspension or withdrawal is due to material breach of Servier's obligations hereunder, and if following such suspension or withdrawal Servier has not used Commercially Reasonable Efforts to have such MA or Regulatory Approval reinstated within a reasonable period of time, Servier shall not have the right to terminate the Agreement under this Section 14.4.

14.5 **Termination for Repudiatory Breach.** If either Party believes that the other is in repudiatory breach of its material obligations hereunder, then the non-breaching Party may deliver notice of such breach to the other Party which notice shall clearly mention the remedies that the non-breaching Party intends to apply should the breach remain uncured. The allegedly breaching Party shall have \*\* from such notice to dispute or cure such breach, except that in the case of money owing, such period shall be \*\*. If (A) the Party receiving notice of breach fails to cure such breach, or fails to dispute any of the matters described in the next sentence, within such \*\* period and (B) the uncured repudiatory breach cannot be adequately remedied through a combination of specific performance and payment of money damages, then the non-breaching Party may terminate this Agreement in its entirety or the country or countries to which such breach relates. If the allegedly

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breaching Party in good faith disputes such repudiatory breach or disputes the failure to cure or remedy such repudiatory breach or the satisfaction of the conditions set forth in subclause (B) and provides written notice of that dispute to the other Party, the matter shall be addressed under the dispute resolution provisions in Article 15, and the notifying Party may not terminate this Agreement until it has been determined under Article 15 that the conditions for termination under this Section 14.5 are met, in which case, such termination shall not be effective until \*\* after the arbitration award determining that the conditions for termination of this Section 14.5 are met, provided that the breach is not cured within such \*\* period. For clarification purposes, for Servier's repudiatory breach of its obligations set forth in Sections 7.1.3 and 7.2.2, CTI shall only be permitted to terminate the Agreement with respect to those countries to which such breach relates and for CTI's repudiatory breach of this Agreement, Servier may terminate this Agreement only with respect to the country or countries to which such breach relates.

**14.6 Effects of Termination of the Agreement.** Upon any early termination of this Agreement (other than, for avoidance of doubt, by operation of Section 14.1), in its entirety or on a country-by-country basis:

**14.6.1 Termination of License.** If Servier terminates the Agreement pursuant to Section 14.2, 14.3 or 14.4 or CTI terminates the Agreement on the basis of a repudiatory breach of the Agreement by Servier under Section 14.5, \*\*, but in the case of termination on a country-by-country basis, \*\*, provided that \*\*.

**14.6.2 Termination for Repudiatory Breach by CTI.** In the case of termination of this Agreement by Servier pursuant to Section 14.5 due to a repudiatory breach by CTI, without prejudice to any other remedies of Servier, including the right to claim damages, \*\*, provided, however, that \*\*, provided that \*\*. After the foregoing has been completed, \*\*.

**14.6.3 Regulatory Materials; Data.** If Servier terminates the Agreement pursuant to Section 14.2 or 14.4 or CTI terminates the Agreement on the basis of a repudiatory breach of the Agreement by Servier under Section 14.5, or except where Servier can reasonably demonstrate that Commercializing the Licensed Product in the terminated country(ies) is detrimental to Servier's sales in the non-terminated countries, at CTI's request which shall be notified to Servier within \*\* of the termination notice, \*\* to the Licensed Product in such terminated country, \*\* by a financially capable entity.

**14.6.4 Termination of Rights and Return of Confidential Information.** If Servier terminates the Agreement pursuant to Section 14.2, 14.3 or 14.4 or CTI terminates the Agreement on the basis of a repudiatory breach of the Agreement by Servier under Section 14.5 or as otherwise expressly provided in this Agreement, Servier

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shall surrender to CTI, or destroy and provide CTI with a certificate signed by an Executive Officer of Servier attesting to the destruction of, all copies of any Confidential Information provided by CTI hereunder. Upon termination of this Agreement, CTI shall surrender to Servier, or destroy and provide Servier with a certificate signed by an Executive Officer of CTI attesting to the destruction of, all copies of any Confidential Information provided by Servier hereunder. Notwithstanding the foregoing, a Party may retain one (1) copy of any Confidential Information in an appropriately secure location.

14.6.5 **Transition.** Upon any termination of Servier other than a termination by Servier for CTI's repudiatory breach of the Agreement under Section 14.5, the Parties shall cooperate in good faith to effect a transition or termination of all Commercial, Development, and Medical Affairs activities in the Servier EU Territory, and Regulatory activities worldwide, such transition or termination at CTI's sole discretion, and at each Party's reasonable cost and expense which will be subject to review.

