

---

---

**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, 2011**

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**

---

**CELL THERAPEUTICS, INC.**

(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.)

**501 Elliott Avenue West, Suite 400**  
**Seattle, Washington**  
(Address of principal executive offices)

**98119**  
(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 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  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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 22, 2011</u>
Common Stock, no par value	1,005,409,554

---

---

CELL THERAPEUTICS, INC.

TABLE OF CONTENTS

	<u>PAGE</u>
<b>PART I - FINANCIAL INFORMATION</b>	
ITEM 1: Financial Statements	
<a href="#">Condensed Consolidated Balance Sheets at March 31, 2011 (unaudited) and December 31, 2010</a>	3
<a href="#">Condensed Consolidated Statements of Operations – Three Months Ended March 31, 2011 and 2010 (unaudited)</a>	4
<a href="#">Condensed Consolidated Statements of Cash Flows – Three Months Ended March 31, 2011 and 2010 (unaudited)</a>	5
<a href="#">Notes to Condensed Consolidated Financial Statements</a>	6
ITEM 2: <a href="#">Management’s Discussion and Analysis of Financial Condition and Results of Operations</a>	17
ITEM 3: <a href="#">Quantitative and Qualitative Disclosures about Market Risk</a>	28
ITEM 4: <a href="#">Controls and Procedures</a>	28
<b>PART II - OTHER INFORMATION</b>	
ITEM 1: <a href="#">Legal Proceedings</a>	29
ITEM 1A: <a href="#">Risk Factors</a>	30
ITEM 2: <a href="#">Unregistered Sales of Equity Securities and Use of Proceeds</a>	49
ITEM 3: <a href="#">Defaults Upon Senior Securities</a>	49
ITEM 4: <a href="#">(Removed and Reserved)</a>	49
ITEM 5: <a href="#">Other Information</a>	49
ITEM 6: <a href="#">Exhibits</a>	50
<a href="#">Signatures</a>	52

**CELL THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(In thousands, except share amounts)**

	March 31, 2011 <u>(unaudited)</u>	December 31, 2010 <u></u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 43,814	\$ 22,649
Prepaid expenses and other current assets	3,798	4,256
Total current assets	<u>47,612</u>	<u>26,905</u>
Property and equipment, net	4,091	3,426
Goodwill	—	17,064
Other assets	9,220	6,197
Total assets	<u>\$ 60,923</u>	<u>\$ 53,592</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 5,459	\$ 6,037
Accrued expenses	9,483	11,008
Current portion of long-term obligations	1,715	1,717
7.5% convertible senior notes	10,243	10,215
5.75% convertible senior notes	12,202	12,093
Total current liabilities	<u>39,102</u>	<u>41,070</u>
Long-term obligations, less current portion	4,010	4,206
Total liabilities	<u>43,112</u>	<u>45,276</u>
Commitments and contingencies		
Common stock purchase warrants	13,461	13,461
Shareholders' equity:		
Common stock, no par value:		
Authorized shares - 1,200,000,000		
Issued and outstanding shares - 1,004,462,095 (unaudited) and 813,751,299 at March 31, 2011 and December 31, 2010, respectively	1,658,148	1,579,866
Accumulated other comprehensive loss	(8,561)	(7,969)
Accumulated deficit	<u>(1,644,717)</u>	<u>(1,576,643)</u>
Total CTI shareholders' equity (deficit)	4,870	(4,746)
Noncontrolling interest	(520)	(399)
Total shareholders' equity (deficit)	<u>4,350</u>	<u>(5,145)</u>
Total liabilities and shareholders' equity	<u>\$ 60,923</u>	<u>\$ 53,592</u>

See accompanying notes.

**CELL THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(In thousands, except per share amounts)**  
**(unaudited)**

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>Revenues:</b>		
License and contract revenue	\$ —	\$ 20
<b>Total revenues</b>	<u>—</u>	<u>20</u>
<b>Operating expenses:</b>		
Research and development	11,494	7,360
Selling, general and administrative	8,576	18,417
<b>Total operating expenses</b>	<u>20,070</u>	<u>25,777</u>
<b>Loss from operations</b>	(20,070)	(25,757)
<b>Other income (expense):</b>		
Investment and other income, net	63	262
Interest expense	(389)	(787)
Amortization of debt discount and issuance costs	(167)	(215)
Foreign exchange gain (loss)	759	(475)
<b>Other income (expense), net</b>	<u>266</u>	<u>(1,215)</u>
<b>Net loss before noncontrolling interest</b>	(19,804)	(26,972)
Noncontrolling interest	70	52
<b>Net loss attributable to CTI</b>	(19,734)	(26,920)
Dividends and deemed dividends on preferred stock	(31,283)	(17,277)
<b>Net loss attributable to CTI common shareholders</b>	<u>\$ (51,017)</u>	<u>\$ (44,197)</u>
<b>Basic and diluted net loss per common share</b>	<u>\$ (0.06)</u>	<u>\$ (0.07)</u>
<b>Shares used in calculation of basic and diluted net loss per common share</b>	<u>878,261</u>	<u>598,984</u>

See accompanying notes.

**CELL THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)  
(unaudited)

	Three Months Ended March 31,	
	2011	2010
<b>Operating activities</b>		
Net loss	\$(19,734)	\$(26,920)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest expense	167	215
Depreciation and amortization	444	483
Equity-based compensation expense	544	7,751
Noncontrolling interest	(70)	(52)
Other	(129)	(120)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	478	(742)
Other assets	(2,645)	(1,325)
Accounts payable	(1,404)	(123)
Accrued expenses	(1,967)	(2,168)
Other liabilities	(286)	(188)
Total adjustments	<u>(4,868)</u>	<u>3,731</u>
Net cash used in operating activities	<u>(24,602)</u>	<u>(23,189)</u>
<b>Investing activities</b>		
Proceeds from the sale of property and equipment	—	11
Purchases of property and equipment	(327)	(1,118)
Net cash used in investing activities	<u>(327)</u>	<u>(1,107)</u>
<b>Financing activities</b>		
Proceeds from issuance of Series 3 preferred stock and warrants, net of issuance costs	—	28,108
Proceeds from issuance of Series 8 preferred stock, warrants and additional investment right, net of issuance costs	23,425	—
Proceeds from issuance of Series 10 preferred stock, warrants and additional investment right, net of issuance costs	23,667	—
Cash paid for repurchase of shares in connection with taxes on restricted stock vesting	(206)	(589)
Other	(4)	(4)
Net cash provided by financing activities	<u>46,882</u>	<u>27,515</u>
Effect of exchange rate changes on cash and cash equivalents	(788)	481
Net increase in cash and cash equivalents	21,165	3,700
Cash and cash equivalents at beginning of period	22,649	37,811
Cash and cash equivalents at end of period	<u>\$ 43,814</u>	<u>\$ 41,511</u>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid during the period for interest	\$ 2	\$ 809
Cash paid for taxes	\$ —	\$ —
<b>Supplemental disclosure of noncash financing and investing activities</b>		
Issuance of common stock upon exercise of common stock purchase warrants	\$ 17,485	\$ —
Issuance of Series 9 preferred stock	\$ 25,000	\$ —
Issuance of Series 11 preferred stock	\$ 24,957	\$ —
Conversion of Series 3 preferred stock to common stock	\$ —	\$ 27,761
Conversion of Series 9 preferred stock to common stock	\$ 25,000	\$ —
Conversion of Series 11 preferred stock to common stock	\$ 24,957	\$ —
Redemption of Series 8 and 10 preferred stock	\$ 36,638	\$ —

See accompanying notes.

**CELL THERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited)**

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

*Description of Business*

Cell Therapeutics, Inc., also referred to in this Quarterly Report on Form 10-Q as CTI, the Company, we, us or our, focuses on the development, acquisition and commercialization of drugs for the treatment of cancer. Our principal business strategy is focused on cancer therapeutics, an area with significant market opportunity that we believe is not adequately served by existing therapies. Subsequent to the closure of our Bresso, Italy operations in September 2009, our operations are now primarily conducted in the United States. During 2008, we had one approved drug, Zevalin® (ibritumomab tiuxetan), or Zevalin, which we acquired in 2007, generating product sales. We contributed Zevalin to a joint venture, RIT Oncology, LLC, or RIT Oncology, upon its formation in December 2008 and in March 2009 we finalized the sale of our 50% interest in RIT Oncology to the other member, Spectrum Pharmaceuticals, Inc., or Spectrum. All of our current product candidates, including Pixuvri (pixantrone dimaleate), or Pixuvri, OPAXIO™ (paclitaxel poliglumex), or OPAXIO, tosedostat and brostallicin, are under development.

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 United States, by the European Medicines Agency, or EMA, in Europe and by comparable agencies in other countries. Obtaining approval for a new therapeutic product is never certain, may take many years and involves expenditure of substantial resources.

*Basis of Presentation*

The accompanying unaudited financial information of CTI as of March 31, 2011 and for the three months ended March 31, 2011 and 2010 has been prepared in accordance with accounting principles generally accepted in the United States 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 month period ended March 31, 2011 are not necessarily indicative of the results that may be expected for the entire year.

Certain information and footnote disclosure 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 SEC. These unaudited financial statements and the related notes should be read in conjunction with our audited annual financial statements for the year ended December 31, 2010 included in our Annual Report on Form 10-K, filed with the SEC on February 16, 2011.

The condensed consolidated balance sheet at December 31, 2010 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 United States for complete financial statements.

*Principles of Consolidation*

The condensed consolidated financial statements include the accounts of CTI and its wholly-owned subsidiaries, which include Systems Medicine LLC, or SM, CTI Commercial LLC, and CTI Life Sciences Limited (from the date of formation in March 2009). CTI Life Sciences Limited opened a branch in Italy in December 2009. We also retain ownership of our branch, Cell Therapeutics Inc. – Sede Secondaria, or CTI (Europe); however, we ceased operations related to this branch in September 2009.

As of March 31, 2011, we also had a 67% interest in our majority-owned subsidiary, Aequus Biopharma, Inc., or Aequus. In accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, 810, *Consolidation*, the noncontrolling interest in Aequus (previously shown as minority interest) is reported below net loss in *noncontrolling interest* in the condensed consolidated statement of operations and shown as a component of equity in the condensed consolidated balance sheet.

All intercompany transactions and balances are eliminated in consolidation.

## [Table of Contents](#)

### *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 for the twelve month period following the date of these financial statements. However, we have incurred losses since inception and expect to generate losses for the next few years primarily due to research and development costs for Pixuvri, OPAXIO, tosedostat and brostallicin.

Our available *cash and cash equivalents* are \$43.8 million as of March 31, 2011. As of March 31, 2011, our total current liabilities were \$39.1 million, including \$10.3 million and \$10.9 million outstanding principal balance related to our 7.5% and 5.75% convertible senior notes, respectively, which are due within the next 12 months. We do not expect that our existing cash and cash equivalents will be sufficient to fund our presently anticipated operations through the third quarter of 2011. This raises substantial doubt about our ability to continue as a going concern.

Since the second quarter of 2010, we have implemented cost saving initiatives to reduce operating expenses, including the reduction of employees related to planned commercial Pixuvri operations. However, we will need to raise additional funds and are currently exploring alternative sources of equity or debt financing. We may seek to raise such capital through public or private equity financings, partnerships, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources of financing.

### *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 is approximately \$5.6 million and \$5.3 million as of March 31, 2011 and December 31, 2010, respectively, of which \$5.4 million and \$5.2 million is included in *other assets* and \$0.2 million and \$0.1 million is included in *prepaid expenses and other current assets* as of March 31, 2011 and December 31, 2010, respectively. This receivable balance relates to our Italian operations and typically has a three year collection period. We review our VAT receivable balance for impairment whenever events or changes in circumstances indicate the carrying amount might not be recoverable.

### *Net Loss Per Share*

Basic net income (loss) per common share is calculated based on the net income (loss) attributable to common shareholders divided by the weighted average number of shares outstanding for the period excluding any dilutive effects of options, warrants, unvested share awards and convertible securities. Diluted net income (loss) per common share 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 share awards using the treasury stock method. As of March 31, 2011 and 2010, options, warrants, unvested share awards, unvested share rights and convertible debt securities aggregating 99.5 million and 40.3 million common share equivalents, respectively, prior to the application of the as-if converted method for convertible securities and the treasury stock method for other dilutive securities, such as options and warrants, are not included in the calculation of diluted net loss per share as they are anti-dilutive.

### *Recently Adopted Accounting Standards*

In April 2010, the FASB issued guidance on the milestone method for revenue recognition purposes. Previously, definitive guidance on when the use of the milestone method was appropriate did not exist. This guidance provides a framework of the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. This guidance was effective on a prospective basis for milestones achieved in fiscal years and interim periods within those years, beginning on or after June 15, 2010 with early adoption permitted. The adoption of this guidance on January 1, 2011 did not have a material impact on our financial statements.

In December 2010, the FASB issued additional guidance on when to perform Step 2 of the goodwill impairment test for reporting units with zero or negative carrying amounts. The criteria for evaluating Step 1 of the goodwill impairment test and proceeding to Step 2 was amended for reporting units with zero or negative carrying amounts and requires performing Step 2 if qualitative factors indicate that it is more likely than not that a goodwill impairment exists. For public entities, this guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2010. Upon adoption of this guidance on January 1, 2011, we performed Step 2 of the goodwill impairment test. Based on a valuation using the income, market and cost approaches, we determined

## [Table of Contents](#)

that all of our \$17.1 million in goodwill was impaired. The related charge was recorded as a cumulative-effect adjustment to beginning retained earnings in the current period.

### *Reclassifications*

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

## 2. Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income or loss. Our other comprehensive income or loss includes unrealized gains and losses on our securities available-for-sale and certain net exchange gains or losses resulting from the translation of assets and liabilities of foreign subsidiaries not recorded in the statement of operations. Total comprehensive loss consisted of the following (in thousands):

	Three Months Ended	
	March 31,	
	2011	2010
Net loss before noncontrolling interest	\$ (19,804)	\$ (26,972)
Foreign currency translation gain (loss)	(560)	290
Net unrealized loss on securities available-for-sale	(33)	—
Comprehensive loss before noncontrolling interest	(20,397)	(26,682)
Noncontrolling interest	70	52
Comprehensive loss attributable to CTI	<u>\$ (20,327)</u>	<u>\$ (26,630)</u>
	March 31,	December 31,
	2011	2010
Foreign currency translation adjustment	\$ (8,670)	\$ (8,111)
Net unrealized gain on securities available-for-sale	109	142
Total accumulated other comprehensive loss	<u>\$ (8,561)</u>	<u>\$ (7,969)</u>

## 3. Goodwill

We adopted the accounting standards update on *Intangibles – Goodwill and Other (Topic 350)*, which provided additional guidance on when to perform Step 2 of the goodwill impairment test for reporting units with zero or negative carrying amounts. Upon adoption of the guidance, we determined that it was more likely than not that a goodwill impairment existed. The implied fair value of goodwill for the reporting unit, after considering unrecognized in-process research and development, was zero. An impairment charge of \$17.1 million was recorded in retained earnings as a cumulative-effective adjustment.

The following table presents the effects of the cumulative-effect application:

	Goodwill	Adjustment	Net
Balance at January 1, 2011	\$ 17,064	\$ —	\$ 17,064
Cumulative effect adjustment	—	(17,064)	(17,064)
Adjusted Goodwill at January 1, 2011	<u>\$ 17,064</u>	<u>\$ (17,064)</u>	<u>\$ —</u>
	Accumulated	Accumulated Other	Total Shareholder's
	Deficit	Comprehensive	(Deficit)
Balance at December 31, 2010	\$ (1,576,643)	\$ —	\$ (5,145)
Cumulative effect adjustment	(17,064)	—	(17,064)
Adjusted Balance at January 1, 2011	<u>\$ (1,593,707)</u>	<u>\$ —</u>	<u>\$ (22,209)</u>



#### 4. Lease Agreements

In 2010, we recorded a charge of \$1.5 million for excess facilities under an operating lease upon vacating a portion of our corporate office space. Our liability for excess facilities was \$1.2 million as of March 31, 2011, of which \$0.3 million was included in *current portion of long-term obligations* and \$0.9 million was included in *long-term obligations, less current portion*. The following table summarizes the changes in the liability for excess facilities during the period ended March 31, 2011:

	<u>Excess Facilities Liability</u>
Balance at December 31, 2010	\$ 1,410
Adjustments	34
Payments	(234)
Balance at March 31, 2011	<u>\$ 1,210</u>

#### 5. Preferred Stock

##### *Series 8 and 9 Preferred Stock*

During the first quarter of 2011, we issued to an institutional investor, or the Investor, 25,000 shares of Series 8 non-convertible preferred stock, or Series 8 Preferred Stock, warrants to purchase up to 22,563,177 shares of common stock and an additional investment right to purchase up to 25,000 shares of Series 9 convertible preferred stock, or Series 9 Preferred Stock, for an aggregate offering price of \$25.0 million. The aggregate offering price was reduced by a 5% commitment fee retained by the Investor for total gross proceeds received of \$23.7 million. We allocated the proceeds on a relative fair value basis, of which \$18.5 million, \$1.3 million and \$3.9 million was allocated to the Series 8 Preferred Stock, warrants and additional investment right, respectively. Issuance costs related to this transaction were approximately \$0.5 million.

The shares of Series 8 Preferred Stock accrued annual dividends at the rate of 10% from the date of issuance, payable in the form of additional shares of Series 8 Preferred Stock. Each share of our Series 8 Preferred Stock was entitled to a liquidation preference equal to the stated value of such share of our Series 8 Preferred Stock plus any accrued and unpaid dividends. The Series 8 Preferred Stock had no voting rights except as otherwise expressly provided in the Company's amended and restated articles of incorporation or as otherwise required by law. The shares of Series 8 Preferred Stock were redeemable by the Company at any time after issuance, either in cash or by offset against recourse notes fully secured with marketable securities, or Recourse Notes, which were issued by the Investor to the Company in connection with the exercise of the warrants and the additional investment right as discussed below.

Each warrant had an initial exercise price of \$0.3878 per share of common stock. The warrants were exercisable immediately and had an expiration date of two years from the date of issuance. The holder of the warrants had the option to pay the exercise price for the warrant either in cash or through the issuance of Recourse Notes to the Company. The Investor exercised all of the warrants to purchase 22,563,177 shares of common stock for a total of \$8.8 million through the issuance of Recourse Notes by the Investor to the Company.

Each additional investment right had an exercise price of \$1,000 per share of Series 9 Preferred Stock. The additional investment right was exercisable immediately upon issuance and had an expiration date of February 11, 2011. The holder of the additional investment right had the option to pay the exercise price in cash or through issuance of Recourse Notes to the Company. The Investor exercised the entire additional investment right to purchase 25,000 shares of Series 9 Preferred Stock for a total of \$25.0 million through the issuance of Recourse Notes by the Investor to the Company. The Investor also elected to convert the 25,000 shares of Series 9 Preferred Stock into 64,466,219 shares of common stock.

Each share of our Series 9 Preferred Stock was entitled to a liquidation preference equal to the stated value of such share of our Series 9 Preferred Stock plus any accrued and unpaid dividends. The Series 9 Preferred Stock was not entitled to dividends except to share in any dividends actually paid on the common stock or any pari passu or junior securities. The Series 9 Preferred Stock was convertible into common stock, at the option of the holder, at an initial conversion price of \$0.3878 per share of common stock, subject to a 9.99% blocker provision. The Series 9

## [Table of Contents](#)

Preferred Stock had no voting rights except as otherwise expressly provided in the Company's amended and restated articles of incorporation or as otherwise required by law.

In March 2011, we redeemed all 25,000 outstanding shares of Series 8 Preferred Stock (plus accrued dividends). Each share of Series 8 Preferred Stock (plus accrued dividends) was offset by \$1,350 principal amount of Recourse Notes (plus accrued interest), regardless of the issuance date of the shares of Series 8 Preferred Stock and Recourse Notes. We recognized \$0.4 million in accrued dividends on the Series 8 Preferred Stock and \$0.1 million accrued interest on the Recourse Notes through the redemption date, both of which are included in *dividends and deemed dividends on preferred stock* for the period ending March 31, 2011. Additionally, we recognized \$15.5 million in *dividends and deemed dividends on preferred stock* upon redemption of the Series 8 Preferred Stock equal to the difference between the \$33.9 million principal balance of Recourse Notes, including accrued interest, and \$18.4 million carrying amount of Series 8 Preferred Stock, including accrued dividends.

### *Series 10 and 11 Preferred Stock*

During the first quarter of 2011, we issued to the Investor 24,957 shares of Series 10 non-convertible preferred stock, or Series 10 Preferred Stock, warrants to purchase up to 25,919,733 shares of common stock and an additional investment right to purchase up to 24,957 shares of Series 11 convertible preferred stock, or Series 11 Preferred Stock, for an aggregate offering price of approximately \$25.0 million. The aggregate offering price was reduced by a 5% commitment fee retained by the Investor for total gross proceeds received of \$23.7 million. We allocated the proceeds on a relative fair value basis, of which \$18.5 million, \$1.3 million and \$3.9 million was allocated to the Series 10 Preferred Stock, warrants and additional investment right, respectively. Issuance costs related to this transaction were approximately \$0.3 million.

The shares of Series 10 Preferred Stock accrued annual dividends at the rate of 10% from the date of issuance, payable in the form of additional shares of Series 10 Preferred Stock. Each share of our Series 10 Preferred Stock was entitled to a liquidation preference equal to the stated value of such share of our Series 10 Preferred Stock plus any accrued and unpaid dividends. The Series 10 Preferred Stock had no voting rights except as otherwise expressly provided in the Company's amended and restated articles of incorporation or as otherwise required by law. The shares of Series 10 Preferred Stock were redeemable by the Company at any time after issuance, either in cash or by offset against Recourse Notes, which were issued by the Investor to the Company in connection with the exercise of the warrants and the additional investment right as discussed below.

Each warrant had an initial exercise price of \$0.337 per share of common stock. The warrants were exercisable immediately and had an expiration date of two years from the date of issuance. The holder of the warrants had the option to pay the exercise price for the warrant either in cash or through the issuance of Recourse Notes to the Company. The Investor exercised all of the warrants to purchase 25,919,733 shares of common stock for a total of \$8.7 million through the issuance of Recourse Notes by the Investor to the Company.

Each additional investment right had an exercise price of \$1,000 per share of Series 11 Preferred Stock. The additional investment right was exercisable immediately upon issuance and had an expiration date of March 19, 2011. The holder of the additional investment right had the option to pay the exercise price in cash or through issuance of Recourse Notes to the Company. The Investor exercised the entire additional investment right to purchase 24,957 shares of Series 11 Preferred Stock for a total of approximately \$25.0 million through the issuance of Recourse Notes by the Investor to the Company. The Investor also elected to convert the 24,957 shares of Series 11 Preferred Stock into 74,056,380 shares of common stock.

Each share of our Series 11 Preferred Stock was entitled to a liquidation preference equal to the stated value of such share of our Series 11 Preferred Stock plus any accrued and unpaid dividends. The Series 11 Preferred Stock was not entitled to dividends except to share in any dividends actually paid on the common stock or any pari passu or junior securities. The Series 11 Preferred Stock was convertible into common stock, at the option of the holder, at an initial conversion price of \$0.337 per share of common stock, subject to a 9.99% blocker provision. The Series 11 Preferred Stock had no voting rights except as otherwise expressly provided in the Company's amended and restated articles of incorporation or as otherwise required by law.

In March 2011, we redeemed all 24,957 outstanding shares of Series 10 Preferred Stock (plus accrued dividends). Each share of Series 10 Preferred Stock (plus accrued dividends) was offset by \$1,350 principal amount of Recourse Notes (plus accrued

## [Table of Contents](#)

interest), regardless of the issuance date of the shares of Series 10 Preferred Stock and Recourse Notes. We recognized \$0.1 million in accrued dividends on the Series 10 Preferred Stock and \$41 thousand accrued interest on the Recourse Notes through the redemption date, both of which are included in *dividends and deemed dividends on preferred stock* for the period ending March 31, 2011. Additionally, we recognized \$15.4 million in *dividends and deemed dividends on preferred stock* upon redemption of the Series 10 Preferred Stock equal to the difference between the \$33.7 million principal balance of Recourse Notes, including accrued interest, and \$18.3 million carrying amount of Series 10 Preferred Stock, including accrued dividends.

### 6. Share-based Compensation Expense

The following table summarizes share-based compensation expense for the three months ended March 31, 2011 and 2010, which was allocated as follows (in thousands):

	Three Months Ended March 31,	
	2011	2010
Research and development	\$ 288	\$ 1,012
Selling, general and administrative	256	6,739
Share-based compensation expense included in operating expenses	<u>\$ 544</u>	<u>\$ 7,751</u>

For the three months ended March 31, 2011 and 2010, we incurred share-based compensation expense due to the following types of awards (in thousands):

	Three Months Ended March 31,	
	2011	2010
December 2009 performance awards	\$ —	\$ 7,176
Restricted stock	522	538
Options	22	37
Total share-based compensation expense	<u>\$ 544</u>	<u>\$ 7,751</u>

### 7. Significant Agreements

During the first quarter of 2011, we entered into an agreement, or the Chroma Agreement, with Chroma Therapeutics Ltd., or Chroma, under which we have an exclusive license to certain technology and intellectual property controlled by Chroma to develop and commercialize the drug candidate tosedostat in North, Central and South America, or the Licensed Territory. Pursuant to the terms of the Chroma Agreement, we paid Chroma an upfront fee of \$5.0 million included in *research and development* expense upon execution of the agreement and will make a milestone payment of \$5.0 million upon the initiation of the first pivotal trial for acute myeloid leukemia, or AML, which could commence as early as the fourth quarter of 2011. The Chroma Agreement also includes additional development- and sales-based milestone payments related to AML and certain other indications, up to a maximum amount of \$209.0 million payable by us to Chroma if all development and sales milestones are achieved.

We will also pay Chroma royalties on net sales of tosedostat in any country within the Licensed Territory, commencing on the first commercial sale of tosedostat in any country in the Licensed Territory and continuing with respect to that country until the later of (a) the expiration date of the last patent claim covering tosedostat in that country, (b) the expiration of all regulatory exclusivity periods for tosedostat in that country or (c) ten years after the first commercial sale in that country. Royalty payments to Chroma are based on net sales volumes in any country within the Licensed Territory and range from the low- to mid-teens as a percentage of net sales.

We will oversee and be responsible for performing the development operations and commercialization activities in the Licensed Territory and Chroma will oversee and be responsible for performing the development operations and commercialization activities worldwide except for the Licensed Territory, or the ROW Territory. Development costs may not exceed \$50.0 million for the first three years of the Chroma Agreement unless agreed by the parties

## [Table of Contents](#)

and we will be responsible for 75% of all development costs, while Chroma will be responsible for 25% of all development costs, subject to certain exceptions. Chroma will be solely responsible for the manufacturing of tosedostat for development purposes in the Licensed Territory and the ROW Territory in accordance with the terms of the supply agreement to be entered into by the parties. We will be solely responsible, by ourselves or through one or more third party contract manufacturers, for the manufacture of tosedostat for commercialization purposes in the Licensed Territory. The Chroma Agreement may be terminated by us at our convenience upon 120 days' written notice to Chroma. The Chroma Agreement may also be terminated by either party following a material breach by the other party subject to notice and cure periods.

### **8. Legal Proceedings**

On January 22, 2007, we filed a complaint in King County Washington Superior Court against The Lash Group, Inc., or Lash, and Documedics Acquisition Co., Inc., our former third-party reimbursement expert for TRISENOX, seeking recovery of damages, including losses incurred by us in connection with our investigation, defense and settlement of claims by the United States concerning Medicare reimbursement for TRISENOX and other claims. On February 28, 2007, Lash removed the case to U.S. District Court in the Western District of Washington. On June 19, 2008, the trial judge dismissed our claims and we filed a timely notice of appeal in the Ninth Circuit Court of Appeals. An appeal hearing was held on August 31, 2009, and on November 18, 2009, the Ninth Circuit reversed the trial court and held that the False Claims Act, or the FCA, did not preclude us from seeking recovery and bringing claims against Lash for indemnification under our service agreement based upon its acts that gave rise to the government's FCA and other claims. On December 1, 2009, Lash filed a petition for rehearing with the Ninth Circuit Court of Appeals, which was formally denied on January 6, 2010. The case has been remanded for trial in the District Court. On April 30, 2010, the District Court denied a motion by Lash to strike our supplemental damages disclosure, and granted our motion for leave to amend our complaint to more fully address our claims for supplemental and independent damages. On May 21, 2010, the District Court issued a minute order setting trial and related dates. On May 24, 2010, Lash filed its answer to the amended complaint and asserted counterclaims for contractual indemnification, common law indemnification and contribution, and declaratory relief. On June 3, 2010, Lash filed a motion to bifurcate the trial to address in the first phase only its assertion that our claims are barred due to FCA liability. We opposed the motion, and on June 10, 2010, we filed our own motion to strike Lash's affirmative defense based on its FCA liability claim. On August 3, 2010, the court entered an order denying Lash's motion to bifurcate and granting our motion to strike Lash's FCA liability affirmative defense. The case is currently scheduled for trial on September 6, 2011. There is no guarantee that we will prevail at trial.

On December 23, 2008, CONSOB sent a notice to us requesting that we issue (i) immediately, a press release providing, among other things, information about our debt restructuring plan, the current state of compliance with the relevant covenants regulating our debt and the equity line of credit agreement we entered into with Midsummer Investment Ltd. on July 29, 2008, and (ii) by the end of each month and starting from the month of December 2008, a press release providing certain information relating to our management and financial situation, updated to the previous month, or the Monthly CONSOB Press Release. On July 31, 2009, CONSOB sent us a notice asserting three violations of the provisions of Section 114, paragraph 5 of the Italian Legislative Decree no. 58/98, as follows: (a) the non-disclosure without delay of the press release described under point (i) above and the subsequent incomplete disclosure of the relevant information through press releases dated January 9, 2009 and January 13, 2009; (b) the non-disclosure of the Monthly CONSOB Press Release in December 2008; and (c) the incomplete disclosure of the Monthly CONSOB Press Release in January 2009. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violations are pecuniary administrative sanctions amounting to between €5,000 and €500,000, or approximately \$7,000 to \$709,000 converted using the currency exchange rate as of March 31, 2011, applicable to each one of the three asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that were submitted to CONSOB on August 28, 2009 (within 30 days of July 31, 2009, the notification date of the relevant charges, according to the applicable Italian rules). On May 5, 2010, CONSOB (1) notified us that it had begun the preliminary investigation for its decision on these administrative proceedings and (2) provided us with a preliminary investigation report in response to our defenses submitted on August 28, 2009. On June 4, 2010 (within 30 days of May 5, 2010, the notification date of the beginning of the aforesaid preliminary investigation, according to the applicable Italian rules), we submitted further defenses that CONSOB had to evaluate before imposing any possible administrative sanctions. On January 21, 2011, CONSOB notified us of a resolution confirming the occurrence of the three asserted violations and applying a fine for each of them in the following amounts: €20,000 for sanction (a) above; €50,000 for sanction (b) above; and €30,000 for sanction (c) above, for an aggregate fine of €100,000, or

## [Table of Contents](#)

approximately \$136,000 converted using the currency exchange rate as of January 21, 2011, for these sanctions. On March 4, 2011, we paid the aggregate fine of €100,000 in full.

Separately, on December 10, 2009, CONSOB sent us a notice claiming two violations of the provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98 due to the asserted late disclosure of certain information then reported, at CONSOB's request, in press releases disseminated on December 19, 2008 and March 23, 2009. Such information concerned, respectively: (i) the conversion by BAM Opportunity Fund LP of 9.66% notes into shares of common stock that occurred between October 24, 2008 and November 19, 2008; and (ii) the contents of the opinion expressed by Stonefield Josephson, Inc., an independent registered public accounting firm, with respect to our 2008 financial statements. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violations are pecuniary administrative sanctions amounting to between €5,000 and €500,000, or approximately \$7,000 to \$709,000 converted using the currency exchange rate as of March 31, 2011, applicable to each of the two asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that were submitted to CONSOB on January 8, 2010 (within 30 days of December 10, 2009, the notification date of the relevant charges, according to the applicable Italian rules). On July 12, 2010, CONSOB (a) notified us that it had begun the preliminary investigation for its decision on these administrative proceedings and (b) provided us with a preliminary investigation report in response to our defenses submitted on January 8, 2010. On August 12, 2010 (within 30 days of July 12, 2010, the notification date of the beginning of the aforesaid preliminary investigation, according to the applicable Italian rules), we submitted further defenses that CONSOB had to evaluate before imposing any possible administrative sanctions. On March 10, 2011, CONSOB notified us of a resolution confirming the occurrence of the violation asserted in clause (i) above and applied a fine in the amount of €40,000, or approximately \$57,000 converted using the currency exchange rate as of March 31, 2011, which we paid on April 5, 2011. CONSOB has not yet notified us of a resolution with respect to the violation asserted in clause (ii) above, but based on our assessment we believe the likelihood that a pecuniary administrative sanction will be imposed on the Company for the violation asserted in clause (ii) is probable.

On April 14, 2009 and December 21, 2009, 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 and 2005, respectively. On June 25, 2010, the ITA issued notices of assessment to CTI (Europe) for the years 2006 and 2007 based on similar findings for the 2003 and 2005 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). 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, or approximately \$0.8 million, \$7.8 million, \$3.6 million and \$1.2 million converted using the currency exchange rate as of March 31, 2011, 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 vigorously defending ourselves against the assessments both on procedural grounds and on the merits of the case. If the decision of the Provincial Tax Court of Milan, or the Tax Court, is unfavorable, then we expect to appeal to the higher courts in order to further defend our interests. However, if we are unable to successfully defend ourselves against the assessments issued by the ITA, we may be requested to pay to the ITA an amount ranging from €4.9 million to €9.4 million, or approximately \$7.0 million to \$13.3 million converted using the currency exchange rate as of March 31, 2011, 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. On February 2, 2011, we paid to the ITA the required deposit in respect of the 2005 VAT in the amount of €1.5 million, or approximately \$2.1 million converted using the currency exchange rate as of February 2, 2011. On March 4, 2011, we paid to the ITA the required deposit in respect of the 2006 VAT in the amount of €0.4 million, or approximately \$0.6 million converted using the currency exchange rate as of March 4, 2011.

**2003 VAT.** We have not received a notice from the ITA requesting a deposit payment for the VAT based on the 2003 assessment as of March 31, 2011. The first hearing for the discussion of the merits of the case was held on March 18, 2011. The Tax Court has not yet released a decision with respect to the 2003 VAT.

**2005 VAT.** On July 14, 2010, the ITA issued a notice requiring a deposit payment for the VAT to CTI (Europe) based on the 2005 assessment, including 50% of the assessed VAT, interest and collection fees for an amount of €1.5 million, or approximately \$2.2 million converted using the currency exchange rate as of March 31, 2011. We successfully filed a petition with the Tax Court for suspension of the 2005 notice of deposit payment. On September 28, 2010, the merits of the case for the year 2005 were discussed in a public hearing before the Tax Court. On January 13, 2011, the Tax Court issued decision no. 4/2010 in which the Tax Court (i) partially accepted our appeal and declared that no penalties can be imposed against us, (ii) confirmed the right of the Italian Tax Authorities to

## [Table of Contents](#)

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. As a result of this decision, our exposure for 2005 VAT assessment is currently reduced by the waiver of penalties of €2.6 million, or approximately \$3.7 million converted using the currency exchange rate as of March 31, 2011. The ITA has the right to appeal the decision to request for confirmation of the penalties. On February 2, 2011, we paid the required VAT deposit of €1.5 million, or approximately \$2.1 million converted using the currency exchange rate as of February 2, 2011, prior to the due date of February 6, 2011. We do not believe that the Tax Court has carefully reviewed all of our arguments, relevant documents and other supporting evidence that our counsel filed and presented during the hearing, including an appraisal from an independent expert, and, therefore, that there are grounds of appeal in order to ask the judges of the higher court to further consider all of our arguments in support of invalidating the entire notice of assessment. Accordingly, we will appeal to the Regional Tax Court and file a complaint with the European Commission. On March 25, 2011, we paid to the Italian collection agent an additional €0.1 million, or approximately \$0.1 million converted using the currency exchange rate as of March 25, 2011. The additional payment was for interest and collection fees during the suspension period. We do not believe this additional payment was due and we intend to pursue recovery of such payment through litigation.

While we contend that services invoiced were non-VAT taxable consulting services and that the VAT returns are correct as originally filed, we have recorded a reserve for VAT assessed, interest and collection fees totalling €2.6 million, or approximately \$3.7 million as of March 31, 2011, of which \$3.2 million is included in *long-term obligations, less current portion* and \$0.5 million of the reserve is accounted for as an offset to VAT receivable included in *other assets*.

**2006 VAT.** On January 10, 2011, we received a notice from the ITA requiring a deposit payment for VAT to CTI (Europe) based on the 2006 assessment, including 50% of the assessed VAT, interest and collection fees for an amount of €0.4 million, or approximately \$0.6 million converted using the currency exchange rate as of March 31, 2011, payable in the first quarter 2011. We filed a request for suspension of the collection of such amount, which request was rejected. On March 4, 2011, we paid to the ITA the required deposit in respect of the 2006 VAT in the amount of €0.4 million, or approximately \$0.6 million converted using the currency exchange rate as of March 4, 2011. The first hearing for the discussion of the merits of the case in front of the Tax Court has been scheduled for May 27, 2011.

**2007 VAT.** We have not received a notice from the ITA requesting a deposit payment for the VAT based on the 2007 assessment. The first hearing for the discussion of the merits of the case in front of the Tax Court has been scheduled for May 27, 2011.

On August 3, 2009, Sicor Italia, or Sicor, filed a lawsuit in the Court of Milan to compel us to source Pixuvri from Sicor according to the terms of a supply agreement executed between Sicor and NovusPharma on October 4, 2002. Sicor alleges that the agreement was not terminated according to its terms. We assert that the supply agreement in question was properly terminated and that we have no further obligation to comply with its terms. A hearing was held on January 21, 2010 to discuss preliminary matters and set a schedule for future filings and hearings. The parties filed the authorized pleadings and submitted to the Court their requests for evidence. On November 11, 2010, a hearing was held to examine and discuss the requests for evidence submitted by the parties in the briefs filed pursuant to article 183, paragraph 6 of the Italian code of civil procedure. At the hearing of November 11, 2010, the judge declared that the case does not require any discovery or evidentiary phase, and may be decided on the basis of the documents and pleadings already filed by the parties. A final hearing is scheduled for October 11, 2012, for the parties to definitively submit to the judge their requests. No estimate of a loss, if any, can be made at this time in the event that we do not prevail.

On March 12, 2010, a purported securities class action complaint was filed in the United States District Court for the Western District of Washington against the Company and certain of its officers and directors, styled *Cyril Sabbagh, individually and on behalf of all others similarly situated v. Cell Therapeutics, Inc., Dr. James A. Bianco, M.D., and Dr. Jack W. Singer* (Case No. 2:10-sv-00414), or the *Sabbagh* action. On March 19, 2010, a substantially similar class action complaint was filed in the same court, styled *Michael Laquidari, individually and on behalf of all others similarly situated v. Cell Therapeutics, Inc., Dr. James A. Bianco, M.D., and Dr. Jack W. Singer* (Case No. 2:10-cv-00480), or the *Laquidari* action. On March 31, 2010, a third substantially similar class action complaint was filed in the same court, styled *William Snyder, individually and on behalf of all others similarly situated v. Cell Therapeutics, Inc., James A. Bianco, Phillip M. Nudelman, Louis A. Bianco, John H. Bauer, Richard L. Love, Mary O. Munding, Jack W. Singer, Frederick W. Telling and Rodman & Renshaw, LLC* (Case No. 2:10-cv-00559), or the *Snyder* action. The securities actions are pending before Judge Marsha Pechman in the Western



## [Table of Contents](#)

District of Washington. The securities complaints allege that the defendants violated the federal securities laws by making certain alleged false and misleading statements. The plaintiffs in the *Sabbagh* and *Laquidari* actions seek unspecified damages on behalf of a putative class of purchasers of the Company's securities from May 5, 2009 through February 8, 2010. The plaintiffs in the *Snyder* action seek unspecified damages on behalf of a putative class of purchasers of the Company's securities from May 5, 2009 through March 19, 2010, including purchasers of securities issued pursuant to or traceable to the Company's July 22, 2009 public offering. On August 2, 2010, the court consolidated the securities actions, appointed lead plaintiffs, and approved lead plaintiffs' counsel. On September 27, 2010, lead plaintiff filed an amended consolidated complaint with a purported class period of March 25, 2008 through March 22, 2010. On October 27, 2010, the defendants filed a motion to dismiss the amended consolidated complaint. Plaintiffs filed an opposition on December 3, 2010, and defendants filed their reply on December 22, 2010. The hearing on the motion to dismiss was held on January 28, 2011. On February 4, 2011, the court issued an order denying in large part the defendants' motion. The court has set a trial date of June 25, 2012 for the securities class action.

On April 1, 2010, a shareholder derivative complaint was filed in the United States District Court for the Western District of Washington, derivatively on behalf of the Company against the members of its Board of Directors, styled *Shackleton v. John A. Bauer, James A. Bianco, Vartan Gregorian, Richard L. Love, Mary O'Neil Munding, Phillip M. Nudelman, Jack W. Singer, and Frederick W. Telling* (Case No. 2:10-cv-564). On April 5, 2010, and April 13, 2010, substantially similar derivative actions were filed in the same court, styled, respectively, *Marbury v. James A. Bianco, et al.* (Case No. 2:10-cv-00578) and *Cyrek v. John H. Bauer, et al.* (Case No. 2:10-cv-00625). The derivative actions are also pending before Judge Marsha Pechman. The derivative complaints allege that the defendants breached their fiduciary duties to the Company under Washington law by making or failing to prevent the disclosure of certain alleged false and misleading statements. The allegations in the derivative actions are substantially similar to those in the securities actions. On May 10, 2010, pursuant to the parties' stipulation, the Court consolidated these three shareholder derivative actions and appointed the law firms Robbins Umeda LLP and Federman & Sherwood as co-lead counsel for derivative plaintiffs.