14.6.6 **Servier Product Mark.** If Servier terminates the Agreement pursuant to Section 14.2, 14.3 or 14.4 or CTI terminates the Agreement on the basis of a repudiatory breach of the Agreement by Servier under Section 14.5, and except where Servier can reasonably demonstrate that Commercializing the Licensed Product under the Servier Product Mark in the terminated country(ies) is detrimental to Servier's sales in the non-terminated countries, at CTI's request which shall be made to Servier within \*\* of the termination notice, Servier shall \*\* in the right to use during the transition period any country code domain names in the terminated countries, if any, containing solely such Servier Product Marks, in each case only to the extent that such Servier Product Mark has actually been utilized previously by Servier in connection with the Commercialization of the Licensed Product in the Licensed Territory and is not used for any other product Controlled by Servier and do not make reference to any other trade name or trademark of Servier.

14.6.7 **CTI Trademark.** If Servier terminates the Agreement pursuant to Section 14.2, 14.3, 14.4 or CTI terminates the Agreement on the basis of a repudiatory breach of the Agreement by Servier under Section 14.5, Servier shall assign to CTI on customary terms and for no consideration, the CTI Trademark filed by Servier in the terminated countries in its name or transferred by CTI to Servier pursuant to Section 11.7.1. In addition, Servier shall cease to use the Second EU Trademark.

14.6.8 **Post Termination Technology Transfer .** Other than termination on the basis of a public health and safety reason under Section 14.3, or termination by Servier on the basis of a repudiatory breach of the Agreement by CTI under Section 14.5 and subject to this Section 14.6.8, at CTI's request which shall be made to Servier within thirty (30) days of the termination notice, Servier shall reasonably cooperate with CTI in order to enable CTI to promptly assume the Development and/or

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Commercialization of all Licensed Compounds and Licensed Products (or the particular Licensed Compound and/or Licensed Product if such termination is only as to one Licensed Compound and/or Licensed Product) then being Commercialized or in Development by Servier in the Licensed Territory (or in a particular country if such termination is only as to such country). Such cooperation and assistance shall be provided in a timely manner (having regard to the nature of the cooperation or assistance requested), provided that CTI shall reimburse Servier of its internal costs and its expenses in relation with such assistance.

14.6.9 **Sole Remedy.** In the event that Servier terminates this Agreement pursuant to Section 14.2 (Unilateral Termination by Servier) or CTI terminates this Agreement for Servier's material breach of its obligations set forth in 7.1.3 and 7.2.2, the provisions set forth in Section 14.6.3, 14.6.6 and/or 14.6.7 if elected by CTI shall constitute CTI's sole remedy.

14.7 **Accrued Rights.** Subject to Section 14.6.9, termination or expiration of this Agreement for any reason shall be \*\* prior to such termination or expiration, \*\*, provided that \*\*. Such termination or expiration shall not relieve either Party from obligations which are expressly indicated to survive termination or expiration of this Agreement.

14.8 **Rights in Bankruptcy.** All rights and licenses granted under or pursuant to any section of this Agreement are and will otherwise be deemed to be for purposes of Section 365(n) of the United States Bankruptcy Code (Title 11, U.S. Code), as amended (the "**Bankruptcy Code**"), licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. The Parties will retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code. Each Party agrees that the other Party, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code or any other provisions of Applicable Law outside the United States that provide similar protection for "intellectual property." The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party under the U.S. Bankruptcy Code or analogous provisions of Applicable Law outside the United States, to the extent permitted by Applicable Law, the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) such intellectual property and all embodiments of such intellectual property, which, if not already in such Party's possession, will be promptly delivered to it upon such Party's written request thereof. Any agreements supplemental hereto will be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of the Bankruptcy Code.

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#### 14.9 Data and Information Transfer.

Within \*\* after \*\*, CTI shall provide to Servier all Licensed Know-How, Data and Regulatory Materials (together the “**Information**”) in a commercially reasonable format consisting of an electronic copy of all Information and a physical copy of all Information to the extent such format is reasonably applicable to such Information. All such Information provided to Servier hereunder shall be at that level of detail reasonably necessary to enable Servier to independently Develop, Manufacture and Commercialize the Licensed Products in or for the Servier Territory in the Field. CTI shall promptly deliver to Servier all updates and modifications made to the Information. Such updates will be considered a part of the Information for the purposes of this Agreement. In addition to and not at the exclusion of the license(s) granted pursuant to this Agreement, during the Term of this Agreement, CTI hereby grants to Servier, an irrevocable, perpetual, worldwide, current, non-exclusive, transferrable and sublicensable, royalty-free, fully paid-up, license to use the Information solely for the Development, Manufacture and Commercialization of Licensed Products in or for the Servier Territory in the Field, but only in the event that this Agreement, or any of Servier’s rights under this Agreement are terminated or otherwise limited as the result of the bankruptcy or insolvency of CTI. This Section 14.10 shall survive any such termination of this Agreement or any such termination or limitation of Servier’s rights under this Agreement, and notwithstanding anything to the contrary contained herein, Servier will have the irrevocable and perpetual right to retain and possess all Information, and will be under no obligation to return to CTI or otherwise destroy any such Information, following any such termination or limitation of rights. For avoidance of doubt, the foregoing shall not apply in the event of termination of this Agreement or limitation of Servier’s rights under this Agreement for reasons other than the bankruptcy or insolvency of CTI.

### ARTICLE 15

#### DISPUTE RESOLUTION

15.1 **Arbitration.** In the event an Arbitrable Matter arises (each, a “**Dispute**”), and the Senior Officers cannot resolve such Dispute within \*\* of the matter being referred to them including disputes pursuant to Section 3.4, subject to the limitations set forth in Sections 3.4.1 and 3.4.3, then either Party may submit such Dispute to arbitration for final resolution by arbitration request (the “**Arbitration Request**”) under the Rules of Arbitration of the \*\* (the “**Rules**”) by three arbitrators appointed in accordance with said Rules (each such arbitration, an “**Arbitration**”). Any Arbitration may be initiated by either Party in accordance with the Rules. Each Arbitration will be conducted in English, and all foreign language documents shall be submitted in the original language and, if so requested by any arbitrator or Party, shall also be accompanied by a translation into English. The place of arbitration shall be \*\*, which location cannot be changed, and the location for all hearings and meetings in any Arbitration shall be selected by a majority vote of the arbitrators. The arbitrators in any Arbitration shall enforce and not modify the terms of this Agreement. The

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governing law set forth in Section 17.2 shall only be applied to the merits of the Dispute, and the Parties agree that none of the procedural rules of such governing law (or any similar procedural laws, including discovery and cross-examination) will apply in any Arbitration; provided, however, that all privileges restricting disclosure established under the governing law set forth in Section 17.2 shall apply and may be invoked by both Parties. The award of the arbitrators shall be final and binding on each Party and its respective successors and assigns, and judgment may be entered thereupon and enforced in any court of competent jurisdiction pursuant to the United Nations Convention on the Recognition and Enforcement of Foreign Arbitral Awards or other Applicable Law. All costs and expenses of any Arbitration, including reasonable attorneys' fees and expenses and the administrative and arbitrator fees and expenses, shall be borne by the Parties as determined by the arbitrators. Nothing in this Section 15.1 shall be construed as limiting the right of a Party to seek, in a court of competent jurisdiction, an injunction or other equitable relief in aid of Arbitration (including to maintain the status quo or preserve the subject matter of the Arbitration) with respect to any actual or threatened breach of this Agreement or otherwise to prevent or avoid irreparable harm. Nothing in this Section 15.1 shall permit the arbitrators to award damages that may not be awarded under Section 16.6.

15.2 **Accelerated Arbitration Procedure.** In the event of a Dispute between the Parties arising out of Section 8.3 that is not resolved pursuant to Section 15.1, either Party may submit such Dispute to arbitration for final resolution pursuant to Section 15.1, with the following additional condition (the "*Accelerated Arbitration Procedure*"): the arbitrators shall use their best efforts to enter an award within six (6) months following the submission of such Dispute to Arbitration, and the Parties shall use reasonable efforts to comply with the procedures and obligations set forth in Section 15.1 so that a final award may be entered within six (6) months following the appointment of the last of the three arbitrators pursuant to the Rules and Section 15.1.

15.3 **Confidential.** Except to the limited extent necessary to comply with Applicable Law, legal process, or a court order or to enforce a final settlement agreement or secure enforcement or vacatur of the arbitrators' award, the Parties agree that the existence, terms and content of any Arbitration, all information and documents disclosed in any Arbitration or evidencing any arbitration results, award, judgment or settlement, or the performance thereof, and any allegations, statements and admissions made or positions taken by either Party in any Arbitration shall be treated and maintained in confidence and are not intended to be used or disclosed for any other purpose or in any other forum.