On June 1, 2010, a fourth related shareholder derivative action was filed in the Western District of Washington, *Souda v. John H. Bauer et al.* (Case No. 2:10-cv-00905). It was subsequently transferred to Judge Pechman and consolidated with the consolidated derivative actions. Plaintiff Souda filed a motion to reconsider the portion of the Court's Order dated May 10, 2010, appointing Robbins Umeda and Federman & Sherwood as co-lead derivative counsel. Souda's motion for reconsideration was denied on November 16, 2010.

On July 27, 2010, a fifth related shareholder derivative action, *Bohland v. John H. Bauer et al.* (Case No. 2:10-cv-1213), was filed in the Western District of Washington and assigned to Judge John C. Coughenour. It was subsequently transferred to Judge Pechman. Plaintiff Bohland filed a motion to consolidate the *Bohland* action with the consolidated derivative actions and to reconsider the portion of the Court's Order dated May 10, 2010, appointing Robbins Umeda and Federman & Sherwood as co-lead derivative counsel. Bohland's motion for reconsideration was denied on November 16, 2010, and *Bohland* was ordered consolidated with the other derivative actions.

On October 4, 2010, a sixth related derivative complaint was filed in the Superior Court of Washington, County of King, *Alexander v. James A. Bianco, et al.* (Case No. 10-2-34849-2-SEA). On October 5, 2010, the complaint was removed to the Western District of Washington and assigned to Judge Pechman. On October 29, 2010, nominal defendant Cell Therapeutics, Inc. filed a Notice of Related Case in the lead derivative case, *Shackleton v. John H. Bauer, et al.*, Case No. 2:10-cv-00564 (Doc. No. 42). The Company notified the Court of this action and requested that it be consolidated with the Derivative Actions per the Court's May 10, 2010 Consolidation Order. On November 18, 2010, the Court issued an Order to Show Cause re Consolidation in *Alexander*. On November 26, 2010, the parties agreed and the court granted consolidation of *Alexander* and ordered that all proceedings be deferred 60 days pending the outcome of the Defendant's motion to dismiss the Securities Class Action suits. On February 4, 2011, following denial of the motion to dismiss in the securities class action, the Court lifted the stay in the derivative actions. Pursuant to the parties' previous stipulation, the parties have agreed to facilitate and coordinate discovery in the derivative and securities actions. Plaintiffs in the derivative action have 45 days following the close of discovery in the securities class action to file an amended complaint. The lawsuits are at a preliminary stage in the proceedings. We believe that the securities class action is without merit and intend to defend it vigorously. For the shareholder derivative action, no estimate of a loss, if any, can be made at this time in the event that we do not prevail.

---

[Table of Contents](#)

In addition to the litigation discussed above, we are from time to time subject to legal proceedings and claims arising in the ordinary course of business, some of which may be covered in whole or in part by insurance.



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

*This Quarterly Report on Form 10-Q, including the following discussion, contains forward-looking statements, which involve risks and uncertainties and should be read in conjunction with the Condensed Consolidated Financial Statements and the related Notes included in Part I, Item I 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, which include statements concerning product sales, research and development expenses, selling, general and administrative expenses, additional financings and additional losses, 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, particularly in "Factors Affecting Our Operating Results and Financial Condition," that could cause actual results, levels of activity, performance or achievement 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 develop, acquire and commercialize novel treatments for cancer. Our goal is to build a leading biopharmaceutical company with a diversified portfolio of proprietary oncology drugs. Our research, development, acquisition and in-licensing activities concentrate on identifying and developing new, less toxic and more effective ways to treat cancer.

We are currently focusing our efforts on Pixuvri, OPAXIO, tosedostat, brostallicin, and novel bisplatinum analogues. As of March 31, 2011, we had incurred aggregate net losses of approximately \$1.6 billion since inception. Unless we execute a partnership agreement for Pixuvri with terms adequate to cover our operating expenses, we expect to generate losses from operations for the next few years.

#### *Pixuvri*

We are developing Pixuvri, a novel aza-anthracenedione, for the treatment of non-Hodgkin's lymphoma, or NHL, and various other hematologic malignancies, and solid tumors. Pixuvri was studied in our EXTEND, or PIX301, clinical trial, which was a phase III single-agent trial of Pixuvri for patients with relapsed, refractory aggressive NHL who received two or more prior therapies and who were sensitive to treatment with anthracyclines. In November 2008, we announced that this trial achieved the primary efficacy endpoint. Based on the outcome of the EXTEND trial and on the basis of pre-New Drug Application, or NDA, communication we received from the FDA relating to this phase III trial, we began a rolling NDA submission to the FDA in April 2009. We completed the submission in June 2009.

The FDA completed its inspection of the facilities at NerPharMa DS, S.r.l. and NerPharMa, S.r.l. (two independent pharmaceutical manufacturing companies belonging to Nerviano Medical Sciences S.r.l., in Nerviano, Italy). The FDA found both manufacturing sites in compliance and acceptable for continued manufacturing of the drug in early March 2010. NerPharMa, S.r.l. agreed to manufacture our drug product, Pixuvri, which will be used for clinical supplies.

On March 22, 2010, the FDA's Oncologic Drugs Advisory Committee, or ODAC, panel voted unanimously that the clinical trial data was not adequate to support approval of Pixuvri for this patient population. In early April 2010, we received a Complete Response Letter from the FDA regarding our NDA for Pixuvri recommending that we design and conduct an additional trial to demonstrate the safety and efficacy of Pixuvri. We met with the FDA in August 2010 at an end of review meeting at which time the FDA informed us that the Pixuvri Investigational New Drug application, or IND, and NDA were being transferred to the newly-formed Division of Hematology Drug Products, or the DHP. We filed an appeal in December 2010 with the FDA's Center for Drug Evaluation and Research regarding the FDA's decision in April 2010 to not approve Pixuvri for relapsed/refractory aggressive NHL. The appeal was filed under the FDA's formal dispute resolution process asking the Office of New Drugs, or the OND, to conclude that PIX301 demonstrated efficacy. In March 2011, we announced that we met with officials of the OND and presented our arguments supporting our belief that the data contained in the NDA support the conclusion that Pixuvri is effective for its planned use. At the meeting, the OND requested additional analyses

## [Table of Contents](#)

from the EXTEND clinical study which we submitted. We are awaiting a decision on the appeal.

We believe the results of the EXTEND trial showed that patients randomized to treatment with Pixuvri achieved a significantly higher rate of confirmed and unconfirmed complete response compared to patients treated with standard chemotherapy, had a significantly increased overall response rate and experienced a statistically significant improvement in median progression free survival. Pixuvri was well tolerated when administered at the proposed dose and schedule in the EXTEND clinical trial in heavily pre-treated patients. The most common (incidence greater than or equal to 10%) grade 3/4 adverse events reported for Pixuvri-treated subjects across studies were neutropenia and leukopenia. Use of growth factor support was minimal. Other common adverse events (any grade) included infection, anemia, thrombocytopenia, asthenia, pyrexia and cough. Overall, the incidence of grade 3 or greater cardiac adverse events was 7% (five patients) on the Pixuvri arm and 2% (one patient) on the comparator arm. There were an equal number of deaths due to an adverse event in both the Pixuvri and comparator arm.

In March 2011, we initiated an additional Pixuvri clinical trial, PIX306, or PIX-R trial, to study Pixuvri in combination with rituximab in patients with relapsed/refractory diffuse large B-cell lymphoma, or DLBCL. The trial will compare a combination of Pixuvri plus rituximab to a combination of gemcitabine plus rituximab in patients with relapsed or refractory DLBCL who have received one to three prior lines of therapy. The PIX-R trial utilizes progression free survival, or PFS, and overall survival, or OS, as co-primary endpoints of the study. The PIX-R trial is targeting to enroll approximately 350 patients and will include patients who have failed at least one line of previous therapy and patients who are not candidates for myeloablative chemotherapy and stem cell transplant. We had discussions with the DHP relating to a Special Protocol Assessment, or SPA, for the study and we were advised that OS as the sole primary endpoint would be the only acceptable trial design in order for us to obtain an SPA agreement for the PIX-R trial; however, the DHP noted that we could conduct a study utilizing PFS along with OS as co-primary endpoints which would be an acceptable design outside of the formal SPA process. Regulatory acceptability will depend on the magnitude of the difference between the trial study arms as well as a risk and benefit analysis. This study would serve as either a post-approval confirmatory study, if Pixuvri were to be approved on the basis of the current NDA, or as a registration study for approval in the United States.

In July 2009, we were notified by the EMA that Pixuvri was eligible to be submitted for an MAA through the EMA's centralized procedure. The centralized review process provides for a single coordinated review for approval of pharmaceutical products that is conducted by the EMA on behalf of all European Union, or EU, member states. The EMA also designated Pixuvri as a New Active Substance, or NAS; if approved by the EMA, compounds designated as an NAS are eligible to receive a 10-year market exclusivity period in EU member states. In September 2009, we applied to the EMA for orphan drug designation for Pixuvri, which was granted in December 2009. In September 2009, we also submitted a Pediatric Investigation Plan, or PIP, to the EMA as part of the required filing process for approval of Pixuvri for treating relapsed, refractory aggressive NHL in Europe. In April 2010, the EMA recommended that we submit an updated PIP for Pixuvri following discussions with us about the preclinical and clinical Pixuvri data, including EXTEND, and the desire to explore the potential benefits Pixuvri may offer to children with lymphoid malignancies and solid tumors. We submitted an expanded PIP to the Pediatric Committee of the EMA, or PDCO, in July 2010. The expanded PIP was accepted for review by the PDCO in August 2010. On October 19, 2010, we announced that the PDCO had adopted an opinion agreeing to our PIP. The PDCO also recommended deferral of the initiation of the clinical studies until after Pixuvri receives EMA approval. In November 2010, the MAA seeking approval for Pixuvri for the treatment of adult patients with multiple relapsed or refractory aggressive NHL was validated and accepted for review by the EMA. Since Pixuvri was initially granted orphan drug status by the EMA for the treatment of DLBCL, we agreed to withdraw the orphan designation from the EU register in November 2010 based on the expansion of the MAA to the broader aggressive NHL population.

In June 2010, the Italian Medicines Agency, or AIFA, the national authority responsible for drug regulation in Italy, approved the facility at NerPharMa DS, S.r.l. for the production of Pixuvri drug substance. In July 2010, we signed a supply agreement with NerPharMa, S.r.l. for Pixuvri drug product manufacturing. The five-year contract provides for both the commercial and clinical supply of Pixuvri drug product.

We have also conducted the RAPID, or PIX203, phase II clinical trial study (CHOP-R vs. CPOP-R) in which Pixuvri is substituted for doxorubicin in the CPOP-R regimen compared to the standard CHOP-R regimen in front-line treatment of patients with aggressive NHL. The study enrolled 124 patients, 61 on the CPOP-R arm and 63 on the CHOP-R arm. An interim analysis of the RAPID trial, reported in July 2007, showed that at that time, a majority of patients on both arms of the study achieved a major objective anti-tumor response (complete response or partial response). Preliminary results were presented in the fourth quarter of 2010 and we expect additional study data to be presented in 2011. Three patients on the CPOP-R arm died on study compared to none of the patients on the CHOP-R arm. These events were observed in patients ages 79 years old or older with higher risk disease. The median number of cycles for the CPOP-R arm was eight compared to six for the CHOP-

## [Table of Contents](#)

R arm. Pixuvri patients had fewer severe cardiac events including declines in left ventricular ejection fraction of 20% (1 versus 8), cases of congestive heart failure (0 versus 4) and on study elevations in levels of Troponin T, a marker of cardiac damage. Other important treatment related side effects such as bone marrow suppression and infections were essentially equivalent between the study arms.

### *Pixuvri for metastatic breast cancer*

Pixuvri is also being studied in patients with HER2-negative metastatic breast cancer who have tumor progression after at least two, but not more than three, prior chemotherapy regimens. In the second quarter of 2010, the North Central Cancer Treatment Group, or the NCCTG, opened for enrollment of this phase II study.

### *OPAXIO*

OPAXIO is our novel biologically enhanced chemotherapeutic agent that links paclitaxel to a biodegradable polyglutamate polymer, resulting in a new chemical entity. We are currently focusing our development of OPAXIO on ovarian, brain and esophageal cancer.

### *OPAXIO for ovarian cancer*

We are currently focusing our development of OPAXIO, which we have previously referred to as XYOTAX, as a potential maintenance therapy for women with advanced stage ovarian cancer who achieve a complete remission following first-line therapy with paclitaxel and carboplatin. This study, the GOG0212 trial, is under the control of the Gynecologic Oncology Group, or GOG, and is expected to enroll 1,100 patients with 788 patients enrolled as of March 31, 2011. The GOG Data Monitoring Committee plans to conduct an interim analysis of overall survival, which could be conducted as early as the end of 2011. If successful, we could utilize those results to form the basis of an NDA for OPAXIO.

### *OPAXIO for brain cancer*

In November 2010, results were presented by the Brown University Oncology Group from a phase II trial of OPAXIO combined with temozolomide, or TMZ, and radiotherapy in patients with newly-diagnosed, high-grade gliomas, a type of brain cancer. The trial demonstrated a high rate of complete and partial responses and an encouragingly high rate of six month progression-free survival. Based on these results, we plan to work with the Brown University Oncology Group to conduct an additional study in a subset of patients with high-grade lymphoma with specific genetic markers for which we believe OPAXIO and radiotherapy could be more beneficial than standard treatment of TMZ and radiotherapy.

### *OPAXIO for esophageal cancer*

In June 2009, we announced that, in a study released from Brown University at the 2009 American Society for Clinical Oncology Annual Meeting, patients with cancer of the lower esophagus had evidence of a high pathological complete response rate when given OPAXIO in addition to cisplatin and full-course radiotherapy. In this phase II clinical trial study, data suggests that OPAXIO may provide enhanced radiation sensitization as compared to standard therapy. We plan to assess the viability of progressing OPAXIO to a phase III study for this indication.

### *OPAXIO for non-small cell lung cancer*

In March 2008, we submitted an MAA to the EMA for first-line treatment of patients with advanced non-small cell lung cancer, or NSCLC, who are poor performance status, or PS2, based on a non-inferior survival and improved side effect profile which we believe was demonstrated in our previous clinical trials. The application was based on a positive opinion we received from the EMA's Scientific Advice Working Party, or SAWP; the EMA agreed that switching the primary endpoint from superiority to non-inferiority is feasible if the retrospective justification provided in the marketing application is adequate. In September 2009, we notified the EMA of our decision to withdraw the MAA and we refocused our resources on the development of OPAXIO for its potential superiority indication in maintenance therapy for ovarian cancer and as a radiation sensitizer in the treatment of esophageal cancer.

Preclinical data presented at the 2006 meeting of the European Organization for Research and Treatment of Cancers, National Cancer Institute and American Association for Cancer Research demonstrated that the efficacy of OPAXIO is enhanced in certain human tumors when mice are given additional estrogen. In subsequent clinical studies, more than 1,900 patients were treated in our four pivotal phase III trials of OPAXIO for the treatment of

## [Table of Contents](#)

NSCLC. While the STELLAR 2, 3 and 4 trials missed their primary endpoint of superior overall survival, women treated with OPAXIO for newly diagnosed advanced NSCLC in STELLAR 3 and 4 had a significant improvement in their overall survival compared to women or men treated with standard chemotherapy. In addition, with single-agent OPAXIO, we observed a significant reduction in most of the severe toxic side effects associated with the standard chemotherapy agents studied in the STELLAR trials.

In September 2007, we initiated our PGT307 trial, which focuses exclusively on NSCLC in women with pre-menopausal estrogen levels, the subset of patients where OPAXIO demonstrated the greatest potential survival advantage in the STELLAR trials. During the second quarter of 2010, we ceased enrollment in the PGT307 trial and the study is now closed.

### *Tosedostat*

In March 2011, we entered into a co-development and license agreement with Chroma, providing us with exclusive marketing and co-development rights to Chroma's drug candidate tosedostat in North, Central and South America. Tosedostat is an oral, aminopeptidase inhibitor that has demonstrated significant anti-tumor responses in blood related cancers and solid tumors in phase I-II clinical trials. We, in collaboration with Chroma, expect to commence a phase III clinical study in the United States and Europe in elderly patients with AML for potential approval by the FDA and the EMA. The FDA and the EMA have granted tosedostat orphan drug status for AML.

### *Brostallicin*

We are developing brostallicin through our wholly-owned subsidiary SM, which holds worldwide rights to use, develop, import and export brostallicin. Brostallicin is a synthetic DNA minor groove binding agent that has demonstrated anti-tumor activity and a favorable safety profile in clinical trials in which more than 230 patients have been treated to date. We use a genomic-based platform to guide the development of brostallicin.

In the second quarter of 2010, the NCCTG opened for enrollment a phase II study of brostallicin in combination with cisplatin in patients with metastatic triple-negative breast cancer, or mTNBC. mTNBC is defined by tumors lacking expression of estrogen, progesterone receptors and without over-expression of HER2. Women with mTNBC have very limited effective treatments and based on the novel mechanism of action of brostallicin and the recognized activity of cisplatin in this disease, the combination of the two agents will be explored by the NCCTG. In addition to standard clinical efficacy measures, biological endpoints will also be evaluated to assist in understanding the specific activity of brostallicin in this disease.

A phase II study of brostallicin in relapsed, refractory soft tissue sarcoma met its predefined activity and safety hurdles and resulted in a first-line phase II clinical trial study that was conducted by the European Organization for Research and Treatment of Cancer, or EORTC. Planned enrollment for this study was completed in August 2008 and the EORTC conducted final data analysis in 2009. The data was reported at the American Society of Clinical Oncology Annual Meeting in June 2010. The EORTC trial demonstrated, in this hard to treat patient group, a modest level of clinical activity with an acceptable level of toxicity. No further development is planned in this indication.

### *Research and Preclinical Development*

Platinates are an important class of chemotherapy agents used to treat a wide variety of cancers. There are three platinates currently commercially available (cisplatin, carboplatin, and oxaliplatin), which are first-line agents in ovarian cancer, lung cancer, testicular cancer, and colorectal cancer, as well as a broad variety of other diseases. We are developing the dinuclear-platinum complex CT-47463. CT-47463 has a different mechanism of action than the commercially available platinum compounds and is substantially more active on many preclinical models including those with resistance to monoplatinates. We have initiated active pharmaceutical ingredient and formulation development as prerequisites to IND enabling activities for bisplatinates.

### **Critical Accounting Estimates**

Management makes certain judgments and uses certain estimates and assumptions when applying accounting principles generally accepted in the United States 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

## [Table of Contents](#)

apparent from other sources. Actual results may vary from what we anticipate and different assumptions or estimates about the future could change our reported results. As described in Item 7, *Management's Discussion and Analysis of Consolidated Financial Condition and Results of Operations*, of our Annual Report on Form 10-K for the year ended December 31, 2010, we consider our policies for license and contract revenue, impairment of long-lived assets, valuation of goodwill, derivatives embedded in certain debt or equity securities, restructuring charges and stock-based compensation expense to be the most critical in the preparation of the condensed consolidated financial statements because they involve the most difficult, subjective, or complex judgments about the effect of matters that are inherently uncertain. There have been no material changes to our application of critical accounting policies and significant judgments and estimates since December 31, 2010.

## RESULTS OF OPERATIONS

### Three months ended March 31, 2011 and 2010

**License and contract revenue.** License and contract revenue for the three months ended March 31, 2010 represents recognition of deferred revenue from the sale of Lisofylline material to DiaKine.

**Research and development expenses.** Research and development costs are expensed as incurred in accordance with ASC 730, Research and Development. In instances where we enter into agreements with third parties for research and development activities, we may prepay fees for services at the initiation of the contract. We record the prepayment as a prepaid asset and amortize the asset into research and development expense over the period of time the contracted research and development services are performed. Other types of arrangements with third parties may be fixed fee or fee for service, and may include monthly payments or payments upon completion of milestones or receipt of deliverables. In instances where we enter into cost-sharing arrangements, all costs reimbursed by the collaborator are a reduction to research and development expense while costs paid to the collaborator are an addition to research and development expense. We expense upfront license payments related to acquired technologies which have not yet reached technological feasibility and have no alternative future use.

Our research and development expenses for compounds under development and preclinical development are as follows (in thousands):

	Three Months Ended	
	March 31,	
	2011	2010
Compounds under development:		
Pixuvri	\$ 2,444	\$2,172
OPAXIO	567	735
Tosedostat	5,000	—
Brostallicin	1	68
Operating expenses	3,445	4,120
Research and Preclinical Development	37	265
Total research and development expenses	<u>\$11,494</u>	<u>\$7,360</u>

Costs for compounds under development include external direct expenses such as principal investigator fees, clinical research organization charges 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, EMA or other regulatory agencies outside the United States and Europe, as well as upfront license fees for acquired technology. Operating costs include our personnel and occupancy expenses associated with developing these compounds. Research and preclinical development costs include primarily costs associated with bisplatin development as well as external laboratory services associated with other compounds. We do not allocate operating costs to the individual compounds under development as our accounting system does not track these costs by individual compound. As a result, we are not able to capture the total cost of each compound. Direct external costs incurred to date for Pixuvri, OPAXIO, tosedostat and brostallicin are approximately \$64.7 million, \$223.6 million, \$5.0 million and \$9.3 million, respectively. Costs for Pixuvri prior to our merger with Novuspharma S.p.A, a public pharmaceutical company located in Italy, or CTI (Europe), in January 2004 are excluded from this amount. Costs for brostallicin prior to our acquisition of SM in July 2007 are also

## [Table of Contents](#)

excluded from this amount. Costs for tosedostat prior to our license agreement with Chroma are also excluded.

Research and development expenses increased to approximately \$11.5 million for the three months ended March 31, 2011 from approximately \$7.4 million for the three months ended March 31, 2010. Pixuvri costs increased primarily due to an increase in clinical activity associated with the startup of the PIX306 study. This increase was partially offset by decreases in manufacturing activity attributable to the delay in commercial launch of Pixuvri and regulatory consulting activity. Costs for our OPAXIO program decreased primarily due to a decrease in clinical activity. Costs for tosedostat relate to the upfront payment upon execution of the co-development and license agreement with Chroma. Costs for brostallicin relate primarily to clinical development activities associated with phase I and phase II studies. Our operating expenses decreased primarily due to a decrease in non-cash share-based compensation expense.

Our lead drug candidates Pixuvri, OPAXIO, tosedostat and brostallicin are currently in clinical trials. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Even if our drugs progress successfully through initial human testing, 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. 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 or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks. Completion of clinical trials depends on, among other things, the number of patients available for enrollment in a particular trial, which is a function of many factors, including the availability and proximity of patients with the relevant condition. 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. We have drug candidates that are still in research and preclinical development, which means that they have not yet been tested on humans. We will need to commit significant time and resources to develop these and additional product candidates.

Our products will be successful and we will be able to generate revenues only if:

- our product candidates are developed to a stage that will enable us to commercialize, sell, or license related marketing rights to third parties; and
- our product candidates, if developed, are approved.

Failure to generate such revenues may preclude us from continuing our research, development and commercial activities for these and other product candidates. 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. Specific comments for individual product candidates are below.

*Pixuvri.* Pixuvri is an aza-anthracenedione that has distinct structural and physiochemical properties that make its anti-tumor unique in this class of agents. The novel pharmacologic differences between Pixuvri and the other agents in the class may allow re-introduction of anthracycline-like potency in the treatment of patients who are otherwise at their lifetime recommended doxorubicin exposure. We are unable to provide the nature, timing, and estimated costs of the efforts necessary to complete the development of Pixuvri because, among other reasons, we cannot predict with any certainty the pace of enrollment of our clinical trials. 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. For these reasons, among others, we cannot estimate the date on which clinical development of Pixuvri will be completed or when we will be able to begin commercializing Pixuvri to generate material net cash inflows.

*OPAXIO.* OPAXIO is our novel biologically enhanced chemotherapeutic agent that links paclitaxel to a biodegradable polyglutamate polymer, resulting in a new chemical entity. We are currently focusing our development of OPAXIO on ovarian, brain and esophageal cancer. We are unable to provide the nature, timing, and estimated costs of the efforts necessary to complete the development of OPAXIO because, among other reasons, a third party is conducting the key clinical trial of OPAXIO and even after a clinical trial has been 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. For these reasons, among others, we cannot

## [Table of Contents](#)

estimate the date on which clinical development of OPAXIO will be completed or when we will be able to begin commercializing OPAXIO to generate material net cash inflows.

**Tosedostat.** Tosedostat is an oral, aminopeptidase inhibitor that has demonstrated significant anti-tumor responses in blood related cancers and solid tumors in phase I-II clinical trials. We are unable to provide the nature, timing, and estimated costs of the efforts necessary to complete the development of tosedostat because, among other reasons, we cannot predict with any certainty the pace of enrollment of our clinical trials. 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. For these reasons, among others, we cannot estimate the date on which clinical development of tosedostat will be completed or when we will be able to begin commercializing tosedostat to generate material net cash inflows.

**Brostallicin.** Brostallicin is a synthetic DNA minor groove binding agent that has demonstrated anti-tumor activity. The NCCTG is conducting a phase II study of brostallicin in combination with cisplatin in patients with mTNBC. We are unable to provide the nature, timing, and estimated costs of the efforts necessary to complete the development of brostallicin because, among other reasons, a third party is conducting the clinical trial of brostallicin for which enrollment is subject to their control and even after a clinical trial has been 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. For these reasons, among others, we cannot estimate the date on which clinical development of brostallicin will be completed or when we will be able to begin commercializing brostallicin to generate material net cash inflows.

**Bisplatinates (CT-47463).** Cisplatin is a platinum-based chemotherapy drug used to treat a wide variety of cancers. We are developing new analogues of the dinuclear-platinum complex, or CT-47463, that is more potent than cisplatin. CT-47463 is endowed with a unique mechanism of action, active in preclinical studies on a large panel of tumor models, sensitive and refractory to cisplatin, and has a safety profile comparable to that of cisplatin. The novel bisplatinum analogues are rationally designed and synthesized to have improved biopharmaceutical properties that reduce the intrinsic reactivity of the molecule and that demonstrate preclinical anti-tumor efficacy in solid tumor models. We are unable to provide the nature, timing, and estimated costs of the efforts necessary to complete the development of CT-47463 because, among other reasons, a third party is conducting the preclinical trial for CT-47463, no clinical trial design for CT-47463 has been developed yet and 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. For these reasons, among others, we cannot estimate the date on which clinical development of CT-47463 will be completed or when we will be able to begin commercializing CT-47463 to generate material net cash inflows.

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 the following risk factors, which begin on page 30 of this Form 10-Q: “*Our financial condition may be adversely affected if third parties default in the performance of contractual obligations.*”; “*We may be delayed, limited or precluded from obtaining regulatory approval of OPAXIO as a maintenance therapy for advanced stage ovarian cancer.*”; “*We are subject to extensive government regulation.*”; “*Even if our drug candidates are successful in clinical trials, we may not be able to successfully commercialize them.*”; “*If we do not successfully develop our product candidates into marketable products, we may be unable to generate significant revenue or become profitable.*”; and “*We may take longer to complete our clinical trials than we expect, or we may not be able to complete them at all.*”

**Selling, general and administrative expenses.** Selling, general and administrative expenses decreased to approximately \$8.6 million for the three months ended March 31, 2011 from approximately \$18.4 million for the three months ended March 31, 2010. This decrease was primarily related to reductions in noncash share-based compensation of \$6.5 million and sales and marketing expenses of \$3.8 million incurred in 2010 associated with the premarketing efforts for Pixuvri and personnel and travel expenses. This decrease was offset in part by discretionary bonuses and increases in legal and patent service expenses.

**Interest expense.** Interest expense decreased to approximately \$0.4 million for the three months ended March 31, 2011 from approximately \$0.8 million for the three months ended March 31, 2010. We fully repaid the remaining \$38.5 million outstanding principal balance of our 4% convertible senior subordinated notes in July 2010 resulting in a decrease in interest expense in the first quarter of 2011 as compared to the same period in 2010.



## [Table of Contents](#)

**Amortization of debt discount and issuance costs.** Amortization of debt discount and issuance costs for the three months ended March 31, 2011 and 2010 is related to the amortization of debt discount and issuance costs incurred on our 5.75% and 7.5% convertible senior notes.

**Foreign exchange gain (loss).** The foreign exchange gain for the three months ended March 31, 2011 and the foreign exchange loss for the three months ended March 31, 2010 is due to fluctuations in foreign currency exchange rates, primarily related to payables and receivables in our European branch denominated in foreign currencies.

### LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2011, we had approximately \$43.8 million in cash and cash equivalents.

Net cash used in operating activities increased to approximately \$24.6 million during the three months ended March 31, 2011 compared to approximately \$23.2 million for the same period during 2010 primarily due to a one-time upfront payment of \$5.0 million related to the licensing of tosedostat included in research and development expense, offset by a decrease in selling, general and administrative expense, excluding the allocation of non-cash share-based compensation.

Net cash used in investing activities decreased to approximately \$0.3 million for the three months ended March 31, 2011 compared to \$1.1 million for the three months ended March 31, 2010. The decrease was primarily due to decreases in purchases of property and equipment.

Net cash provided by financing activities of approximately \$46.9 million for the three months ended March 31, 2011 was primarily due to the issuance of our preferred stock. In January 2011, we received approximately \$23.4 million in net proceeds from the issuance of 25,000 shares of our Series 8 Preferred Stock, warrants to purchase 22.6 million shares of common stock and an additional investment right to purchase 25,000 shares of Series 9 Preferred Stock. We also received approximately \$23.7 million in net proceeds from the issuance of 24,957 shares of our Series 10 preferred stock, warrants to purchase 25.9 million shares of common stock and an additional investment right to purchase 24,957 shares of our Series 11 Preferred Stock. Net cash provided by financing activities of approximately \$27.5 million for the three months ended March 31, 2010 was primarily due to \$28.1 million in net proceeds received from the issuance of 30,000 shares of our Series 3 preferred stock and warrants to purchase approximately 8.6 million shares of our common stock in January 2010.

We have prepared our 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. We have incurred net losses since inception and expect to generate losses from operations for the next few years primarily due to research and development costs for Pixuvri, OPAXIO, tosedostat and brostallicin.

We do not expect that our existing cash and cash equivalents will be sufficient to fund our presently anticipated operations through the third quarter of 2011. This raises substantial doubt about our ability to continue as a going concern.

Since the second quarter of 2010, we have implemented cost saving initiatives to reduce operating expenses, including the reduction of employees related to planned commercial Pixuvri operations. We will need to raise additional funds and are currently exploring alternative sources of financing. We may seek to raise such capital through public or private equity financings, partnerships, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources. Our future capital requirements will depend on many factors, including:



## Table of Contents

- results of our clinical trials;
- regulatory approval of our products;
- success in acquiring or divesting products, technologies or businesses;
- progress in and scope of our research and development activities;
- finding appropriate partners for the development and commercialization of our products if they are approved for marketing; and
- competitive market developments.

Future capital requirements will also depend on the extent to which we acquire or invest in businesses, products and technologies or sell or license our products to others. We will require additional financing and such financing may not be available when needed or, if available, we may not be able to obtain it on terms favorable to us or to our shareholders. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. If we fail to obtain capital when required, we may be required to delay, scale back, or eliminate some or all of our research and development programs, which may adversely affect our ability to operate as a going concern and we may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection.

The following table includes information relating to our contractual obligations as of March 31, 2011 (in thousands):

<u>Contractual Obligations</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>1 Year</u>	<u>2-3 Years</u>	<u>4-5 Years</u>	<u>After 5 Years</u>
7.5% convertible senior notes (1)	\$10,250	\$10,250	\$ —	\$ —	\$ —
5.75% convertible senior notes (2)	10,913	10,913	—	—	—
Interest on convertible notes	508	508	—	—	—
Operating leases:					
Facilities	5,630	3,914	1,672	44	—
Long-term obligations (3)	829	432	384	13	—
Purchase commitments	837	696	141	—	—
	<u>\$28,967</u>	<u>\$26,713</u>	<u>\$ 2,197</u>	<u>\$ 57</u>	<u>\$ —</u>

- (1) The 7.5% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 11.96298 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$83.59 per share.
- (2) The 5.75% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 33.33333 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$30.00 per share.
- (3) Long-term obligations do not include \$1.7 million related to excess facilities charges and \$3.2 million related to the reserve for VAT assessments.

### *Manufacturing Supply Agreement*

We signed a manufacturing supply agreement, or the NerPharMa Agreement, with NerPharMa, S.r.l., or NerPharMa (a pharmaceutical manufacturing company belonging to Nerviano Medical Sciences, S.r.l., in Nerviano, Italy), for our drug candidate Pixuvri. The NerPharMa Agreement is a five year non-exclusive agreement and provides for both the commercial and clinical supply of Pixuvri. The NerPharMa Agreement commenced on July 9, 2010 and expires on the fifth anniversary date of the first government approval obtained either in the United States or Europe. The NerPharMa Agreement may be terminated for an uncured material breach, insolvency or the filing of bankruptcy, or by mutual agreement. We may also terminate the NerPharMa Agreement (i) upon prior written notice in the event of failure of three or more of seven consecutive lots of product or (ii) in the event NerPharMa is acquired or a substantial portion of NerPharMa's assets related to the NerPharMa Agreement are sold to another entity.

**Additional Milestone Activities**

*Chroma Therapeutics, Ltd.*

We have an agreement, or the Chroma Agreement, with Chroma Therapeutics Ltd., or Chroma, under which we have an exclusive license to certain technology and intellectual property controlled by Chroma to develop and commercialize the drug candidate tosedostat in North, Central and South America, or the Licensed Territory. Pursuant to the terms of the Chroma Agreement, we paid Chroma an upfront fee of \$5.0 million upon execution of the agreement and will make a milestone payment of \$5.0 million upon the initiation of the first pivotal trial for AML, which could commence as early as the fourth quarter of 2011. The Chroma Agreement also includes additional development- and sales-based milestone payments related to AML and certain other indications, up to a maximum amount of \$209.0 million payable by us to Chroma if all development and sales milestones are achieved.

We will also pay Chroma royalties on net sales of tosedostat in any country within the Licensed Territory, commencing on the first commercial sale of tosedostat in any country in the Licensed Territory and continuing with respect to that country until the later of (a) the expiration date of the last patent claim covering tosedostat in that country, (b) the expiration of all regulatory exclusivity periods for tosedostat in that country or (c) ten years after the first commercial sale in that country. Royalty payments to Chroma are based on net sales volumes in any country within the Licensed Territory and range from the low- to mid-teens as a percentage of net sales.

We will oversee and be responsible for performing the development operations and commercialization activities in the Licensed Territory and Chroma will oversee and be responsible for performing the development operations and commercialization activities worldwide except for the Licensed Territory, or the ROW Territory. Development costs may not exceed \$50.0 million for the first three years of the Chroma Agreement unless agreed by the parties and we will be responsible for 75% of all development costs, while Chroma will be responsible for 25% of all development costs, subject to certain exceptions. Chroma will be solely responsible for the manufacturing of tosedostat for development purposes in the Licensed Territory and the ROW Territory in accordance with the terms of the supply agreement to be entered into by the parties. We will be solely responsible, by ourselves or through one or more third party contract manufacturers, for the manufacture of tosedostat for commercialization purposes in the Licensed Territory. The Chroma Agreement may be terminated by us at our convenience upon 120 days' written notice to Chroma. The Chroma Agreement may also be terminated by either party following a material breach by the other party subject to notice and cure periods.

*Gynecologic Oncology Group*

We have an agreement with the GOG related to the GOG0212 trial, which the GOG is conducting. Under this agreement we are required to pay up to \$3.5 million in additional milestone payments related to the trial, of which \$1.7 million will become due when 800 patients are enrolled and \$0.5 million will become due upon receipt of the interim analysis and data transfer, both of which may occur in 2011. There were 788 patients enrolled as of March 31, 2011.

*Nerviano Medical Sciences*

Under a license agreement entered into with Nerviano Medical Sciences, S.r.l. for brostallicin, we may be required to pay up to \$80.0 million in milestone payments based on the achievement of certain product development results. Due to the early stage of development that brostallicin is in, we are not able to determine whether the clinical trials will be successful and therefore cannot make a determination that the milestone payments are reasonably likely to occur at this time.

*PG-TXL*

We have an agreement, or the PG-TXL Agreement, with PG-TXL Company, L.P., or PG-TXL, which grants 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 are 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 is 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 are required to make royalty payments to PG-TXL based on net sales. Our royalty payments range from low-single digits to mid-single digits as a percentage of net sales. Unless otherwise terminated, the term of the PG-TXL Agreement continues until no royalties are

## [Table of Contents](#)

payable to PG-TXL. We may terminate the PG-TXL Agreement (i) upon advance written notice to PG-TXL in the event issues regarding the safety of the products licensed pursuant to the PG-TXL Agreement arise during development or clinical data obtained reveal a materially adverse tolerability profile for the licensed product in humans or (ii) for any reason upon advance written notice. In addition, either party may terminate the PG-TXL Agreement (a) upon advance written notice in the event certain license fee payments are not made; (b) in the event of an uncured material breach of the respective material obligations and conditions of the PG-TXL Agreement; or (c) in the event of liquidation or bankruptcy of a party.

### *Cephalon*

Pursuant to an acquisition agreement entered into with Cephalon, Inc., or Cephalon, in June 2005, we may receive up to \$100.0 million in payments upon achievement by Cephalon of specified sales and development milestones related to TRISENOX. However, the achievement of any such milestones is uncertain at this time.

### *Novartis*

In September 2006, we entered into an exclusive worldwide licensing agreement, or the Novartis Agreement, with Novartis International Pharmaceutical Ltd., or Novartis, for the development and commercialization of OPAXIO. Total product and registration milestones to us for OPAXIO under the Novartis Agreement could reach up to \$270 million. Royalty payments to us for OPAXIO are based on worldwide OPAXIO net sales volumes and range from the low-twenties to mid-twenties as a percentage of net sales.

Pursuant to the Novartis Agreement, we are responsible for the development costs of OPAXIO and have control over development of OPAXIO unless and until Novartis exercises its development rights, or the Development Rights. In the event that Novartis exercises the Development Rights, then from and after the date of such exercise, or the Novartis Development Commencement Date, Novartis will be solely responsible for the development of OPAXIO. Prior to the Novartis Development Commencement Date, we are solely responsible for all costs associated with the development of OPAXIO, but will be reimbursed by Novartis for certain costs after the Novartis Development Commencement Date. After the Novartis Development Commencement Date, Novartis will be responsible for costs associated with the development of OPAXIO, subject to certain limitations; however, we are also responsible for reimbursing Novartis for certain costs pursuant to the Novartis Agreement.

The Novartis Agreement also provides Novartis with an option to develop and commercialize Pixuvri based on agreed terms. If Novartis exercises its option on Pixuvri under certain conditions and we are able to negotiate and sign a definitive license agreement with Novartis, Novartis would be required to pay us a \$7.5 million license fee, up to \$104 million in registration and sales related milestones and a royalty on Pixuvri worldwide net sales. Royalty payments to us for Pixuvri are based on worldwide Pixuvri net sales volumes and range from the low-double digits to the low-thirties as a percentage of net sales.

Royalties for OPAXIO are based on worldwide sales volumes of OPAXIO and royalties for Pixuvri are based on sales volumes in the United States and sales volumes in other countries.

Royalties for OPAXIO and Pixuvri are payable from the first commercial sale of a product until the later of the expiration of the last to expire valid claim of the licensor or the occurrence of other certain events, or the Royalty Term. Unless otherwise terminated, the term of the Novartis Agreement continues on a product-by-product and country-by-country basis until the expiration of the last-to-expire Royalty Term with respect to a product in such certain country. In the event Novartis does not exercise its Development Rights until the earlier to occur of (i) the expiration of 30 days following receipt by Novartis of the product approval information package pursuant to the Novartis Agreement or (ii) Novartis' determination, in its sole discretion, to terminate the Development Rights exercise period by written notice to us (events (i) and (ii) collectively being referred to as the "Development Rights Exercise Period"), the Novartis Agreement will automatically terminate upon expiration of the Development Rights Exercise Period. In the event of an uncured material breach of the Novartis Agreement, the non-breaching party may terminate the Novartis Agreement. Either party may terminate the Novartis Agreement without notice upon the bankruptcy of the other party. In addition, Novartis may terminate the Novartis Agreement without cause at any time (a) in its entirety within 30 days written notice prior to the exercise by Novartis of its Development Rights or (b) on a product-by-product or country-by-country basis on 180 days written notice after the exercise by Novartis of its Development Rights. If we experience a change of control that involves certain major pharmaceutical companies,

## [Table of Contents](#)

Novartis may terminate the Novartis Agreement by written notice within a certain period of time to us or our successor entity.

As of March 31, 2011, we have not received any milestone payments and we will not receive any milestone payments unless Novartis elects to exercise its option to participate in the development and commercialization of Pixuvri or exercise its Development Rights for OPAXIO.

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

#### *Foreign Exchange Market Risk*

We are exposed to risks associated with foreign currency transactions insofar as we use U.S. dollars to make contract payments denominated in euros or vice versa. As the net positions of our unhedged foreign currency transactions fluctuate, our earnings might be negatively affected. As of March 31, 2011, our foreign currency transactions are minimal and changes to the exchange rate between the U.S. dollar and foreign currencies would have an immaterial affect on our earnings. In addition, the reported carrying value of our euro-denominated assets and liabilities will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. As of March 31, 2011, we had a net asset balance excluding intercompany payables and receivables in our European branches subsidiaries denominated in euros. As of March 31, 2011, if the euro were to weaken 20% against the dollar, our net asset balance would decrease by approximately \$1.1 million as of this date.

### **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, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the 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 Chief Executive Officer and Executive Vice President, Finance and Administration, or EVP of Finance, 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 Chief Executive Officer and EVP of Finance 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.

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

There have been no changes to our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q 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**

Information pertaining to legal proceedings can be found in Part I under the caption “Item 1. Financial Statements—Note 8. Legal Proceedings” and is incorporated by reference herein.