15.4 **Communications with Internal Counsel.** In the course of the negotiation and implementation of this Agreement and the resolution of any disputes, investigations, administrative or other proceedings relating thereto, each Party will call upon

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the members of its internal legal department to provide advice to such Party and its directors, employees and agents on legal matters. Notwithstanding any rights to the contrary under applicable procedural or substantive rules of law, each Party agrees not to request, produce or otherwise use any such communications between members of its legal department and directors, employees or agents in connection with any such disputes, investigations, administrative or other proceedings, to the extent such communications, if they had been exchanged between such Party and external attorneys, would have been covered by legal privilege and not disclosable.

## ARTICLE 16

### INDEMNIFICATION

16.1 **Indemnification by CTI in the CTI Territory.** CTI shall, at its sole expense, defend, indemnify and hold harmless Servier, the Affiliates of Servier, and their respective officers, directors, employees, successors and assigns (each, a “*Servier Indemnité*”) from and against any and all Third Party Claims that arise in or derive from (i) \*\*, or (ii) any breach by CTI of its representations and warranties or covenants.

16.2 **Indemnification by Servier in the Servier Territory.** Servier shall, at its sole expense, indemnify, and hold harmless CTI, the Affiliates of CTI, and their respective officers, directors, employees successors, and assigns (each, a “*CTI Indemnité*”) from and against any and all Third Party Claims that arise in or derive from (i) \*\*, or (ii) any breach by Servier of its representations and warranties or covenants.

16.3 **Right of Contractual Actions.** Subject to Article 15, the indemnity obligations pursuant to Sections 16.1 and 16.2 are without prejudice to the right of either Party to claim damages from the other Party pursuant to this Agreement for any breach of this Agreement, or gross negligence or willful misconduct of the other Party in accordance with Article 16 (and for the avoidance of doubt, unless such possibility to claim damages or seek an injunction against or other relief from the other Party is excluded in this Agreement). Notwithstanding the foregoing, in no event shall either Party be liable for any Losses arising out of or connected to any Product Liability Claim arising in or deriving from the other Party’s Respective Territory, except that CTI shall be liable vis-à-vis Servier for Losses arising out of or connected to any Product Liability Claim arising in or deriving from the Servier Territory to the extent related to (i) any Manufacturing defect of the Drug Substance, Drug Product or Finished Product provided by or on behalf of CTI pursuant to the Supply Agreement or otherwise, (ii) a breach by CTI of its representations and warranties hereunder, (iii) a breach by CTI of its obligations hereunder, including but not limited to those relating to the PIX306 Trial and \*\* and (iv) any failure to file any Regulatory Material with the EMA.

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#### 16.4 Indemnification and Defense Procedures.

16.4.1 **Notice of Claim.** All claims for indemnification and/or defense by a Party as provided herein shall be made solely by the Party seeking indemnification and/or defense. The Party seeking indemnification and/or defense of a Third Party Claim or remedies for any Losses shall give written notice of the same to the other Party reasonably promptly after the assertion against the Party of any Third Party Claim or fact in respect of which the Party intends to base a claim for indemnification hereunder (a “**Claim Notice**”), provided, however, that failure or delay to provide such Claim Notice shall not affect the other Party’s indemnification and/or defense obligations, except to the extent such failure materially and adversely affects the ability to defend such claim. Each Claim Notice must contain a description of the claim and the nature and amount of any Losses (to the extent that the nature and amount of such Losses is known at such time). The Party seeking indemnification and/or defense shall furnish promptly to the other Party copies of all notices, papers, correspondence, communications and official documents (including court papers) previously received or sent and thereafter that it continues to receive or send in respect of any such Third Party Claim.

#### 16.4.2 Indemnification Procedures.

16.4.2.1 The Party from which indemnity is sought pursuant to Article 16 (the “**Indemnifying Party**”) shall assume the defense and handling of such Third Party Claim, at the Indemnifying Party’s sole expense in accordance with Section 16.4.2.2.

16.4.2.2 In assuming the defense of any Third Party Claim, the Indemnifying Party: (a) shall act diligently and in good faith with respect to all matters relating to the defense, settlement or disposition of such Third Party Claim as the defense, settlement or disposition relates to the Party seeking indemnity pursuant to this Article 16 (the “**Indemnified Party**”); (b) may, at its own cost, appoint as counsel in connection with conducting the defense and handling of such Third Party Claim any law firm or counsel reasonably selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party; (c) shall keep the Indemnified Party informed of the status of such Third Party Claim; (d) shall have the right to settle the Claim on any terms the Indemnifying Party chooses, subject to prior notification to the Indemnified Party; provided that the Indemnifying Party shall not settle or otherwise resolve any Third Party Claim which could lead to liability or create any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to indemnification hereunder or which admits any wrongdoing or responsibility for the claim on behalf of the Indemnified Party, without prior written consent of the Indemnified Party, which may not be

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unreasonably withheld or delayed. The Indemnified Party shall reasonably cooperate with the Indemnifying Party in its defense of any Third Party Claim for which the Indemnifying Party has assumed the defense in accordance with this Section 16.4.2, and shall have the right (at its own expense) to be present in person or through counsel at all legal proceedings giving rise to the right of indemnification.