## 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 following 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, 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 impair our business, financial condition, operating results and prospects and the trading price of our securities.*

### Factors Affecting Our Operating Results and Financial Condition

*We need to raise additional funds and expect that we will need to continue to raise funds in the future, and additional funds may not be available on acceptable terms, or at all; failure to raise significant additional funds may cause us to cease development of our products and operations.*

We have substantial operating expenses associated with the development of our product candidates and as of March 31, 2011, we had cash and cash equivalents of \$43.8 million. As of March 31, 2011, our total current liabilities were \$39.1 million, including \$10.3 million and \$10.9 million outstanding principal balance related to our 7.5% and 5.75% convertible senior notes, respectively, which are due within the next 12 months. We do not expect that our existing cash and cash equivalents, as well as proceeds received from our offerings to date, will provide sufficient working capital to fund our presently anticipated operations through the third quarter of 2011.

Raising additional capital will likely require that we issue additional shares of our common stock. Because of the number of shares reserved for issuance under various convertible securities, derivative securities and otherwise, we have very few authorized shares of common stock available for issuance and it is difficult for us to obtain an increase in our authorized shares. If we do not have enough shares authorized to effect an equity financing, our ability to raise capital through equity financings may be adversely affected.

To the extent that we raise additional capital through the sale of equity securities, or securities convertible into our equity securities, our shareholders may experience dilution of their proportionate ownership of us. We have held preliminary discussions with several investment funds regarding a potential investment in our company, but we have no current agreements or commitments with respect to any investment by these investment funds or any other investors. There can be no assurance that our discussions with these investment funds or any other investors will result in an investment in our company or that we will have sufficient earnings, access to liquidity or cash flow in the future to meet our operating expenses and other obligations, including our debt service obligations.

We may not be able to raise such capital or, if we can, it may not be on favorable terms. We may seek to raise additional capital through public or private equity financings, partnerships, joint ventures, dispositions of assets, debt financings or restructurings, bank borrowings or other sources. To obtain additional funding, we may need to enter into arrangements that require us to relinquish rights to certain technologies, drug candidates, products and/or potential markets. In addition, some financing alternatives may require us to meet additional regulatory requirements in Italy and the United States and we may be subject to certain contractual limitations, which may increase our costs and adversely affect our ability to obtain additional funding. If adequate funds are not otherwise available, we will further curtail operations significantly, including the delay, modification or cancellation of operations and plans related to Pixuvri, OPAXIO, tosedostat, brostallicin and bisplatinates 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, including the rights to Pixuvri, OPAXIO, tosedostat and brostallicin.

*We need to implement a reduction in expenses across our operations.*

We need substantial additional capital to fund our current operations. If we are unable to secure additional financing on acceptable terms in the near future, we will need to implement additional cost reduction initiatives, such as further reductions in the cost of our workforce and the discontinuation of a number of business initiatives to further reduce our rate of cash utilization and extend our existing cash balances. We believe that these additional cost reduction initiatives, if undertaken, could provide us with additional time to continue our pursuit of additional funding sources and also strategic alternatives. In the event that we are unable to obtain financing on acceptable terms and reduce our expenses, we may be required to limit or cease our operations, pursue a plan to sell our

## [Table of Contents](#)

operating assets, seek bankruptcy protection, or otherwise modify our business strategy, which could materially harm our future business prospects.

*Our common stock is listed on The NASDAQ Capital Market and the MTA and we may not be able to maintain those listings or trading on these exchanges may be halted or suspended, which may make it more difficult for investors to sell shares of our common stock.*

Effective with the opening of trading on January 8, 2009, the U.S. listing of our common stock was transferred to The NASDAQ Capital Market, subject to meeting a minimum market value of listed securities of \$35.0 million. The Listing Qualifications Panel, or the Panel, of The NASDAQ Stock Market LLC, or the NASDAQ, approved this transfer after our market capitalization did not comply with the minimum market capitalization required for companies listed on The NASDAQ Global Market, and we presented a plan to the Panel for regaining compliance with the NASDAQ Marketplace Rules. On January 23, 2009, we received an Additional Staff Determination Letter from NASDAQ that stated that the NASDAQ staff had concluded that we had violated NASDAQ Marketplace Rule 4350(i)(1)(C) (now NASDAQ Marketplace Rule 5635), which requires shareholder approval in connection with an acquisition if the issuance or potential issuance is greater than 20% of the pre-acquisition shares outstanding, and that we had at times not complied with Marketplace Rule 4310(c)(17) regarding submission of a "Listing of Additional Shares" form. On February 18, 2009, we updated the Panel on our plan for regaining compliance and requested an extension of the deadline to regain compliance with the minimum market capitalization requirement for The NASDAQ Capital Market. On March 6, 2009, we were notified by NASDAQ that the Panel determined to continue the listing of our common stock on The NASDAQ Capital Market, subject to the condition that, on or before April 6, 2009, we demonstrated compliance with all applicable standards for continued listing on The NASDAQ Capital Market, including the \$35.0 million minimum market capitalization requirement. In addition, the Panel issued a public reprimand for our prior failures to comply with the shareholder approval requirements and late filing of "Listing of Additional Shares" forms. On April 2, 2009, we were notified by NASDAQ that we had complied with the Panel's decision dated March 6, 2009, and, accordingly, the Panel determined to continue the listing of our common stock on The NASDAQ Capital Market.

NASDAQ reinstated the \$1.00 minimum bid price requirement on August 3, 2009. On May 3, 2010, we received notice from NASDAQ indicating that for the last 30 consecutive business days the closing bid price of our common stock was below the minimum \$1.00 per share requirement for continued listing of our common stock on The NASDAQ Capital Market under NASDAQ Marketplace Rule 5550(a)(2). This notification had no immediate effect on the listing of or the ability to trade our common stock on The NASDAQ Capital Market. In accordance with NASDAQ Marketplace Rule 5810(c)(3)(A), we were provided a grace period of 180 calendar days, or until November 1, 2010, to regain compliance. We would have achieved compliance if the bid price of our common stock closed at \$1.00 per share or more for a minimum of ten consecutive trading days before November 1, 2010. In addition, we were eligible for an additional 180-day grace period if we met all of the initial listing standards of NASDAQ, with the exception of the closing bid price. On November 2, 2010, we received notice from NASDAQ that it granted us an additional 180 days, or until May 2, 2011, to regain compliance with the minimum \$1.00 per share requirement for continued listing of our common stock on The NASDAQ Capital Market under NASDAQ Marketplace Rule 5550(a)(2).

We are awaiting a response from the FDA on our December 2010 appeal of the FDA's April 2010 decision not to approve Pixuvri for relapsed/refractory aggressive NHL. We believe that a positive response from the OND could have the effect of increasing the price per share of our common stock to a closing bid price that would satisfy the minimum bid price of \$1.00, or at least strengthen the price per share enough to expand our options in regaining compliance, such as by a more favorable ratio in the event we determine that a reverse stock split of our common stock is necessary. As of the date of this Quarterly Report on Form 10-Q, we have not received notice of the FDA's decision in response to our appeal. Moreover, as of the date of this Quarterly Report on Form 10-Q, the closing bid price of our common stock has not reached the minimum bid price and there are less than ten days left prior to May 2, 2011. Accordingly, we will not be in compliance with the minimum bid price requirement prior to May 2, 2011.

We expect to receive a delisting determination from NASDAQ. In the event that we receive a delisting determination from NASDAQ, the Company intends to request a hearing before the Panel while we await the FDA's response to our appeal and otherwise seek to attain compliance with the minimum bid price requirement, such as through a reverse stock split. Pursuant to the Business Corporation Act of Washington, the Board may unilaterally determine that it is in the best interests of the shareholders and the Company to effectuate a reverse stock split. The primary objective of the reverse stock split, if undertaken, would be an anticipated increase of the per share trading price of our common stock, which may enable us to satisfy the minimum bid price requirement and facilitate higher levels of institutional stock ownership, as investment policies of many institutional investors require minimum securities price points. There can be no assurance that a reverse stock split would have the intended effect, that any increase in the trading price of our common stock would be proportional to the decrease in the number of outstanding shares, or that the Board would be able to complete a reverse stock split in time to avoid the delisting of our common stock. Moreover, there can be no assurance that the Panel would delay an unfavorable delisting decision or grant any further extension period.

## [Table of Contents](#)

The level of trading activity of our common stock may decline if it is no longer listed on The NASDAQ Capital Market. Furthermore, our failure to maintain a listing on The NASDAQ Capital Market may constitute an event of default under certain of our indebtedness which would accelerate the maturity date of such debt. As such, if our common stock ceases to be listed for trading on The NASDAQ Capital Market for any reason, it may harm our stock price, increase the volatility of our stock price and make it more difficult for investors to sell shares of our common stock. In the event our common stock is delisted from The NASDAQ Capital Market, we currently expect that our common stock would be eligible to be listed on the OTC Bulletin Board or Pink Sheets. We do not know what impact delisting from The NASDAQ Capital Market may have on our listing with the Borsa Italiana.

Although we continue to be listed on The NASDAQ Capital Market, trading in our common stock may be halted or suspended due to market conditions or if NASDAQ, CONSOB or the Borsa Italiana determine that trading in our common stock is inadvisable. Trading in our common stock was halted by the Borsa Italiana on February 10, 2009, and, as a consequence, trading in our common stock was also halted by NASDAQ. After we provided CONSOB with additional information and clarification on our business operations and financial condition, as requested, and published a press release containing such information in Italy, the Borsa Italiana, and NASDAQ lifted the trading halts on our common stock. In addition, on March 23, 2009, the Borsa Italiana halted trading of our common stock on the MTA and resumed trading prior to the opening of the MTA the next day after we filed a press release regarding the explanatory paragraph in our auditor's reports on our December 31, 2008 and 2007 consolidated financial statements regarding their substantial doubt as to our ability to continue as a going concern. As a consequence, NASDAQ also halted trading in our common stock on March 23, 2009, but re-initiated trading later that day. Although we file press releases with CONSOB at the end of each month regarding our business and financial condition, CONSOB may make additional inquiries about our business and financial condition at any time, and there can be no guarantee that the Borsa Italiana, CONSOB or NASDAQ will not halt trading in our shares again in the future. If our common stock ceases to be listed for trading on The NASDAQ Capital Market or the MTA, or both, for any reason, or if trading in our stock is halted or suspended on The NASDAQ Capital Market or the MTA, or both, such events may harm the trading price of our securities, increase the volatility of the trading price of our securities and make it more difficult for investors to buy or sell shares of our common stock. Moreover, if our common stock ceases to be listed for trading on The NASDAQ Capital Market or if trading in our stock is halted or suspended on The NASDAQ Capital Market, we may become subject to certain obligations. In addition, if we are not listed on The NASDAQ Capital Market and/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.

*We may be unable to obtain a quorum for meetings of our shareholders or obtain necessary shareholder approvals and therefore be unable to take certain corporate actions.*

Our amended and restated articles of incorporation, or our articles of incorporation, require that a quorum, generally consisting of one-third of the outstanding shares of voting stock, be represented in person or by proxy in order to transact business at a meeting of our shareholders. In addition, amendments to our articles of incorporation, such as an amendment to increase our authorized capital stock, generally require the approval of a majority of our outstanding shares. Our shareholders have been asked to vote on a proposal to amend our articles of incorporation to increase the number of authorized shares of common stock at a special meeting of shareholders, which is expected to be held on May 31, 2011. There is a risk that we may not get shareholder approval to increase the number of authorized shares of common stock. If we do not receive shareholder approval for the proposed increase in authorized shares, our ability to raise capital through equity financings will be significantly harmed.



## [Table of Contents](#)

A substantial majority 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 2006, when a quorum required a majority of the outstanding shares of our voting stock be represented in person or by proxy, we scheduled two annual meetings of shareholders, but were unable to obtain quorum at either meeting. Following that failure to obtain quorum, we contacted certain depository banks in Italy where significant numbers of shares of our common stock were held and asked them to cooperate by making a book-entry transfer of their share positions at Monte Titoli 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 contacted agreed to make the share transfer pursuant to these arrangements as of the record date of the 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. Under Rule 452 of the New York Stock Exchange, or Rule 452, the U.S. broker-dealer may vote shares absent direction from the beneficial owner on certain "routine" matters, such as an amendment to our amended and restated articles of incorporation to increase authorized shares that are to be used for general corporate purposes and the ratification of our auditors. We were able to obtain a quorum to hold special meetings of the shareholders in April 2007, January 2008 and March 2009 and annual meetings of the shareholders in September 2007, June 2008, October 2009 and September 2010. Nevertheless, obtaining a quorum at future meetings even at the lower threshold and obtaining necessary shareholder approvals will 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 participate in custody transfer arrangements in the future. We are continuing to explore other alternatives to achieve quorum for and shareholder representation at our meetings; however, we cannot be certain that we will find an alternate method if we are unable to continue to use the custody transfer arrangements. As a result, we may be unable to obtain a quorum at future annual or special meetings of shareholders or obtain shareholder approval of proposals when needed.

If we are unable to obtain a quorum at our shareholder meetings and/or fail to get shareholder approval of corporate actions, such failure could harm us. Even if we obtain a quorum, we may not obtain enough votes to approve matters to be resolved upon at the shareholders' meeting. In addition, brokers may only vote on those matters for which broker discretionary voting is allowed under Rule 452, and we may not be able to obtain the required number of votes to approve certain proposals that require a majority of all outstanding shares to approve the proposal due to our reliance on broker discretionary voting. Our ability to obtain necessary shareholder approvals may also depend on obtaining broker discretionary voting under Rule 452. Revisions to Rule 452 that further limit matters for which broker discretionary voting is allowed may harm our ability to obtain a quorum and shareholder approval of certain matters. Therefore it is possible that even if we are able to obtain a quorum for our meetings of the shareholders we still may not receive enough votes to approve proxy proposals presented at such meeting and, depending on the proposal in question, including if a proposal is submitted to our shareholders to increase the number of authorized shares of common stock, such failure could harm us. For example, a proposal to approve a reverse stock split failed to receive sufficient votes to pass at the March 2009 shareholders meeting.

*We may 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, 2011, we had an accumulated deficit of \$1.6 billion. We are pursuing regulatory approval for Pixuvri, OPAXIO, tosedostat and brostallicin. We will need to conduct research, development, testing and regulatory compliance activities and undertake manufacturing and drug supply activities the costs of which, together with projected general and administrative expenses, may result in operating losses for the foreseeable future. We may never become profitable even if we are able to commercialize products currently in development or otherwise.

*Our debt and operating expenses exceed our net revenues.*

We have a substantial amount of debt outstanding, and our annual interest expense with respect to our debt is significant. Unless we raise substantial additional capital and reduce our operating expenses, we may not be able to pay all of our operating expenses or repay our debt or the interest on our debt, liquidated damages or other payments that may become due with respect to our debt. In the event we are unable to reduce our expenses and/or repay our debt or the interest on our debt, we may be required to limit or cease our operations, pursue a plan to sell our operating assets, seek bankruptcy protection, or otherwise modify our business strategy, which could materially harm our future business prospects. Bankruptcy may result in the termination of agreements pursuant to which we license certain intellectual property rights, including the rights to Pixuvri, OPAXIO, tosedostat and brostallicin.

## Table of Contents

*We may be unable to use our net operating losses.*

We have substantial tax loss carryforwards for U.S. federal income tax purposes. As a result of prior changes in the stock ownership of the Company, 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. Moreover, future changes in the ownership of our stock, including those resulting from the issuance of shares of our common stock upon exercise of outstanding warrants, may further limit our ability to use our net operating losses.

*We have received audit reports with a going concern disclosure on our consolidated financial statements.*

As we may need to raise additional financing to fund our operations and satisfy obligations as they become due, our independent registered public accounting firm has included an explanatory paragraph in their reports on our December 31, 2010, 2009 and 2008 consolidated financial statements regarding their substantial doubt as to our ability to continue as a going concern. This may have a negative impact on the trading price of our common stock and we may have a more difficult time obtaining necessary financing.

*If we make any acquisitions, we will incur a variety of costs and may never realize the anticipated benefits.*

If appropriate opportunities become available, we may attempt to acquire businesses and assets that we believe are a strategic fit with our business. We currently have no agreements to consummate any pending material acquisitions. If we pursue any such transaction, the process of negotiating the acquisition and integrating an acquired business and assets may result in operating difficulties and expenditures and 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. Moreover, we may never realize the anticipated benefits of any acquisition. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to goodwill and other intangible assets, which could harm our business, financial condition, operating results and prospects and the trading price of our securities.

*The global financial crisis may have an impact on our business and financial condition in ways that we currently cannot predict, and may further limit our ability to raise additional funds.*

The ongoing credit crisis and related turmoil in the global financial system has had and may continue to have an impact on our business and our financial condition. We may face significant challenges if conditions in the financial markets do not improve or continue to worsen. In particular, our ability to access the capital markets and raise funds required for our operations may be severely restricted at a time when we would like, or need, to do so, which could have an adverse effect on our ability to meet our current and future funding requirements and on our flexibility to react to changing economic and business conditions.

*We are required to comply with the regulatory structure of Italy because our stock is traded on the Mercato Telematico Azionario stock market in Italy, or the MTA, which could result in administrative and other challenges and additional expenses.*

Our common stock is traded on the MTA and we are required to also comply with the rules and regulations of the Commissione Nazionale per le Società e la Borsa, or CONSOB, which is the public authority responsible for regulating the Italian securities market, and the Borsa Italiana, which ensures the development of the managed market in Italy. Collectively, these entities regulate companies listed on Italy's public markets. Conducting our operations in a manner that complies with all of the applicable laws and rules requires us to devote additional time and resources to regulatory compliance matters. For example, the process of seeking to understand and comply with the laws of each country, including tax, labor and regulatory laws, might require us to incur the expense of engaging additional outside counsel, accountants and other professional advisors and might result in delayed business initiatives as we seek to ensure that each new initiative will comply with all of the applicable regulatory regimes. In addition, the Borsa Italiana and CONSOB have made several requests for information asking us to provide additional clarifications about our business operations and financial condition, and we have complied with such requests and have met with CONSOB on several occasions to answer questions. Compliance with Italian regulatory requirements may delay additional issuances of our common stock; we are currently taking steps to attempt to conform to the requirements of the Italian stock exchange and CONSOB to allow such additional issuances.

## [Table of Contents](#)

In addition, under Italian law, we must publish a listing prospectus that has been approved by CONSOB prior to issuing common stock that exceeds, in any twelve-month period, 10% of the number of shares of our common stock outstanding at the beginning of that period (except for certain applicable exceptions).

If we are unable to maintain a listing prospectus to cover general financing efforts under Italian law, we may be required to raise money using alternative forms of securities. For example, we may need to use convertible preferred stock and convertible debt since the common stock resulting from the conversion of such securities, subject to the provisions of European Directive No. 71/2003 and according to the interpretations of the Committee of European Securities Regulators, is not subject to the 10% limitation imposed by EU and Italian law.

Moreover, on December 23, 2008, CONSOB sent a notice to us requesting that we issue (i) immediately, a press release providing, among other things, information about our debt restructuring plan, the current state of compliance with the relevant covenants regulating our debt and the equity line of credit agreement we entered into with Midsummer Investment Ltd. on July 29, 2008, and (ii) by the end of each month and starting from the month of December 2008, a press release providing certain information relating to our management and financial situation, updated to the previous month, or the Monthly CONSOB Press Release. On July 31, 2009, CONSOB sent us a notice asserting three violations of the provisions of Section 114, paragraph 5 of the Italian Legislative Decree no. 58/98, as follows: (a) the non-disclosure without delay of the press release described under point (i) above and the subsequent incomplete disclosure of the relevant information through press releases dated January 9, 2009 and January 13, 2009; (b) the non-disclosure of the Monthly CONSOB Press Release in December 2008; and (c) the incomplete disclosure of the Monthly CONSOB Press Release in January 2009. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violations are pecuniary administrative sanctions amounting to between €5,000 and €500,000, or approximately \$7,000 to \$709,000 converted using the currency exchange rate as of March 31, 2011, applicable to each one of the three asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that were submitted to CONSOB on August 28, 2009 (within 30 days of July 31, 2009, the notification date of the relevant charges, according to the applicable Italian rules). On May 5, 2010, CONSOB (1) notified us that it had begun the preliminary investigation for its decision on these administrative proceedings and (2) provided us with a preliminary investigation report in response to our defenses submitted on August 28, 2009. On June 4, 2010 (within 30 days of May 5, 2010, the notification date of the beginning of the aforesaid preliminary investigation, according to the applicable Italian rules), we submitted further defenses that CONSOB will have to evaluate before imposing any possible administrative sanctions. On January 21, 2011, CONSOB notified us of a resolution confirming the occurrence of the three asserted violations and applying a fine for each of them in the following amounts: €20,000 for sanction (a) above; €50,000 for sanction (b) above; and €30,000 for sanction (c) above, for an aggregate fine of €100,000, or approximately \$136,000 converted using the currency exchange rate as of January 21, 2011, for these sanctions. On March 4, 2011, we paid the aggregate fine of €100,000 in full.

## [Table of Contents](#)

Separately, on December 10, 2009, CONSOB sent us a notice claiming two violations of the provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98 due to the asserted late disclosure of certain information then reported, at CONSOB's request, in press releases disseminated on December 19, 2008 and March 23, 2009. Such information concerned, respectively: (i) the conversion by BAM Opportunity Fund LP of 9.66% notes into shares of common stock that occurred between October 24, 2008 and November 19, 2008; and (ii) the contents of the opinion expressed by Stonefield Josephson, Inc., an independent registered public accounting firm, with respect to our 2008 financial statements. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violations are pecuniary administrative sanctions amounting to between €5,000 and €500,000, or approximately \$7,000 to \$709,000 converted using the currency exchange rate as of March 31, 2011, applicable to each of the two asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that were submitted to CONSOB on January 8, 2010 (within 30 days of December 10, 2009, the notification date of the relevant charges, according to the applicable Italian rules). On July 12, 2010, CONSOB (a) notified us that it had begun the preliminary investigation for its decision on these administrative proceedings and (b) provided us with a preliminary investigation report in response to our defenses submitted on January 8, 2010. On August 12, 2010 (within 30 days of July 12, 2010, the notification date of the beginning of the aforesaid preliminary investigation, according to the applicable Italian rules), we submitted further defenses that CONSOB will have to evaluate before imposing any possible administrative sanctions. On March 10, 2011 CONSOB notified us of a resolution confirming the occurrence of the violation asserted in clause (i) above and applied a fine in the amount of €40,000, which we paid on April 5, 2011. CONSOB has not yet notified us of a resolution with respect to the violation asserted in clause (ii) above, but based on our assessment, we believe the likelihood that a pecuniary administrative sanction will be imposed on the Company for such asserted violation (ii) is probable.

*Our assets and liabilities that remain in our Italian branches make us subject to increased 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. As long as we continue to have assets and liabilities held in our Italian branches the carrying value of these assets and liabilities will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. Changes in the value of the U.S. dollar as compared to the euro might have an adverse effect on our reported results of operations and financial condition.

*We may owe additional amounts for value added taxes related to our operations in Europe.*

Our European operations are subject to value added tax, or VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable is \$5.6 million and \$5.3 million as of March 31, 2011 and December 31, 2010, respectively. On April 14, 2009 and December 21, 2009, 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 and 2005, respectively. On June 25, 2010, the ITA issued notices of assessment to CTI (Europe) for the years 2006 and 2007 based on similar findings for the 2003 and 2005 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). 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, or approximately \$0.8 million, \$7.8 million, \$3.6 million and \$1.2 million converted using the currency exchange rate as of March 31, 2011, 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 vigorously defending ourselves against the assessments both on procedural grounds and on the merits of the case. If the decision of the Provincial Tax Court of Milan, or the Tax Court, is unfavorable, then we expect to appeal to the higher courts in order to further defend our interests. However, if we are unable to successfully defend ourselves against the assessments issued by the ITA, we may be requested to pay to the ITA an amount ranging from €4.9 million to €9.4 million, or approximately \$7.0 million to \$13.3 million converted using the currency exchange rate as of March 31, 2011, 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. On February 2, 2011, we paid to the ITA the required deposit in respect of the 2005 VAT in the amount of €1.5 million, or approximately \$2.1 million converted using the currency exchange rate as of February 2, 2011. On March 4, 2011, we paid to the ITA the required deposit in respect of the 2006 VAT in the amount of €0.4 million, or approximately \$0.6 million converted using the currency exchange rate as of March 4, 2011. Further information pertaining to these cases can be found in Part I under the caption "Item 1. Financial Statements—Note 8. Legal Proceedings" and is incorporated by reference herein.

## [Table of Contents](#)

*Our financial condition may be adversely affected if third parties default in the performance of contractual obligations.*

Our business is dependent on the performance by third parties of their responsibilities under contractual relationships and if third parties default on their performance of their contractual obligations, we could suffer significant financial losses and operational problems, which could in turn adversely affect our financial performance, cash flows or results of operations and may jeopardize our ability to maintain our operations.

*We may not realize any royalties, milestone payments or other benefits under the License and Co-Development Agreement entered into with Novartis.*

We have entered into a License and Co-Development agreement related to OPAXIO and Pixuvri with Novartis pursuant to which Novartis received an exclusive worldwide license for the development and commercialization of OPAXIO and an option to enter into an exclusive worldwide license to develop and commercialize Pixuvri. We will not receive any royalty or milestone payments under this agreement unless Novartis exercises its option related to Pixuvri and we are able to reach a definitive agreement or Novartis elects to participate in the development and commercialization of OPAXIO. Novartis is under no obligation to make such election and enter into a definitive license agreement or exercise such right and may never do so. In addition, even if Novartis exercises such rights, any royalties and milestone payments we may be eligible to receive from Novartis are subject to the receipt of the necessary regulatory approvals and the attainment of certain sales levels. In the event Novartis does not elect to participate in the development of OPAXIO or Pixuvri, we may not be able to find another suitable partner for the commercialization and development of those products, which may have an adverse effect on our ability to bring those drugs to market. In addition, we would need to obtain a release from Novartis prior to entering into any agreement to develop and commercialize Pixuvri or OPAXIO with a third party. As announced on April 9, 2010, we received a Complete Response Letter from the FDA, regarding our NDA for Pixuvri. The FDA cited as its primary reason for the action its concerns previously raised at the ODAC meeting on March 22, 2010 and recommended that we conduct an additional trial to demonstrate the safety and efficacy of Pixuvri. In December 2010, we filed an appeal with the OND's Center for Drug Evaluation and Research regarding the FDA's April 2010 decision to not approve Pixuvri for relapsed/refractory aggressive NHL. We filed our appeal under the FDA's formal dispute resolution process asking the OND to conclude that PIX301 demonstrated efficacy. We are awaiting a decision on our appeal, but we cannot predict or guarantee the outcome of our appeal. We may never receive the necessary regulatory approvals and our products may not reach the necessary sales levels to generate royalty or milestone payments even if Novartis elects to exercise its option with regard to Pixuvri and enter into a definitive license agreement or to participate in the development and commercialization of OPAXIO. Novartis has the right under the agreement in its sole discretion to terminate such agreement at any time upon written notice to us.

*We cannot guarantee that we will obtain regulatory approval to manufacture or market any of our drug candidates.*

Obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and risky. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent regulatory approval.

At the ODAC meeting on March 22, 2010, the ODAC panel did not recommend approval of our NDA for Pixuvri. Subsequently, in April 2010, we received a Complete Response Letter from the FDA regarding our NDA for Pixuvri. The FDA cited as its primary reason for the action its concerns previously raised at the ODAC meeting on March 22, 2010, and recommended that we conduct one additional clinical trial to demonstrate the safety and efficacy of Pixuvri. Moreover, we expect that we will need at least an additional clinical trial to obtain FDA approval of our NDA for Pixuvri and we do not know what this trial will cost or whether the FDA will accept our SPA for this trial. In March 2011, we initiated a randomized pivotal trial of Pixuvri for the treatment of relapsed/refractory DLBCL. This clinical trial, referred to as PIX-R, is now open to patient enrollment. PIX-R will compare a combination of Pixuvri plus rituximab to a combination of gemcitabine plus rituximab in patients with relapsed or refractory DLBCL who have received one to three prior lines of therapy. We cannot predict the outcome of PIX-R or whether PIX-R will serve as either a post-marketing commitment trial or as a pivotal trial. We may also need to take additional steps to obtain regulatory approval of Pixuvri. The expense to design and conduct clinical trials are substantial and any additional clinical trials or actions we may need to pursue to obtain approval of our NDA for Pixuvri may negatively affect our business, financial condition and results of operations.

## [Table of Contents](#)

*We may be delayed, limited or precluded from obtaining regulatory approval of OPAXIO as a maintenance therapy for advanced stage ovarian cancer.*

Our future financial success depends in part on obtaining regulatory approval of OPAXIO. We are currently focusing our development of OPAXIO as a potential maintenance therapy for women with advanced stage ovarian cancer who achieve a complete remission following first-line therapy with paclitaxel and carboplatin. This study, the GOG0212 trial, is under the control of the GOG and is expected to enroll 1,100 patients with 788 patients enrolled as of March 31, 2011. The GOG Data Monitoring Committee plans to conduct an interim analysis of overall survival and based on current enrollment and study duration, the interim analysis could be conducted as early as 2011. If successful, we could utilize those results to form the basis of an NDA for OPAXIO. However, prior clinical trials for OPAXIO have not been successful. In March 2005, we announced the results of STELLAR 3, and in May 2005, we announced the results of STELLAR 2 and 4, our phase III clinical trials of OPAXIO in NSCLC. All three trials failed to achieve their primary endpoints of superior overall survival compared to current marketed agents for treating NSCLC. Accordingly, there can be no assurance that the GOG0212 will provide compelling evidence or any positive results, which would preclude our planned submission of an NDA to the FDA. In addition, we cannot predict the outcome of the GOG0212 study and that study may not demonstrate or be adequate to support regulatory approval of OPAXIO by the FDA.

In March 2008, we submitted an MAA to the EMA for first-line treatment of patients with advanced NSCLC who are poor performance status, or PS2, based on a non-inferior survival and improved side effect profile which we believe was demonstrated in our previous clinical trials. The application was based on a positive opinion we received from the SAWP; the EMA agreed that switching the primary endpoint from superiority to non-inferiority is feasible if the retrospective justification provided in the marketing application is adequate. In September 2009, we notified the EMA of our decision to withdraw the MAA and we refocused our resources on the approval of OPAXIO for its potential superiority indication in maintenance therapy for ovarian cancer and as a radiation sensitizer in the treatment of esophageal cancer.

*We are subject to extensive government regulation.*

We are subject to rigorous and extensive regulation by the FDA in the United States and by comparable agencies in other states and countries, including the EMA's review of our MAA for Pixuvri. Failure to comply with regulatory requirements could result in various adverse consequences, including possible delay in approval or refusal to approve a product, withdrawal of approved products from the market, product seizures, injunctions, regulatory restrictions on our business and sales activities, monetary penalties, or criminal prosecution.

Our products may not be marketed in the United States until they have been approved by the FDA and may not be marketed in other countries until they have received approval from the appropriate agencies. None of our current product candidates have received approval for marketing in any country. On April 13, 2009, we began submission of a rolling NDA to the FDA for Pixuvri to treat relapsed aggressive NHL. We completed the submission in June 2009 and as announced on April 9, 2010, we received a Complete Response Letter from the FDA regarding our NDA for Pixuvri. The FDA cited as its primary reason for the action its concerns previously raised at the ODAC meeting on March 22, 2010 and recommended that we conduct an additional trial to demonstrate the safety and effectiveness of Pixuvri. Based on the FDA's ODAC presentation, which provided ODAC and us with alternative options to consider making investigational drugs available to patients if drugs need to be studied further prior to approval, we will evaluate the establishment of an expanded access program for Pixuvri while we conduct an additional study in aggressive NHL.

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. In addition, data obtained from preclinical and clinical trials are susceptible to varying interpretations, and government regulators and our collaborators may not agree with our interpretation of our clinical trial results. If our products are not approved quickly enough to provide net revenues to defray our debt and operating expenses, our business, financial condition and results of operations will be adversely affected.

## [Table of Contents](#)

In the event that we receive marketing approval for any of our product candidates, we will be subject to numerous regulations and statutes regulating the manner of selling and obtaining reimbursement for those products. For example, federal statutes generally prohibit providing certain discounts and payments to physicians to encourage them to prescribe our product. Violations of such regulations or statutes may result in treble damages, criminal or civil penalties, fines or exclusion of us or our employees from participation in federal and state health care programs. Although we have policies prohibiting violations of relevant regulations and statutes, unauthorized actions of our employees or consultants, or unfavorable interpretations of such regulations or statutes may result in third parties or regulatory agencies bringing legal proceedings or enforcement actions against us. Because we will likely need to develop a new sales force for any future marketed products, we may have a greater risk of such violations from lack of adequate training or experience. The expense to retain and pay legal counsel and consultants to defend against any such proceedings would be substantial, and together with the diversion of management's time and attention to assist in any such defense, may negatively affect our business, financial condition and results of operations.

In addition, both before and after approval, our contract manufacturers and our products are subject to numerous regulatory requirements covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, distribution and export. Manufacturing processes must conform to current Good Manufacturing Practice, or cGMPs. The FDA and other regulatory authorities periodically inspect manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort to maintain compliance. Failure 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.

The marketing and promotion of pharmaceuticals is also heavily regulated, particularly with regard to prohibitions on the promotion of products for off-label uses. In April 2007, we paid a civil penalty of \$10.6 million and entered into a settlement agreement with the United States Attorney's Office for the Western District of Washington arising out of their investigation into certain of our prior marketing practices relating to TRISENOX, which was divested to Cephalon Inc. in July 2005. As part of that settlement agreement and in connection with the acquisition of Zevalin, we also entered into a corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services, which required us to establish a compliance committee and compliance program and adopt a formal code of conduct.

*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 development. We anticipate that we will face increased competition in the future as new companies enter the market. Our competitors in the United States and elsewhere are numerous and include, among others, major multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. Specifically:

- If we are successful in bringing Pixuvri to market, Pixuvri will face competition from currently marketed anthracyclines, such as mitoxantrone (Novantrone®), and new anti-cancer drugs with reduced toxicity that may be developed and marketed.
- If we are successful in bringing OPAXIO to market, we will face direct competition from oncology-focused multinational corporations. OPAXIO will compete with other taxanes. Many oncology-focused multinational corporations currently market or are developing taxanes, epothilones, and other cytotoxic agents, which inhibit cancer cells by a mechanism similar to taxanes, or similar products. Such corporations include, among others, Bristol-Myers Squibb Co. and others, which market paclitaxel and generic forms of paclitaxel; Sanofi-Aventis, which markets docetaxel; Genentech, Roche and OSI Pharmaceuticals, which market Tarceva™; Genentech and Roche, which market Avastin™; Eli Lilly, which markets Alimta®; and Abraxis, which markets Abraxane™. In addition, other companies such as NeoPharm Inc. and Telik, Inc. are also developing products, which could compete with OPAXIO.
- If we are successful in bringing tosedostat to market, we will face direct competition from oncology-focused multinational corporations including Eisai, Sanofi-Aventis, Celgene, and others. Currently some generic compounds are also available which may be used in treating conditions where tosedostat may have application, this could result in additional competitive pressure on price and volume. Additionally there are other products in development for AML from both large and small pharmaceutical companies which may compete with tosedostat.
- If we are successful in bringing brostallicin to market, we will face direct competition from other minor groove binding agents including Yondelis®, which is currently developed by PharmaMar and has received Authorization of Commercialization from the European Commission for soft tissue sarcoma.



## [Table of Contents](#)

Many of our competitors, particularly the multinational pharmaceutical companies, either alone or together with their collaborators, have substantially greater financial resources and substantially larger development and marketing teams than us. In addition, many of our competitors, either alone or together with their collaborators, have significantly greater experience than we do in developing, manufacturing and marketing products. As a result, these companies' products 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 our current or future products would likely suffer and we might never recoup the significant investments we are making to develop these product candidates.

*Uncertainty regarding third-party reimbursement and healthcare cost containment initiatives may limit our returns.*

The ongoing efforts of governmental and third-party payors to contain or reduce the cost of healthcare may affect our ability to commercialize our products successfully. Governmental and other third-party payers continue to attempt to contain healthcare costs by:

- challenging the prices charged for health care products and services;
- limiting both coverage and the amount of reimbursement for new therapeutic products;
- denying or limiting coverage for products that are approved by the FDA but are considered experimental or investigational by third-party payors;
- refusing in some cases to provide coverage when an approved product is used for disease indications in a way that has not received FDA marketing approval; and
- denying coverage altogether.

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. In the United States, given the comprehensive health care reform legislation that the President signed into law on March 23, 2010, under the Patient Protection and Affordable Care Act (HR 3590), or the PPACA, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of healthcare services and products and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of these proposals could significantly influence the purchase of healthcare services and products, resulting in lower prices and reducing demand for our products. In addition, 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 will be determined by national regulatory authorities.

Even if we succeed in bringing any of our proposed products to the market, they may not be considered cost-effective and third-party reimbursement might not be available or sufficient. If adequate third-party coverage is not available, we may not be able to maintain price levels sufficient to realize an appropriate return on our investment in research and product development. In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us before or after any of our proposed products are approved for marketing.

*If users of our products are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not achieve anticipated revenues.*

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as health maintenance organizations, or HMOs. Third-party payers are increasingly challenging the prices charged for medical care. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to further reform health care or reduce government insurance programs, may all result in lower prices for our products if approved for commercialization. The cost containment measures that health care payers and providers are instituting and the effect of any health care reform could materially harm our ability to sell our products at a profit.



## [Table of Contents](#)

*Products that appear promising in research and development may be delayed or fail to reach later stages of development or the market.*

The successful development of pharmaceutical products is highly uncertain and obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and risky. Products that appear promising in research and development may be delayed or fail to reach later stages of development or the market for several reasons, including:

- clinical trial results may show the product to be less effective than desired or to have harmful or problematic side effects;
- preclinical tests may show the product to be toxic or lack efficacy in animal models;
- failure to receive the necessary U.S. and international regulatory approvals or a delay in receiving such approvals;
- difficulties in formulating the product, scaling the manufacturing process or getting approval for manufacturing;
- manufacturing costs, pricing, reimbursement issues or other factors may make the product uneconomical to commercialize;
- other companies or people have or may have proprietary rights to a product candidate, such as patent rights, and will not let the product candidate be sold on reasonable terms, or at all; or
- the product candidate is not cost effective in light of existing therapeutics.

Preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent regulatory approval. In addition, any significant problem in the production of our products, such as the inability of a supplier to provide raw materials or supplies used to manufacture our products, equipment obsolescence, malfunctions or failures, product quality or contamination problems, or changes in regulatory requirements or standards that require modifications to our manufacturing process could delay, limit or prevent regulatory approval which could harm our business, financial condition and results or the trading price of our securities. There can be no assurance as to whether or when we will receive regulatory approvals for our products.

*If any of our license agreements for intellectual property underlying Pixuvri, OPAXIO, tosedostat, brostallicin or any other products are terminated, we may lose the right to develop or market that product.*

We have licensed intellectual property, including patent applications relating to intellectual property for Pixuvri, tosedostat and brostallicin. We have also in-licensed the intellectual property for our drug delivery technology relating to OPAXIO which uses polymers that are linked to drugs, known as polymer-drug conjugates. Some of our product development programs depend on our ability to maintain rights under these licenses. 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.

*If there is an adverse outcome in the securities class actions and shareholder derivative litigation that have been filed against us, our business may be harmed.*

We and certain of our officers and directors are named as defendants in purported securities class actions and shareholder derivative lawsuits filed in the U.S. District Court for the Western District of Washington. These securities class action lawsuits are brought on behalf of a putative class of purchasers of our securities from March 25, 2008 through March 22, 2010, and seek unspecified damages. All of the purported securities class actions have been consolidated into one securities class action, a lead plaintiff has been appointed, and a consolidated amended complaint has been filed. The defendants filed a motion to dismiss the consolidated amended complaint on October 27, 2010. Plaintiffs filed their opposition to the motion on December 3, 2010, and the defendants filed their reply on December 22, 2010. The motion was heard on January 28, 2011. On February 4, 2011, the court issued an order denying in large part the defendants' motion. Defendants have answered and filed affirmative defenses to the Complaint's claims. The court has set a trial date of June 25, 2012 for the securities class action. The currently filed shareholder derivative lawsuits have also been consolidated into one derivative action and co-lead plaintiffs have been appointed. The court ordered the derivative action stayed pending the outcome of the defendants' motion to dismiss in the securities class action. On February 4, 2011, the court lifted the stay. The parties to that action are negotiating a schedule to coordinate activity in that matter with that in the class action discussed above. As with any litigation proceeding, we cannot predict with certainty the eventual outcome of pending litigation. Furthermore, we may have to incur substantial expenses in connection with these lawsuits. In the event of an adverse outcome, our business could be materially harmed.

## [Table of Contents](#)

*If we fail to adequately protect our intellectual property, our competitive position 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 patent protection for our products or processes both in the United States and other countries;
- protect trade secrets; and
- prevent others from infringing on our proprietary rights.

When polymers are linked, or conjugated, to drugs, the results are referred to as polymer-drug conjugates. We are developing drug delivery technology that links chemotherapy to biodegradable polymers. For example, OPAXIO is paclitaxel, the active ingredient in Taxol<sup>®</sup>, one of the world's best selling cancer drugs, linked to polyglutamate. We may not receive a patent for all of our polymer-drug conjugates and we may be challenged by the holder of a patent covering the underlying drug and/or methods for its use or manufacture.

The patent position of biopharmaceutical firms 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 United States 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. 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.

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.

*Our products could infringe 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.*

We attempt to monitor patent filings for patents that may be relevant to our products and product candidates in an effort to guide the design and development of our products to avoid infringement, but have not conducted an exhaustive search. We may not be able to successfully challenge the validity of these 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 a third-party's 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. Even if infringement claims against us are without merit, or if we challenge the validity of issued patents, lawsuits take significant time, may be expensive and may divert management attention from other business concerns.

*We could fail in financing efforts or be delisted from NASDAQ if we fail to receive shareholder approval when needed.*

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 or NASDAQ. Funding of our operations in the future may require issuance of additional equity securities that would comprise more than 20% of the total shares of our common stock outstanding, but we might not be successful in obtaining the required shareholder approval for such an issuance, particularly in light of the difficulties we have experienced in obtaining a quorum and holding shareholder meetings as outlined above. If we are unable to obtain financing due to shareholder approval difficulties, such failure may harm our ability to continue operations.

## [Table of Contents](#)

*We may be unable to obtain the raw materials necessary to produce our OPAXIO product candidate in sufficient quantity to meet demand when and if such product is approved.*

We may not be able to continue to purchase the materials necessary to produce OPAXIO, including paclitaxel, in adequate volume and quality. Paclitaxel is derived from certain varieties of yew trees and the supply of paclitaxel is controlled by a limited number of companies. We purchase the raw materials paclitaxel and polyglutamic acid from single sources. Should the paclitaxel or polyglutamic acid purchased from our sources prove to be insufficient in quantity or quality, should a supplier fail to deliver in a timely fashion or at all, or should these relationships terminate, we may not be able to qualify and obtain a sufficient supply from alternate sources on acceptable terms, or at all.

*We may be unable to obtain the raw materials necessary to produce our tosedostat product candidate in sufficient quantity to meet demand when and if such product is approved.*

We may not be able to obtain the raw materials necessary to produce tosedostat. We currently do not have a firm to manufacture the commercial drug product and drug substance. Should we be unable to identify, negotiate and contract with a manufacturing firm for the commercial drug product and drug substance in sufficient quantity or quality, or should a contracted supplier fail to deliver in a timely fashion or at all, or should these relationships, if any, terminate, we may not be able to qualify and obtain a sufficient supply on acceptable terms, or at all.

*Our dependence on third-party manufacturers means that we do not always have direct control over the manufacture, testing or distribution of our products.*

We do not currently have internal analytical laboratory or manufacturing facilities to allow the testing or production and distribution of drug products in compliance with cGMPs. Because we do not directly control our suppliers, these vendors may not be able to provide us with finished product when we need it.

We will be dependent upon these third parties to supply us in a timely manner with products manufactured in compliance with cGMPs or similar manufacturing standards imposed by United States and/or foreign regulatory authorities where our products will be tested and/or marketed. While the FDA and other regulatory authorities maintain oversight for cGMP compliance of drug manufacturers, contract manufacturers and contract service providers may at times violate cGMPs. The FDA and other regulatory authorities may take action against a contract manufacturer who violates cGMPs. Failure 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.

In addition, one of our other products under development, OPAXIO, has a complex manufacturing process and supply chain, which may prevent us from obtaining a sufficient supply of drug product for the clinical trials and commercial activities currently planned or underway on a timely basis, if at all. The active pharmaceutical ingredients and drug products for Pixuvri and brostallicin are both manufactured by a single vendor. Finished product manufacture and distribution for both Pixuvri and brostallicin are to be manufactured and distributed by different single vendors. We are currently disputing our right to cancel the exclusive manufacturing contract between us and the former manufacturer of Pixuvri. We assert multiple grounds for terminating this exclusive manufacturing agreement, which the former manufacturer disputes. The former manufacturer has asserted that we do not have the right to terminate the manufacturing contracts and has filed a lawsuit in the Court of Milan to compel us to source Pixuvri from that manufacturer. A hearing was held on January 21, 2010 to discuss preliminary matters and set a schedule for future filings and hearings. On November 11, 2010 a hearing was held aimed at examining and discussing the requests for evidence submitted by the parties in the briefs filed pursuant to article 183, paragraph 6 of the Italian code of civil procedure. At the hearing of November 11, the judge declared that the case does not require any discovery or evidentiary phase, as it may be decided on the basis of the documents and pleadings filed by the parties. The judge fixed accordingly the last hearing for October 11, 2012, for the parties to definitively submit to the judge their requests.

*Even if our drug candidates are successful in clinical trials, we may not be able to successfully commercialize them.*

Since our inception in 1991, we have dedicated substantially all of our resources to the research and development of our technologies and related compounds. All of our compounds currently are in research or development, and have not received marketing approval.

Prior to commercialization, each product candidate requires significant research, development and preclinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval. The development of anti-cancer drugs, including those we are currently developing, is unpredictable and subject to

## [Table of Contents](#)

numerous risks. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons including that they may:

- be found ineffective or cause harmful side effects during preclinical testing or clinical trials;
- fail to receive necessary regulatory approvals;
- be difficult to manufacture on a scale necessary for commercialization;
- be uneconomical to produce;
- fail to achieve market acceptance; or
- be precluded from commercialization by proprietary rights of third parties.

The occurrence of any of these events could adversely affect the commercialization of our products. Products, if introduced, may not be successfully marketed and/or may not achieve customer acceptance. 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.

*If we do not successfully develop our product candidates into marketable products, we may be unable to generate significant revenue or become profitable.*

We divested our commercial product, TRISENOX, in July 2005 and fully divested our commercial product, Zevalin, in March 2009. Currently, we do not have a marketed product, and unless we are able to develop one of our product candidates, such as Pixuvri, into an approved commercial product, we will not generate any significant revenues from product sales, royalty payments, license fees or otherwise. Pixuvri, OPAXIO, tosedostat and brostallicin are currently in clinical trials; these clinical trials may not be successful and, even if they are, we may not be successful in developing any of them into a commercial product. For example, our STELLAR phase III clinical trials for OPAXIO for the treatment of non-small cell lung cancer failed to meet their primary endpoints. In addition, 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. We will need to commit significant time and resources to develop these and any additional product candidates. Even if our trials are viewed as successful, we may not get regulatory approval. Our product candidates will be successful only if:

- our product candidates are developed to a stage that will enable us to commercialize them or sell related marketing rights to pharmaceutical companies;
- we are able to commercialize product candidates in clinical development or sell the marketing rights to third parties; and
- our product candidates, if developed, are approved by the regulatory authorities.

We are dependent on the successful completion of these goals in order to generate revenues. The failure to generate such revenues may preclude us from continuing our research and development of these and other product candidates.

*If we are unable to enter into new in-licensing arrangements, our future product portfolio and potential profitability could be harmed.*

One component of our business strategy is in-licensing drug compounds developed by other pharmaceutical and biotechnology companies or academic research laboratories. All of our product candidates in clinical development are in-licensed from a third-party, including Pixuvri, OPAXIO, tosedostat and brostallicin.

Competition for new promising compounds and commercial products can be intense. If we are not able to identify future in-licensing opportunities and enter into future licensing arrangements on acceptable terms, our future product portfolio and potential profitability could be harmed.

*We may take longer to complete our clinical trials than we expect, or we may not be able to complete them at all.*

Before regulatory approval for any potential product can be obtained, we must undertake extensive clinical testing on humans to demonstrate the safety and efficacy of the product. Although for planning purposes we forecast the commencement and completion of clinical trials, the actual timing of these events can vary dramatically due to a number of factors. For example:

## Table of Contents

- we may not obtain authorization to permit product candidates that are already in the preclinical development phase to enter the human clinical testing phase;
- the FDA or the EMA may object to proposed protocols;
- there may be shortages of available product supplies or the materials that are used to manufacture the products;
- the quality or stability of the product candidates may fall below acceptable standards;
- authorized preclinical or clinical testing may require significantly more time, resources or expertise than originally expected to be necessary;
- clinical testing may not show potential products to be safe and efficacious and, as with many drugs, may fail to demonstrate the desired safety and efficacy characteristics in human clinical trials;
- clinical testing may show that potential products are not appropriate for the specific indication for which they are being tested;
- the results from preclinical studies and early clinical trials may not be indicative of the results that will be obtained in later-stage clinical trials;
- we or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks or for other reasons; and
- the rates of patient recruitment and enrollment of patients who meet trial eligibility criteria may be lower than anticipated, which is a function of many factors, including the number of patients with the relevant conditions, the nature of the clinical testing, the proximity of patients to clinical testing centers, the eligibility criteria for tests as well as competition with other clinical testing programs involving the same patient profile but different treatments.

We have limited experience in conducting clinical trials. We expect to continue to rely on third parties, such as contract research organizations, academic institutions and/or cooperative groups, to conduct, oversee and monitor clinical trials as well as to process the clinical results and manage test requests, which may result in delays or failure to complete trials if the third parties fail to perform or to meet the applicable standards.

If we fail to commence, complete, experience delays in any of our present or planned clinical trials or need to perform more or larger clinical trials than planned, our development costs may increase and/or our ability to commercialize our product candidates may be adversely affected. If delays or costs are significant, our financial results and our ability to commercialize our product candidates may be adversely affected.

*If we fail to establish and maintain collaborations or if our partners do not perform, we may be unable to develop and commercialize our product candidates.*

We have entered into collaborative arrangements with third-parties to develop and/or commercialize product candidates and are currently seeking additional collaborations. For example, we entered into an agreement with the GOG to perform a phase III trial of OPAXIO in patients with ovarian cancer. Additional collaborations might be necessary in order for us to fund our research and development activities and third-party manufacturing arrangements, seek and obtain regulatory approvals and successfully commercialize our existing and future product candidates. If we fail to enter into additional collaborative arrangements or fail to maintain our existing collaborative arrangements, the number of product candidates from which we could receive future revenues would decline. For example, in 2005 we sold our product TRISENOX to Cephalon and, pursuant to the terms of the purchase agreement under which TRISENOX was sold, we are entitled to receive milestone payments upon the approval by the FDA of new labeled uses for TRISENOX; however, Cephalon may decide not to submit any additional information to the FDA to apply for label expansion of TRISENOX, in which case we would not receive a milestone payment under the agreement.

Our dependence on collaborative arrangements with third parties will subject us to a number of risks that could harm our ability to develop and commercialize products, including that:

- collaborative arrangements may not be on terms favorable to us;
- disagreements with partners may result in delays in the development and marketing of products, termination of our collaboration agreements or time consuming and expensive legal action;

## [Table of Contents](#)

- we cannot control the amount and timing of resources partners devote to product candidates or their prioritization of product candidates and partners may not allocate sufficient funds or resources to the development, promotion or marketing of our products, or may not perform their obligations as expected;
- partners may choose to develop, independently or with other companies, alternative products or treatments, including products or treatments which compete with ours;
- agreements with partners may expire or be terminated without renewal, or partners may breach collaboration agreements with us;
- business combinations or significant changes in a partner's business strategy might adversely affect that partner's willingness or ability to complete its obligations to us; and
- the terms and conditions of the relevant agreements may no longer be suitable.

The occurrence of any of these events could adversely affect the development or commercialization of our products.

*Because we base several of our drug candidates on unproven technologies, we may never develop them into commercial products.*

We base several of our product candidates upon novel technologies that we are using to develop drugs for the treatment of cancer. These technologies have not been proven. Furthermore, preclinical results in animal studies may not predict outcomes in human clinical trials. Our product candidates may not be proven safe or effective. If these technologies do not work, our drug candidates will not develop into commercial products.

*Because there is a risk of product liability associated with our products, we face potential difficulties in obtaining insurance.*

Our business exposes us to potential product liability risks inherent in the testing, manufacturing and marketing of human pharmaceutical products, and we may not be able to avoid significant product liability exposure. While we have insurance covering the product use in our clinical trials for our product candidates, it is possible that we will not be able to maintain such insurance on acceptable terms or that any insurance obtained will not provide 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 in excess of our insurance coverage could exceed our net worth.

*Since we use hazardous materials in our business, we may be subject to claims relating to improper handling, storage or disposal of these materials.*

Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to international, federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by the 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 laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

*We may not be able to conduct animal testing in the future, which could harm our research and development activities.*

Certain of our research and development activities involve animal testing. Such activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting activities through protests and other means. To the extent the activities of these groups are successful, our business could be materially harmed by delaying or interrupting our research and development activities.

## [Table of Contents](#)

*The unfavorable outcome of litigation and other claims against us could harm our financial condition and results of operations.*

We are subject to a variety of claims and lawsuits from time to time, some of which arise in the ordinary course of our business. Adverse outcomes in some or all of such pending cases may result in significant monetary damages or injunctive relief against us. While we currently believe that resolution of these matters, individually or in the aggregate, will not have a material adverse impact on our financial position, results of operations or trading price of our securities, the ultimate outcome of litigation and other claims is subject to inherent uncertainties, and our view of these matters may change in the future. It is possible that our financial condition and results of operations could be harmed in any period in which the effect of an unfavorable final outcome becomes probable and reasonably estimable.

*Our financial condition and results of operations could be adversely affected by public health issues, wars and other military action, as well as terrorist attacks and threats and government responses thereto, especially if any such actions were directed at us or our facilities or customers.*

Public health issues, terrorist attacks in the United States and elsewhere, government responses thereto, and military actions in Iraq, Afghanistan and elsewhere, may disrupt our operations or those of our customers and suppliers and may affect the availability of materials needed to manufacture our products or the means to transport those materials to manufacturing facilities and finished products to customers. A health pandemic could cause damage or disruption to international commerce by creating economic and political uncertainties that may have a strong negative impact on the global economy, us, and our customers or suppliers. Should a severe public health issue arise, we could be negatively impacted by the need for more stringent employee travel restrictions, additional limitations in the availability of freight services, governmental actions limiting the movement of products between various regions and disruptions in the operations of our customers or suppliers. The long-term effects of public health issues, the terrorist attacks, and the ongoing war on terrorism on our business and on the global economy remain unknown. In addition, any of these events could increase volatility in the United States and world financial markets which may depress the price of our common stock and may limit the capital resources available to us or our customers or suppliers, which could result in decreased orders from customers, less favorable financing terms from suppliers, and scarcity or increased costs of materials and components of our products. Additionally, terrorist attacks directly upon us may significantly disrupt our ability to conduct our business. Any of these occurrences could have a significant impact on our operating results, revenues and costs and may result in increased volatility of the trading price of our securities.

*Higher health care costs could adversely affect our business.*

We will be impacted by the recent passage of the PPACA. Under the PPACA, we may be required to amend our health care plans to, among other things, provide affordable coverage, as defined in the PPACA, to all employees, or otherwise be subject to a payment per employee based on the affordability criteria in the Act: cover adult children of our employees to age 26; delete lifetime limits; and delete pre-existing condition limitations. Many of these requirements will be phased in over a period of time. Additionally, some states and localities have passed state and local laws mandating the provision of certain levels of health benefits by some employers. Increased health care costs could harm our business, financial condition and results of operations.

### **Risks Related To the Securities Markets**

*The market price 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 24 month period ended April 22, 2011, our stock price has ranged from a low of \$0.12 to a high of \$2.23. Fluctuations in the trading price or liquidity of our common stock may adversely affect the value of your investment in our common stock.

Factors that may have a significant impact on the market price and marketability of our securities include:

- announcements by us or others of results of preclinical testing and clinical trials and regulatory actions;
- announcements of technological innovations or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;

## [Table of Contents](#)

- our issuance of additional debt, equity or other securities, which we need to pursue in 2011 to generate additional funds to cover our current debt and operating expenses;
- our quarterly operating results;
- developments or disputes concerning patent or other proprietary rights;
- developments in our relationships with collaborative partners;
- acquisitions or divestitures;
- litigation and government proceedings;
- adverse legislation, including changes in governmental regulation;
- third-party reimbursement policies;
- changes in securities analysts' recommendations;
- short selling;
- changes in health care policies and practices;
- halting or suspension of trading in our common stock by NASDAQ, CONSOB or the Borsa Italiana;
- economic and other external factors; and
- general market conditions.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. For example, in the case of our company, we and certain of our officers and directors are named as defendants in purported securities class action and shareholder derivative lawsuits brought on behalf of a putative class of purchasers of our securities from March 25, 2008 through March 22, 2010. These lawsuits seek unspecified damages and, as with any litigation proceeding, we cannot predict with certainty the eventual outcome of pending litigation. Furthermore, we may have to incur substantial expenses in connection with these lawsuits and our management's attention and resources could be diverted from operating our business as we respond to the litigation. We maintain significant insurance to cover these risks for us and our directors and officers, but our insurance is subject to high deductibles to reduce premium expense, 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.

*Shares of common stock are equity securities and are subordinate to our existing and future indebtedness.*

Shares of our common stock are common equity interests. This means that our common stock ranks junior to any preferred stock that we may issue in the future, to our indebtedness and 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 existing and future indebtedness and our preferred stock may restrict payment of dividends on our common stock.

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 shareholders generally.

*The market price of our common stock may be adversely affected by market conditions affecting the stock markets in general, including price and trading fluctuations on The NASDAQ Capital Market.*

The market price of our common stock may be adversely affected by market conditions affecting the stock markets in general, including price and trading fluctuations on The NASDAQ Capital Market. These conditions may result in (i) volatility in the level of, and fluctuations in, the market prices of stocks generally and, in turn, our shares of common stock, and (ii) sales of substantial amounts of our common stock in the market, in each case that could be unrelated or disproportionate to changes in our operating performance.



## [Table of Contents](#)

*There may be future sales or other dilution of our equity, which may adversely affect the market price of shares of our common stock.*

We are not restricted from issuing additional shares of common stock or preferred stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, shares of common stock or preferred stock or any substantially similar securities. The market price of our shares of common stock or preferred stock could decline as a result of sales of a large number of shares of our common stock or preferred stock or similar securities in the market, or the perception that such sales could occur in the future.

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

Provisions of our amended and restated articles of incorporation and amended and restated 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:

- a classified board so that only approximately one third of our board of directors is elected each year;
- 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 amended and restated 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 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, deferring 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 law which imposes restrictions on some transactions between a corporation and certain significant shareholders. These 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**

None.

### **Item 3. Defaults Upon Senior Securities**

None.

### **Item 4. (Removed and Reserved)**

### **Item 5. Other Information**

Not applicable.

**Item 6. Exhibits**

(a) Exhibits

- 3.1 Registrant's Amended and Restated Articles of Incorporation (incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-3 (File No. 333-153358), filed on September 5, 2008).
- 3.2 Registrant's Articles of Amendment to Amended and Restated Articles of Incorporation, Designation of Preferences, Rights and Limitations of Series F Preferred Stock (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on February 9, 2009).
- 3.3 Registrant's Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on March 27, 2009).
- 3.4 Registrant's Articles of Amendment to Amended and Restated Articles of Incorporation, Designation of Preferences, Rights and Limitations of Series 1 Preferred Stock (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on April 13, 2009).
- 3.5 Registrant's Articles of Amendment to Amended and Restated Articles of Incorporation, Designation of Preferences, Rights and Limitations of Series 2 Preferred Stock (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on August 21, 2009).
- 3.6 Registrant's Articles of Amendment to Amended and Restated Articles of Incorporation, Certificate of Designation, Preferences and Rights of Series ZZ Junior Participating Cumulative Preferred Stock (incorporated by reference to the exhibits to the Registrant's Registration Statement on Form 8-A, filed on December 28, 2009).
- 3.7 Registrant's Articles of Amendment to Amended and Restated Articles of Incorporation, Designation of Preferences, Rights and Limitations of Series 3 Preferred Stock (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on January 19, 2010).
- 3.8 Registrant's Articles of Amendment to Amended and Restated Articles of Incorporation, Designation of Preferences, Rights and Limitations of Series 4 Preferred Stock (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on April 5, 2010).
- 3.9 Registrant's Articles of Amendment to Amended and Restated Articles of Incorporation, Designation of Preferences, Rights and Limitations of Series 5 Preferred Stock (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on May 27, 2010).
- 3.10 Registrant's Articles of Amendment to Amended and Restated Articles of Incorporation, Designation of Preferences, Rights and Limitations of Series 6 Preferred Stock (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on July 27, 2010).
- 3.11 Registrant's Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on September 17, 2010).
- 3.12 Registrant's Articles of Amendment to Amended and Restated Articles of Incorporation, Designation of Preferences, Rights and Limitations of Series 7 Preferred Stock (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on October 22, 2010).
- 3.13 Registrant's Articles of Amendment to Amended and Restated Articles of Incorporation, Designation of Preferences, Rights and Limitations of Series 8 Preferred Stock (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on January 18, 2011).
- 3.14 Registrant's Articles of Amendment to Amended and Restated Articles of Incorporation, Designation of Preferences, Rights and Limitations of Series 9 Preferred Stock (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on January 18, 2011).

## Table of Contents

- 3.15 Registrant's Articles of Amendment to Amended and Restated Articles of Incorporation, Designation of Preferences, Rights and Limitations of Series 10 Preferred Stock (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on February 24, 2011).
- 3.16 Registrant's Articles of Amendment to Amended and Restated Articles of Incorporation, Designation of Preferences, Rights and Limitations of Series 11 Preferred Stock (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on February 24, 2011).
- 3.17 Registrant's Second Amended and Restated Bylaws (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on February 22, 2010).
- 4.1 Form of Series 8 Preferred Stock Certificate (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on January 18, 2011).
- 4.2 Form of Common Stock Purchase Warrant, dated January 12, 2011 (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on January 18, 2011).
- 4.3 Form of Series 9 Preferred Stock Certificate (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on January 18, 2011).
- 4.4 Form of Series 10 Preferred Stock Certificate (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on February 24, 2011).
- 4.5 Form of Common Stock Purchase Warrant, dated February 17, 2011 (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on February 24, 2011).
- 4.6 Form of Series 11 Preferred Stock Certificate (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on February 24, 2011).
- 10.1† License and Co-Development, dated September 15, 2006, by and among the Registrant, Cell Therapeutics Europe S.r.l. and Novartis International Pharmaceutical Ltd. (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on September 18, 2006).
- 10.2 Form of Securities Purchase Agreement, dated January 12, 2011 (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on January 18, 2011).
- 10.3 Form of Securities Purchase Agreement, dated February 17, 2011 (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on February 24, 2011).
- 10.4 Employment Agreement, dated March 10, 2011, between the Registrant and James A. Bianco, M.D. (incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on March 15, 2011).
- 10.5† Co-Development and License Agreement, dated March 11, 2011, by and between Chroma Therapeutics Ltd. and the Registrant.\*
- 10.6 Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement for Employees.\*
- 10.7 Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement for Directors.\*
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*
- 32 Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*

\* Filed herewith.

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



\*\* 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.

Execution Copy

## CO-DEVELOPMENT AND LICENSE AGREEMENT

This **CO-DEVELOPMENT AND LICENSE AGREEMENT** (the “**Agreement**”) is entered into as of March 11, 2011 (the “**Effective Date**”) by and between **CELL THERAPEUTICS, INC.**, a Washington corporation, with its principal place of business at 501 Elliott Ave. W. #400, Seattle, Washington 98119, U.S.A. (“**CTI**”), and **CHROMA THERAPEUTICS LTD**, a company registered under the laws of England and Wales, with its principal place of business at 93 Milton Park, Abingdon, Oxon OX14 4RY, UK (“**Chroma**”). Chroma and CTI are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties.**”

### RECITALS

**WHEREAS**, Chroma is developing its proprietary Tosedostat product for cancer;

**WHEREAS**, CTI possesses substantial resources and expertise in the development, marketing, and commercialization of pharmaceutical products for the treatment of cancer in the Licensed Territory (as defined below); and

**WHEREAS**, CTI desires to collaborate with Chroma on the further development of the Product (as defined below) in the Field (as defined below) through regulatory approval in the Licensed Territory, and to obtain commercialization rights to the Product in the Field in the Licensed Territory, and Chroma is willing to so collaborate and to grant such rights on the terms and conditions hereof.

**NOW THEREFORE**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

### ARTICLE 1

#### DEFINITIONS

**1.1 “Accounting Standards”** means US GAAP (United States Generally Accepted Accounting Principles) as generally and consistently applied throughout each Party’s organization.

**1.2 “Additional Product”** means any (a) new formulation, dosage form, improvement, or mode of administration of the Compound, or (b) pharmaceutical composition that contains a derivative or modified form of the Compound including those analogues of the Compound with the structures set forth in Exhibit A-2.

\*\* 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.

**1.3 “Additional Studies”** means, other than the Currently Ongoing Studies, Licensed Territory Specific Studies, Extraterritorial Studies, and studies that can be both an Extraterritorial Study and a Licensed Territory Specific Study agreed to be conducted by the Parties as part of the Development Plan under the terms and conditions of this Agreement.

**1.4 “Affiliate”** means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word “control” (including, with correlative meaning, the terms “controlled by” or “under the common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, or by contract or otherwise.

**1.5 “Agreement”** has the meaning set forth in the preamble.

**1.6 “Applicable Transaction”** has the meaning set forth in Section 9.2(a).

**1.7 “Approval Date”** has the meaning set forth in Section 15.9.

**1.8 “Audited Party”** has the meaning set forth in Section 4.3(d).

**1.9 “Best Knowledge”** means, as applied to a Party, that the applicable Party’s senior management with operational responsibility for the Development or Commercialization of the Product is actually aware of a particular fact or other matter following reasonably diligent inquiry of its management employees with primary responsibility for the applicable subject matter.

**1.10 “Chroma”** has the meaning set forth in the preamble.

**1.11 “Chroma Indemnitees”** has the meaning set forth in Section 11.2.

**1.12 “Chroma Know-How”** means all Know-How that is Controlled by Chroma or its Affiliates as of the Effective Date or during the Term and is necessary or reasonably useful for the Development or Commercialization of the Product in the Field in accordance with the terms of this Agreement. For clarity, Chroma Know-How includes Know-How relating to previously conducted Non-Clinical Studies for the Product, Past Studies, and Currently Ongoing Studies, but excludes Information contained within the Chroma Patents. Chroma Know-How shall not include any rights to any independent Know-How of any Third Party entity which obtains “control” (as defined in the definition of Affiliate) of Chroma after the Effective Date, provided that (i) such transaction is not entered into in an effort to circumvent the license granted under this Agreement and (ii) any Know-How constituting “Chroma Know-How” immediately prior to such acquisition of “control”, or would become “Chroma Know-How” but for such acquisition of “control”, shall continue to be licensed under the terms of this Agreement.

\*\* 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.

**1.13 “Chroma Patents”** means any Patent that (a) is Controlled by Chroma or its Affiliates as of the Effective Date or at any time during the Term (including any Patent arising from Chroma’s Sole Inventions but excluding Joint Patents), and (b) would, but for the license granted by Chroma hereunder, be infringed by the Development, Manufacture, have manufacture, use, sale, offer for sale, having sold, distribution, import, or any other Commercialization of the Product by or on behalf of CTI or its sublicensee(s) in the Field. Chroma Patents shall include without limitation those Patents listed on Exhibits B-1 and the Manufacturing Patent (except that the Manufacturing Patent will be licensed non-exclusively to CTI under the terms of Section 2.1(a)(ii)), and any patent issuing from an application claiming priority thereto or otherwise continuing therefrom. “Chroma Patents” shall not include any rights to any independent Patents of any Third Party entity which acquires “control” (as defined in the definition of Affiliate) of Chroma after the Effective Date, provided that (i) such transaction is not entered into in an effort to circumvent the license granted under this Agreement and (ii) any Patents constituting “Chroma Patents” immediately prior to such acquisition of “control”, or would become “Chroma Patents” but for such acquisition of “control”, shall continue to be licensed under the terms of this Agreement.

**1.14 “Chroma Technology”** means the Chroma Patents and Chroma Know-How.

**1.15 “Claims”** has the meaning set forth in Section 11.1.

**1.16 “CMC”** means chemistry, manufacturing and controls as specified by the FDA.

**1.17 “Commercial Information”** means sales call activity reports, listing of major accounts including addresses, lists and contact details of distributors and volume of sales activity over the preceding twelve (12) months, list of reimbursement assistance vendors and contact details, list of ongoing investigator sponsored trials including study title and location, managed care and HMO agreements and contact lists, copies of current sales promotional material as well as master production materials, any other similar general information that is solely related to the Commercialization of the Product in the Licensed Territory. Commercial Information expressly excludes any proprietary CTI Know-How. For the avoidance of doubt, no rights under Patents Controlled by CTI are licensed to Chroma in connection with any provision of Commercial Information to Chroma under this Agreement.

**1.18 “Commercialization,”** with a correlative meaning for “Commercialize” and “Commercializing,” means all activities undertaken before and after obtaining Regulatory Approvals relating specifically to the pre-launch, launch, promotion, Detailing, medical education and medical liaison activities, publication, marketing, pricing, reimbursement, sale, offering for sale, distribution and import of the Product, including: (a) strategic marketing, sales force detailing, advertising, medical education and liaison, and market and Product support; and (b) all customer support, Product distribution, invoicing and sales activities.

**1.19 “Commercialization Sublicensee”** means any Third Party to which CTI or its Affiliate sublicenses its rights under Sections 2.1(a)(i) and 2.1(a)(ii).

\*\* 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.

**1.20 “Committee”** has the meaning set forth in Section 3.3(a).

**1.21 “Competing Product”** means any product, other than the Product, containing tosedostat as an active ingredient, or any other product which has as its primary mode of action the inhibition of aminopeptidases.

**1.22 “Compound”** means tosedostat (designated by Chroma as CHR-2797), which has the structure set forth on Exhibit A-1, its prodrugs and metabolites, as well as its and their acids, bases, isomers, enantiomers, esters, salts, hydrates, solvates and polymorphs, in any dosage form or form of administration.

**1.23 “Confidential Information”** means, with respect to a Party, all non-public Information of such Party that is disclosed to the other Party under this Agreement, whether in oral, written, graphic, or electronic form. All non-public Information disclosed by either Party pursuant to the Mutual Confidential Disclosure Agreement between the Parties dated October 1, 2010 (the “**CDA**”), or the Non-binding Proposal for the Licensing of Tosedostat dated February 2, 2011, shall be deemed to be such Party’s Confidential Information disclosed hereunder.

**1.24 “Control”** means, with respect to any material, Know-How, or intellectual property right, that a Party (a) owns or (b) has a license to such material, Know-How, or intellectual property right and, in each case, has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other arrangement with any Third Party.

**1.25 “Corresponding Share”** has the meaning set forth in Section 4.4(b).

**1.26 “CTI”** has the meaning set forth in the preamble.

**1.27 “CTI Indemnitees”** has the meaning set forth in Section 11.1.

**1.28 “Currently Ongoing Studies”** means, collectively, the following clinical studies: (a) “Extension Study With Tosedostat in Relapsed/Refractory Acute Myeloid Leukemia”; NCT01180426 [Recruiting], and (b) “Safety and Anti-Disease Activity of Oral Tosedostat (CHR-2797) in Elderly Subjects With Refractory or Relapsed AML (OPAL)”, NCT00780598 [Active, not recruiting], and (c) “A program of randomized phase II multicenter studies to assess the tolerability and efficacy of the addition of new drugs to standard induction chemotherapy in AML and RAEB  $\geq$  66 years and very poor risk AML  $\geq$  18 years”, Hovon 103, 2009-014455-68 [Recruiting].

**1.29 “Defaulting Party”** has the meaning set forth in Section 13.3.

**1.30 “Designated Executive”** has the meaning set forth in Section 3.1(b).



\*\* 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.

**1.31 “Detail”** means a face-to-face or electronic presentation and any associated in-service training regarding the features of the Product by a Party’s sales representative to one or several medical professional(s) having prescribing authority in the Field (including pharmacists), as well as to other individuals or entities that have significant impact or influence on prescribing decisions in the Field.

**1.32 “Develop” or “Development”** means all research and development activities relating to preparing and conducting and documenting Non-Clinical Studies, human clinical studies, CMC development and regulatory activities (*e.g.*, regulatory applications) with respect to the Product.

**1.33 “Development Budget”** means the binding annual budget for the Development activities to be undertaken by the Parties under the Development Plan, which Development Budget shall be included in and based on the then-current Development Plan.

**1.34 “Development Costs”** means reasonable expenses and other costs, including external regulatory expenses, directly incurred by or on behalf of a Party in connection with the Development activities to be undertaken by the Parties in accordance with the approved Development Plan and Development Budget, including, without limitation, the external costs of clinical trials, the preparation, collation and/or validation of data from such clinical trials and the preparation of medical writing and publishing, but excluding any Indirect Costs and any costs of external fees related to the filing of Regulatory Materials. Without limitation of the generality of the foregoing, Development Costs shall include:

(a) all Out-of-Pocket Costs incurred by the Parties or their Affiliates;

(b) the cost of clinical supply, including without limitation (i) costs of clinical supplies of Product, (ii) expenses incurred to purchase and/or package comparator drugs, and (iii) costs and expenses of disposal of clinical samples; and

(c) the costs of consultation and pre-submission meetings with Regulatory Authorities, including any costs related to pharmacovigilance, to the extent such costs are to be considered Development Costs in accordance with the Development Plan.

**1.35 “Development Designee”** means a Third Party appointed by a Party to conduct Development activities on behalf of such Party as permitted under Section 4.6.

**1.36 “Development Documentation”** means all Development Information for the Product, including any documentation containing test data for the Product (including pharmacological, biological, chemical, biochemical, clinical study data and data resulting from Non-Clinical Studies), Regulatory Materials, CMC information, drug master files, stability data, and other manufacturing or study data for the Product.

**1.37 “Development Plan”** has the meaning set forth in Section 4.3(a). For clarity, the Development Plan includes the Initial Development Plan as well as any amendments or updates

\*\* 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.

thereto provided under the terms and conditions of this Agreement, including those provided under Sections 4.3(a)(iii), 4.4, and 4.9.

**1.38 “Diligent Efforts”** means, with respect to a Party’s obligation under this Agreement to Develop or Commercialize the Product, efforts and resources which would normally be used by a pharmaceutical company in the pharmaceutical industry for a product owned by or licensed to it, and activities related to the development and commercialization of such product, which is of similar commercial potential at a similar stage in its development or product lifecycle, taking into account various issues, such as its safety and efficacy, product profile, cost to develop, cost and availability of supply, the time required to complete development, the competitiveness of the marketplace, the company’s patent position with respect to such product (including the company’s ability to obtain or enforce, or have obtained or enforced, such patent rights), the third-party patent landscape relevant to the product, the regulatory structure involved, the likelihood of regulatory approval, the anticipated or actual profitability of the applicable product, and all other relevant factors, all as measured by the facts and circumstances at the time such efforts are due provided that in relation to CTI’s obligations under this Agreement CTI shall not be entitled to factor in sums owed to Chroma under this Agreement or any sums due to any Third Party licensor of Intellectual Property which CTI licenses and is used in relation to the Product.

**1.39 “Dollar”** means a U.S. dollar, and “\$” shall be interpreted accordingly.

**1.40 “Effective Date”** has the meaning set forth in the preamble.

**1.41 “Effective Date of Termination”** means the date that this Agreement is terminated under the terms of any of Section 13.2, 13.3, 13.4 or 13.5, as applicable, including the expiration of any cure period or dispute resolution provided thereunder.

**1.42 “Executive Steering Committee” or “ESC”** means the committee formed by the Parties as described in Section 3.1.

**1.43 “Extraterritorial Studies”** means all Non-Clinical Studies and clinical studies wheresoever conducted during the Term, whether conducted prior to or following Regulatory Approval of the Product, pertaining to the Regulatory Approval of the Product in the Field solely for the ROW Territory including: Phase 1, 2, 3 or 4 Clinical Studies or pivotal studies (including studies for additional indications or label expansion); investigator-sponsored trials, safety or surveillance studies; pharmacoeconomic studies; pharmacoepidemiology studies; reimbursement studies; and other studies.

**1.44 “FDA”** means the U.S. Food and Drug Administration or any successor entity.

**1.45 “FD&C Act”** means the U.S. Federal Food, Drug and Cosmetic Act, as amended.

**1.46 “Field”** means cancer therapy (including, without limitation, tumor metastasis and growth).

\*\* 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.

**1.47 “First Commercial Sale”** means the first sale to a Third Party of a Product in a given regulatory jurisdiction after Regulatory Approval has been obtained in such jurisdiction, excluding any pre-regulatory named patient sales, expanded access sales or MTA sales.

**1.48 “First Line”** means use of the Product as the initial treatment for a given condition or indication.

**1.49 “Funding Cap”** has the meaning set forth in Section 4.3(b)(iii).

**1.50 “Generic Version”** has the meaning set forth in Section 8.4(c).

**1.51 “Good Clinical Practices” or “GCP”** means the then-current standards, practices and procedures for good clinical practice promulgated or endorsed or required by the Regulatory Authority in the Licensed Territory and the ROW Territory as applicable including by the FDA as set forth in the guidelines entitled “Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance,” including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures in jurisdictions outside the U.S. including the European Union, as they may be updated from time to time, including applicable quality guidelines promulgated under the International Conference on Harmonization (“ICH”).

**1.52 “Good Laboratory Practices” or “GLP”** means the then-current good laboratory practice standards promulgated or endorsed or required by the Regulatory Authority in the Licensed Territory and the ROW Territory as applicable including by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards in jurisdictions outside the U.S. including the European Union, as they may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

**1.53 “Good Manufacturing Practices,” “cGMP” or “GMP”** means the then-current good manufacturing practices as required by the Regulatory Authority in the Licensed Territory and ROW Territory, as applicable, including by the FDA as defined in the U.S. Current Good Manufacturing Practices, 21 CFR Parts 210 and 211 including related regulatory requirements imposed by the FDA for the manufacture and testing of pharmaceutical materials, and comparable regulatory standards in jurisdictions outside the U.S. including the European Union, as they may be updated from time to time, including applicable quality guidelines promulgated under the ICH and other applicable regulations.

**1.54 “Governmental Authority”** means any multi-national, federal, state, local, municipal, provincial or other government authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

**1.55 “HSR Filing Date”** has the meaning set forth in Section 15.9.

**1.56 “IND”** means (a) an Investigational New Drug application as defined in the FD&C Act and applicable regulations promulgated hereunder by the FDA, or (b) the equivalent

\*\* 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.

application to the equivalent Governmental Authority in any other regulatory jurisdiction outside the U.S., the filing of which is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

**1.57 “Indemnified Party”** has the meaning set forth in Section 11.3.

**1.58 “Indemnifying Party”** has the meaning set forth in Section 11.3.

**1.59 “Indirect Costs”** means any indirect costs and expenses incurred by either Party, including internal personnel costs (such as compensation and benefits) or other internal overhead costs, rental expenses, lease expenses, utilities, travel and depreciation.

**1.60 “Information”** means any data, results, technology, business and financial information and information of any type whatsoever, in any tangible or intangible form, including, without limitation, specifications, software, algorithms, marketing reports, test data (including pharmacological, biological, chemical, biochemical, clinical study data and data resulting from Non-Clinical Studies), CMC information, stability data, and other study data.

**1.61 “Initial Development Plan”** has the meaning set forth in Section 4.3(a)(ii).

**1.62 “Initial Notice”** has the meaning set forth in Section 9.2(a).

**1.63 “Initial Period”** has the meaning set forth in Section 9.2(a).

**1.64 “Initiation”** of a clinical trial shall mean the first dosing of the first patient in such trial.

**1.65 “Joint Development Committee”** or **“JDC”** means the committee formed by the Parties as described in Section 3.2.

**1.66 “Joint Inventions”** has the meaning set forth in Section 9.1.

**1.67 “Joint Patent”** has the meaning set forth in Section 9.4(b).

**1.68 “Know-How”** means all technical Information and know-how, including inventions, discoveries, trade secrets, instructions, processes, formulae, materials, expertise and other technology applicable to formulations, compositions, products or 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 Materials and copies thereof, relevant to the Development, Manufacture, use or Commercialization of and/or which may be useful in studying, testing, Development, production or formulation of products, or intermediates for the synthesis thereof.

\*\* 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.

**1.69 “Laws”** means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign, including without limitation 21 CFR part 54, HIPAA.

**1.70 “Licensed Territory”** means North, Central and South Americas, including their respective territories and possessions. This includes, without limitation, the United States, Canada, Mexico, Brazil, Argentina, Venezuela and their respective territories and possessions.

**1.71 “Licensed Territory Specific Studies”** means all Non-Clinical Studies and clinical studies wheresoever conducted during the Term, whether conducted prior to or following Regulatory Approval of the Product, pertaining to the Regulatory Approval of the Product in the Field solely for the Licensed Territory including; Phase 1, 2, 3, 4 Clinical Studies or pivotal studies (including studies for additional indications or label expansions; investigator sponsored trials, safety or surveillance studies, pharmaco-economic studies; pharmacoepidemiology studies, reimbursement studies; and other studies.

**1.72 “Manufacture”** with a correlative meaning for **“Manufacturing,”** means all activities related to the manufacturing of a pharmaceutical product, or any ingredient thereof, including manufacturing Product in finished form for Development, manufacturing finished Product for Commercialization, packaging, in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of product, all stability studies including those for registration, the development and validation of testing methods used for, but not limited to, release test, stability test and every testing method for commercial use, preparation of the documents of any “Manufacture” related reports in “common technical document” form described in the ICH guidelines, and documents necessary for clinical and market authorization development including but not limited to development history reports for drug substance and drug product, comparability studies and reports, in the Licensed Territory and ROW Territory and regulatory activities related to any of the foregoing.

**1.73 “Manufacturing Patent”** means US Patent 5,912,360.

**1.74 “Marketing Authorization Application”** or **“MAA”** means an application to the appropriate Regulatory Authority for approval to market the Product (but excluding pricing approval) in any particular jurisdiction.

**1.75 “Meetings”** has the meaning set forth in Section 6.8.

**1.76 “NDA”** means a New Drug Application in the United States for authorization for marketing of a pharmaceutical product, as defined in the applicable Laws and filed with the FDA.

**1.77 “Negotiation Period”** has the meaning set forth in Section 9.2(a).

\*\* 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.

**1.78 “Net Sales”** means, with respect to a particular time period, the total amounts invoiced by CTI, its Affiliates and their respective sublicensees for sales of Products made during such time period to unaffiliated Third Parties, less the following deductions in each case to the extent reasonable and customary and actually allowed or incurred with respect to such sales:

- (a) \*\*;
- (b) \*\*;
- (c) \*\*;
- (d) \*\*;
- (e) \*\*;
- (f) \*\*; and
- (g) \*\*.

Notwithstanding the foregoing, amounts invoiced by CTI, its Affiliates, or their sublicensees for the sale of Product among CTI, its Affiliates or their respective sublicensees for resale shall not be included in the computation of Net Sales hereunder and such amounts shall be accounted for only once. For purposes of determining Net Sales, a “sale” shall not include reasonable transfers or dispositions, at no cost, as samples or for charitable purposes, or transfers or dispositions at no cost for Non-Clinical Studies, clinical or regulatory purposes. Net Sales shall be accounted for in accordance with standard CTI practices for operation by CTI, its Affiliates or sublicensees, as practiced in the relevant country in the Licensed Territory, but in any event in accordance with Accounting Standards, consistently applied in such country in the Licensed Territory. Product sales are recognized when persuasive evidence of an arrangement with a Third Party at a fixed or determinable price exists, title and risk of loss has passed to the Third Party (generally upon receipt by the Third Party, and collectability of amounts billed is reasonably assured). Provisions for \*\* shall be recorded at the time of sale.