16.4.2.3 If the Indemnifying Party fails to conduct the defense and handling of any Third Party Claim in good faith, (i) the Indemnified Party may at the Indemnifying Party's expense, select counsel reasonably acceptable to the Indemnifying Party in connection with conducting the defense and handling of such Third Party Claim and defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Third Party Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party shall regularly inform the Indemnifying Party of the status of such claim and consult with the Indemnifying Party but shall have no obligation hereunder to obtain any consent from the Indemnifying Party in connection therewith, except that the Indemnified Party shall not settle such Third Party Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld or delayed); and (ii) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Article 16. If the Indemnified Party elects to defend or handle such Third Party Claim in accordance with this Section 16.4.2.3, the Indemnifying Party shall cooperate with the Indemnified Party, at the Indemnified Party's request but at no expense to the Indemnified Party, and shall be entitled to participate in the defense and handling of such Third Party Claim with its own counsel and at its own expense.<sup>1</sup>

16.5 **Insurance.** \*\*, each Party shall procure and maintain adequate insurance coverage with international reputable company(ies) or a program of self-insurance (which shall be of types and amounts sufficient to cover the liabilities hereunder, contingent or otherwise of such Party and its Affiliates). It is understood that such insurances shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under Article 16. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least \*\* prior to the cancellation, non-renewal or material change in such insurance.

16.6 **Disclaimer of Liability for Consequential Damages.** IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS RESPECTIVE AFFILIATES AND THEIR RESPECTIVE OFFICERS, DIRECTORS AND EMPLOYEES BE LIABLE UNDER THIS AGREEMENT FOR SPECIAL, INDIRECT, PUNITIVE, INCIDENTAL OR CONSEQUENTIAL DAMAGES SUFFERED BY THE OTHER PARTY UNDER

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THIS AGREEMENT, OF ANY KIND WHATEVER AND HOWEVER CAUSED, AND WHETHER BASED ON AN ACTION OR CLAIM IN CONTRACT, TORT (INCLUDING NEGLIGENCE), BREACH OF STATUTORY DUTY OR OTHERWISE, AND EVEN IF FORESEEABLE OR SUFFERED IN CIRCUMSTANCES WHERE A PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSSES.

## ARTICLE 17

### MISCELLANEOUS

17.1 **Assignment.** This Agreement and any rights granted or obligations imposed hereunder are personal to each Party and shall not be sold, assigned, delegated or otherwise transferred (each, a “*Transfer*”), directly or indirectly, by operation of law or otherwise, by either Party without the prior written consent of the other Party, which consent may be granted or withheld in such other Party’s sole discretion; provided, however, that either Party, at any time for any reason and without the consent of the other Party, may Transfer (a) any right or obligation hereunder, in whole or in part, to any of its sufficiently capitalized Affiliates who agree to be bound by the applicable terms and conditions of this Agreement, or (b) this Agreement in whole to any successor of such Party by merger or sale of all or substantially all of its business or assets to which this Agreement relates which agrees in writing to be bound by the applicable terms and conditions of this Agreement. The assigning Party shall provide the other Party with prompt written notice of any such assignment. Any permitted assignee shall assume all obligations of its assignor under this Agreement (or related to the assigned portion in case of a partial assignment to an Affiliate), and no permitted assignment, other than an assignment pursuant to clause (b) above, shall relieve the assignor of liability hereunder. Any attempted Transfer of this Agreement or any of the rights granted hereunder in violation of this Section 17.1 shall be void ab initio. Any transaction that results in an entity to which this Agreement, or any rights or obligations hereunder, were Transferred in reliance on clause (a) above ceasing to be an Affiliate shall be deemed a Transfer subject to this Section 17.1. The consent by any Party to any Transfer shall not constitute a waiver of the necessity for such consent in any subsequent Transfer. Each Party shall remain jointly and severally liable to the other Party with respect to any failure by its permitted successors and assigns to perform obligations under this Agreement Transferred by the Party to (i) any of its Affiliates, or (ii) any Third Party other than an assignment pursuant to clause (b) above unless the other Party consents to such Transfer, such consent not to be unreasonably withheld, conditioned or delayed. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective permitted successors and assigns.