**1.79 “Non-Clinical Studies”** means *in vivo* animal or *in vitro* pharmacology, pharmacokinetic, or toxicology testing.

**1.80 “Non-Defaulting Party”** has the meaning set forth in Section 13.3.

**1.81 “Non-Opted In Additional Product Development”** has the meaning set forth in Section 4.9(a).

**1.82 “Non-Opted In Study”** has the meaning set forth in Section 4.4(a).

**1.83 “Non-Proposing Party”** has the meaning set forth in Section 4.4(a).

\*\* 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.

**1.84 “Out-of-Pocket Costs”** means reasonable, direct and documented expenses paid to Third Parties and specifically identifiable and incurred in connection with the Development of the Product. Such expenses shall have been recorded as income statement items in accordance with the applicable Accounting Standards and, for the avoidance of doubt, shall not include \*\*.

**1.85 “Party” and “Parties”** has the meaning set forth in the preamble.

**1.86 “Past Studies”** means, collectively, the following clinical studies that have been completed or terminated prior to the Effective Date: (a) “Clinical Trial to Test the Safety and Effectiveness of an Investigational Drug CHR-2797 With Erlotinib in Patients With Locally Advanced or Metastatic Non-small Cell Lung Cancer”, NCT00522938 [Terminated–Poor Recruitment], (b) “Safety Study to Evaluate CHR-2797 in Patients With Advanced Tumours”, NCT00692354 [Completed], (c) “A Study of the Safety and Tolerability of the Addition of CHR-2797 to Paclitaxel in Patients With Advanced or Refractory Tumours”, NCT00737555 [Completed], and (d) “ A Phase I-II Study to Evaluate the Safety, Tolerability and Anti-Disease Activity of the Aminopeptidase Inhibitor, CHR-2797, in Elderly and/or Treatment Refractory Patients with Acute Myeloid Leukaemia or Multiple Myeloma”, NCT00689000 [Completed].

**1.87 “Patents”** means (a) pending patent applications (and patents issuing therefrom), issued patents, utility models and designs; and (b) reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any patents, patent applications, utility models or designs, in each case being enforceable within the applicable territory.

**1.88 “Patent Term Extension”** means any term extensions, supplementary protection certificates, and equivalents thereof offering patent or patent-like protection beyond the initial term with respect to any issued Patents.

**1.89 “Phase 1 Clinical Trial”** means a clinical trial of a pharmaceutical product on healthy subjects or patients with the primary purpose of determining safety, metabolism and pharmacokinetic properties and clinical pharmacology of such product.

**1.90 “Phase 2 Clinical Trial”** means a clinical trial of a pharmaceutical product on patients, including possibly pharmacokinetic studies, the principal purposes of which are to make a preliminary determination that such product is safe for its intended use and to obtain sufficient information about such product’s efficacy to permit the design of a Phase 3 Clinical Trial.

**1.91 “Phase 3 Clinical Trial”** means a clinical trial on sufficient numbers of patients, which trial(s) are designed to (a) establish that a drug is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the drug in the dosage range to be prescribed; and (c) support approval of an application to a Regulatory Authority for the commercial marketing of such drug.

**1.92 “Phase 4 Clinical Trial”** means a clinical trial of a pharmaceutical product conducted after Regulatory Approval of the product has been obtained from an appropriate

\*\* 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.

Regulatory Authority, which trial is (a) conducted voluntarily by a Party to enhance marketing or scientific knowledge of such product (e.g., for expansion of product labeling or dose optimization), or (b) conducted as a condition for sale or post-approval commitment to or requirement of a Regulatory Authority. For clarity, a human clinical trial conducted to support a new Regulatory Approval for a new indication of a product shall not be considered a Phase 4 Clinical Trial.

**1.93 “Product”** means (a) the Compound or (b) any Additional Product, in finished dosage pharmaceutical form, whether administered together as a single pharmaceutical product or co-administered together with one or more other biologic or pharmaceutically active products or agents.

**1.94 “Product Complaint”** means any written, verbal or electronic expression of dissatisfaction regarding the Product, including without limitation reports of actual or suspected product tampering, contamination, mislabeling or inclusion of improper ingredients.

**1.95 “Product Infringement”** has the meaning set forth in Section 9.6(b).

**1.96 “Product Mark”** has the meaning set forth in Section 6.6.

**1.97 “Proposing Party”** has the meaning set forth in Section 4.4(a).

**1.98 “Quality Agreement”** has the meaning set forth in Section 7.2.

**1.99 “Regulatory Approval”** means all approvals necessary, excluding price approval, for the commercial sale of the Product for the Field in a given country or regulatory jurisdiction.

**1.100 “Regulatory Authority”** means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction.

**1.101 “Regulatory Exclusivity”** means any exclusive marketing rights or data exclusivity rights conferred by any Governmental Authority with respect to the Product, in a country under the jurisdiction of such Government Agency in the Licensed Territory, other than a Patent right, including, without limitation, rights conferred in the U.S. under the Hatch-Waxman Act or the FDA Modernization Act of 1997, or rights similar thereto outside the U.S.

**1.102 “Regulatory Materials”** means regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Governmental Authority in order to Develop, Manufacture, market, sell or otherwise Commercialize the Product in a particular country, territory or possession. Regulatory Materials include, without limitation, INDs, NDAs and MAAs.



\*\* 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.

**1.103 “Retained Liabilities”** has the meaning set forth in Section 11.4.

**1.104 “Reviewing Party”** has the meaning set forth in Section 4.3(d).

**1.105 “ROFR Notice”** has the meaning set forth in Section 9.2(b).

**1.106 “ROFR Notice Period”** has the meaning set forth in Section 9.2(b).

**1.107 “ROW Territory”** means worldwide except the Licensed Territory.

**1.108 “Royalty Term”** means, with respect to a particular Product within a particular country in the Licensed Territory, the period of time beginning upon the date of First Commercial Sale of such Product in such particular country and continuing until the later of: (a) the date of expiration of the last Valid Claim in such country that would be infringed by the Development, Manufacture, use or sale of such Product in such country, (b) the expiration of all Regulatory Exclusivity periods with respect to the Product in such country, or (c) ten (10) years after the First Commercial Sale in such country. Thereafter, no further royalties shall be due with respect to such Product in such country.

**1.109 “r/r AML”** means relapsed/refractory acute myelogenous leukemia.

**1.110 “r/r MDS”** means relapsed/refractory myelodysplastic syndromes.

**1.111 “r/r MM”** means relapsed/refractory multiple myeloma.

**1.112 “Sales and Marketing Plan”** has the meaning set forth in Section 6.2.

**1.113 “Sales Event 1”** has the meaning set forth in Section 8.3.

**1.114 “Sales Event 2”** has the meaning set forth in Section 8.3.

**1.115 “Sales Event 3”** has the meaning set forth in Section 8.3.

**1.116 “Sole Inventions”** has the meaning set forth in Section 9.1.

**1.117 “Study Report IP”** means the copyright in study report C09/IIC/001 to manufacture BB-76163 in accordance with the route described in that study report.

**1.118 “Subject CTI Rights”** has the meaning set forth in Section 9.2.

**1.119 “Supply Agreement”** has the meaning set forth in Section 7.2.

**1.120 “Take the Lead”** shall mean, with respect to a particular Party, that such Party is primarily responsible for, and has the authority to make, all day-to-day decisions (in accordance with the approved Development Plan and Sales and Marketing Plan) as they relate to such Party’s responsibilities, rights and/or obligations hereunder; provided, however, the Parties shall

\*\* 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.

consult with each other with respect to any matters as requested by either Party or as otherwise required by the terms of this Agreement.

**1.121 “Taxes”** means taxes (other than income taxes), duties, tariffs or other governmental charges levied on the sale of Products, including, without limitation, consumption taxes.

**1.122 “Term”** means the term of this Agreement, as determined in accordance with Article 13.

**1.123 “Third Party”** means any entity other than Chroma or CTI or an Affiliate of either of them.

**1.124 “Third Party Royalties”** has the meaning set forth in Section 8.4(d)(ii).

**1.125 “Threshold”** has the meaning set forth in Section 8.4(c).

**1.126 “Transition Development Plan”** has the meaning set forth in Section 13.8(a).

**1.127 “Transition Period”** has the meaning set forth in Section 13.7(e).

**1.128 “Transition Plan”** has the meaning set forth in Section 13.7(e).

**1.129 “Upstream Agreements”** means the agreements listed on Exhibit B-2.

**1.130 “Valid Claim”** means a pending or issued claim of a Patent within the Chroma Patents which: (a) has not been held unpatentable, invalid or unenforceable by a court or other government agency of competent jurisdiction in a decision from which no appeal can or has been taken; and (b) which has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise. Notwithstanding the foregoing, if a claim of a pending patent application within the Patents has not issued as a claim of a patent within five (5) years from first filing of the application, such claim shall not be a Valid Claim for the purposes of this Agreement, unless and until such claim issues as a claim of an issued patent (from and after which time the same shall be deemed a Valid Claim subject to paragraphs (a) and (b) above). With respect to a Valid Claim of a pending patent application, the phrase to “infringe a Valid Claim” means to engage in an activity that would infringe (i.e., by either directly infringing, contributorily infringing, or inducing infringement of) such Valid Claim if it were contained in an issued patent.

**1.131 “Vernalis”** means Vernalis (R&D) Limited (formerly Vernalis (Oxford) Limited) registered in England with number 1985479.

**1.132 “Vernalis Agreement”** means the agreement between Vernalis and Chroma dated 24 November 2003 as amended by amendment No.1 dated 30 March 2007.

\*\* 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.

## ARTICLE 2

### LICENSES AND EXCLUSIVITY

#### 2.1 Licenses to CTI under Chroma Technology.

##### (a) License Grants.

(i) Subject to the terms and conditions of this Agreement, Chroma hereby grants, and shall cause each of its Affiliates to grant CTI, a royalty-bearing, exclusive license under the Chroma Technology, with the right to sublicense as provided below, to Develop, Manufacture, use, make, and have made the Product in the Field in the Licensed Territory, in each case in accordance with the Development Plan and the Supply Agreement and to sell, offer for sale, have sold, distribute, import and otherwise Commercialize the Product in the Field in the Licensed Territory.

(ii) Subject to the terms and conditions of this Agreement, Chroma hereby grants and shall cause each of its Affiliates to grant CTI a royalty-bearing, non-exclusive license under the Manufacturing Patent and the Study Report IP, with the right to sublicense as provided below, to Manufacture and have made the Product in the Field in the Licensed Territory.

(iii) The Chroma Patents identified on Exhibit B-1 are licensed to Chroma by Vernalis under the Vernalis Agreement. CTI acknowledges and agrees that its sublicense rights to such Patents under this Agreement are at all times subject to the applicable terms of the Vernalis Agreement, current copies of which have been provided to CTI as of the Effective Date, provided that Chroma shall at all times be responsible for any payment obligations to Vernalis pursuant to the Vernalis Agreement. Chroma shall provide prior notice to CTI of any proposed amendment of the Vernalis Agreement and shall not, without CTI's prior written consent, amend or terminate the Vernalis Agreement, which consent shall not be unreasonably withheld, conditioned or delayed. If Chroma becomes aware of any amendment or termination of any other Upstream Agreement, Chroma shall promptly notify CTI of the same. If Chroma receives a notice of default or termination from Vernalis, Chroma shall promptly provide a copy of such notice to CTI. Chroma will use commercially reasonable efforts to cure any such default to avoid termination of the Vernalis Agreement. At CTI's option, but without any obligation and without limiting any remedies CTI may have against Chroma, CTI may cure any payment default on behalf of Chroma under the Vernalis Agreement. Any such payments made by CTI, whether to cure any default of Chroma or to pay royalties on behalf of Chroma under the Vernalis Agreement, may be deducted from royalties and milestone payments otherwise due to Chroma under Article 8.

(b) **Chroma Retained Rights.** Notwithstanding the rights granted to CTI in Section 2.1(a) and without limiting the generality of Section 2.4, Chroma retains the right to (i) conduct the Development and Commercialization activities in the ROW Territory as expressly permitted to be conducted by Chroma under this Agreement, including the conduct of any

\*\* 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.

Extraterritorial Studies designated to be performed by Chroma under Section 4.3(c)(ii) of this Agreement; (ii) to Develop, Manufacture, use, make and have made the Product in the Field in the Licensed Territory for the purposes of exercising its rights in relation to the Product in the ROW Territory or to supply Product to CTI in the Licensed Territory; and (iii) the right to Develop, Manufacture, use make, have made, import and use Product in the Licensed Territory for the purposes of complying with its obligations under this Agreement with respect to any Additional Studies, or with the prior written approval of CTI (such approval not to be unreasonably withheld, conditioned or delayed), to carry out clinical trials in the Licensed Territory for the exclusive purpose of supporting regulatory activities in the ROW Territory.

**(c) Sublicense Rights.** CTI shall have the right to sublicense any of the rights set forth in Section 2.1(a), subject to Chroma's prior written approval, which shall not be unreasonably withheld, delayed or conditioned provided that any such sublicense which is granted to an Affiliate of CTI shall not require Chroma's prior written approval unless and until such Affiliate ceases to be an Affiliate of CTI. Promptly after the execution of any sublicense agreement, CTI shall notify Chroma and, if requested in writing by Chroma, provide Chroma with a copy of such agreement; provided, that any information CTI reasonably deems to be confidential may be redacted. CTI hereby covenants that it will include in all agreements granting sublicenses under the rights granted in Section 2.1(a) provisions consistent with the terms of this Agreement as applicable to a sublicense, including without limitation those contained in Article 4, Article 5, Article 6 and Article 8. CTI shall be liable to Chroma for all acts or omissions of any such sublicensee in connection with such sublicense.

## **2.2 Negative Covenants.**

**(a) No Grant of Rights.** Chroma agrees not to grant to any Third Party (i) any rights inconsistent with the rights and licenses granted to CTI under this Agreement, including any rights or licenses in or to the Chroma Technology in the Licensed Territory, whether under a material transfer agreement or otherwise; and (ii) subject to Section 2.1(b) above without CTI's prior written approval (which shall not be unreasonably withheld, delayed or conditioned), any rights or licenses in or to the Chroma Technology to any Third Party in the Field in the ROW Territory. Chroma hereby covenants that it will include in all agreements granting sublicenses under the Chroma Technology in the Field in the ROW Territory provisions consistent with the terms of this Agreement as applicable to a sublicense, including without limitation those contained in Article 4, Article 5 and Article 6.

### **(b) Non-Competition.**

**(i)** Chroma shall not during the term of this Agreement anywhere in the Licensed Territory, Develop, Manufacture, market, promote, advertise, sell or offer to sell, or otherwise Commercialize (or license or collaborate with a Third Party to do any of the foregoing) a Competing Product. Chroma shall not, during the term of this Agreement, Commercialize the Product to or with a particular entity in the ROW Territory that Chroma knows or reasonably should know will distribute or sell the Product in the Licensed Territory,

\*\* 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.

provided that this obligation applies to Chroma only and does not require Chroma to police its sublicensees in this regard. For the purposes of this Section 2.2(b)(i), any act or activity undertaken, or failure to act, by an Affiliate of Chroma, which, if committed by Chroma would constitute a breach of this Section, shall constitute a breach by Chroma.

(ii) CTI shall not during the term of this Agreement anywhere in the ROW Territory, Develop, Manufacture, market, promote, advertise, sell or offer to sell, or otherwise Commercialize (or license or collaborate with a Third Party to do any of the foregoing) a Competing Product. CTI shall not, during the term of this Agreement, Commercialize the Product to or with a particular entity in the Licensed Territory that CTI knows or reasonably should know will distribute or sell the Product in the ROW Territory, provided that this obligation applies to CTI only and does not require CTI to police its sublicensees in this regard. For the purposes of this Section 2.2(b)(ii), any act or activity undertaken, or failure to act, by an Affiliate of CTI, which, if committed by CTI would constitute a breach of this Section, shall constitute a breach by CTI.

(c) **No Liens.** During the Term, Chroma shall not grant any liens, security interests or other encumbrances on the Chroma Technology, other than security interest to lenders similar to the one described on Exhibit B-1 that is granted in Chroma's ordinary course of business covering Chroma's assets generally.

**2.3 Registration of License.** Notwithstanding anything to the contrary in Article 12, CTI, at its expense, may register the licenses granted under this Agreement in any country of the Licensed Territory. Upon request by CTI, Chroma agrees promptly to, and to cause each of its Affiliates to, execute any "short form" licenses consistent with the terms and conditions of this Agreement submitted to it by CTI, or effect any registrations of its own, which are reasonably necessary to effect the foregoing registration in such country.

**2.4 No Implied Licenses.** Except as explicitly set forth in this Agreement, neither Party grants any license, express or implied, under its intellectual property rights to the other Party.

### ARTICLE 3

#### OVERVIEW; MANAGEMENT

##### 3.1 Executive Steering Committee.

(a) **Formation and Role.** The Parties agree to establish and convene a Executive Steering Committee (or "ESC") for the overall coordination and oversight of the Parties' activities under this Agreement, promptly after the Effective Date. Each Party shall have an equal number of representatives on the ESC. The ESC shall operate by the procedures set forth in Section 3.3. Except as otherwise provided in Section 14.3(b) and subject to Section 14.2(b), the role of the Executive Steering Committee shall be:

\*\* 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.

(i) For the Licensed Territory and the ROW Territory, to review and discuss the overall strategy for the Development, Manufacture, Regulatory Approval (including the initial approval and any supplements and expansions thereof) and Commercialization of the Product;

(ii) to review, discuss and approve the Development Plans (including the Development Budget) on or before March 1 of each calendar year;

(iii) to review, discuss and approve any changes or revisions to the Development Plan (including the Development Budget);

(iv) to review and discuss the Sales and Marketing Plan, and any proposed amendments or revisions to such plan;

(v) to resolve any disputes arising within the JDC; and

(vi) to establish such subcommittees, including without limitation the regulatory working group as provided in Section 5.3 and the Publication Team as provided in Section 6.7, and to perform such other functions as appropriate to further the purposes of this Agreement, as mutually agreed by the Parties in writing.

**(b) ESC Decisions and Actions.** Actions to be taken by the Executive Steering Committee shall be taken only following unanimous vote, with each Party having one (1) vote per representative. Except as otherwise provided in Section 14.3(b), if the Executive Steering Committee fails to reach unanimous agreement on a matter before it for decision for a period in excess of fifteen (15) days from the date first presented to the ESC in writing, the matter shall be submitted immediately to the Chief Executive Officer of each Party (each, the “**Designated Executive**”) for resolution in accordance with the decision-making procedures described in Section 14.2, including the specific decision-making rights of each Party as described in such section.

### 3.2 Joint Development Committee.

**(a) Formation and Role.** The Parties also agree to establish a Joint Development Committee (or “**JDC**”) which will monitor and coordinate communication and operations regarding the Parties’ efforts with respect to the Development, Manufacture, and Regulatory Approval of the Product in the Field and in the Licensed Territory and the ROW Territory. Each Party shall have an equal number of representatives on the Joint Development Committee. The Joint Development Committee shall operate by the procedures set forth in Section 3.3. The role of the Joint Development Committee shall be:

(i) to facilitate the exchange of Information between the Parties under this Agreement with respect to their Product-related activities (including activities conducted in the Licensed Territory and the ROW Territory), including as and to the extent necessary for each Party to perform its obligations under this Agreement;

\*\* 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.

(ii) to review and comment on the Initial Development Plan and all updates thereto, and to submit such plan to the ESC for approval (it being understood that the JDC shall submit such plan with sufficient time for the ESC to review and approve such plan on or before March 1 of each calendar year);

(iii) to review and comment on any proposed changes or revisions to the Development Plan (including the Development Budget);

(iv) to review and comment on the Sales and Marketing Plans, and CTI's Commercialization activities for the Product in the Licensed Territory and Chroma's Commercialization activities for the Product in the ROW Territory;

(v) to establish a global branding strategy for the Product at least twelve (12) months prior to any Product launch in the Licensed Territory or the ROW Territory, including the determination of ownership rights related to Product Marks and related trademark registrations.

(vi) to establish such working teams or subcommittees and to perform such other functions as appropriate to further the purposes of this Agreement, as determined by the Parties in writing.

**(b) JDC Decisions and Actions.** Except as expressly provided in this Section 3.2, actions to be taken by the JDC shall only be taken following unanimous vote, with each Party having one (1) vote per representative. Except as otherwise provided in Section 14.3(b), if the Joint Development Committee fails to reach unanimous agreement on a matter before it for decision for a period in excess of ten (10) days from the date first presented to the JDC in writing, the matter shall be referred immediately to the Executive Steering Committee.

### 3.3 Committee Membership and Procedures.

**(a) Membership.** Chroma and CTI shall each designate an equal number of representatives to serve on each of the ESC and JDC (each, a "Committee") by written notices to the other Party. Initially, each Party shall designate three (3) such representatives. Each Committee may elect to vary the number of representatives from time to time during the Term. Either Party may designate substitutes for its Committee representatives if one (1) or more of such Party's designated representatives is unable to be present at a meeting. From time to time each Party may replace its Committee representatives by written notice to the other Party specifying the prior representative(s) and their replacement(s). Any such substitutes or replacements shall be designated consistent with the following principles: at least one (1) representative shall have appropriate expertise in the clinical development of pharmaceutical products; provided, that each Committee may vary the expertise required for the representatives of each Party as it deems appropriate as the Parties gain experience with the Product. Each Committee will have a chairperson, to be designated as described below. The chairperson shall be responsible for (i) calling meetings, and (ii) preparing and circulating an agenda for the upcoming meeting, but shall have no special authority over the other members of the Committee, and shall have no additional

\*\* 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.

voting rights. The alliance managers described in Section 3.4 shall be responsible for preparing and issuing minutes of each ESC and JDC meeting within thirty (30) days thereafter. Such minutes shall not be finalized until each Committee representative reviews and approves such minutes in writing; provided that any minutes shall be deemed approved unless a member of the ESC or the JDC (as applicable) objects to the accuracy of such minutes within fifteen (15) days after the circulation of the minutes by the chairperson. The chairpersons of other subcommittees will be responsible for generating minutes from their respective meetings.

**(b) Chairperson.**

(i) The chairperson of the ESC shall be appointed for a calendar year, with Chroma appointing the initial chairperson. On January 1 of each year after the Effective Date, the Parties shall rotate designation of the chairperson for the ESC for the commencing year.

(ii) The chairperson of the JDC shall be appointed for a calendar year. The initial chairperson of the JDC will be designated by CTI. On January 1 of each year after the Effective Date, the Parties shall rotate designation of the chairperson for the JDC for the commencing year, provided that promptly following submission of the first NDA or other Regulatory Approval for a Product in the Licensed Territory, CTI will be entitled to replace the chairperson with a CTI representative to serve for at least twelve (12) months after which time Chroma shall again be entitled to designate the chairperson on the following January 1. Thereafter, the Parties shall rotate designation of the chairperson for the JDC for the subsequent years.

**(c) Meetings.** Meetings of a Committee shall be effective only if at least two (2) representatives of each Party are present or participating. A Committee may meet either (i) in person at either Party's facilities or at such locations as the Parties may otherwise agree; or (ii) by audio or video teleconference. With the prior consent of the other Party's representatives (such consent not to be unreasonably withheld or delayed), each Party may invite non-members to participate in the discussions and meetings of a Committee, provided that such participants shall have no voting rights or powers and shall be subject to the confidentiality provisions set forth in Article 12. Additional meetings of a Committee may be held with the consent of each Party, as required under this Agreement, or to resolve any dispute referred to it and neither Party will unreasonably withhold or delay its consent to hold such an additional meeting (and in the case of any dispute referred to the ESC, such meeting shall be held within five (5) business days following referral to the ESC, or as soon as reasonably possible). Each Party shall be responsible for all of its own expenses incurred in connection with participating in the Committees including expenses associated with an initial alliance kick-off meeting.

(i) The ESC shall hold at least three (3) meetings per year, or as otherwise agreed to by the Parties, with at least one (1) of such meetings being held in person.



\*\* 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.

(ii) The JDC shall each hold a meeting at least every other month, or as otherwise agreed to by the Parties. Unless otherwise agreed to by the Parties, the JDC shall hold at least four (4) meetings in person each year to facilitate alignment and communication.

**3.4 Alliance Managers.** Promptly following the Effective Date, each Party shall designate in writing an individual to facilitate communication and coordination of the Parties' activities under this Agreement relating to Products.

**3.5 Authority.** The ESC and JDC shall each perform its responsibilities under this Agreement based on the principles of prompt and diligent Development, Manufacture and Commercialization of Products in the Licensed Territory and the ROW Territory. The Committees shall each have only the powers assigned expressly to it in this Article 3 and elsewhere in this Agreement, and shall not have any power to amend, modify or waive compliance with this Agreement.

**3.6 Collaboration Guidelines.** Subject to the terms of this Agreement, the activities and resources of each Party shall be managed by such Party, acting independently and in its individual capacity. The relationship between Chroma and CTI is that of independent contractors and neither Party shall have the power to bind or obligate the other Party in any manner, other than as may be expressly set forth in this Agreement.

**3.7 Diligence.** CTI shall use Diligent Efforts to Develop, to seek Regulatory Approval for and to Commercialize Products for use in the Field in the Licensed Territory after receipt of applicable Regulatory Approval in accordance with the terms of this Agreement and the Development Plan, consistent with good pharmaceutical practices. Notwithstanding the foregoing sentence, CTI's obligation to use Diligent Efforts shall not apply to the extent of any delay or failure by or on behalf of Chroma to (i) perform its Development obligations or responsibilities under the Development Plan, (ii) timely supply the Product for Development purposes pursuant to the terms of the Supply Agreement, or (iii) timely transfer manufacturing technology to CTI or its designee. Chroma shall use Diligent Efforts to conduct, in accordance with the terms of this Agreement, the Development to be performed by it under this Agreement in accordance with the Development Plan.

**3.8 Sublicensing.** In the event that either Party sublicenses a material portion of its rights in the Product to a Third Party in accordance with the terms of this Agreement, the Parties shall in good faith discuss and, as appropriate, amend the structures of the ESC, JDC and any subcommittees to reflect the revised division of responsibilities following execution of such sublicenses.

## ARTICLE 4

### PRODUCT DEVELOPMENT

**4.1 Overview of Product Development.** The Parties desire and intend to collaborate with respect to the Development of the Product in the Field, as and to the extent set forth in this

\*\* 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.

Agreement. The general allocation of responsibilities for conducting Development of the Product shall be as follows: (a) CTI will oversee and shall be responsible for performing the Development activities in the Licensed Territory, including for the sponsorship of Licensed Territory Specific Studies; and (b) Chroma will oversee and shall be responsible for performing the Development activities in the ROW Territory, including for the sponsorship of Extraterritorial Studies; in each case unless otherwise agreed to by the JDC.

**4.2 Principles of Product Development.** Each Party's Development of the Product in the Field shall be conducted in a manner consistent with the following principles: (a) seeking Regulatory Approval that includes the appropriate label for such Product in light of the clinical data, and (b) obtaining Regulatory Approval for such Product consistent with the preceding clause and in a timely manner.

#### **4.3 Development Operations and Expenses.**

##### **(a) Development Plan.**

**(i) General.** The Parties shall collaboratively conduct the Development of the Product pursuant to a mutually agreed written development plan (the "**Development Plan**"). The Development Plan will contain the following information, to the extent such information is available:

**(1)** scope and target timelines for all Development activities in reasonable detail as agreed by the Parties supporting Regulatory Approvals in the Field for the Product in the Licensed Territory and the ROW Territory, including the performance of Currently Ongoing Studies and any Additional Studies as mutually agreed upon by the Parties under the terms of Section 4.4;

**(2)** a Development Budget; and

**(3)** plans and timeline for preparing the necessary Development Regulatory Materials in support of obtaining Regulatory Approval in the Licensed Territory and the ROW Territory for the first indication and any label expansion.

**(ii) Initial Development Plan.** The Parties have agreed upon an initial Development Plan, which is attached hereto as Exhibit C (the "**Initial Development Plan**").

**(iii) Updates to Development Plan.** On at least an annual basis and in the timeframe provided in Section 3.2(a)(ii), commencing in 2012, and at such other times as deemed necessary by the JDC, the JDC shall update and amend, as appropriate (taking into account relevant issues, such as safety and efficacy results, costs of development, the time required to complete development, etc.), the then-current Development Plan. The JDC shall submit all proposed updates and amendments to the Development Plan approved by it to the ESC for review and final approval. Once approved by the ESC, each updated or amended

\*\* 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.

Development Plan shall become effective and supersede the previous Development Plan as of the date of such approval or at such other time as decided by the ESC.

**(b) Development Costs.**

**(i) Allocation of Costs.** As between the Parties, as outlined in the Initial Development Plan and subsequent Development Plans, subject to the Funding Cap, CTI shall be responsible for seventy-five percent (75%) of all Development Costs in the Licensed Territory and the ROW Territory, and Chroma (or its Development Designee) shall be responsible for twenty-five percent (25%) of all Development Costs in the Licensed Territory and the ROW Territory, provided that such cost sharing shall not apply to development costs related to the Currently Ongoing Studies incurred prior to April 1, 2011. Each Party will bear their own Indirect Costs. For clarity, (A) neither Party shall be responsible to the other Party for any costs or expenses incurred by the other Party for any Development activities that are not specifically subject to an agreed-upon Development Plan and Development Budget, and (B) if actual Development Costs for either Party will exceed the applicable Development Budget, the cost overruns must be reviewed and approved by the JDC and the ESC as set forth in Sections 3.1(a)(iii) and 3.2(a)(iii). No Party shall be obliged to fund its applicable proportion of an overrun unless such overrun has been prior approved by the JDC and the ESC.

**(ii) Quarterly True-up.** Within thirty (30) days of the end of each calendar quarter, each Party will submit to the other Party a report detailing such Party's Development Costs incurred during such calendar quarter, including copies of invoices and any other supporting evidence necessary to substantiate the actual Development Costs. In the event that a Party's Development Costs have exceeded its applicable allocation as set forth in Section 4.3(b)(i), as evidenced by the report submitted to the other Party, then, within sixty (60) days of the delivery of the report from such Party, the other Party shall pay to such Party the difference between the actual Development Costs and the applicable portion that is allocated to such Party under Section 4.3(b)(i). Any such difference not paid within such sixty (60) day period will accrue simple interest until the date of payment at the per annum rate of two percent (2%) over the then-current prime rate quoted by Citibank in New York City or the maximum rate allowable by applicable Law, whichever is lower.

**(iii) Initial Funding Cap.** The total Development Costs under the Initial Development Plan and subsequent Development Plans, from the period commencing with the Effective Date and continuing for three (3) years after such date, shall not exceed \$50,000,000 (or such greater amount as the Parties may agree to in writing) (the "**Funding Cap**"). For clarity, as between the Parties, seventy-five percent (75%) of the Funding Cap (\$37,500,000) is the responsibility of CTI, and twenty-five percent (25%) (\$12,500,000) is the responsibility of Chroma.

**(c) Conduct of Studies.**

\*\* 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.

**(i) Currently Ongoing Studies.** The Parties intend and agree that any and all Currently Ongoing Studies shall be conducted by Chroma in consultation with the JDC, and in accordance with the Development Plan.

**(ii) Extraterritorial Studies.** The Parties intend and agree that any and all Extraterritorial Studies shall be conducted by Chroma, in collaboration and consultation with CTI and in consultation with the JDC, and in accordance with the Development Plan.

**(iii) Licensed Territory Specific Studies.** The Parties intend and agree that any and all Licensed Territory Specific Studies shall be conducted by CTI, in collaboration and consultation with Chroma and in consultation with the JDC, and in accordance with the Development Plan.

**(iv) Performance.** Each Party agrees to conduct the studies allocated to it as described in this Section 4.3(c) in accordance with the Development Plan. Chroma and CTI each shall provide the JDC with annual reports detailing its Development activities under the Development Plan and the results thereof. Where Chroma licenses any of its rights under the Chroma Technology in the ROW Territory in accordance with Section 2.2(a)(ii) Chroma will use its Diligent Efforts to obtain such detailed reports related to the Development activities from the relevant Third Party on the same basis. However, where Chroma, despite using such Diligent Efforts, is unable to obtain such reports Chroma will provide CTI such information as it does receive from the Third Party, provided that this in no event limits Chroma's obligation to obtain safety or other pharmacovigilance related data from its sublicensees.

**(v) Phase 4 Clinical Studies.** If a Party wishes to carry out Phase 4 Clinical Studies on a voluntary basis such studies will be carried out by that Party in consultation with the other Party through the JDC and the Party carrying out such study shall, unless otherwise agreed by the Parties, be responsible for all of the Development Costs associated with such study.

**(d) Records; Audits.** Each Party (the "**Audited Party**") will maintain complete and accurate records in sufficient detail to permit the other Party (the "**Reviewing Party**") to confirm the accuracy of the Development Costs under this Agreement. Upon reasonable prior notice, such records shall be available during regular business hours for a period of three (3) years from the end of the calendar year to which they pertain for examination at the expense of the Reviewing Party, and not more often than once each calendar year, by an independent certified public accountant selected by the Reviewing Party and reasonably acceptable to the Audited Party, for the sole purpose of verifying the accuracy of the financial reports furnished by the Audited Party pursuant to this Agreement. Any such auditor shall not disclose the Audited Party's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the Audited Party or the amount of Development Costs allocated under this Agreement.

#### 4.4 Development Opt-In.

\*\* 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.

**(a) Prior to Initiation of Development.** In the event that either Party proposes (the “**Proposing Party**”) to conduct any Extraterritorial Study, any Licensed Territory Specific Study or any study that is both an Extraterritorial Study and a Licensed Territory Specific Study (each of the foregoing for the Product but not an Additional Product) that is not subject to the then-current Development Plan or Development Budget (including with respect to any additional clinical studies regarding indications other than r/r AML or r/r MDS), prior to beginning such Development activities, such Party shall provide notice to the JDC and ESC of its intentions thereof, and copies of any Information of such Party reasonably requested by the JDC and/or ESC. Within sixty (60) days of delivery of such notice, in accordance with the terms of Section 4.3(a)(iii), the JDC and ESC will review and decide whether such additional Extraterritorial Study or Licensed Territory Specific Study will become part of and incorporated into the Development Plan and Development Budget. In the event that the JDC and ESC approve the proposed amendments to the Development Plan and Development Budget, then any such additional Extraterritorial Study or Licensed Territory Specific Study will be performed and paid for subject to the terms and conditions of such amended Development Plan and the terms and conditions of this Agreement, provided that if any such study is requested or required by any Regulatory Authority, the JDC and ESC must include such study in an amended Development Plan and Development Budget. Subject to the foregoing, in the event that the JDC and ESC do not approve the proposed amendments to the Development Plan and Development Budget to include the newly proposed Extraterritorial Study or Licensed Territory Specific Study, but the Proposing Party proceeds on its own accord to conduct such additional Extraterritorial Study or any Licensed Territory Specific Study that it otherwise has the right to conduct under the terms of this Agreement (“**Non-Opted In Study**”), then the non-proposing Party (“**Non-Proposing Party**”) will not be obligated to pay for or assume any Development Costs and expenses under Section 4.3(b) related to any Non-Opted In Study. The Non-Proposing Party will also not be entitled to have access to or use for any purpose any data, information or results developed by or on behalf of the Proposing Party as a result of any Non-Opted In Study except for routine adverse event reporting as provided in Section 5.5.

**(b) Subsequent to Initiation of Development.** For any Non-Opted In Study as provided in paragraph (a), the Non-Proposing Party may subsequently provide written notice to the Proposing Party that it wishes to opt in to the Non-Opted In Study. If such notice is provided at or prior to the mid point of enrolled patients as described in the protocol of such Non-Opted In Study, then the Non-Proposing Party shall pay (i) the Non-Proposing Party’s corresponding share of the Development Cost up to the effective date of opting in, as provided in Section 4.3(b), had the Non-Proposing Party opted to participate in such Non-Opted In Study from day one (“**Corresponding Share**”) and (ii) an additional payment of \*\* of its Corresponding Share. If such notice is provided subsequent to the mid point of enrolled patients as described in the protocol of such Non-Opted In Study, then the Non-Proposing Party shall pay (i) its Corresponding Share and (ii) an additional payment of \*\* of its Corresponding Share.

**(c) After Opting In.** Following opt in to any previously Non-Opted In Study as provided in paragraph (b) above, including payment of the applicable amounts specified therein, the Non-Proposing Party will have the same rights, as provided under the terms of this

\*\* 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.

Agreement, to the data, information and results generated from any such previously Non-Opted In Study as though the Non-Proposing Party had participated from day one. Within thirty (30) days after the opt in notice and payment by the Non-Proposing Party as provided in paragraph (b) above, the Parties shall amend the Development Plan and Development Budget to include the previously Non-Opted In Study. The Non-Proposing Party shall, from the date of the opt in notice, also pay for its Corresponding Share of the future Development Costs set out in such amended Development Plan and Development Budget for such previously Non-Opted In Study. Each Party acknowledges and agrees that it shall obligate its sublicensees to agree to comply with the terms and conditions of this Section 4.4 and provide the other Party the benefits under this Section 4.4.

**4.5 Cooperation; Compliance with Laws.** Each Party shall conduct its Development activities under this Agreement in good scientific manner and in compliance in all material respects with all applicable Laws, including without limitation applicable national and international (*e.g.*, ICH, GCP, GLP, and GMP) guidelines.

#### **4.6 Subcontracting.**

**(a) Chroma Development Designees.** CTI acknowledges and agrees that portions of the Development to be performed by Chroma under this Agreement may be performed on behalf of Chroma by a Development Designee appointed by Chroma, provided that (i) Chroma shall first have obtained CTI's prior written consent (which consent may not be unreasonably withheld, conditioned or delayed) with respect to the proposed subcontractor, (ii) Chroma shall first have obtained written confidentiality agreements with any such subcontractor and written assignments of, or equivalent rights under, all Patent rights and Know-How which relate to the Product that such subcontractor may develop by reason of work performed under this Agreement, and (iii) Chroma shall be and remain responsible to CTI for the performance of its subcontractors.

**(b) CTI Development Designees.** Chroma acknowledges and agrees that portions of the Development to be performed by CTI under this Agreement may be performed on behalf of CTI by a Development Designee appointed by CTI, provided that (i) CTI shall first have obtained Chroma's prior written consent (which consent may not be unreasonably withheld, conditioned or delayed) with respect to the proposed subcontractor, (ii) CTI shall first have obtained written confidentiality agreements with any such subcontractor, and (iii) CTI shall be and remain responsible to Chroma for the performance of its subcontractors.

**4.7 Records, Reports and Information.** Each Party shall maintain, and cause its Affiliates and sublicensees to maintain, complete, current and accurate records of all Development activities conducted by it hereunder, and all data and other Information resulting from or relating to such activities, including but not limited to the investigator brochure, IND annual report, and any safety plans established during Development. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory purposes. Each Party shall document, and cause its Affiliates and sublicensees to document, all Non-Clinical Studies and

\*\* 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.

clinical trials in formal written study reports according to applicable national and international (*e.g.*, ICH, GCP, GLP, and GMP) guidelines. Each Party shall have the right to review such records maintained by the other Party at reasonable times, upon written request, which shall not exceed once a year.

**4.8 Data Exchange and Use.** Each Party shall promptly provide the other Party with copies of all final reports with respect to the conduct of any Development of the Product in the Field and with access to, upon request of a Party, all data with respect to the conduct of any Development of the Product in the Field, in each case as such data and reports become available to the Party performing the corresponding studies. Each Party will have the right to (a) use such data and reports for the purposes of carrying out its obligations and exercising its rights under this Agreement and (b) to provide all such data and reports generated by the other Party to such Party's sublicensees or prospective sublicensees subject to the applicable provisions of this Agreement. All data and reports disclosed by one Party to the other under this Agreement shall be deemed Confidential Information of the disclosing Party and may be used by the receiving Party for the purposes of this Agreement, subject to the permitted uses and disclosures described in Section 4.4 and in this Section 4.8 and disclosure to any Regulatory Authority in connection with a Party's obligations under Article 5.

**4.9 Designation of Additional Products.** If either Party desires to commence development of an Additional Product in the Field, then such Party shall notify the JDC and ESC in writing and provide a draft development plan for such Additional Product to the JDC and ESC. The JDC and ESC shall consider such development plan in good faith in accordance with the terms of this Agreement. Upon approval by the JDC and ESC, the Parties shall either amend the then-current Development Plans and Sales and Marketing Plans to include such Additional Product or prepare separate plans to include terms relating to such Additional Product, including allocation of costs and such other terms similar to those provided in Section 4.3. The Parties shall determine a reasonable process for the timely delivery of Information regarding any potential Additional Products by each Party to the JDC and/or ESC.

**(a) If Not Approved by ESC.** In the event that the JDC and ESC do not approve the development of any Additional Product after consideration as provided above, the Proposing Party may pursue any such development on its own ("**Non-Opted In Additional Product Development**"). If the Proposing Party proceeds on its own accord to pursue any Non-Opted In Additional Product Development, then the Non-Proposing Party will not be obligated to pay for or assume any development costs and expenses related to such Non-Opted In Additional Product Development. The Non-Proposing Party will not be entitled to use for any purpose any data, information or results developed by or on behalf of the Proposing Party as a result of such Non-Opted In Additional Product Development except for routine adverse event reporting as provided in Section 5.5.

**(b) Subsequent to Initiation of Development.** The Non-Proposing Party may, however, subsequently provide written notice to the Proposing Party that it wishes to opt in to the Non-Opted In Additional Product Development. If such notice is provided at or prior to any

\*\* 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.

clinical studies, then the Non-Proposing Party shall pay (i) its Corresponding Share of development costs for such Non-Opted In Additional Product Development under the same terms as those contained in Section 4.3(b) and (ii) an additional payment of \*\* of such Corresponding Share. If such notice is provided subsequent to the Initiation of clinical studies, then the Non-Proposing Party shall pay (i) its Corresponding Share of development costs for such Non-Opted In Additional Product Development under the same terms as those contained in Section 4.3(b) and (ii) an additional payment of \*\* of such Corresponding Share.

**(c) After Opting In.** Following opt in to any previously Non-Opted In Additional Product Development, the Non-Proposing Party will have the same rights, as provided under the terms of this Agreement, to the data, information and results generated from any such previously Non-Opted In Additional Product Development as though the Non-Proposing Party had participated from day one. Within thirty (30) days after the opt in notice and payment by the Non-Proposing Party as provided in paragraph (b) above, the Parties shall either amend the then-current Development Plans and Sales and Marketing Plans to include such Additional Product or prepare separate plans to include terms relating to such Additional Product, including allocation of costs and such other terms similar to those provided in Section 4.3. The Non-Proposing Party shall, from the date of the opt in notice, also pay for its Corresponding Share of the future development costs for such Non-Opted In Additional Product Development set out in such plan. Each Party acknowledges and agrees that it shall obligate its sublicensees to agree to comply with the terms and conditions of this Section 4.9 and provide the other Party the benefits under this Section 4.9.

## ARTICLE 5

### REGULATORY MATTERS

**5.1 Initial Transfer.** Within sixty (60) days after the Effective Date, Chroma shall make available to CTI copies of all Development Documentation that are Controlled by Chroma generated as of the Effective Date and relating to the use of the Product in the Field, including any drug master files and Regulatory Materials for the Past Studies. Within ninety (90) days after the Effective Date, Chroma shall submit to the FDA or equivalent foreign Regulatory Authority in the Licensed Territory to transfer to CTI ownership of, and CTI shall own in CTI's name, any IND, NDA or MAA submissions for the Product in the Licensed Territory including, IND number 75,503 or any foreign equivalents thereof (as applicable) in the Licensed Territory, at no additional charge to CTI. Chroma shall execute and deliver to the applicable Regulatory Authority such documents as are required to notify such Regulatory Authority of the transfer of such IND or any foreign equivalent thereof to CTI.

#### **5.2 Preparation of Regulatory Materials.**

##### **(a) Licensed Territory.**

(i) CTI shall Take the Lead and be the responsible party, in consultation with Chroma, for preparing, filing and holding any and all Regulatory Materials in



\*\* 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.

the Licensed Territory associated with any IND, NDA or MAA submissions for the Product or amendments or supplements thereto. Such Regulatory Materials and related Regulatory Approvals shall be owned solely by CTI and held in its name, subject to Chroma's rights of reference under this Agreement. Except as required by applicable Law or Regulatory Authority, CTI shall not withdraw any such Regulatory Materials or Regulatory Approvals without prior consultation with and approval of Chroma, which shall not be unreasonably withheld, delayed or conditioned. CTI shall be primarily responsible, in consultation with Chroma, for performing all activities required by such Regulatory Authority with respect to (1) maintaining the IND, NDA and MAA submissions, maintaining the Regulatory Approval following its receipt, safety monitoring as further described in Section 5.5 below, promotional activities, compliance, and annual reporting to such Regulatory Authorities, as well as associated document retention, and (2) filing any and all Regulatory Materials for subsequent indications in the Licensed Territory, and holding any such Regulatory Materials, amendments or supplements thereto. CTI shall be responsible for any field alert reporting in the Licensed Territory and Chroma shall reasonably assist CTI with its annual reporting obligations.

(ii) Upon the request of Chroma, CTI shall inform each applicable Regulatory Authority in the Licensed Territory that one (1) or more representatives of Chroma will attend and, to the extent permitted by applicable Law, participate in all major meetings between CTI and such Regulatory Authority, subject to the confidentiality provisions set forth under Article 12. CTI shall timely inform Chroma of any such scheduled meetings, as soon as practicably possible.

(iii) CTI and Chroma shall as soon as reasonably possible following the Effective Date, through the JDC establish a plan and schedule of regulatory activities to be performed by the Parties in connection with obtaining approval for the first NDA or MAA for the Product in the Licensed Territory and for amendments or supplements thereto.

**(b) ROW Territory.**

(i) Chroma shall retain sponsorship of the clinical trial applications currently active in Europe. Except as required by applicable Law or Regulatory Authority, Chroma shall not withdraw any Regulatory Materials or Regulatory Approvals without prior consultation with and approval of CTI, which shall not be unreasonably withheld, delayed or conditioned.

(ii) Chroma shall Take the Lead and be the responsible party in consultation with CTI, for preparing, filing, holding and maintaining any and all Regulatory Materials for the Product in the ROW Territory associated with any IND or MAA for the Product or amendments or supplements thereto. Such Regulatory Materials and related Regulatory Approvals shall be owned solely by Chroma and held in its name, subject to CTI's rights of reference under this Agreement. Chroma shall be primarily responsible, in consultation with CTI, for performing all activities required by such Regulatory Authority with respect to (1) maintaining the MAA submissions, maintaining the Regulatory Approval following its receipt,

\*\* 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.

safety monitoring as further described in Section 5.5 below, promotional activities, compliance, and annual reporting to such Regulatory Authorities, as well as associated document retention, and (2) filing any and all Regulatory Materials for subsequent indications in the ROW Territory, and holding any such Regulatory Materials, amendments or supplements thereto. Chroma shall be responsible for any field alert reporting in the ROW Territory and CTI shall reasonably assist Chroma with its annual reporting obligations.

(iii) Upon the request of CTI, Chroma shall inform each applicable Regulatory Authority in the ROW Territory that one (1) or more representatives of CTI will attend and, to the extent permitted by applicable Law, participate in all major meetings between Chroma and such Regulatory Authority, subject to the confidentiality provisions set forth under Article 12. Chroma shall timely inform CTI of any such scheduled meetings, as soon as practicably possible.

(iv) The Parties agree and acknowledge that the regulatory strategy for the ROW Territory shall be coordinated with CTI's activities in the Licensed Territory and consistent with the overall objective of facilitating Regulatory Approval in both the ROW Territory and Licensed Territory.

**5.3 Cooperation, Consultation and Review.** The Parties shall establish a joint regulatory working group as soon as reasonably possible following the Effective Date and shall cooperate with each other to achieve the regulatory objectives contemplated herein in a timely, accurate and responsive manner. Each Party shall assist the other Party as such other Party may reasonably request in connection with the preparation and filing of all Regulatory Materials contemplated in this Article 5. Each Party shall provide the other Party with copies of any proposed Regulatory Materials to be submitted by such Party (other than routine correspondence) and shall reasonably consider any comments thereto provided by the other Party to the extent practicable.

**5.4 Rights of Reference to Regulatory Materials.** Subject to the provisions of Sections 4.4 and 4.9, Chroma hereby grants to CTI a right of reference to all Regulatory Materials filed by or for Chroma for the Product solely for the purpose of seeking, obtaining and maintaining Regulatory Approvals for, and the Commercialization of, the Products in the Licensed Territory, consistent with the roles of the Parties set forth in this Agreement. Subject to the provisions of Sections 4.4 and 4.9, CTI hereby grants to Chroma a right of reference to all Regulatory Materials filed by or for CTI for the Product solely for the purpose of seeking, obtaining and maintaining Regulatory Approvals for, and the Commercialization of, the Products in the ROW Territory, consistent with the roles of the Parties set forth in this Agreement.

#### **5.5 Adverse Event Reporting and Safety Data Exchange.**

(a) **Licensed Territory.** The Parties agree that CTI will be primarily responsible for (i) maintaining the global safety database and (ii) monitoring of all clinical experiences in the Licensed Territory and (iii) safety monitoring, pharmacovigilance surveillance, compliance and filing of all required safety reports to Regulatory Authorities in the Licensed

\*\* 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.

Territory, including without limitation annual safety reports, throughout the Development of the Product in the Licensed Territory as and to the extent required by applicable Law for any study conducted under an IND held by CTI and in respect of the Commercialization of the Product by CTI in the Licensed Territory. The Parties shall cooperate to develop methods and/or procedures for transitioning the activities described in this section to CTI. Chroma will be responsible for all of such matters (except the global safety database) in the ROW Territory.

**(b) Safety Information Exchange; Agreement.** The Parties shall cooperate to develop methods and/or procedures for sharing information relating to the clinical experiences and in accordance with safety reporting requirements of the respective Regulatory Authorities and as necessary for a Party to comply with applicable Law.

**(c) Regulatory Reporting.** Each Party shall be permitted, and have the right, to perform pharmacovigilance activities and/or make such safety reports to applicable Regulatory Authorities, to comply with applicable Laws, international best practices for pharmacovigilance activities and/or other activities that the Party, in its reasonable and good faith judgment, believes necessary for the health, safety and protection of patients and/or clinical trial subjects. The Parties shall work together to agree to one opinion with respect to safety issues and to report said opinion to safety boards of any nature, investigators, and to applicable Regulatory Authorities. In the event that, after reasonable medical and scientific consultation, the Parties cannot agree to one opinion with respect to safety issues to be reported to any applicable Regulatory Authority, including but not limited to, individual adverse events or other matters affecting the health, safety or welfare of a patient, then, notwithstanding the provisions of Article 3, the Parties shall follow the dispute resolution procedure provided in Section 14.3(b). For clarity, the obligation to follow such dispute resolution procedure shall not limit either Party's right, as provided in the first sentence of this Section 5.5(c), to report safety matters to Regulatory Authorities that may be necessary prior to the conclusion of the dispute resolution procedure.

**(d) Separate Pharmacovigilance Agreement.** Within ninety (90) days of the Effective Date, the Parties shall negotiate in good faith and enter into a separate pharmacovigilance agreement to further detail the provisions of this Section 5.5.

**5.6 Recalls.** Any decision to initiate a recall of the Product in the Licensed Territory shall be made by CTI and in the ROW Territory shall be made by Chroma, in each case subject to the remaining provisions of this Section 5.6. Before initiating a recall of the Product each Party will consult with the other Party and shall take into account any reasonable comments made by the other Party. The costs of any recall in the Licensed Territory shall be borne by CTI and the costs of any recall in the ROW Territory shall be borne by Chroma, subject to any provisions to the contrary contained in the Supply Agreement.

**5.7 Regulatory Authority Communications Received by a Party.** Each Party shall keep the other Party informed in a timely manner compliant with the reporting requirements of Regulatory Authorities of notification of any action by, or notification or other information which it receives (directly or indirectly) from any Regulatory Authority which: (a) raises any

\*\* 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.

material concerns regarding the safety or efficacy of the Product; (b) indicates or suggests a potential material liability of either Party to Third Parties in connection with the Product; (c) is reasonably likely to lead to a recall or market withdrawal of the Product; or (d) relates to expedited and periodic reports of adverse events with respect to the Product, or Product Complaints, and which may have a material impact on Development of the Product, Regulatory Approval or the continued Commercialization of the Product. The other Party will fully cooperate with and assist such Party in complying with regulatory obligations and communications, including by providing to such Party, in a timely manner after a request, such information and documentation in the other Party's possession as may be necessary or helpful for the Party to prepare a response to an inquiry from a Regulatory Authority. Each Party will provide the other Party in a timely manner with a copy of all correspondence received from a Regulatory Authority specifically regarding the matters referred to above.

**5.8 Audit.** If a Regulatory Authority desires to conduct an inspection or audit of a Party's facility or a facility under contract with such Party with regard to the Product, then the audited Party shall notify the other Party as soon as practicably possible after receipt of such notification of such audit or inspection and provide copies of any materials provided to it by the applicable Regulatory Authority; provided, that the audited Party shall not be required to notify the other Party of audits or inspections that are of a routine nature or that do not relate to the Product, except where such audits result in communications or actions of such Regulatory Authority which have an impact upon the Product. In addition, if a Regulatory Authority conducts an unannounced inspection or audit of a Party's facility or a facility under contract with such Party with regard to the Product, then the audited Party shall notify the other Party within twenty-four (24) hours of commencement of such audit or inspection. The audited Party shall cooperate, and shall use reasonable efforts to cause the contract facility to cooperate, with such Regulatory Authority and the other Party during such inspection or audit. Following receipt of the inspection or audit observations of such Regulatory Authority (a copy of which the audited Party will immediately provide to the other Party), the audited Party will also provide the other Party with copies of any written communications received from Regulatory Authorities with respect to such facilities in a timely manner after receipt, to the extent such written communications relate to the Product or the Manufacture thereof, and will prepare the response to any such observations. The audited Party will provide the other Party with a copy of any proposed response to such communications and will implement such other Party's reasonable comments with respect to such proposed response. The audited Party agrees to conform its activities under this Agreement to any commitments made in such a response.

## ARTICLE 6

### COMMERCIALIZATION

**6.1 Overview of Commercialization in the Licensed Territory.** Subject to the other terms and conditions of this Article 6, as between the Parties, CTI control all aspects of the Commercialization of the Product in the Field in the Licensed Territory, including, without limitation: (a) developing and executing a commercial launch and pre-launch plan; (b) marketing

\*\* 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.

and promotion; (c) booking sales and distribution and performance of related services; (d) handling all aspects of order processing, invoicing and collection, inventory and receivables; (e) publications; (f) providing customer support, including handling medical queries, and performing other related functions; and (g) conforming its practices and procedures in all material respects to the applicable Laws relating to the marketing, detailing and promotion of the Products in the Field in the countries of the Licensed Territory. Except as otherwise provided in this Article 6, CTI shall bear all of the costs and expenses incurred in connection with all such Commercialization activities. For clarity, it is understood that CTI would be not responsible for any Commercialization of the Product in the ROW Territory, and as between the Parties, all costs and expenses thereof shall be borne by Chroma and the responsibility therefore shall be Chroma's.

**6.2 Sales and Marketing Plan.** Each Party will Commercialize the Products in its applicable territory pursuant to a detailed plan prepared by such Party and submitted to the JDC for review and comment (the "**Sales and Marketing Plans**"), but for clarity, not approval or consent. The Sales and Marketing Plans will include information, budgets and timelines regarding the applicable Party's Commercialization activities, including Product life cycle management, market research, sales training, distribution channels, customer service and sales force matters related to the launch and sale of the Product in the Field and in the applicable territory. The initial Sales and Marketing Plan for each Party shall be delivered to the JDC not later than three (3) months prior to the planned date for NDA submission to the FDA. On at least an annual basis (no later than March 1 of each calendar year thereafter), each Party shall update and amend, as appropriate, its then-current Sales and Marketing Plan. Each Party shall submit all updates and amendments to the Sales and Marketing Plan to the JDC for review and comment. The Parties agree that, as between the Parties (a) CTI will have planning, oversight, and final decision making authority (as provided expressly in Section 14.2) and responsibility for all sales, marketing, and promotional activities related to the Product in the Licensed Territory, and (b) Chroma will have planning, oversight, and final decision making authority (as provided expressly in Section 14.2) and responsibility for all sales, marketing, and promotional activities related to the Product in the ROW Territory, as expressly described in this Agreement. Each Party will have the opportunity, through the JDC, to confer with the other Party on such sales, marketing and promotional matters.

### **6.3 Pricing; Reimbursement.**

(a) As between the Parties, CTI shall have the sole right to determine all pricing of the Product in the Licensed Territory. Notwithstanding anything in this Agreement express or implied to the contrary, Chroma shall not have any right to direct, control, or approve CTI's pricing of Products for the Licensed Territory.

(b) As between the Parties, CTI shall have the sole right to determine the reimbursement strategy for the Product in the Licensed Territory. Chroma shall confer with CTI on the development of the reimbursement strategy for the Product for the initial indication in the

\*\* 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.

Licensed Territory in order to share the research and planning information relating to reimbursement processes already developed by Chroma.

(c) Chroma shall have the sole right to determine all pricing and reimbursement of the Product in the ROW Territory.

**6.4 Commercial Diligence.** CTI shall devote Diligent Efforts to Commercialize the Product and to maximize Net Sales of the Product, subject to compliance with applicable Laws, throughout the Licensed Territory following receipt of Regulatory Approval, including price approval, of such Product in accordance with this Agreement. CTI will launch the Product in the United States within ninety (90) days of receiving Regulatory Approval, including price approval, for the Product in the United States.

#### **6.5 Compliance.**

(a) **Licensed Territory.** CTI, its Affiliates and sublicensees shall comply with all applicable Laws and guidelines in the Licensed Territory applicable to the Commercialization of pharmaceutical products.

(b) **ROW Territory.** Chroma, its Affiliates and sublicensees shall comply with all applicable Laws and guidelines in the ROW Territory applicable to the Commercialization of pharmaceutical products.

(c) **No Obligation.** No Party shall be required to take any action, undertake any obligation, or incur any cost or reimbursement obligation, in connection with any activity under this Agreement that such Party believes, in good faith, may violate any applicable Laws.

#### **6.6 Trademark Matters.**

(a) **Product Mark.** It is the intention of the Parties that the Product be sold and marketed under a single worldwide brand, where practicable, legally and commercially viable, in accordance with the global branding strategy to be established by the JDC under Section 3.2(a)(v). Notwithstanding the foregoing, the Parties acknowledge such a single brand approach may not be viable for some countries. Unless determined otherwise by the JDC in the global branding strategy, as between the Parties, CTI will own the trademarks for the names of the Product to be used in the Licensed Territory and Chroma will own the trademarks for the names of the Products to be used in the ROW Territory (each a "**Product Mark**"), provided that in no event shall either Party be permitted to use the name of the other Party or any brand, logo or trademark of the other Party not solely used for the Product without such Party's express prior written consent. Each Party will be responsible at its own expense to perform any trademark clearance or registration for any Product Mark in its respective territory.

(b) **Marks.** Each Party shall provide the other with samples of any materials that incorporate the Product Marks prior to distributing such materials for use. Each Party acknowledges the other's exclusive ownership of the Product Marks in its respective territory and

\*\* 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.

agrees not to take any action inconsistent with such ownership, and any goodwill arising from the use of the Product Marks shall inure to the benefit of the owning Party. Neither Party shall use any Product Mark in a way that would adversely affect its value. Each Party covenants that it shall not use any trademark confusingly similar to or containing any Product Mark in connection with any products (including the Product).

## **6.7 Publication.**

**(a) Strategy.** The Publication Team, established pursuant to Section 6.7(b), in close cooperation with the JDC will agree in advance on any publication of study results from the Currently Ongoing Studies, any Additional Studies, Licensed Territory Specific Studies or Extraterritorial Studies and prepare a joint publication strategy and publication plan, subject to the provisions of this Section 6.7.

**(b) Publication Team.** The ESC shall establish a Publication Team composed of an equal number of representatives from each of CTI and Chroma with the reasonable balance of medical and scientific qualifications to agree on the detailed planning of the publication strategy and publication plan detailing the intended timing, venue, media, authors etc. for all publications of matters covered under this Section 6.7 including scientific articles, abstracts and posters intended for presentation at congresses. All health economic publications and communication at any congress shall be an integrated part of the publication strategy and plan. The Publication Team shall be co-chaired by representatives from both Parties and shall convene as deemed necessary to accomplish the above. In case of any dispute concerning publication the matter shall be referred to the ESC for resolution; provided, however, any such resolution shall be consistent with the guidelines set forth in Section 6.7(d).

**(c) Publication Review.** Except for disclosures permitted pursuant to Section 12.1 and consistent with the mutually agreed publication strategy pursuant to Section 6.7(a), either Party, its employees or consultants wishing to make a publication of matters covered under this Section 6.7 shall deliver to the other Party a copy of the proposed written publication or an outline of an oral disclosure at least sixty (60) days (or earlier if reasonably practicable, or within forty-five (45) days with respect to agreements existing as of the Effective Date that Chroma has with a Third Party performing clinical trials, research or the like in connection with such publication) prior to submission for publication or presentation. The reviewing Party shall have the right (a) to propose modifications to the publication or presentation for patent reasons or trade secret reasons and/or (b) to request a reasonable delay in publication or presentation in order to protect patentable information. If the reviewing Party requests a delay, the Parties shall in good faith discuss and agree on the timing of such publication and if the Parties cannot agree the publishing Party shall delay submission or presentation for a period of sixty (60) days (or forty-five (45) days with respect to agreements existing as of the Effective Date that Chroma has with a Third Party performing clinical trials, research or the like in connection with such publication) to enable patent applications protecting each Party's rights in such information to be filed in accordance with Article 9 below. Upon expiration of such sixty (60) days (or forty-five (45) days as provided above), the publishing Party shall be free to proceed with the

\*\* 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.

publication or presentation. If the reviewing Party requests modifications to the publication or presentation, the publishing Party shall edit such publication to prevent disclosure of trade secret or proprietary business information prior to submission of the publication or presentation.

**(d) Standards.** All publications of matters covered under this Section 6.7 shall be prepared, presented and/or published in accordance with pharmaceutical industry accepted guidelines including, but not limited to: (i) International Committee of Medical Journal Editors (ICMJE) guidelines, (ii) Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication, (iii) Pharmaceutical Research and Manufacturers of America (PhRMA) guidelines, and (iv) PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results.

**6.8 International Meetings.** The Parties shall consult with each other and coordinate their attendance at meetings, symposia, conferences and the like (“**Meetings**”) with regard to the Product. CTI will Take the Lead with regard to any Meetings with regard to the Product which are held in the Licensed Territory and Chroma will Take the Lead with regard to any Meetings with regard to the Product which are held in the ROW Territory.

**6.9 Key Opinion Leaders.** Each Party shall coordinate its activities with the other Party with regard to interactions with key opinion leaders in the Field related to the Product provided that neither Party shall be restricted from approaching or otherwise dealing with any particular key opinion leader.

## ARTICLE 7

### MANUFACTURE AND SUPPLY

**7.1 General Supply Terms.** As between the Parties Chroma will be solely responsible for the Manufacture of the Product for Development purposes in both the Licensed Territory and the ROW Territory in accordance with the terms of the Supply Agreement. As between the Parties, CTI will be solely responsible, by itself or through one or more Third Party contract manufacturers, for the Manufacture of the Product for Commercialization in the Licensed Territory. As between the Parties, Chroma will be solely responsible for the Manufacture of the Product for Commercialization in the ROW Territory.

**7.2 Supply Agreement.** The Parties shall decide, through the JDC, and as reflected in the terms of the Supply Agreement, a mutually acceptable supply chain for the manufacture of the Product for use in clinical trials, including which Party will be responsible for oversight, negotiations and management of Third Party vendors responsible for manufacturing the Product; provided, however, that neither Party will be obligated to use the same supply chain or to enter into joint contractual arrangements with one another or Third Parties relating to the manufacture of the Product. On or before a date to be established by the ESC but in no event later than ninety (90) days after the Effective Date, the Parties shall enter into a supply agreement governing the supply of Product to CTI for Development purposes (the “**Supply Agreement**”) and (b) a quality agreement governing the quality control, quality assurance and validation of such Product (the



\*\* 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.

“**Quality Agreement**”). The terms of such Supply Agreement and such Quality Agreement shall be negotiated in good faith by the Parties and will contain customary terms and conditions that are consistent with this Agreement. The purchase price for the Product under the Supply Agreements will be Chroma’s cost of manufacture and such purchase price will be considered part of the Development Costs. In the event that CTI wishes to have Chroma supply the Product for Commercialization purposes, the initial purchase price for such supply shall not exceed Chroma’s cost of manufacture plus \*\*. The Supply Agreement will provide appropriate technology transfer provisions (including provision of DMFs and other customary terms in the industry) sufficient to enable CTI to Manufacture the Product for Commercialization in the Licensed Territory in advance of any anticipated Product launch in the Licensed Territory. The Supply Agreement will provide that such technology transfer may be initiated by CTI at any time during the term of the Supply Agreement at CTI’s option by written notice and that Chroma will be obligated to provide such technology transfer. The Supply Agreement will also provide appropriate provisions to address supply related issues post termination under each of the termination scenarios addressed in Sections 13.7 and 13.8.

## ARTICLE 8

### COMPENSATION

**8.1 Upfront Fee.** Upon the date this Agreement is signed by both Parties, CTI shall pay to Chroma a one-time non-creditable, non-refundable (subject to the provisions of Section 15.9) upfront fee of \$5,000,000.

**8.2 Development Milestone Payments.** CTI shall make non-creditable, non refundable milestone payments to Chroma based on achievement of certain milestone events for the Product as set forth in this Section 8.2. CTI shall pay to Chroma the amounts set forth below within thirty (30) days after receipt of Chroma’s invoice following the achievement of the corresponding milestone event. Each milestone payment by CTI to Chroma hereunder shall be payable only once, regardless of the number of times achieved by the Products, and shall not be cumulative.

<u>Milestone Event</u>	<u>Milestone Payment</u>
<b>Indication: Acute Myelogenous Leukemia (AML) Milestone Payments</b>	
Upon Initiation of the first pivotal study (Phase 2 Clinical Trial and/or Phase 3 Clinical Trial) for AML, as set forth in the Development Plan	\$ 5,000,000

\*\* 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.

Upon first successful completion of a first pivotal study (Phase 2 Clinical Trial and/or Phase 3 Clinical Trial) for AML, as set forth in the Development Plan (measured by FDA acceptance to file NDA for AML)	\$	**
Within 90 days of first Regulatory Approval of an NDA by the FDA in r/r AML	\$	**
Upon first Regulatory Approval of an NDA by the FDA in First Line AML	\$	**

**Indication: Myelodysplastic Syndromes (MDS) Milestone Payments**

Upon first successful randomized Phase 2 Clinical Trial safety/efficacy results in MDS, as set forth in the Development Plan	\$	**
Upon first successful completion of Phase 3 Clinical Trial in MDS, as set forth in the Development Plan (measured by FDA acceptance to file NDA for MDS)	\$	**
Upon first Regulatory Approval by the FDA of an NDA in r/r MDS	\$	**
Upon first Regulatory Approval by the FDA of an NDA in First Line MDS	\$	**

**Indication: Multiple Myeloma (MM) Milestone Payments**

Upon first successful Phase 2 Clinical Trial safety/efficacy results in MM, as set forth in the Development Plan	\$	**
Upon first successful completion of Phase 3 Clinical Trial in MM, as set forth in the Development Plan (measured by FDA acceptance to file NDA for MM)	\$	**
Upon first Regulatory Approval by the FDA of an NDA in r/r MM	\$	**
Upon first Regulatory Approval by the FDA of an NDA in First Line MM	\$	**

**Indication: Solid Tumor Milestone Payments**

\*\* 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.

Upon first successful randomized Phase 2 Clinical Trial safety/efficacy results for solid tumors, as set forth in the Development Plan	\$	**
Upon first successful completion of Phase 3 Clinical Trial for solid tumors, as set forth in the Development Plan (measured by FDA acceptance to file NDA for the relevant solid tumor indication)	\$	**
First Regulatory Approval by the FDA of an NDA in r/r solid tumors affecting <10,000 pts/yr, as per the FDA approved label indication	\$	**
First Regulatory Approval by the FDA of an NDA in First Line solid tumors affecting > 10,000 <50,000 pts/yr, as per the per FDA approved label indication	\$	**
First Regulatory Approval by the FDA of an NDA in First Line solid tumors affecting > 50,000 pts/yr, as per the per FDA approved label indication	\$	**

For the avoidance of doubt, “acceptance” as used above shall mean acceptance for review of the applicable regulatory filing by the FDA, and “successful safety/efficacy results” means meeting the primary endpoint(s) of the applicable protocol as set forth in the final analysis plan submitted to the applicable Regulatory Authority.

If upon achievement of any development milestone for each indication described above, a previous development milestone for that indication has not been paid, then each such previous development milestone for that indication shall be payable along with the payment for the milestone then achieved for such indication.

CTI will provide written notice to Chroma of the achievement of any milestone above within thirty (30) calendar days of such achievement.

**8.3 Sales Milestones.** CTI shall make the following one-time, milestone payments to Chroma. Each milestone payment by CTI to Chroma hereunder shall be payable only once, regardless of the number of times achieved by the Products, and shall not be cumulative except for last milestone which is payable on cumulative Net Sales.

\*\* 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.

<u>Milestone Event</u>	<u>Milestone Payment</u>
Upon the first achievement of annual Net Sales in the Licensed Territory of \$75,000,000 (“Sales Event 1”).	\$ **
Upon the first achievement of annual Net Sales in the Licensed Territory of \$150,000,000 (“Sales Event 2”).	\$ **
Upon the first achievement of cumulative Net Sales in the Licensed Territory of \$250,000,000 (“Sales Event 3”).	\$ **

If Sales Event 1 and Sales Event 2 are achieved in a single calendar year, milestone payments for each of such events will be payable in that same calendar year. However, if Sales Event 2 and Sales Event 3 are achieved in a single calendar year, only the milestone payment for Sales Event 3 will be due in that same calendar year and the milestone payment for Sales Event 2 in such case will not be due until 1 January in the next calendar year.

CTI shall provide written notice to Chroma of the achievement of any sales milestone above within forty-five (45) calendar days after the end of the calendar quarter in which such sales milestone was achieved. Except as otherwise provided above in this Section 8.3, each sales milestone payment will be due within thirty (30) days of the date of Chroma’s invoice therefor. Each milestone payment shall be non-refundable and non-creditable.

#### **8.4 Royalties.**

**(a) Royalty Rates for Licensed Territory.** Subject to Sections 8.4(b), 8.4(c) and 8.4(d) below, and during the applicable Royalty Term, CTI shall pay to Chroma a running royalty at the following incremental royalty rates, on aggregate, annual Net Sales of the Products in the Licensed Territory.

<u>Net Sales in the Licensed Territory</u>	<u>Royalty Rate</u>
For that portion of annual Net Sales less than or equal to \$150,000,000	**0%
For that portion of annual Net Sales greater than \$150,000,000 but less than or equal to \$350,000,000	**0%
For that portion of annual Net Sales greater than \$350,000,000	**0%

\*\* 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.

**(b) Single Royalty.** Royalties payable under Section 8.4(a) will be payable only once with respect to a particular unit of the Product and will be paid only once regardless of the number of Chroma Patents applicable to such Product.

**(c) Reduction of Royalty Following Entry of Generic Product.** Following (i) (1) expiration of the last-to-expire Chroma Patent or (2) any lack of protection or enforcement of all non-expired Chroma Patents (as provided in Article 9) covering the Development, Manufacture, use or sale of Products in a country of the Licensed Territory (including any Patent Term Extensions thereof) or (ii) expiration of all Regulatory Exclusivity periods with respect to the Product in such country, the royalty rates set forth in Section 8.4(a) for Net Sales during the remainder of the Royalty Term in such country shall be reduced by \*\* at the end of the first to occur six (6) month period during which one or more Third Parties sells a number of equivalent units of a Generic Version of the Product in such country of the Licensed Territory comprising, during such time period, \*\* or more of the aggregate combined number of equivalent units of such Product and such Generic Version(s) of such Product sold in such time period in such country ("**the Threshold**"), provided that in no event shall the royalty rates set forth in Section 8.4(a) be reduced below a figure which is the sum of \*\* and the applicable royalty payable by Chroma to Vernalis under the Vernalis Agreement for any such period during the Royalty Term. All such determinations of unit volume shall be based upon a mutually acceptable calculation method and using market share data provided by a reputable and mutually agreed upon provider, such as IMS Health. As used in this Section 8.4(c), "**Generic Version**" means, with respect to the Product, a product sold by a Third Party that (A) contains a Compound as an active ingredient, and (B) has been approved for sales introduction into interstate commerce by reference to the Product pursuant to (1) Section 505(b)(2) or Section 505(j) of the United States Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2) and 21 U.S.C. 355(j), respectively), or (2) any similar approval in any other country of the Licensed Territory, which similar approval is based on reference to the Regulatory Approval for the Product in such country and a demonstration of bio-equivalence or similarity to the Product. At any time following introduction of the initial Generic Version of the Product in a country achieving a market share of at least the Threshold and upon written notice of CTI expressing concern regarding the continued commercial viability of the Product in such country, the Parties agree to negotiate in good faith a mutually acceptable strategy to address CTI's concerns with a view toward preserving the historic economic balance and profit splits between the Parties.

**(d) Third Party Royalties.**

**(i)** During the Term, Chroma shall remain responsible for the payment of royalties and other payment obligations, if any, due to Third Parties under any Chroma Technology which has been licensed to Chroma and is sublicensed to CTI hereunder, including without limitation any payments due under the Upstream Agreements.

**(ii)** Except as set forth in clause (i) or (iii) of this Section 8.4 (d), or to the extent of any Claim for which Chroma provides indemnification under Section 11.1, or as the Parties may otherwise agree in writing, CTI shall bear any payments associated with any

\*\* 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.

royalties owed to any Third Party for intellectual property that is necessary or useful for the Development, Manufacture, storage, handling, use, promotion, sale, offer for sale, importation or other Commercialization of Products for sale in the Licensed Territory (the “**Third Party Royalties**”).

(iii) During the Term, if CTI determines, in good faith, that it is necessary to seek or exercise any license from any Third Party for intellectual property that is necessary for the Development, Manufacture, storage, handling, use, promotion, sale, offer for sale, importation of other Commercialization of Products for sale in the Licensed Territory, CTI may credit up to \*\* of the amount of any Third Party Royalties paid by CTI for Third Party intellectual property pursuant to clause (ii) above against royalties payable to Chroma under Section 8.4(a) provided that in no event shall the royalty rates set forth in Section 8.4(a) be reduced below the sum of \*\* and the applicable royalty rate payable by Chroma to Vernalis under the Vernalis Agreement. CTI may take such credit during any calendar quarter for which royalties are payable hereunder; provided, that in no event will such credit reduce the royalties payable to Chroma for such calendar quarter by more than \*\*. Any share of such Third Party Royalties that remains uncredited due to the application of such floor may be carried forward to subsequent calendar quarters.

**8.5 No Projections.** Chroma and CTI acknowledge and agree that nothing in this Agreement shall be construed as representing an estimate or projection of anticipated sales of any Product, and that the milestones and Net Sales levels set forth in Sections 8.3 and 8.4 or elsewhere in this Agreement or that have otherwise been discussed by the Parties are merely intended to define the milestone payments and royalty obligations to Chroma in the event such milestones and/or Net Sales levels are achieved.

**8.6 Royalty Reports and Payment.** Within forty five (45) calendar days following the end of each calendar quarter during the Term, CTI shall provide Chroma with a report containing the following information for the applicable calendar quarter: the amount of gross sales of Product on a country-by-country basis in the Licensed Territory, an itemized calculation of Net Sales in the Licensed Territory showing deductions, to the extent practicable, provided for in the definition of “Net Sales,” a calculation of the royalty payment due on such sales, an accounting of the number of units and prices for Product sold, the exchange rate for each country in which Product was sold, the application of the reductions, if any, made in accordance with the terms of Section 8.4(c) or Section 8.4(d), and any other information reasonably required by Chroma for the purpose of calculating royalties and other amounts due under this Agreement. Any royalty payments due to Chroma will be paid on the date of delivery of such report. In the event that either party determines that the calculation of Net Sales for a calendar quarter deviates from the amounts previously reported to Chroma for any reason (such as, on account of additional amounts collected or Product returns), CTI and Chroma shall reasonably cooperate to reconcile any such deviations to the extent necessary under applicable legal or financial reporting requirements.

\*\* 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.

**8.7 Foreign Exchange.** The rate of exchange to be used in computing the amount of currency equivalent in Dollars owed to a Party under this Agreement shall be the monthly average exchange rate between each currency of origin and U.S. Dollars as reported by Bloomberg or an equivalent resource as agreed by the Parties.

**8.8 Payment Method; Late Payments.** All payments due to Chroma under Article 8 shall be made in U.S. Dollars by wire transfer of immediately available funds into an account designated by Chroma. If Chroma does not receive payment of any sum due to it under Article 8 on or before the due date, simple interest shall thereafter accrue on the sum due to Chroma until the date of payment at the per annum rate of two percent (2%) over the then-current prime rate quoted by Citibank in New York City or the maximum rate allowable by applicable Law, whichever is lower.

**8.9 Records; Audits.** CTI will maintain complete and accurate records in sufficient detail to permit Chroma to confirm the accuracy of the calculation of royalty and milestone payments under this Article 8. Upon reasonable prior notice, such records shall be available during regular business hours for a period of four (4) years from the end of the calendar year to which they pertain for examination at the expense of Chroma, and not more often than once each calendar year, by an independent certified public accountant selected by Chroma and reasonably acceptable to CTI, for the sole purpose of verifying the accuracy of the financial reports furnished by CTI pursuant to this Article 8. Any such auditor shall not disclose CTI's Confidential Information. Any amounts shown to be owed but unpaid shall be paid within thirty (30) days from the accountant's report, plus interest (as set forth in Section 8.8) from the original due date. Any amounts shown to have been overpaid shall be refunded within thirty (30) days from the accountant's report. Chroma shall bear the full cost of such audit unless such audit discloses an underpayment by CTI of more than \*\* of the amount due, in which case CTI shall bear the full cost of such audit.

#### **8.10 Taxes.**

**(a) Cooperation and Coordination.** The Parties acknowledge and agree that it is their mutual objective and intent to appropriately calculate, to the extent feasible and legal, taxes payable with respect to their collaborative efforts under this Agreement and that they shall use all commercially reasonable efforts to cooperate and coordinate with each other to achieve such objective. Without limiting the foregoing, Chroma agrees to provide to CTI reasonable assistance and information regarding any Value Added Tax assessments and requirements.

**(b) Payment of Tax.** A Party receiving a payment pursuant to this Article 8 shall pay any and all taxes levied on such payment. If applicable Laws require that taxes be deducted and withheld from a payment made pursuant to this Article 8, the remitting Party shall (i) deduct those taxes from the payment; (ii) pay the taxes to the proper taxing authority; and (iii) send evidence of the obligation together with proof of payment to the other Party within sixty (60) days following that payment. The paying Party shall cooperate with and provide reasonable assistance to the receiving Party to prevent the application of any withholding, to obtain the

\*\* 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.

benefit of any double taxation treaty or to obtain repayment of any tax which is required to be withheld.

**(c) Tax Residence Certificate.** A Party (including any entity to which this Agreement may be assigned, as permitted under Section 15.5) receiving a payment pursuant to this Article 8 shall provide the remitting Party appropriate certification from relevant revenue authorities that such Party is a tax resident of that jurisdiction, if such receiving Party wishes to claim the benefits of an income tax treaty to which that jurisdiction is a party. Upon the receipt thereof, any deduction and withholding of taxes shall be made at the appropriate treaty tax rate.

**(d) Assessment.** Either Party may, at its own expense, protest any assessment, proposed assessment, or other claim by any Governmental Authority for any additional amount of taxes, interest or penalties or seek a refund of such amounts paid if permitted to do so by applicable Law. The Parties shall cooperate with each other in any protest by providing records and such additional information as may reasonably be necessary for a Party to pursue such protest.

## ARTICLE 9

### INTELLECTUAL PROPERTY MATTERS

**9.1 Ownership of Inventions.** Each Party shall own any inventions made and funded solely by its or its Affiliates own employees, agents, or independent contractors in the course of conducting its activities under this Agreement, together with all intellectual property rights therein (“**Sole Inventions**”). The Parties shall jointly own any inventions that are (a) made jointly by employees, agents, or independent contractors of each Party or their Affiliates or (b) jointly funded by the Parties (including as a result of any Development activities jointly funded by the Parties pursuant to Article 4) in the course of performing activities under this Agreement, together with all intellectual property rights therein (“**Joint Inventions**”). Inventorship shall be determined in accordance with U.S. patent laws. Subject to the terms of this Agreement (including without limitation the licenses granted in Article 2), each Party may use and practice the Joint Inventions for any purpose and may assign, license or otherwise transfer or exploit its rights to the Joint Inventions to an Affiliate or Third Party, without the other Party’s consent and without a duty of accounting to the other Party. For the avoidance of doubt, Chroma’s interest in the Joint Inventions (including its interest in the Joint Patents) will be exclusively licensed to CTI under the same terms the licenses granted in Section 2.1 but will not be subject to royalty payments set forth in Section 8.4. CTI grants to Chroma an exclusive, royalty free, sublicensable (in accordance with the terms of this Agreement) license under CTI’s interest in any Joint Invention to Develop, Manufacture, use, make, have made, sell, offer for sale, have sold, distribute, import and otherwise Commercialize the Product in the Field in the ROW Territory.

**9.2 Right of First Negotiation and Refusal.** With respect to CTI’s Sole Inventions necessary or useful in the Development, Manufacture or Commercialization of the Product in the Field in the ROW Territory (“**Subject CTI Rights**”), Chroma has the following right of first negotiation and right of first refusal during the Term, subject to any rights CTI has already



\*\* 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.

granted to Third Parties as of the Effective Date with respect to Patents and Know-How Controlled by CTI.

(a) CTI shall not propose, negotiate or enter into a contract or arrangement with any Third Party to license or otherwise dispose of the Subject CTI Rights, unless CTI has first notified Chroma in writing (“**Initial Notice**”) of its intent to license or otherwise dispose of the Subject CTI Rights (“**Applicable Transaction**”). The Initial Notice shall provide the material commercially reasonable terms for the Applicable Transaction. Chroma will have \*\* days from the date of the Initial Notice (“**Initial Period**”) to notify CTI whether Chroma wishes to engage in negotiations for the Applicable Transaction. If Chroma elects to proceed with such discussions, Chroma shall so notify CTI in writing and the Parties will use good faith efforts to enter into the Applicable Transaction within \*\* days from the date of Chroma’s notice (“**Negotiation Period**”). If Chroma notifies CTI in writing that it does not wish to enter into the Applicable Transaction or if CTI does not receive a written notice from Chroma at the end of the Initial Period or if the Parties cannot execute a definitive agreement for the Applicable Transaction by the end of the Negotiation Period, CTI will be free to pursue the Applicable Transaction with any Third Party, subject to Chroma’s right of first refusal below.

(b) Prior to consummating any Applicable Transaction with any Third Party after Chroma’s right of first negotiation provided in Section (a) above has ceased, CTI shall provide Chroma written notice of the proposed material terms in any proposed Applicable Transaction with such Third Party (“**ROFR Notice**”). If Chroma notifies CTI within \*\* business days of the date of the ROFR Notice (“**ROFR Notice Period**”) that Chroma wishes to consummate the Applicable Transaction described in the ROFR Notice, then CTI and Chroma shall enter into a definitive agreement including the material terms described in the ROFR Notice for the proposed Applicable Transaction in a period of no greater than \*\* days. Subsequent to such \*\* day time period, or if Chroma does not notify CTI in writing that it wishes to enter into the Applicable Transaction described in the ROFR Notice within the ROFR Notice Period, or if Chroma rejects the Applicable Transaction described in the ROFR Notice, then CTI may enter into negotiations and/or an agreement regarding the Applicable Transaction as described in the ROFR Notice with the Third Party without further obligations to Chroma.