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17.2 **Governing Law; Jurisdiction.** This Agreement shall be governed by and construed and enforced in accordance with the laws of England and Wales, to the exclusion of its conflict of law provisions.

17.3 **Severability.** If any one or more of the provisions of this Agreement shall be held to be invalid, illegal or unenforceable as a matter of law, then this Agreement shall be construed as if such provision were not contained herein and the validity, legality or enforceability of the remaining provisions hereof shall not in any way be affected or impaired thereby and shall continue in full force and effect. In the event any provisions shall be held invalid, illegal or unenforceable, the Parties shall use commercially reasonable efforts to substitute a valid, legal and enforceable provision, which conforms as nearly as possible to the original intent of the Parties.

17.4 **Notices.** Any notices, consents, waivers, requests, reports, approvals, designations, responses, or other communications provided for in this Agreement to be made by either of the Parties to the others shall be in writing to the other at its/their address set forth below. Any such notice or communication may be given by mail, hand, overnight courier, email or facsimile. Either Party may, by like notice, specify an address to which notices and communications shall thereafter be sent. Any such notice, instruction or communication shall be deemed to have been delivered when (i) received if delivered by hand or overnight courier (with written confirmation of receipt), (ii) received if delivered by an internationally recognized overnight delivery service (receipt requested), and (iii) sent by fax or by email (with written confirmation of receipt), provided that a copy is immediately sent by an internationally recognized overnight delivery service (receipt requested); in each case, if such transmission is on a Business Day, otherwise, on the next Business Day following such transmission, and if sent to the appropriate addresses and fax numbers set forth below (or to such other addresses and fax numbers as a Party may designate by notice).

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In the case of Servier:

LES LABORATOIRES SERVIER

50 Rue Carnot

92284 Suresnes Cedex

France

Attention: Alliance Management Director & US Licenses

Facsimile: +33 1 55 72 54 66

email: \*\*

In the case of CTI:

CTI BioPharma Corp.

3101 Western Ave., Suite 600

Seattle, WA 98121

Telephone: (206) 272-4000

Facsimile: (206) 272-4302

Email: \*\*

Attention: Matthew J. Plunkett, Ph.D., EVP & Chief Business Officer

With required copies (which shall not constitute notice) to:

LES LABORATOIRES SERVIER

50 Rue Carnot

92284 Suresnes Cedex

France

Attention: Director Contract Department

Facsimile: +33 1 57 72 39 00

email: \*\*

With required copies (which shall not constitute notice) to:

O'Melveny & Myers LLP

Two Embarcadero Center

San Francisco, CA 94111-3823

Telephone: (415) 984-8700

Facsimile: (415) 984-8701

Email: \*\*

Attention: C. Brophy Christensen, Esq.

and

CTI Legal Affairs Attention: Vice President, Legal Affairs

17.5 **No Waiver.** None of the provisions of this Agreement can be waived except in a writing signed by the Party granting the waiver. No failure by a Party to exercise any right under this Agreement or to insist upon compliance with any term or condition of this Agreement shall operate as a waiver of such right, or excuse a similar subsequent failure to perform any such term or condition by the other Party, nor shall any

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single or partial exercise of any right preclude any other or further exercise of that right or the exercise of any other rights. The waiver by any Party of any breach of this Agreement shall not be deemed a waiver of any prior or subsequent breach. All remedies of either Party shall be cumulative, and the pursuit of one remedy shall not be deemed a waiver of any other remedy.

17.6 **Further Assurances.** Each Party shall (and shall cause its Affiliates and Sublicensees to) execute, acknowledge and deliver, without additional consideration, such further assurances, instruments and documents, and shall take such further actions, as the other Party shall reasonably request in order to fulfill the intent of this Agreement and the transactions contemplated hereby.

17.7 **No Third Party Beneficiaries.** Except as expressly set forth in this Agreement, no Person other than the Parties and their successors, their respective Affiliates and permitted assigns hereunder shall be deemed a third party beneficiary under the Contracts (Rights of Third Parties) Act 1999 or have any right to enforce any obligation of this Agreement.

17.8 **Relationship of the Parties.** The relationship of the Parties under this Agreement shall be solely that of independent contractors and nothing herein shall be construed to create or imply any relationship of employment, agency, joint venture, partnership or any relationship other than that of independent contractors. Moreover, each Party agrees not to construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other. Servier and CTI acknowledge and agree that each of them is engaged in a separate and independent business and neither shall state, represent or imply any interest in or control over the business of the other.