**9.3 Disclosure of Inventions.** Each Party shall promptly disclose to the other any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing inventions that are either Sole Inventions or Joint Inventions, and all information relating to such inventions to the extent necessary for the preparation, filing and maintenance of any Patent with respect to such invention.

#### **9.4 Prosecution of Patents.**

(a) **Chroma Patents.** The Chroma Patents in existence as of the Effective Date are listed in Exhibit B-1 hereto. The Parties shall update such Exhibit as appropriate (and at least once per calendar quarter) to add to Exhibit B-1 each Patent filed after the Effective Date by Chroma or its Affiliates (or any applicable licensor) which would constitute an Chroma Patent

\*\* 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.

hereunder. Except as otherwise provided in this Section (a), as between the Parties, Chroma shall have the sole right and authority to prepare, file, prosecute and maintain the Chroma Patents on a worldwide basis. Chroma shall bear all costs of preparation, filing, prosecution and maintenance of Chroma Patents. Chroma shall provide CTI reasonable opportunity to review and comment on such efforts regarding such Chroma Patents, including by providing CTI with a copy of material communications from any patent authority regarding such Chroma Patent, and by providing drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. If Chroma determines in its sole discretion to abandon or not maintain any Chroma Patent(s) that is being prosecuted or maintained by Chroma, then Chroma shall provide CTI with written notice of such determination within a period of time reasonably necessary to allow CTI to determine its interest in such Chroma Patent(s). In the event CTI provides written notice expressing its interest in obtaining such Chroma Patent(s), Chroma shall free of charge assign and transfer to CTI the ownership of, and interest in, such Chroma Patent(s), at CTI's sole expense, and Chroma shall cooperate with CTI for assignment and transfer of such Chroma Patent(s) at CTI's sole expense. CTI shall thereafter bear all costs of preparation, filing, prosecution and maintenance of such assigned and transferred Patents. In the event that CTI decides to abandon or not maintain any such Patent(s), CTI shall promptly provide Chroma with written notice of such decision. Chroma shall only be obliged to comply with the provisions of this Section 9.4(a) and 9.4(c) below with respect to any Chroma Patent which is licensed to Chroma under the Vernalis Agreement to the extent that Chroma is not prohibited to do so pursuant to the terms of the Vernalis Agreement, provided that in any event Chroma shall use commercially reasonable efforts to cause Vernalis to comply with these provisions. If, despite Chroma's commercially reasonable efforts, Chroma is not able to cause Vernalis to so comply, CTI's commercial diligence obligations under Section 6.4 shall be equitably adjusted in light of such lack of compliance.

**(b) Joint Patents.** Except as otherwise provided in this Section 9.4(b), CTI shall have the primary right and authority to prepare, file, prosecute and maintain the Patents filed in relation to the Joint Inventions ("**Joint Patents**") on a worldwide basis. Chroma and CTI shall share equally all reasonable costs of preparation, filing, prosecution and maintenance of the Joint Patents. CTI shall provide Chroma with the reasonable opportunity (and unless necessary to avoid a material adverse impact on such Joint Patents, at least thirty (30) days) to review and comment on such efforts regarding such Joint Patent, including by providing Chroma with a copy of material communications from any patent authority in such country(ies) regarding such Joint Patent, and by providing drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses, and CTI shall give due consideration to any reasonable comments made by Chroma. If CTI determines in its sole discretion to abandon or not maintain any Joint Patent(s) in any country(ies) of the world, then CTI shall provide Chroma with written notice of such determination within a period of time reasonably necessary to allow Chroma to determine its interest in such Joint Patent(s). In the event Chroma provides written notice expressing its interest in obtaining such Joint Patent(s), CTI shall free of charge assign and transfer to Chroma the ownership of, and interest in, such Joint Patent(s) in such country(ies), at Chroma's sole expense, and CTI shall cooperate with Chroma with regard to the assignment and transfer of such Joint Patent(s) in such country.

\*\* 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.

**(c) Cooperation in Prosecution.** Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent prosecution efforts provided above in this Section 9.4, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution, as well as further actions as set forth below.

**(i)** The Parties shall respectively prepare, file, maintain and prosecute the Chroma Patents and Joint Patents as set forth in this Section 9.4. As used herein, "prosecution" of such Patents shall include, without limitation, all communication and other interaction with any patent office or patent authority having jurisdiction over a patent application in connection with pre-grant proceedings. Post-grant proceedings shall be governed by Section 9.9(b).

**(ii)** All communications between the Parties relating to the preparation, filing, prosecution or maintenance of the Chroma Patents and Joint Patents, including copies of any draft or final documents or any communications received from or sent to patent offices or patenting authorities with respect to such Patents, shall be considered Confidential Information and subject to the confidentiality provisions of Article 12.

**9.5 Patent Term Extensions.** The ESC will discuss and recommend for which, if any, of the Patents within the Chroma Patents and Joint Patents the Parties should seek Patent Term Extensions. Chroma, in the case of the Chroma Patents, and CTI in the case of the Joint Patents, shall have the final decision-making authority with respect to applying for any such Patent Term Extensions, and will act with reasonable promptness in light of the development stage of Products to apply for any such Patent Term Extensions, where it so elects; provided, however, that if in a particular country or jurisdiction only one such Patent can obtain a Patent Term Extension, then the Parties will consult in good faith to determine which such Patent should be the subject of efforts to obtain a Patent Term Extension, and in any event CTI's decision on such matter will control in the case of a disagreement with regard to the Licensed Territory and Chroma's decision on such matters will control in the case of disagreement with regard to the ROW Territory. The Party that does not apply for an extension hereunder will cooperate fully with the other Party in making such filings or actions, for example and without limitation, making available all required regulatory data and information and executing any required authorizations to apply for such Patent Term Extension. All expenses incurred in connection with activities of each Party with respect to the Patent(s) for which such Party seeks Patent Term Extensions pursuant to this Section 9.5 shall be entirely borne by such Party. Chroma shall only be obliged to comply with the provisions of this Section 9.5 with respect to any Chroma Patent which is licensed to Chroma under the Vernalis Agreement to the extent that Chroma is not prohibited to do so pursuant to the terms of the Vernalis Agreement, provided that in any event Chroma shall use commercially reasonable efforts to cause Vernalis to comply with these provisions. If, despite Chroma's commercially reasonable efforts, Chroma is not able to cause Vernalis to so comply, CTI's commercial diligence obligations under Section 6.4 shall be equitably adjusted in light of such lack of compliance. CTI's rights under this Section 9.5 will

\*\* 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.

be correspondingly limited by the rights which Chroma is able to exercise pursuant to the Vernalis Agreement.

#### **9.6 Infringement of Patents by Third Parties.**

**(a) Notification.** Each Party shall promptly notify the other Party in writing of any existing or threatened infringement of the Chroma Patents or Joint Patents of which it becomes aware, and shall provide all evidence in such Party's possession demonstrating such infringement.

##### **(b) Infringement of Chroma Patents or Joint Patents in the Licensed Territory.**

**(i)** If a Third Party infringes any Chroma Patent or Joint Patent in the Licensed Territory by making, using, importing, offering for sale or selling the Product or a competitive product (a "**Product Infringement**"), each Party shall share with the other Party all information available to it regarding such alleged infringement. CTI shall have the first right, but not the obligation, to bring an appropriate suit or other action against any person or entity engaged in such Product Infringement in the Licensed Territory, subject to Section 9.6(b)(ii) through 9.6(b)(v), below.

**(ii)** CTI shall have a period of thirty (30) days after the first notice under 9.6(a) to elect to enforce such Chroma Patent or Joint Patent against such Product Infringement. In the event CTI does not so elect, CTI shall so notify Chroma in writing, and Chroma shall have the right to commence a suit or take action to enforce the applicable Patent against such Third Party perpetrating such Product Infringement in the Licensed Territory at its own cost and expense. If one Party elects to bring suit or take action against the Product Infringement, then the other Party shall have the right, prior to commencement of the trial, suit or action, to join any such suit or action.

**(iii)** Each Party shall provide to the Party enforcing any such rights under this Section 9.6(b) reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by applicable Law to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts, shall reasonably consider the other Party's comments on any such efforts, and shall seek consent of the other Party in any important aspects of such enforcement including, without limitation, determination of litigation strategy, filing of important papers to the competent court, which shall not be unreasonably withheld or delayed.

**(iv)** Each Party shall bear all of its own internal costs incurred in connection with its activities under this Section 9.6(b); provided, that in the event that the Parties are joined in suit or action against the Product Infringement and represented by the same outside counsel, then the Parties shall share equally in the external costs and expenses for such action.

\*\* 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.

(v) The Party not bringing an action with respect to Product Infringement in the Licensed Territory under this Section 9.6(b) shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the Party bringing such action.

(c) **Settlement.** Neither Party shall settle any claim, suit or action that it brought under this Section 9.6 involving Chroma Patents or Joint Patents without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed.

(d) **Allocation of Proceeds.** If either Party recovers monetary damages from any Third Party in a suit or action brought under Sections 9.6(b) or 9.6(c), whether such damages result from the infringement of Chroma Patents or Joint Patents, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation and any remaining amounts shall be split as follows: such amounts shall be allocated \*\* to Chroma and \*\* to CTI.

(e) **Upstream Agreements.** Chroma shall only be obliged to comply with the provisions of this Section 9.6 with respect to any Chroma Patent which is licensed to Chroma under the Vernalis Agreement to the extent that Chroma is not prohibited to do so pursuant to the terms of the Vernalis Agreement, provided that in any event Chroma shall use commercially reasonable efforts to cause Vernalis to comply with these provisions. If, despite Chroma's commercially reasonable efforts, Chroma is not able to cause Vernalis to so comply, CTI's commercial diligence obligations under Section 6.4 shall be equitably adjusted in light of such lack of compliance. CTI's rights under Section 9.6 will be correspondingly limited by the rights which Chroma is able to exercise pursuant to the Vernalis Agreement.

**9.7 Infringement of Third Party Rights.** If any Product Developed, Manufactured, made, have made, stored, handled, used, promoted, sold, offered for sale, imported or otherwise Commercialized by either Party, its Affiliates, licensees or sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent granted by a jurisdiction within the Licensed Territory or the ROW Territory, the Party first having notice of the claim or assertion shall promptly notify the other Party, the Parties shall agree on and enter into an "identity of interest agreement" wherein such Parties agree to their shared, mutual interest in the outcome of such potential dispute, and thereafter, the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action provided that each Party shall be entitled to defend any such Third Party claim or assertion made against it as it reasonably determines.

**9.8 Patent Marking.** CTI (or its Affiliate, sublicensee or distributor) shall mark Products marketed and sold by CTI (or its Affiliate, sublicensee or distributor) hereunder with appropriate patent numbers or indicia at Chroma's reasonable request; provided, however, that CTI shall only be required to so mark such Products to the extent such markings or such notices would impact recoveries of damages or equitable remedies available under applicable Law with respect to infringements of Patents in the Licensed Territory.

**9.9 Patent Oppositions and Other Proceedings.**

\*\* 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.

**(a) Third-Party Patent Rights.** If either Party desires to bring, anywhere in the world, an opposition, action for declaratory judgment, nullity action, interference, declaration for non-infringement, reexamination or other attack upon the validity, title or enforceability of a Patent owned or controlled by a Third Party and having one or more claims that covers the Product, or the use, sale, offer for sale or importation of the Product, such Party shall so notify the other Party and the Parties shall promptly confer to determine whether to bring such action or the manner in which to settle such action. CTI shall have the exclusive right, but not the obligation, to bring at its own expense and in its sole control such action in the Licensed Territory. If CTI does not bring such an action in the Licensed Territory, within ninety (90) days of notification thereof pursuant to this Section 9.9(a) (or earlier, if required by the nature of the proceeding), then Chroma shall have the right, but not the obligation, to bring, at Chroma's sole expense, such action. The Party not bringing an action under this Section 9.9(a) shall be entitled to separate representation in such proceeding by counsel of its own choice and at its own expense, and shall cooperate fully with the Party bringing such action. Any awards or amounts received in bringing any such action shall be first allocated to reimburse the initiating Party's expenses in such action, and any remaining amounts shall be retained by such Party.

**(b) Parties' Patent Rights.** If any Chroma Patent or Joint Patent becomes the subject of any proceeding commenced by a Third Party within the Licensed Territory or the ROW Territory in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability thereof (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, an action for infringement against a Third Party under Section 9.6, in which case the provisions of Section 9.6 shall govern), then the Party responsible for filing, preparing, prosecuting and maintaining such Patent as set forth in Section 9.4 hereof, shall control such defense at its own cost and expense. The controlling Party shall permit the non-controlling Party to participate in the proceeding to the extent permissible under applicable Law, and to be represented by its own counsel in such proceeding, at the non-controlling Party's expense.

**9.10 Vernalis Agreement.** Within \*\* days after the execution of this Agreement, Chroma shall use commercially reasonable efforts to either (i) \*\* or (ii) amend the Vernalis Agreement to address issues related to \*\*, in each case subject to CTT's prior written approval, not to be unreasonably withheld, delayed or conditioned.

## ARTICLE 10

### REPRESENTATIONS AND WARRANTIES

**10.1 Mutual Representations and Warranties.** Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows:

**(a) Organization, Existence and Power.** As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is organized, and has full organizational (whether corporate or

\*\* 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.

otherwise) power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement.

**(b) Authority and Binding Agreement.** As of the Effective Date, (i) it has the organizational power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary organizational action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (iii) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

**(c) No Conflict; Covenant.** It is not a party to any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under the Agreement.

**(d) No Debarment.** In the course of the development of Products, each Party shall not use, during the Term, any employee or consultant who has been debarred by any Regulatory Authority, or, to the best of such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority.

**10.2 Additional Representations and Warranties of Chroma.** Chroma represents and warrants, on its behalf and on behalf of each of its Affiliates, to CTI as follows:

**(a) Chroma Patents.** Exhibits B-1 sets forth a complete and accurate list of all Chroma Patents in existence as of the Effective Date. Chroma is the exclusive licensee of those Chroma Patents listed on Exhibit B-1, free and clear of any liens, security interests, encumbrances (other than the security interest described on Exhibit B-1). To Chroma's Best Knowledge, no party to any Upstream Agreement has granted any liens, security interests or encumbrances to the Chroma Technology. Chroma is listed in the records of the appropriate United States and/or foreign governmental agencies in the Licensed Territory as the sole and exclusive licensee of record for each registration, grant and application included in the Chroma Patents.

**(b) Chroma Know-How.** Chroma is the sole and exclusive owner of all of the Chroma Know-How, free and clear of any liens, security interests, encumbrances or claims of ownership of license from a Third Party (other than the security interest specifically described on Exhibit B-1). Chroma has the right to use and disclose and to enable CTI to use and disclose (in each case under appropriate conditions of confidentiality) the Chroma Know-How. Chroma has taken all reasonable precautions to preserve the confidentiality of the Chroma Know-How, and has not disclosed to any Third Party any Chroma Know-How that is or was confidential except under terms which preserved its confidentiality.

**(c) Rights to Grant Licenses.** Chroma has the right to grant to CTI the licenses under the Chroma Technology that it purports to grant hereunder.

\*\* 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.

**(d) No Out-Bound Agreements.** Chroma has not granted any Third Party, including any academic organization or agency, any rights to the Product other than the material transfer agreements disclosed to CTI prior to the Effective Date.

**(e) Sufficiency of Chroma Technology.** As of the Effective Date, to Chroma's Best Knowledge, the Chroma Technology constitutes all intellectual property necessary for, and no Third Party Know-How is needed to, Develop, Manufacture, use, make, have made, sell, offer for sale, have sold, distribute, import and otherwise Commercialize the Product in the Licensed Territory. Without limiting the foregoing, Chroma represents and warrants that the Chroma Patents listed on Exhibit B-1 have all been licensed to Chroma under the Vernalis Agreement and, to Chroma's Best Knowledge, none of the intellectual property (including Patents) licensed to \*\*, is necessary or useful to Develop, Manufacture, use, make, have made, sell, offer for sale, have sold, distribute, import and otherwise Commercialize the Product in the Field in the Licensed Territory. Chroma further represents and warrants that none of its Affiliates, as of the Effective Date, have any ownership of or any rights to any intellectual property (including Patents) in the Licensed Territory relating to the Chroma Technology.

**(f) Non-Infringement of Chroma Technology by Third Parties.** As of the Effective Date, to Chroma's Best Knowledge, there are no ongoing activities by Third Parties that would constitute infringement or misappropriation of the Chroma Technology within the Licensed Territory.

**(g) Non-Infringement.** As of the Effective Date, to Chroma's Best Knowledge, none of the manufacture, use or the sale of the Product in the Licensed Territory infringes any Patent owned by a Third Party or infringes or misappropriates any other Third Party intellectual property. As of the Effective Date, Chroma has not received any verbal or written claim or demand of any person or entity that the manufacture, use, or sale of the Product in the Licensed Territory infringes a Third Party Patent.

**(h) Chroma Patents Not Invalid or Unenforceable.** As of the Effective Date, the Chroma Patents exist, and Chroma has not received any written notice from a Government Authority or from any Third Party that the Chroma Patents are invalid or unenforceable, in whole or in part. To Chroma's Best Knowledge, Chroma has filed and prosecuted patent applications within the Chroma Patents in good faith and complied with all duties of disclosure with respect thereto and Chroma is not aware of any prior art or third party rights that would challenge the validity of the Chroma Patents. In addition, to Chroma's Best Knowledge, Chroma has not committed any act, or omitted to commit any act, that may cause the Chroma Patents to expire prematurely or be declared invalid or unenforceable.

**(i) Disclosure.** Prior to the Effective Date, Chroma made available to CTI, or provided CTI with, copies of all information with respect to the Product as requested by CTI in writing. In addition, as of the Effective Date Chroma has disclosed to CTI any material information known to Chroma as of such date with respect to (i) the safety of the Product, (ii) the efficacy of the Product, (iii) any then-existing circumstance which would be reasonably likely to



\*\* 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.

prohibit or prevent the Development, Manufacturing and/or Commercialization of the Product in the Licensed Territory.

**(j) Non-Action or Claim.** As of the Effective Date, to Chroma's Best Knowledge, there are no actual, pending, alleged or threatened adverse actions, suits, claims, interferences or formal governmental investigations involving the Product and/or the Chroma Technology by or against Chroma or any of its Affiliates in or before any court, governmental or Regulatory Authority. In particular, as of the Effective Date, to its Best Knowledge, there is no pending or threatened product liability action involving the Product. As of the Effective Date, there are no claims, judgments or settlements against or owed by Chroma relating to the Chroma Technology or the Product.

**(k) Regulatory Materials and Studies.** To Chroma's Best Knowledge, all Regulatory Materials Controlled by Chroma in existence as of the Effective Date and to which CTI has rights of use or reference hereunder, including the Regulatory Materials described in Section 5.1, have been prepared, maintained and retained in accordance with applicable Laws. All preclinical and clinical studies conducted with respect to the Product, including such studies from which the data described in Section 5.1 are derived, have to Chroma's Best Knowledge been conducted substantially in accordance with applicable Laws by persons with appropriate education, knowledge and experience.

**(l) Upstream Agreements.** (i) Chroma has provided CTI with a complete, current and accurate copy of each of the Upstream Agreements, including all amendments of each, as such agreements exist on the date hereof; (ii) Chroma has complied at all times with its obligations under the Vernalis Agreement, (iii) Chroma is not in default or breach, and there are no circumstances existing on the date hereof which, with notice or the passage of time or both, could reasonably be expected to result in a default under the Vernalis Agreement, (iv) the Upstream Agreements are in full force and effect and are legal, valid and binding agreements, and enforceable in accordance with their terms, (v) as of the date hereof, Chroma or its Affiliates have not received any rights to any Chroma Technology from any Third Party except under the terms of the Vernalis Agreement provided to CTI and (vi) as of the date hereof, Chroma is not aware of any agreement related to the ownership or rights in the Chroma Technology other than the Upstream Agreements. The warranties given in (i) and (iv) of this paragraph (l) with respect to the other Upstream Agreements that are not the Vernalis Agreement are given to Chroma's Best Knowledge, provided that no such knowledge qualification applies to the Vernalis Agreement.

**10.3 No Other Representations or Warranties.** EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS OR ACHIEVEMENT OF ANY PARTICULAR SALES LEVEL, IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL

\*\* 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.

REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

## ARTICLE 11

### INDEMNIFICATION

**11.1 Indemnification by Chroma.** Chroma shall defend, indemnify, and hold CTI and its Affiliates and CTI's and its Affiliates' officers, directors, employees, and agents (the "**CTI Indemnitees**") harmless from and against any and all Third Party claims, suits, proceedings, damages, expenses (including court costs and reasonable attorneys' fees and expenses), and recoveries (collectively, "**Claims**") to the extent that such Claims arise out of, are based on, or result from (a) the Development, Manufacture, storage, handling, use, promotion, sale, offer for sale, importation or other Commercialization of Products by or on behalf of Chroma or its Affiliates, distributors (other than CTI), sublicensees (other than CTI), or contract manufacturers (unless and to the extent such liability for Manufacturing activities are covered by separate indemnification pursuant to the Supply Agreement, which in such event will control), or (b) the breach of any representation, warranty or covenant of Chroma in this Agreement, or (c) the willful misconduct or negligent acts of Chroma, its Affiliates, or the officers, directors, employees, or agents of Chroma or its Affiliates. The foregoing indemnity obligation shall not apply to the extent that (i) the CTI Indemnitees fail to comply with the indemnification procedures set forth in Section 11.3 and Chroma's defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim arises from, is based on, or results from any activity for which CTI is obligated to indemnify the Chroma Indemnitees under Section 11.2.

**11.2 Indemnification by CTI.** CTI shall defend, indemnify, and hold Chroma and its Affiliates and Chroma's and its Affiliates' officers, directors, employees, and agents (the "**Chroma Indemnitees**") harmless from and against any and all Claims to the extent that such Claims arise out of, are based on, or result from (a) the Development, storage, handling, distribution, use, Manufacture (unless and to the extent liability for Manufacturing activities are covered by separate indemnification pursuant to the Supply Agreement, which in such event will control) promotion, sale, offer for sale, importation or other Commercialization of Products by CTI or its Affiliates, or its or their sublicensees, or distributors or contract manufacturers, or (b) the breach of any representation, warranty or covenant of CTI set forth in this Agreement, or (c) the willful misconduct or negligent acts of CTI or its Affiliates, or the officers, directors, employees, or agents of CTI or its Affiliates. The foregoing indemnity obligation shall not apply to the extent that (i) the Chroma Indemnitees fail to comply with the indemnification procedures set forth in Section 11.3 and CTI's defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim arises from, is based on, or results from any activity for which Chroma is obligated to indemnify the CTI Indemnitees under Section 11.1.

**11.3 Indemnification Procedures.** The Party claiming indemnity under this Article 11 (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") in a reasonably timely manner after learning of such

\*\* 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.

Claim. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the Indemnifying Party shall have the right to assume and conduct the defense of the claim with counsel of its choice. The Indemnifying Party shall not settle any claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the Indemnifying Party is actively defending the claim in good faith, the Indemnified Party shall not settle any such claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the claim as provided above, (a) the Indemnified Party may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided in this Article 11.

**11.4 No Assumed Obligations and Liabilities.** Notwithstanding the foregoing and anything else to the contrary in this Agreement, Chroma expressly acknowledges and agrees that CTI does not, under the terms of this Agreement or otherwise, assume any liability or obligation related to the Product to the extent relating to periods before the Effective Date, including any liability or obligation with respect to any Products that were used or distributed by or for Chroma, including any liabilities or obligations with respect to the Past Studies (collectively, the "**Retained Liabilities**"). Chroma shall retain and be solely responsible and liable for all Retained Liabilities.

**11.5 Limitation of Liability.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 11.1 OR 11.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 12, A PARTY'S LIABILITY FOR FRAUD, DEATH OR PERSONAL INJURY CAUSED BY THEIR NEGLIGENCE OR ANY OTHER LIABILITY WHICH MAY NOT BE EXCLUDED BY LAW.

**11.6 Insurance.** Each Party shall procure and maintain insurance, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being clinically tested in human subjects or commercially distributed or sold by such Party. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 11. Each Party

\*\* 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.

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 thirty (30) days prior to the cancellation, non-renewal or material change in such insurance or self-insurance which materially adversely affects the rights of the other Party hereunder.

## ARTICLE 12

### CONFIDENTIALITY

**12.1 Confidentiality.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties during a period that is the longer of (i) the Term, or (ii) fifteen (15) years from the Effective Date, each Party agrees that it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement any Confidential Information furnished to it by the other Party pursuant to this Agreement except for that portion of such information or materials that the receiving Party can demonstrate by competent written proof:

(a) was already rightfully known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party or its Affiliate by a Third Party who has a legal right to make such disclosure; or

(e) was independently discovered or developed by the receiving Party or its Affiliate without the aid, application, or use of the disclosing Party's Confidential Information, as evidenced by a contemporaneous writing.

**12.2 Authorized Disclosure.** Each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following situations:

(a) regulatory filings and other filings with Governmental Authorities, including filings with the Securities and Exchange Commission, the Commissione Nazionale per le Società e la Borsa or other securities regulatory authority, The Nasdaq Stock Market LLC, the Mercato Telematico Azionario or other relevant exchange on which such Party is listed;

(b) prosecuting or defending litigation;

\*\* 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.

(c) complying with applicable Laws;

(d) disclosure to its employees, agents, consultants, and any bona fide Third Party potential (sub)-licensees (including potential Third Party contract manufacturers and other licensees or collaborators) only on a need-to-know basis and solely as necessary in connection with the performance of or as otherwise contemplated by this Agreement, provided that in each case the recipient of such Confidential Information must agree to be bound by similar obligations of confidentiality and non-use at least as equivalent in scope as those set forth in this Article 12 prior to any such disclosure; and

(e) disclosure of the material terms of this Agreement to any bona fide potential investor, investment banker, acquiror, merger partner, licensees, sublicensees or other potential or actual financial or commercial partner; provided that in connection with such disclosure, the disclosing Party shall use all reasonable efforts to inform each recipient of the confidential nature of such Confidential Information and cause each recipient of such Confidential Information to treat such Confidential Information as confidential.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to clause (a) through (c) of this Section 12.2, it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and, if reasonably requested by the other Party, use diligent efforts to secure confidential treatment of such information. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder except as otherwise provided in this Agreement. Each Party will be responsible for any acts or omissions of any Third Party to which such Party discloses Confidential Information in accordance with this Section 12.2.

### 12.3 Publicity.

(a) The Parties shall make a joint public announcement of the execution of this Agreement in the form attached as Exhibit D, which shall be issued at a time to be mutually agreed by the Parties. The Parties, will as soon as reasonably possible following the Effective Date but prior to any required filing timelines, agree on a redacted version of this Agreement to be filed by CTI on any public register pursuant to any securities law or regulation, provided that there is no assurance that such redactions will be acceptable to the applicable Governmental Authorities.

(b) Neither Party shall issue any additional press release or other publicity materials, or make any public presentation with respect to the terms or conditions of, this Agreement (but excluding the timelines for the programs being conducted pursuant to this Agreement or efforts and progress against such timelines, which may be the subject of additional press releases, other publicity materials and public presentations without the need to obtain the prior written consent of the other Party), in each case without the prior written consent of the other Party. The restriction in this paragraph (b) shall not apply to any future disclosures required by Law or regulation, including as may be required in connection with any filings made with, or by the requirements of the securities exchange on which such Party's securities are traded; provided,

\*\* 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.

that the disclosing Party uses all reasonable efforts to inform the other Party at least three (3) business days prior to making any such disclosures and, if reasonably requested by the other Party, cooperates with the other Party in seeking a protective order or other appropriate remedy (including redaction). In addition, where required by Law of the applicable securities exchange upon which a Party may be listed, such Party shall have the right to make a press release announcing the achievement of each milestone under this Agreement as it is achieved, and the achievements of Regulatory Approvals in the Licensed Territory as they occur, subject only to the review procedure set forth in the preceding sentence. In relation to the other Party's review of such an announcement, such other Party may make specific, reasonable comments on such proposed press release within the prescribed time for commentary, but shall not withhold its consent to disclosure of the information that the relevant milestone has been achieved and triggered a payment hereunder. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement that has already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 12.3.

## ARTICLE 13

### TERM AND TERMINATION

**13.1 Term.** This Agreement shall (subject to Section 15.9) become effective on the Effective Date and, unless earlier terminated pursuant to this Article 13, shall remain in effect, on a Product-by-Product basis and on a country-by-country basis, until the expiration of the Royalty Term of such Product in such country.

**13.2 Early Termination.** CTI shall have the right to terminate this Agreement for convenience, upon one hundred and twenty (120) days' written notice to Chroma.

**13.3 Termination for Breach.** If either Party is in material breach of the obligations, covenants and representations contained in this Agreement the other Party (the "**Non-Defaulting Party**") shall be entitled to give to the Party in default (the "**Defaulting Party**") written notice specifying the nature of the default and requiring it to cure such default. If such default is not cured (a) in the case of a failure to make any undisputed payment (other than with respect to any refund contemplated by Section 15.9, which shall be made immediately upon the occurrence of any such termination) or credit due pursuant to this Agreement, within thirty (30) days after receipt of such notice, or (b) in the case of any other default, within ninety (90) days after the receipt of such notice (or, if such breach is not capable of being cured within such ninety (90) day period, within such amount of time as may be reasonably necessary to cure such breach (but no longer than one-hundred and eighty (180) days), so long as the Defaulting Party is making diligent efforts to do so), the Non-Defaulting Party shall be entitled, without prejudice to any other rights conferred on it by this Agreement, and in addition to any other remedies available to it by law or in equity, immediately to terminate this Agreement by giving written notice to the Defaulting Party. The right of a Party to terminate this Agreement, as herein provided, shall not be affected in any way by its waiver or failure to take action with respect to any previous default.

\*\* 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.

If either Party disputes the existence of a material breach, then such dispute shall be resolved under the terms of Article 14 before this Agreement may be terminated for such material breach.

**13.4 Insolvency.** Either Party may terminate this Agreement upon written notice if, at any time, the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for an arrangement or for the appointment of a receiver or trustee of the other Party or of substantially all of its assets, or if the other Party enters into a written agreement of composition, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within ninety (90) calendar days after the filing thereof, or if the other Party is a party to any dissolution or liquidation, or if the other Party shall make an assignment of substantially all of its assets for the benefit of creditors or if the other Party shall be subject to a procedure which is similar to or the same as any of the foregoing in any country.

**13.5 Termination for Patent Challenge by CTI.** If CTI or any of its Affiliates: (a) commences or otherwise voluntarily determines to participate in (other than as a response to any action or proceeding initiated by Chroma or its Affiliates (other than relating to a matter covered under Section 13.3), or as may be necessary or reasonably required to assert a cross-claim or a counter-claim, or to respond to a court request or order or administrative law request or order) any action or proceeding (including any patent opposition or re-examination proceeding), challenging or denying the validity of any Chroma Patent or any claim thereof; or (b) actively assists any other person (other than as a response to any action or proceeding initiated by Chroma or its Affiliates (other than relating to a matter covered under Section 13.3), or as may be necessary or reasonably required to assert a cross-claim or counter-claim, or to respond to a court request or order or administrative law request or order) in bringing or prosecuting any action or proceeding (including any patent opposition or re-examination proceeding) challenging or denying the validity of any of such Chroma Patent or any claim thereof, Chroma shall have the right to terminate this Agreement on ninety (90) days written notice to CTI unless CTI or its Affiliates promptly terminates any such challenge within thirty (30) days after its receipt of such notice from Chroma. CTI shall include this obligation in its agreements with its sublicensees, provided that if any such sublicense initiates a patent challenge against Chroma as described above, subject to the exceptions noted above, CTI's termination of such sublicense agreement shall be deemed a cure under this provision and Chroma will not be entitled to terminate this Agreement under this provision in such instance.

**13.6 Continuing Rights of Commercialization Sublicensees.** Upon any termination of any license rights granted to CTI under this Agreement, each sublicense previously granted by CTI or any of its Affiliates under such license rights to any Commercialization Sublicensee shall remain in effect and shall become a direct license or sublicense, as the case may be, of such rights by Chroma to such Commercialization Sublicensee, provided that such Commercialization Sublicensee is not in breach of its agreement with CTI, and subject to the Commercialization Sublicensee agreeing in writing to assume CTI's terms, conditions and obligations to Chroma under this Agreement as they pertain to the sublicensed rights.

\*\* 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.

**13.7 Effect of Termination for CTI.** The following provisions shall apply if (a) CTI terminates this Agreement in its entirety pursuant to Section 13.2, or (b) Chroma terminates this Agreement due to CTI's material uncured breach under Section 13.3 (c) due to CTI's insolvency under Section 13.4 or, (d) due to CTI's patent challenge under Section 13.5.

**(a) Termination of Licenses.** The licenses granted to CTI under this Agreement shall terminate, including restriction on Chroma's right to exercise rights under the Joint Inventions set forth under Section 9.1. After the Effective Date of Termination and except as provided below, either Party will be free to use and practice the Joint Inventions for any purpose on a worldwide basis and may assign, license or otherwise transfer or exploit its rights to the Joint Inventions to an Affiliate or Third Party, without the other Party's consent and without a duty of accounting to the other Party.

**(b) Outstanding Payment Obligations.** CTI shall be responsible for any outstanding payment obligations of CTI under Article 8 that existed or accrued prior to the Effective Date of Termination.

**(c) Transfer of Materials.**

**(i) Development Documentation.** CTI will transfer and assign to Chroma all Development Documentation related to the Product developed under the Development Plan.

**(ii) Commercial Information.** CTI will provide a written and electronic copy of the Commercial Information, to the extent such information has not already been provided to Chroma through its participation in the JDC. All Commercial Information shall be treated as CTI's Confidential Information under Sections 12.1 and 12.2 and may only be used by or for Chroma in the Commercialization of the Product and for no other purpose.

**(iii) Inventory.** Chroma shall have the option to purchase existing Product inventories from CTI at the price CTI paid for such inventories.

**(iv) Product Marks.** For the Product Marks solely used for the Products by or for CTI in the Licensed Territory at the time of termination, CTI will transfer such Product Marks to Chroma without additional consideration, including registrations therefor and any goodwill associated therewith, provided that in no event will such transfer include any rights in CTI's name or any brand, logo or trademark of CTI not solely used for the Product.

**(v) Costs.** CTI will be responsible for all costs associated with any transfer or transition pursuant to this paragraph (c) (other than the purchase price for the inventory as provided above).

**(d) Option for Rights Not Transferred.**



\*\* 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.

**(i) Non-Opted In Study or Non-Opted In Additional Product Development.** For any Non-Opted In Study or any Non-Opted In Additional Product Development for which Chroma did not opt in under the terms of Sections 4.4 or 4.9, respectively, Chroma may opt in, during the Transition Period only, to any such Non-Opted In Study or any Non-Opted In Additional Product Development under the respective terms in Sections 4.4 and 4.9. If Chroma opts in under such terms, Chroma's access to any Regulatory Materials, data, or other information generated from such studies will be the same under the terms of this Agreement as though Chroma had opted in to any such Non-Opted In Study or Non-Opted In Additional Product Development prior to the termination of this Agreement. If Chroma does not opt in to any Non-Opted In Study or any Non-Opted In Additional Product Development during the Transition Period, CTI will have no further obligations to Chroma, and Chroma will not have any right, with respect to such study or product.

**(ii) Subject CTI Rights.** If Chroma desires to license rights to Subject CTI Rights after the termination of this Agreement, Chroma may request such rights with a written notice to CTI and the Parties will enter into good faith negotiation during the Transition Period to provide such rights to Chroma on customary industry terms, including milestone and royalty payments. If the Parties cannot agree on the terms of any such license during the Transition Period or if Chroma does not request such rights in writing during the Transition Period, CTI will have no further obligations to Chroma, and Chroma will not have any right, with respect to Subject CTI Rights.

**(e) Transition Plan.** Within ninety (90) days after the Effective Date of Termination, the Parties shall negotiate in good faith and establish a transition plan to effectuate the transfer and transition provided in this Section 13.7 ("**Transition Plan**") within one hundred and twenty (120) days after the date of the Transition Plan ("**Transition Period**"). In addition to the items described above in this Section 13.7, the Transition Plan will also address the transition of the following items, including the allocation of cost and responsibility related to the transition of such items. Other than obligations expressly set forth in the Transition Plan (some of which may continue after the Transition Period), CTI will not have any further obligation related to the Development Manufacture or Commercialization of the Product.

**(i)** whether and how the existing contracts exclusively related to the supply of the Product or clinical trials of the Product should be transitioned or terminated; and

**(ii)** what Development activities, including any on going clinical trials, set forth in the then current Development Plan should be continued on the same terms (including allocation of cost provided that where any clinical trials cannot be terminated under applicable Law, CTI will continue to be responsible for 75% of the Development Costs set forth in the then current Development Plan associated with any such clinical trial contained in an agreed Development Plan until the completion of such trial, provided that CTI will not be responsible for the costs associated with the enrollment of additional patients for such trial unless such additional enrollment is required by applicable Law).

\*\* 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.

**(f) Further Assurances.** CTI shall, at Chroma's request and CTI's expense, take such other reasonable and customary actions and execute such other reasonable and customary instruments, assignments and documents as may be necessary to effect the transfer of rights and materials expressly provided in this Section 13.7 above. After the Effective Date of Termination and before such items are transferred to Chroma or its designated Affiliate, CTI shall hold them on trust for Chroma, and shall maintain them in force and shall not encumber, amend, cancel or surrender or take any step in relation thereto unless requested to do so by Chroma or any applicable government or Regulatory Authority.

### 13.8 Effect of Termination for Chroma.

**(a) Continuation of Rights.** If CTI has the right to terminate this Agreement pursuant to Sections 13.3 or 13.4 and does not exercise such right, CTI will have the right to retain the licenses and rights granted under this Agreement to the Chroma Technology existing at the date of CTI's notice to Chroma that it wishes to retain such rights and licenses, subject to payment of milestones and royalties under the terms of Article 8. CTI will also have the right to continue to use Chroma's Regulatory Materials, Development Documentation and Confidential Information existing at the date of CTI's notice to Chroma that it wishes to retain its rights and licenses under this Agreement, subject to the terms and conditions of this Agreement related to such items. Within ninety (90) days after CTI's notice that CTI wishes to retain such licenses and rights, the Parties shall negotiate in good faith and establish a transition plan to address any ongoing or remaining Development activities under the then current Development Plan ("**Transition Development Plan**"). Such activities shall be conducted under same cost allocation terms as provided under this Agreement for the Development Plan. After the completion of Development activities provided under the Transition Development Plan, neither Party will have any further Development obligations under this Agreement.

**(b) Termination of Agreement.** If CTI has the right to terminate this Agreement pursuant to Sections 13.3 or 13.4 and does exercise such right, the provisions of Sections 13.7(c), 13.7(d), 13.7(e), and 13.7(f) shall apply except that Chroma will be solely responsible for all costs associated with any transfer or transition of such items, including all Development Costs for any Development activities provided to continue in the Transition Plan.

**13.9 Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by Chroma or CTI are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the licensee of such rights under this Agreement shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any other applicable Law. 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 any other applicable Law, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in such other Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding

\*\* 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.

upon the other Party's written request therefor, unless the Party subject to the proceeding's elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a), following the rejection of this Agreement by the Party subject to the proceeding's upon written request therefor by the other Party. Notwithstanding anything in this Agreement to the contrary, it is the intention of the Parties that upon any commencement of a bankruptcy proceedings, the Party subject to the proceeding shall have the right to assume and assign this Agreement and its rights and obligations hereunder pursuant to Section 365 of the U.S. Bankruptcy Code or any other applicable Law.

**13.10 Survival.** The following provisions shall survive any expiration or termination of this Agreement for the period of time specified in the applicable section or, if no time is specified, indefinitely: Article 10, Article 11, Article 12, Article 14, and Article 15. To the extent Development or Commercialization obligations or rights survive under the terms of Sections 13.7 or 13.8, Article 4, Article 5 and Article 6 will survive for the duration of such Development or Commercialization obligations or rights. Termination or expiration of this Agreement for any reason shall not release a Party from any liability or obligation that already has accrued prior to such expiration or termination, nor affect the survival of any provision hereto to the extent it is expressly stated to survive such termination.

## ARTICLE 14

### DISPUTE RESOLUTION

**14.1 Disputes.** The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 14 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, if and when a dispute arises under this Agreement.

#### **14.2 Referred from Committee.**

**(a) General.** Except for disputes subject to Section 14.3(b), either Party may, by written notice to the other Party, have any dispute arising from a Committee pursuant to the terms of Article 3 referred to each Party's Designated Executive for attempted resolution by good faith negotiations within thirty (30) days after such notice is received, or in less time if necessary to ensure patient safety or compliance with applicable Laws. If the Designated Executives are not able to resolve such dispute within such thirty (30) day period, either Party may at any time thereafter pursue binding arbitration under the terms of Section 14.5.

**(b) Specific Decision-Making Rights.** Except for disputes subject to Section 14.3(b), if the Designated Executives of the Parties are not able to resolve a dispute within the thirty (30) day period described above, and the dispute is related to one of the areas listed in

\*\* 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.

the immediate subparagraphs below, then each of Chroma and CTI shall have the unilateral right to settle such matter as provided below.

**(i) CTI Decisions.** The Designated Executive of CTI shall have the right to make the final decision with respect to matters involving the Development, Manufacture and Commercialization of the Product solely in the Licensed Territory; provided that such decision shall be made in good faith, cannot be inconsistent with the terms of this Agreement, and such decision cannot materially and adversely affect Chroma's right and ability to Develop, Manufacture and Commercialize the Product in the ROW Territory.

**(ii) Chroma Decisions.** The Designated Executive of Chroma shall have the right to make the final decision with respect to matters involving the Development, Manufacture and Commercialization of the Product solely in the ROW Territory; provided that such decision shall be made in good faith, cannot be inconsistent with the terms of this Agreement, and such decision cannot materially and adversely affect CTI's right and ability to Develop, Manufacture and Commercialize the Product in the Licensed Territory.