17.9 **Entire Agreement.** This Agreement and the Appendices, Exhibits and Schedules attached hereto, the Pharmacovigilance Agreement and the Supply Agreement, constitute the entire understanding between the Parties relating to the subject matter hereof and thereof as of the Restatement Date, and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter, including the Original Agreement which is hereby terminated as of the Restatement Date. In the event of any conflict between a substantive provision of this Agreement and any Exhibit hereto, the substantive provisions of this Agreement shall prevail. No amendment or modification to this Agreement shall be valid or binding upon the Parties unless designated as such, made in writing and signed by the representatives of such Parties.

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17.10 **Counterparts.** This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which together, shall constitute one and the same instrument.

17.11 **Compliance with Applicable Law.** Each Party shall comply with Applicable Law in the course of performing its obligations or exercising its rights pursuant to this Agreement. Neither Party (nor any of its Affiliates or Sublicensees) shall, or shall be required to, under this Agreement take any action or omit to take any action otherwise required to be taken or omitted by it under this Agreement, or shall be penalized for not taking or omitting to take, if the taking or omitting of such action, as the case may be, could in its opinion violate any settlement, consent order, corporate integrity agreement or judgment to which it may be subject from time to time during the Term.

17.12 **Force Majeure.** Neither Party shall be responsible to the other for any failure or delay in performing any of its obligations under this Agreement, or for other nonperformance hereunder, if such delay or nonperformance is caused by strike, stoppage of labor, lockout or other labor trouble, fire, flood, accident, war, act of terrorism, act of God or of the government of any country or of any local government, which is unavoidable and beyond the control of the Party relying on such event to excuse its performance hereunder. In such event, the Party affected shall use commercially reasonable efforts to resume performance of its obligations.

17.13 **English Language.** This Agreement is written and executed in the English language. Any translation into any other language shall not be an official version of this Agreement and in the event of any conflict in interpretation between the English version and such translation, the English version shall prevail.

17.14 **Expenses.** Except as otherwise expressly provided in this Agreement, each Party shall pay the fees and expenses of its respective lawyers and other experts and all other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution and delivery of this Agreement.

17.15 **Exit of the United Kingdom or other country from European Union.**

At either Party's request, the Parties will discuss and agree upon such amendments to this Agreement as may be necessary to fairly and reasonably adjust the terms of this Agreement in light of the United Kingdom's or any other EU Member State's exit from the European Union. Any such amendment should preserve the basic economic and legal terms of this Agreement insofar as possible in light of the change in circumstances caused by the United Kingdom's or any other EU Member State's exit from the European Union.

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17.16 **Interpretation.** Unless otherwise expressly specified herein, references to Articles, Sections and Schedules contained herein or attached hereto shall refer to Articles and Sections of this Agreement or its Schedules as applicable, and references to this Agreement include all Appendices hereto. The terms of each Schedule and Appendices hereto are expressly incorporated herein by reference as if fully set forth herein. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words “include,” “includes” or “including” shall be construed as incorporating also the phrase “but not limited to” or “without limitation;” (b) the word “day” or “year” or “quarter” shall mean a calendar day or year or quarter, unless otherwise specified; (c) the word “notice” shall mean notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (d) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement (including any Schedules); (e) provisions that require that a Party, the Parties or a Committee hereunder “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise; (f) words of any gender include the other gender; (g) words using the singular or plural number also include the plural or singular number, respectively; (h) references to any specific law, rule or regulation, or article, Section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof; and (i) the word “will” shall be construed to have the same meaning and effect as the word “shall.” Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties, and no rule of strict construction shall be applied against either Party hereto. This Agreement should be interpreted in its entirety and the fact that certain provisions of this Agreement may be cross-referenced in a Section shall not be deemed or construed to limit the application of other provisions of this Agreement to such Section and vice versa. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement.

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IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals by their duly authorized representatives as of the date and year first above written.

LES LABORATOIRES SERVIER

CTI BIOPHARMA CORP.

By: _____ /s/	By: _____ /s/ Adam Craig
Name: **	Name: Adam Craig
Title: **	Title: President & Chief Executive Officer

By:  
Name: \*\*  
Title: \*\*

INSTITUT DE RECHERCHES INTERNATIONALES CTI LIFE SCIENCES LIMITED  
SERVIER

By: _____ /s/	By: _____ /s/ Bruce Seeley
Name: **	Name: Bruce Seeley
Title: **	Title: Director

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List of Exhibits and Schedules

Exhibit A: List of Licensed Patents

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**EXHIBIT A**

**LIST OF LICENSED PATENTS**

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<b>AN IMPROVED METHOD OF SYNTHESIS FOR 6,9-BIS(2-AMINOETHYL)AMINO]BENZO G] ISOQUINOLINE-5, 10-DIONE AND ITS DIMALEATE SALT</b>		
<b>Country</b>	<b>Application Number</b>	<b>Patent Number (if applicable)</b>
Austria-SPC	SZ 45/2012	SZ 45/2012
Belgium-SPC	2012C/046	2012/046
Brazil	PI9507257-8	
Czech Republic-SPC	SPC/CZ2012/245	284937/245
Denmark-SPC	CA 201200044	CR 2012 00044
Finland-SPC	C 20120036	375
Greece-SPC	20120800031	8000433
Hungary-SPC	S 12 00026/4	S000151
Ireland-SPC	2012/038	2012/038
Luxembourg-SPC	92089	92089
Netherlands-SPC	300548	300548
Norway-SPC	2012020	2012020
Portugal-SPC	501	501
Sweden-SPC	1290036-1	1290036-1

<b>INJECTABLE PHARMACEUTICAL COMPOSITIONS OF AN ANTHRACENEDIONE DERIVATIVE WITH ANTI-TUMORAL ACTIVITY</b>		
<b>Country</b>	<b>Application Number</b>	<b>Patent Number</b>
Canada	2486001	2486001
European Patent Convention	3729997.1	1503797
France-SPC	12C0064	13/33
France	3729997.1	1503797
Germany-SPC	122012000080.2	122012000080
Germany	3729997.1	60318310.7
Great Britain-SPC	SPC/GB12/044	SPC/GB12/044
Great Britain	3729997.1	1503797
Italy-SPC	UB 2012 P001264	1264
Italy	502008901611642	1503797
Italy	102002901017789	1339739
Japan	2004-505097	4624780
Mexico	PA/A/2004/011348	247429
Spain-SPC	C 2013 00042	C201200042
Spain	3729997.1	1503797

*[Exhibit A to Amended and Restated Exclusive License and Collaboration Agreement]*

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Confidential Treatment Requested

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Confidential Treatment Requested

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Confidential Treatment Requested

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*[Exhibit 7.1.2 to Amended and Restated Exclusive License and Collaboration Agreement]*

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*[Exhibit 7.1.2 to Amended and Restated Exclusive License and Collaboration Agreement]*

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*[Exhibit 7.3.2 to Amended and Restated Exclusive License and Collaboration Agreement]*

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*[Exhibit 7.3.2 to Amended and Restated Exclusive License and Collaboration Agreement]*

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*[Exhibit 13.3.4 to Amended and Restated Exclusive License and Collaboration Agreement]*

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO  
SECURITIES EXCHANGE ACT OF 1934 RULES 13a-14(a) AND 15d-14(a)  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Adam R. Craig, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CTI BioPharma Corp.;
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 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 we 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 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) of internal control over financial reporting:
  - (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.

Dated: May 3, 2017

By: /s/ Adam R. Craig  
Adam R. Craig  
President and Chief Executive Officer

**CERTIFICATION OF PRINCIPAL CHIEF FINANCIAL OFFICER  
PURSUANT TO  
SECURITIES EXCHANGE ACT OF 1934 RULES 13a-14(a) AND 15d-14(a)  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Bruce J. Seeley, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CTI BioPharma Corp.;
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 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 we 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 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) of internal control over financial reporting:
  - (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.

Dated: May 3, 2017

By: /s/ Bruce J. Seeley

Bruce J. Seeley  
Executive Vice President,  
Chief Commercial and Administrative Officer

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER  
PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Adam R. Craig, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in my capacity as an officer of CTI BioPharma Corp., that, to my knowledge, the Quarterly Report of CTI BioPharma Corp. on Form 10-Q for the fiscal quarter ended March 31, 2017 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of CTI BioPharma Corp.

A signed original of this written statement required by Section 906 has been provided to CTI BioPharma Corp. and will be retained by CTI BioPharma Corp. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: May 3, 2017

By: /s/ Adam R. Craig  
Adam R. Craig  
President and Chief Executive Officer

I, Bruce J. Seeley, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in my capacity as an officer of CTI BioPharma Corp., that, to my knowledge, the Quarterly Report of CTI BioPharma Corp. on Form 10-Q for the fiscal quarter ended March 31, 2017 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of CTI BioPharma Corp.

A signed original of this written statement required by Section 906 has been provided to CTI BioPharma Corp. and will be retained by CTI BioPharma Corp. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: May 3, 2017

By: /s/ Bruce J. Seeley  
Bruce J. Seeley  
Executive Vice President,  
Chief Commercial and Administrative Officer