**(iii) Development Costs.** Notwithstanding the above provisions neither Party's share of Development Costs can be increased unless both Parties agree to any such increase as part of the Development Plan or any amendments thereto, subject to the Development opt in mechanism described in Sections 4.4.

#### **14.3 Arising Between the Parties.**

**(a) General Matters.** Except for disputes subject to Section 14.3(b) below or referred from Committee and subject to Section 14.2 above, the Parties shall refer all other disputes arising under or in connection with this Agreement, including, without limitation, any claim or controversy relating to the validity, enforceability, interpretation, performance, breach or termination hereof to the Designated Executive for each Party for attempted resolution by good faith negotiations within thirty (30) days after such dispute is first identified by either Party in writing to the other. With respect to any dispute that is not resolved by such Designated Executives within such period, either Party may at any time thereafter pursue binding arbitration under the terms of Section 14.5.

**(b) Safety Matters.** In the event that the Parties cannot agree to one opinion with respect to an individual adverse event or other matter affecting the health, safety or welfare of a patient, then, the Parties shall convene the relevant Committee to discuss and seek resolution of such matter as expeditiously as possible to ensure patient safety and compliance with applicable Laws. In connection with such discussions, the Parties may convene any joint working groups or outside consultants and/or experts in the subject matter of the disagreement to assist the Parties to reach one opinion. If such discussions do not result in one opinion between the Parties in a reasonably timely fashion, then the most conservative opinion shall prevail.

**14.4 Injunctive Relief.** Nothing herein may prevent either Party from seeking a preliminary injunction or temporary restraining order in any court of competent jurisdiction in

\*\* 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.

order to prevent any Confidential Information from being disclosed without appropriate authorization under this Agreement or to prevent any termination of this Agreement under Section 13.3 if the existence of a material breach is in dispute.

**14.5 Binding Arbitration.** Any dispute arising under or in connection with this Agreement, that is not resolved by the Designated Executives pursuant to Section 14.3(a) within the time period set forth therein shall be submitted to binding arbitration under the Rules of Arbitration of the London Court of International Arbitration before an arbitral tribunal of three arbitrators. Each Party shall nominate one arbitrator, and the two co-arbitrators, in consultation with the Party nominating them, shall together nominate the third arbitrator, who shall serve as the chairperson of the arbitral tribunal. The place of arbitration shall be New York, New York, and all hearings in the arbitration shall be conducted there. The arbitral tribunal's award shall be (i) in writing, stating the reasons for such decision; (ii) based solely on the terms and conditions of this Agreement, as interpreted, if applicable, in accordance with the laws of England and Wales; (iii) final and binding upon the Parties hereto; and (iv) enforceable in any court of competent jurisdiction.

## ARTICLE 15

### MISCELLANEOUS

**15.1 Entire Agreement; Amendment.** This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof, including the CDA and term sheet. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties with respect to the subject matter hereof other than as are set forth herein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

**15.2 Force Majeure.** Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including without limitation, an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar

\*\* 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.

circumstances). If a force majeure persists for more than ninety (90) days, then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such force majeure.

**15.3 Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 15.3, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by confirmed facsimile or a reputable courier service, or (b) five (5) business days after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested.

If to Chroma: CHROMA THERAPEUTICS LTD  
93 Milton Park  
Abingdon, Oxon OX14 4RY, UK  
Attn: Chief Executive Officer  
Fax: \*\*

with a copy to: CHROMA THERAPEUTICS LTD  
93 Milton Park  
Abingdon, Oxon OX14 4RY, UK  
Attn: Chief Financial Officer  
Fax: \*\*

If to CTI: CELL THERAPEUTICS, INC.  
501 Elliott Ave. W. #400  
Seattle, Washington 98119, U.S.A.  
Attn: Chief Executive Officer  
Fax: \*\*

with a copy to: CELL THERAPEUTICS, INC.  
501 Elliott Ave. W. #400  
Seattle, Washington 98119, U.S.A.  
Attn: General Counsel  
Fax: \*\*

**15.4 No Strict Construction; Headings.** This Agreement has been prepared jointly and shall not be strictly construed against either Party. 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 headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. Except where the context otherwise requires, the use of any gender shall be applicable to all genders, and the word

\*\* 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.

“or” is used in the inclusive sense (and/or). The term “including” as used herein means including, without limiting the generality of any description proceeding such term.

**15.5 Assignment.** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other (which shall not be unreasonably withheld, delayed or conditioned), except that a Party may make such an assignment without the other Party’s prior written consent to a successor-in-interest to all or substantially all of the assets of the relevant Party to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction, provided that such transaction is not entered into in an effort to circumvent the requirement to obtain the consent of the other Party. Any successor or assignee of rights and/or obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations, and the assigning party shall remain liable for all obligations of the assignee after the assignment. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 15.5 shall be null, void and of no legal effect.

**15.6 Non-Solicitation.** While the Parties are performing Development and Commercialization activities under this Agreement and for a period of two (2) years thereafter, neither Party shall, without the express written consent of the other Party, recruit, solicit or induce any employee of the other Party to terminate his or her employment with such other Party. The foregoing provision shall not, however, restrict either Party or its Affiliates from advertising employment opportunities in any manner that does not directly target the other Party or its Affiliates or from hiring any persons who respond to such generalized public advertisements.

**15.7 Performance by Affiliates.** Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party’s Affiliate of any of such Party’s obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party’s Affiliate.

**15.8 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**15.9 HSR Filing.** Each of CTI and Chroma agrees to prepare and make appropriate filings under the HSR Act relating to this Agreement and the transactions contemplated hereby as soon as reasonably practicable after the Effective Date (the “**HSR Filing Date**”). The Parties agree to cooperate in the antitrust clearance process and to furnish promptly to the Federal Trade Commission (FTC), the Antitrust Division of the Department of Justice and any other agency or authority, any information reasonably requested by them in connection with such filings. Other than the provisions of this Section 15.9, Section 8.1 and Articles 11 and 12, the rights and

\*\* 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.

obligations of the Parties under this Agreement shall not become effective until the waiting period provided by the HSR Act shall have terminated or expired without any action by any government agency or challenge to the transaction (the date of such termination or expiration shall be the “**Approval Date**” of this Agreement), provided that neither Party shall grant any rights to engage in any act that would conflict with the terms and conditions of this Agreement until such Approval Date. Upon the occurrence of the Approval Date, all provisions of this Agreement shall become effective as of the Effective Date automatically without the need for further action by the Parties. In the event that antitrust clearance from the FTC and Antitrust Division of the Department of Justice is not obtained within ninety (90) days after the HSR Filing Date, or such other date as the Parties may mutually agree, this Agreement may be terminated by either Party. If this Agreement is terminated for such reason, (a) all rights granted in this Agreement shall revert back to the grantor, (b) Chroma shall repay to CTI immediately the upfront fee of \$5,000,000 and (c) the Parties will not have any further rights or obligations to each other under this Agreement except as provided in Section 13.10. In the event a provision of this Agreement needs to be deleted or substantially revised in order to obtain regulatory clearance of this transaction, the Parties will negotiate in good faith in accordance with Section 15.10.

**15.10 Severability.** If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

**15.11 No Waiver.** Any delay in enforcing a Party’s rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party’s rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

**15.12 Independent Contractors.** Subject to the terms of this Agreement, the activities and resources of each Party shall be managed by such Party, acting independently and in its individual capacity. The relationship between Chroma and CTI is that of independent contractors and neither Party shall have the power to bind or obligate the other Party in any manner, other than as may be expressly set forth in this Agreement. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

**15.13 English Language; Governing Law.** This Agreement, including any dispute, claim or controversy arising out of or related to validity, enforceability, interpretation, performance, breach or termination hereof, shall be governed by and construed under the laws of England and Wales, without giving effect to any choice of law principles that would require the application of the laws of a different state, provided that Laws of any governing Regulatory



\*\* 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.

Authority, as well as the intellectual property laws of the jurisdiction in which any intellectual property rights at issue were granted, shall also govern to the extent applicable.

**15.14 Counterparts.** This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement shall be binding upon the delivery by each Party of an executed signature page to the other Party, which may include by facsimile transmission.

**[Signature Page Follows]**

\*\* 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.

IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals by their duly authorized officers as of the Effective Date.

**CELL THERAPEUTICS, INC.**

**CHROMA THERAPEUTICS LTD**

By: /s/ James A. Bianco

By: /s/ Ian Nicholson

Name: James A. Bianco, M.D.

Name: Ian Nicholson

Title: Chief Executive Officer

Title: Chief Executive Officer

*Signature Page to the Co-Development and License Agreement entered into as of March 11, 2011*

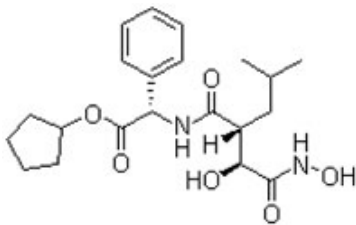
\*\* Indicates that certain information contained herein has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

\*\*\*\* 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.

**EXHIBIT A-1**  
**COMPOUND DESCRIPTION**

Name Tosedostat  
Synonyms 2S-[2R-(S-Hydroxy-hydroxycarbamoyl-methyl)-4-methylpentanoylamino]-2-phenylethanoic acid cyclopentyl ester

Molecular Structure



Molecular Formula  $C_{21}H_{30}N_2O_6$   
Molecular Weight 406.47  
CAS Registry Number 238750-77-1

\*\* 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.

**EXHIBIT A-2**  
**ANALOGUES OF TOSEDOSTAT**

\*\*\*\*

\*\* 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.

**EXHIBIT B-1  
CHROMA PATENTS**

**BB-76163 (CHR-2797) Patent Portfolio**

**Patents and Patent Applications Derived from International Patent**

**Application WO 98/11063**

<u>Country</u>	<u>Status</u>	<u>Application No</u>	<u>Patent No</u>
Australia	Granted	41277/97	718890
Belgium	Granted	EP97939052.3	EP 0925278
Canada	Granted	2265666	2,265,666
Switzerland	Granted	EP97939052.3	EP 0925278
Czech Republic	Granted	PV 821-99	298048
Germany	Granted	EP97939052.3	EP 0925278
Spain	Granted	EP97939052.3	EP 0925278
France	Granted	EP97939052.3	EP 0925278
UK	Granted	EP97939052.3	EP 0925278
Italy	Granted	EP97939052.3	EP 0925278
Japan	Granted	1988-513347	4238334
Norway	Granted	19991139	314227
New Zealand	Granted	333923	333923
Poland	Granted	P-333369	P-333369
USA	Granted	08/925584	6169075
USA (divisional)	Granted	09/514083	6790834

**Patents and Patent Applications Derived from International Patent**

**Application WO 99/46241**

<u>Country</u>	<u>Status</u>	<u>Application No</u>	<u>Patent No</u>
Australia	Granted	64106/98	747977
Canada	Granted	2323414	2,323,414
China	Granted	98813847.6	ZL 98813847.6
Czech Republic	Granted	PV 2000-3317	299610
Germany	Granted	EP98 909 620.1	EP 1062202
France	Granted	EP98 909 620.1	EP 1062202
UK	Granted	EP98 909 620.1	EP 1062202
Ireland	Granted	EP98 909 620.1	EP 1062202
Israel	Granted	137774	137774
Japan	Granted	2000-535622	4324324

\*\* 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.

Mexico	Granted	8762	224080
New Zealand	Granted	506293	506293
Poland	Granted	P-342811	190637
USA	Granted	09/100539	6462023

**SECURITY INTEREST:**

\*\*

\*\* 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.

**EXHIBIT B-2  
UPSTREAM AGREEMENTS**

<u>Other Party(ies)</u>	<u>Title of Agreement</u>	<u>Effective Date</u>
Vernalis (Oxford) Ltd.	Exclusive License Agreement Covering BB-76163 for Use in Cancer	November 24, 2003
Vernalis (R&D) Limited (formerly known as Vernalis (Oxford) Limited)	Amendment No. 1 to Exclusive License Agreement Covering BB-76163 for Use in Cancer	March 30, 2007
1. **	**	**
2. **		
1. **	**	**
2. **		

\*\* 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.

**EXHIBIT C  
DEVELOPMENT PLAN**

\*\*\*\*



\*\* 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.

**EXHIBIT D  
PRESS RELEASE**

**Cell Therapeutics Acquires Exclusive Marketing and Co-Development Rights  
in the Americas to Chroma Therapeutics' Tosedostat, a First in Class Tumor  
Selective Oral Therapy for Treatment of Blood Related and Other Cancers**

***Phase III Pivotal Trial in Acute Myeloid Leukemia Expected to Start in Q4 2011***

***Provides Potential Portfolio and Commercial Synergies with Pixantrone***

***Conference Call and Webcast to be Held on Monday, March 14, 2011 at 8:30 AM Eastern  
time/1:30 PM Central European time/5:30 AM Pacific time***

**March 14, 2011 Seattle and Oxford, UK**—Cell Therapeutics, Inc. (“CTI”) (NASDAQ and MTA: CTIC) and Chroma Therapeutics Ltd. (“Chroma”) announced today that the companies have entered into a co-development and license agreement providing CTI with exclusive marketing and co-development rights to Chroma’s drug candidate tosedostat in North, Central and South America. Tosedostat is an oral, aminopeptidase inhibitor that has demonstrated significant anti-tumor responses in blood related cancers and solid tumors in phase I-II clinical trials. CTI, in collaboration with Chroma, expects to commence a phase III clinical study in the United States and Europe in elderly patients with relapsed or refractory acute myeloid leukemia (“AML”) for potential approval by the U.S. Food and Drug Administration (“FDA”) and the European Medicines Agency (“EMA”). The FDA and the EMA have granted tosedostat orphan drug status for AML.

Pursuant to the terms of the agreement, CTI will make an upfront payment of \$5 million and a milestone payment of \$5 million when the AML pivotal trial is initiated, which is expected to occur in the fourth quarter of 2011. The agreement also includes customary development-based milestone payments related to AML, myelodysplastic syndrome (“MDS”) and certain other indications, as well as royalties on net sales in CTI’s territories. CTI will oversee development operations and commercialization activities in its territories and Chroma will oversee development operations and commercialization activities in the rest of the world. Subject to a funding cap of \$50 million for the first three years, CTI will be responsible for 75% of development costs and Chroma will be responsible for 25% of development costs.

“Tosedostat, similar to drugs like bortezomib and lenalidomide, represents a departure from conventional cytotoxic chemotherapy toward more tumor selective targeted therapy that interferes with cellular pathways necessary for tumor survival,” commented James A. Bianco, M.D., CEO of CTI. “In initial clinical studies, tosedostat was well-tolerated, given orally once a day and produced encouraging response

\*\* 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.

rates in difficult to treat patients with acute leukemia and a variety of blood related cancers. We are excited to add tosedostat to our late-stage product pipeline alongside pixantrone as we continue with our strategy of building a pipeline of novel drugs for treating blood-related cancers.”

Chroma is an Oxford, UK based private company led by a management team with extensive public biotechnology and large pharmaceutical company experience, including former executives of Celltech, British Biotech, AstraZeneca and Roche, and backed by leading specialist investors. Chroma is focused on harnessing chromatin biology and its novel cell accumulation (ESM) technology to develop new targeted therapies for cancer and inflammatory disorders.

“We believe that this is a collaboration that should enable the rapid progression of tosedostat toward seeking regulatory approval, given CTI’s development and commercialization capabilities and experience in the blood-related cancer space,” said Ian Nicholson, CEO of Chroma. “In working with clinicians in developing tosedostat we have clearly identified significant unmet medical needs where tosedostat could provide an important therapeutic advance for patients if approved.”

AML is a hematologic cancer that is an aggressive, fast-growing cancer that starts inside the bone marrow with the production of abnormal blood cells. The American Cancer Society estimates that 12,330 new cases of AML will be diagnosed and approximately 8,950 deaths from AML will occur in the U.S. in 2010. AML is generally a disease affecting older people with the average patient age at onset of approximately 67 years. There remain a substantial proportion of elderly patients who do not receive intensive chemotherapy due to their inability to tolerate such regimens, and other risk factors. Therefore, there is a significant unmet medical need in developing a well-tolerated and effective treatment for these patients.

Tosedostat is an orally dosed aminopeptidase inhibitor which blocks the M1/17 family of aminopeptidases. Disrupting aminopeptidases deprives sensitive tumor cells of amino acids by blocking protein recycling resulting in tumor cell death. Tosedostat has been studied in Chroma’s phase I-II clinical trials both as a single agent and in combination with other chemotherapeutic agents. Such studies have demonstrated significant anti-tumor responses without the typical side effects of conventional, non-targeted cytotoxic therapies. Initial target indications include AML, MDS and multiple myeloma.

#### **Conference Call Information**

On Monday, March 14, 2011, at 8:30 a.m. Eastern time/1:30 p.m. Central European time/5:30 a.m. Pacific time, members of CTI’s and Chroma’s management teams will host a conference call to discuss the co-development and licensing agreement.

#### **Conference Call Numbers**

Monday, March 14, 2011 8:30 a.m. Eastern/1:30 p.m. Central European/5:30 a.m. Pacific Time

\*\* 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.

1-877-941-0843 (US Participants – Toll-Free)

1-480-629-9643 (US Participants)

800-149-038 (Italy Participants – Toll-Free)

39-06-45-210-8364 (Italy Participants)

0800 358 0857 (UK Participants – Toll-Free)

44-20-8515-2302 (UK Participants)

Call-back numbers for post-listening available at 11:30 a.m. Eastern Time:

1-800-406-7325 (US Participants)

1-303-590-3030 (International)

Passcode: 4423141#

**Live audio webcast** at [www.celltherapeutics.com](http://www.celltherapeutics.com) will be archived for post-call listening approximately two hours after call ends.

#### **About Cell Therapeutics, Inc.**

Headquartered in Seattle, CTI is a biopharmaceutical company committed to developing an integrated portfolio of oncology products aimed at making cancer more treatable. For additional information, please visit [www.CellTherapeutics.com](http://www.CellTherapeutics.com).

Sign up for email alerts and get RSS feeds at our Web site,

[http://www.CellTherapeutics.com/investors\\_alert](http://www.CellTherapeutics.com/investors_alert)

#### **About Chroma Therapeutics**

Chroma Therapeutics, based in Oxford (UK), is a drug discovery and development company focused in the fields of oncology and inflammatory disorders. Chroma is building a broad pipeline of first- or best-in-class treatments utilizing its expertise in chromatin biology and its novel intracellular accumulation technologies, which include the ability to selectively target drugs' tomacrophages. Chroma is backed by a number of leading specialist investors, including Abingworth, Essex Woodlands, Gilde, Phase4 and The Wellcome Trust. More information about Chroma can be found at [www.chromatherapeutics.com](http://www.chromatherapeutics.com).

*This press release includes forward-looking statements that involve a number of risks and uncertainties the outcome of which could materially and/or adversely affect actual future results and the market price of the Company's securities. Specifically, the risks and uncertainties that could affect the development and commercialization of tosedostat include risks associated with preclinical, clinical and sales and marketing developments in the biopharmaceutical industry in general and in particular, including, without limitation, the potential failure of tosedostat to prove safe and effective (including complete and overall response rates) for the treatment of blood related and other cancers as determined by the FDA and/or the EMA, that the FDA may not accept the proposed clinical trial design of tosedostat and/or may request additional clinical trials, that clinical trials may not demonstrate the safety and effectiveness of tosedostat, that the Company cannot predict or guarantee the pace or geography of enrollment of clinical trials of tosedostat, including whether or not the majority of the patients will be enrolled in the U.S., that the phase III pivotal trial for tosedostat for AML may not start during the fourth quarter of*

\*\* 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.

*2011, that the Company cannot predict or guarantee the outcome or results of clinical trials of tosedostat, that the Company cannot predict or guarantee whether the co-development and license agreement will strengthen the Company's business, financial condition, operating results and prospects or the trading price of the Company's securities, that the Company cannot predict or guarantee whether milestones will be achieved pursuant to the Agreement, the Company's ability to continue to raise capital as needed to fund its operations and make milestone payments, as applicable, determinations by regulatory, patent and administrative governmental authorities, competitive factors, technological developments, costs of developing, producing and selling the Company's products under development and co-development, and other economic, business, competitive, and/or regulatory factors affecting the Company's business generally, including those set forth in the Company's filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for its most recent fiscal year and its most recent Quarterly Report on Form 10-Q, especially in the "Factors Affecting Our Operating Results" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections, and its Current Reports on Form 8-K. Except as may be required by law, the Company does not intend to update or alter its forward-looking statements whether as a result of new information, future events, or otherwise.*

###

**Media Contact:**

Dan Eramian  
T: 206.272.4343  
C: 206.854.1200  
E: [deramian@ctiseattle.com](mailto:deramian@ctiseattle.com)  
[www.CellTherapeutics.com/press\\_room](http://www.CellTherapeutics.com/press_room)

**Investors Contact:**

Ed Bell  
T: 206.282.7100  
Lindsey Jesch Logan  
T: 206.272.4347  
F: 206.272.4434  
E: [invest@ctiseattle.com](mailto:invest@ctiseattle.com)  
[www.CellTherapeutics.com/investors](http://www.CellTherapeutics.com/investors)

**Medical Information Contact:**

T: 800.715.0944  
E: [info@askarm.com](mailto:info@askarm.com)

**Chroma Therapeutics Ltd.:**

Ian Nicholson, CEO  
Richard Bungay, CFO  
T: +44 (0) 1235 829120

Brunswick PR

\*\* 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.

Jon Coles  
Justine McIlroy  
T: +44 (0)20 7404 5959

**CELL THERAPEUTICS, INC.  
2007 EQUITY INCENTIVE PLAN  
RESTRICTED STOCK AWARD AGREEMENT**

**THIS RESTRICTED STOCK AWARD AGREEMENT** (this “**Award Agreement**”) is dated as of [\_\_\_\_\_, 20\_\_] (the “**Award Date**”) by and between Cell Therapeutics, Inc., a Washington corporation (the “**Company**”), and [\_\_\_\_\_] (the “**Participant**”).

**W I T N E S S E T H**

**WHEREAS**, pursuant to the Cell Therapeutics, Inc. 2007 Equity Incentive Plan (the “**Plan**”), the Company hereby grants to the Participant, effective as of the date hereof, a restricted stock award (the “**Award**”), upon the terms and conditions set forth herein and in the Plan.

**NOW THEREFORE**, in consideration of services rendered and to be rendered by the Participant, and the mutual promises made herein and the mutual benefits to be derived therefrom, the parties agree as follows:

**1. Defined Terms.** Capitalized terms used herein and not otherwise defined herein shall have the meaning assigned to such terms in the Plan.

**2. Grant.** Subject to the terms of this Award Agreement, the Company hereby grants to the Participant an Award with respect to an aggregate of [\_\_\_\_\_] restricted shares of common stock of the Company (the “**Restricted Shares**”).

**3. Vesting; Forfeiture.**

(a) **Vesting.** Subject to Sections 3(b) and (c) below, the Award shall vest and become nonforfeitable with respect to [\_\_\_\_\_] percent of the total number of Restricted Shares subject to the Award (subject to adjustment under Section 4.3 of the Plan) on each of [\_\_\_\_\_].

(b) **Termination Date.** Notwithstanding any other provision herein, upon the date on which the Participant ceases to be employed by the Company or a Subsidiary (regardless of the reason for such termination of employment, whether with or without cause, voluntarily or involuntarily, or due to death or disability) (the “**Termination Date**”), the Participant’s Restricted Shares (and related Restricted Property as defined in Section 8 hereof), to the extent such shares have not become vested pursuant to Section 3(a) as of the Termination Date, shall be forfeited to the Company as provided in Section 3(c) upon the Termination Date.

(c) **Forfeiture Procedures.** Upon the occurrence of any forfeiture of Restricted Shares pursuant to Section 3(b), such unvested, forfeited shares and related Restricted Property shall be automatically transferred to the Company as of the applicable forfeiture date without any other action by the Participant (or the Participant’s beneficiary or personal representative in the event of the Participant’s death or disability, as applicable). No consideration shall be paid by the Company with respect to such transfer. The Company may exercise its powers under Section 7(d) hereof and take any other action necessary or advisable to evidence such transfer. The

Participant (or the Participant's beneficiary or personal representative in the event of the Participant's death or disability, as applicable) shall deliver any additional documents of transfer that the Company may request to confirm the transfer of such unvested, forfeited shares and related Restricted Property to the Company.

**4. Continuance of Employment.** The vesting schedule requires continued employment through each applicable vesting date as a condition to the vesting of the applicable installment of the Award and the rights and benefits under this Award Agreement. Employment for only a portion of the vesting period, even if a substantial portion, will not entitle the Participant to any proportionate vesting or avoid or mitigate a termination of rights and benefits upon or following a termination of employment as provided in Section 3 above.

Nothing contained in this Award Agreement or the Plan constitutes an employment or service commitment by the Company, affects the Participant's status as an employee at will who is subject to termination without cause, confers upon the Participant any right to remain employed by or in service to the Company or any of its Subsidiaries, interferes in any way with the right of the Company or any of its Subsidiaries at any time to terminate such employment or services, or affects the right of the Company or any of its Subsidiaries to increase or decrease the Participant's other compensation or benefits. Nothing in this paragraph, however, is intended to adversely affect any independent contractual right of the Participant without his or her consent thereto.

**5. Dividend and Voting Rights.** After the Award Date, the Participant shall be entitled to cash dividends and voting rights with respect to the Restricted Shares subject to the Award even though such shares are not vested; provided, however, that such rights shall terminate immediately as to any Restricted Shares that are forfeited pursuant to Section 3 above; and provided, further, that the Participant agrees that promptly following any such forfeiture of Restricted Shares, the Participant will make a cash payment to the Company equal to the amount of any cash dividends received by the Participant in respect of any such unvested, forfeited shares. To the extent the shares are forfeited after the record date and before the payment date for a particular dividend, the Participant shall, promptly after the dividend is paid, make a cash payment to the Company equal to the amount of any such cash dividend received by the Participant in respect of such forfeited shares.

**6. Restrictions on Transfer.** Prior to the time that they have become vested pursuant to Section 3 hereof, neither the Restricted Shares, nor any interest therein, amount payable in respect thereof, or Restricted Property (as defined in Section 8 hereof) may be sold, assigned, transferred, pledged or otherwise disposed of, alienated or encumbered, either voluntarily or involuntarily. The transfer restrictions in the preceding sentence shall not apply to (a) transfers to the Company, or (b) transfers by will or the laws of descent and distribution.

**7. Stock Certificates.**

(a) Book Entry Form. The Company shall issue the Restricted Shares subject to the Award either: (a) in certificate form as provided in Section 7(b) below; or (b) in book entry form, registered in the name of the Participant with notations regarding the applicable restrictions on transfer imposed under this Award Agreement.

(b) **Certificates to be Held by Company; Legend.** Any certificates representing the Restricted Shares that may be delivered to the Participant by the Company prior to vesting shall be redelivered to the Company to be held by the Company until the restrictions on such shares shall have lapsed and the shares shall thereby have become vested or the shares represented thereby have been forfeited hereunder. Such certificates shall bear the following legend and any other legends the Company may determine to be necessary or advisable to comply with all applicable laws, rules, and regulations:

*“The ownership of this certificate and the shares of stock evidenced hereby and any interest therein are subject to substantial restrictions on transfer under an Agreement entered into between the registered owner and Cell Therapeutics, Inc. A copy of such Agreement is on file in the office of the Secretary of Cell Therapeutics, Inc.”*

(c) **Delivery of Certificates Upon Vesting.** Promptly after the vesting of any shares of Restricted Stock pursuant to Section 3 hereof and the satisfaction of any and all related tax withholding obligations pursuant to Section 9, the Company shall, as applicable, either remove the notations on any Restricted Shares issued in book entry form which have vested or deliver to the Participant a certificate or certificates evidencing the number of Restricted Shares which have vested (or, in either case, such lesser number of shares as may result after giving effect to Section 9). The Participant (or the beneficiary or personal representative of the Participant in the event of the Participant’s death or disability, as the case may be) shall deliver to the Company any representations or other documents or assurances as the Company or its counsel may determine to be necessary or advisable in order to ensure compliance with all applicable laws, rules, and regulations with respect to the grant of the Award and the delivery of Shares in respect thereof. The Shares so delivered shall no longer be Restricted Shares hereunder.

(d) **Stock Power; Power of Attorney.** Concurrently with the execution and delivery of this Award Agreement, the Participant shall deliver to the Company an executed stock power in the form attached hereto as **Exhibit A**, in blank, with respect to the Restricted Shares. The Company shall not deliver any share certificates in accordance with this Award Agreement unless and until the Company shall have received such stock power executed by the Participant. The Participant, by acceptance of the Award, shall be deemed to appoint, and does so appoint by execution of this Award Agreement, the Company and each of its authorized representatives as the Participant’s attorney(s)-in-fact to effect any transfer of unvested forfeited shares (or shares otherwise reacquired by the Company hereunder) to the Company as may be required pursuant to the Plan or this Award Agreement and to execute such documents as the Company or such representatives deem necessary or advisable in connection with any such transfer.

**8. Adjustments upon Specified Events.** Upon the occurrence of certain events relating to the Company’s stock contemplated by Section 4.3 of the Plan, the Committee shall make adjustments in accordance with such section in the number and kind of securities that may become vested under the Award. If any adjustment is made under Section 4.3 of the Plan and the Restricted Shares are not fully vested upon such event or prior thereto, the restrictions applicable to such Restricted Shares shall continue in effect with respect to any consideration, property or



other securities (the “**Restricted Property**” and, for the purposes of this Award Agreement, “Restricted Shares” shall include “Restricted Property”, unless the context otherwise requires) received in respect of such Restricted Shares. Such Restricted Property shall vest at such times and in such proportion as the Restricted Shares to which the Restricted Property is attributable vest, or would have vested pursuant to the terms hereof if such Restricted Shares had remained outstanding. To the extent that the Restricted Property includes any cash (other than regular cash dividends), such cash shall be invested, pursuant to policies established by the Committee, in interest bearing, FDIC-insured (subject to applicable insurance limits) deposits of a depository institution selected by the Committee, the earnings on which shall be added to and become a part of the Restricted Property.

**9. Tax Withholding.** The Company (or any of its Subsidiaries last employing the Participant) shall be entitled to require a cash payment by or on behalf of the Participant and/or to deduct from other compensation payable to the Participant any sums required by federal, state or local tax law to be withheld with respect to the vesting of any Restricted Shares. Alternatively, the Company may (but is not required to) permit the Participant to elect, in such manner and at such time or times prior to any applicable tax date as may be permitted or required under Section 11 of the Plan and rules established by the Committee, to have the Company withhold and reacquire Restricted Shares at their Fair Market Value at the time of vesting to satisfy any withholding obligations of the Company or its Subsidiaries with respect to such vesting. Any election to have shares so held back and reacquired shall be subject to such rules and procedures as the Committee may impose, and shall not be available if the Participant makes or has made an election pursuant to Section 83(b) of the Code with respect to such Award.

**10. Notices.** Any notice to be given under the terms of this Award Agreement shall be in writing and addressed to the Company at its principal office to the attention of the Secretary, and to the Participant at the Participant’s last address reflected on the Company’s payroll records. Any notice shall be delivered in person or shall be enclosed in a properly sealed envelope, addressed as aforesaid, registered or certified, and deposited (postage and registry or certification fee prepaid) in a post office or branch post office regularly maintained by the United States Government. Any such notice shall be given only when received, but if the Participant is no longer employed by the Company or a Subsidiary, shall be deemed to have been duly given five business days after the date mailed in accordance with the foregoing provisions of this Section 10.

**11. Plan.** The Award and all rights of the Participant under this Award Agreement are subject to the terms and conditions of the provisions of the Plan, incorporated herein by reference. The Participant agrees to be bound by the terms of the Plan and this Award Agreement. The Participant acknowledges having read and understanding the Plan, the Prospectus for the Plan, and this Award Agreement. Unless otherwise expressly provided in other sections of this Award Agreement, provisions of the Plan that confer discretionary authority on the Board or the Committee do not (and shall not be deemed to) create any rights in the Participant unless such rights are expressly set forth herein or are otherwise in the sole discretion of the Board or the Committee so conferred by appropriate action of the Board or the Committee under the Plan after the date hereof.

**12. Entire Agreement.** This Award Agreement and the Plan constitute the entire agreement and supersede all prior understandings and agreements, written or oral, of the parties hereto with respect to the subject matter hereof. The Plan may be amended pursuant to Section 10.1 of the Plan. This Award Agreement may be amended by the Committee from time to time. Any such amendment must be in writing and signed by the Company. Any such amendment that materially and adversely affects the Participant's rights under this Award Agreement requires the consent of the Participant in order to be effective with respect to the Award. The Company may, however, unilaterally waive any provision hereof in writing to the extent such waiver does not adversely affect the interests of the Participant hereunder, but no such waiver shall operate as or be construed to be a subsequent waiver of the same provision or a waiver of any other provision hereof.

**13. Counterparts.** This Award Agreement may be executed simultaneously in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

**14. Section Headings.** The section headings of this Award Agreement are for convenience of reference only and shall not be deemed to alter or affect any provision hereof.

**15. Governing Law.** This Award Agreement shall be governed by and construed and enforced in accordance with the laws of the State of Washington without regard to conflict of law principles thereunder.

*[Remainder of page intentionally left blank]*

**IN WITNESS WHEREOF**, the Company has caused this Award Agreement to be executed on its behalf by a duly authorized officer and the Participant has hereunto set his or her hand as of \_\_\_\_\_, 20\_\_.

**CELL THERAPEUTICS, INC.,**  
**a Washington corporation**

By: \_\_\_\_\_  
[Name]  
[Title]

**PARTICIPANT**

\_\_\_\_\_  
*Signature*

\_\_\_\_\_  
*Print Name*

**STOCK POWER**

FOR VALUE RECEIVED and pursuant to that certain Restricted Stock Award Agreement between Cell Therapeutics, Inc., a Washington corporation (the "Company"), and the individual named below (the "Individual") dated as of \_\_\_\_\_, 20\_\_, the Individual, hereby sells, assigns and transfers to the Company, an aggregate \_\_\_\_\_ Shares of the Company, standing in the Individual's name on the books of the Company and represented by stock certificate number(s) \_\_\_\_\_ to which this instrument is attached, and hereby irrevocably constitutes and appoints \_\_\_\_\_ as his or her attorney in fact and agent to transfer such shares on the books of the Company, with full power of substitution in the premises.

Dated \_\_\_\_\_, \_\_\_\_\_

\_\_\_\_\_  
*Signature*

\_\_\_\_\_  
*Print Name*

*(Instruction: Please do not fill in any blanks other than the signature line. The purpose of the assignment is to enable the Company to exercise its sale/purchase option set forth in the Restricted Stock Award Agreement without requiring additional signatures on the part of the Individual.)*

**CELL THERAPEUTICS, INC.  
2007 EQUITY INCENTIVE PLAN  
DIRECTOR RESTRICTED STOCK AWARD AGREEMENT**

**THIS DIRECTOR RESTRICTED STOCK AWARD AGREEMENT** (this “**Award Agreement**”) is dated as of [\_\_\_\_\_, 20\_\_] (the “**Award Date**”) by and between Cell Therapeutics, Inc., a Washington corporation (the “**Company**”), and [\_\_\_\_\_] (the “**Director**”).

**W I T N E S S E T H**

**WHEREAS**, pursuant to the Cell Therapeutics, Inc. 2007 Equity Incentive Plan (the “**Plan**”), the Company hereby grants to the Director, effective as of the date hereof, a restricted stock award (the “**Award**”), upon the terms and conditions set forth herein and in the Plan.

**NOW THEREFORE**, in consideration of services rendered and to be rendered by the Director, and the mutual promises made herein and the mutual benefits to be derived therefrom, the parties agree as follows:

**1. Defined Terms.** Capitalized terms used herein and not otherwise defined herein shall have the meaning assigned to such terms in the Plan.

**2. Grant.** Subject to the terms of this Award Agreement, the Company hereby grants to the Director an Award with respect to an aggregate of [\_\_\_\_\_] restricted shares of common stock of the Company (the “**Restricted Shares**”).

**3. Vesting; Forfeiture.**

(a) **Vesting.** Subject to Sections 3(b) and (c) below, the Award shall vest and become nonforfeitable with respect to [\_\_\_\_\_] percent of the total number of Restricted Shares subject to the Award (subject to adjustment under Section 4.3 of the Plan) on each of [\_\_\_\_\_]; provided that if a Change in Control occurs, any Restricted Shares subject to the Award that are outstanding and unvested immediately prior to the Change in Control shall accelerate and become vested upon (or, to the extent necessary to give effect to the acceleration, immediately prior to) the Change in Control.

(b) **Termination Date.** Notwithstanding any other provision herein, upon the date on which the Director ceases to provide services to the Company or a Subsidiary as a member of the Board of Directors (regardless of the reason for such termination of services, whether with or without cause, voluntarily or involuntarily, or due to death or disability) (the “**Termination Date**”), the Director’s Restricted Shares (and related Restricted Property as defined in Section 8 hereof), to the extent such shares have not become vested pursuant to Section 3(a) as of the Termination Date, shall be forfeited to the Company as provided in Section 3(c) upon the Termination Date.

(c) **Forfeiture Procedures.** Upon the occurrence of any forfeiture of Restricted Shares pursuant to Section 3(b), such unvested, forfeited shares and related Restricted Property shall be automatically transferred to the Company as of the applicable forfeiture date without any

other action by the Director (or the Director's beneficiary or personal representative in the event of the Director's death or disability, as applicable). No consideration shall be paid by the Company with respect to such transfer. The Company may exercise its powers under Section 7(d) hereof and take any other action necessary or advisable to evidence such transfer. The Director (or the Director's beneficiary or personal representative in the event of the Director's death or disability, as applicable) shall deliver any additional documents of transfer that the Company may request to confirm the transfer of such unvested, forfeited shares and related Restricted Property to the Company.

**4. Continuation of Service.** The vesting schedule requires continued service through each applicable vesting date as a condition to the vesting of the applicable installment of the Award and the rights and benefits under this Award Agreement. Service for only a portion of the vesting period, even if a substantial portion, will not entitle the Director to any proportionate vesting or avoid or mitigate a termination of rights and benefits upon or following a termination of services as provided in Section 3 above.

Nothing contained in this Award Agreement or the Plan constitutes a continued service commitment by the Company or interferes in any way with the right of the Company or any of its Subsidiaries at any time to terminate such services, or affects the right of the Company or any of its Subsidiaries to increase or decrease the Director's other compensation or benefits. Nothing in this paragraph, however, is intended to adversely affect any independent contractual right of the Director without his or her consent thereto.

**5. Dividend and Voting Rights.** After the Award Date, the Director shall be entitled to cash dividends and voting rights with respect to the Restricted Shares subject to the Award even though such shares are not vested; provided, however, that such rights shall terminate immediately as to any Restricted Shares that are forfeited pursuant to Section 3 above; and provided, further, that the Director agrees that promptly following any such forfeiture of Restricted Shares, the Director will make a cash payment to the Company equal to the amount of any cash dividends received by the Director in respect of any such unvested, forfeited shares. To the extent the shares are forfeited after the record date and before the payment date for a particular dividend, the Director shall, promptly after the dividend is paid, make a cash payment to the Company equal to the amount of any such cash dividend received by the Director in respect of such forfeited shares.

**6. Restrictions on Transfer.** Prior to the time that they have become vested pursuant to Section 3 hereof, neither the Restricted Shares, nor any interest therein, amount payable in respect thereof, or Restricted Property (as defined in Section 8 hereof) may be sold, assigned, transferred, pledged or otherwise disposed of, alienated or encumbered, either voluntarily or involuntarily. The transfer restrictions in the preceding sentence shall not apply to (a) transfers to the Company, or (b) transfers by will or the laws of descent and distribution.

**7. Stock Certificates.**

(a) **Book Entry Form.** The Company shall issue the Restricted Shares subject to the Award either: (a) in certificate form as provided in Section 7(b) below; or (b) in book entry

form, registered in the name of the Director with notations regarding the applicable restrictions on transfer imposed under this Award Agreement.

(b) Certificates to be Held by Company; Legend. Any certificates representing the Restricted Shares that may be delivered to the Director by the Company prior to vesting shall be redelivered to the Company to be held by the Company until the restrictions on such shares shall have lapsed and the shares shall thereby have become vested or the shares represented thereby have been forfeited hereunder. Such certificates shall bear the following legend and any other legends the Company may determine to be necessary or advisable to comply with all applicable laws, rules, and regulations:

*“The ownership of this certificate and the shares of stock evidenced hereby and any interest therein are subject to substantial restrictions on transfer under an Agreement entered into between the registered owner and Cell Therapeutics, Inc. A copy of such Agreement is on file in the office of the Secretary of Cell Therapeutics, Inc.”*

(c) Delivery of Certificates Upon Vesting. Promptly after the vesting of any shares of Restricted Stock pursuant to Section 3 hereof and the satisfaction of any and all related tax withholding obligations, the Company shall, as applicable, either remove the notations on any Restricted Shares issued in book entry form which have vested or deliver to the Director a certificate or certificates evidencing the number of Restricted Shares which have vested. The Director (or the beneficiary or personal representative of the Director in the event of the Director’s death or disability, as the case may be) shall deliver to the Company any representations or other documents or assurances as the Company or its counsel may determine to be necessary or advisable in order to ensure compliance with all applicable laws, rules, and regulations with respect to the grant of the Award and the delivery of Shares in respect thereof. The Shares so delivered shall no longer be Restricted Shares hereunder.

(d) Stock Power; Power of Attorney. Concurrently with the execution and delivery of this Award Agreement, the Director shall deliver to the Company an executed stock power in the form attached hereto as Exhibit A, in blank, with respect to the Restricted Shares. The Company shall not deliver any share certificates in accordance with this Award Agreement unless and until the Company shall have received such stock power executed by the Director. The Director, by acceptance of the Award, shall be deemed to appoint, and does so appoint by execution of this Award Agreement, the Company and each of its authorized representatives as the Director’s attorney(s)-in-fact to effect any transfer of unvested forfeited shares (or shares otherwise reacquired by the Company hereunder) to the Company as may be required pursuant to the Plan or this Award Agreement and to execute such documents as the Company or such representatives deem necessary or advisable in connection with any such transfer.

**8. Adjustments upon Specified Events**. Upon the occurrence of certain events relating to the Company’s stock contemplated by Section 4.3 of the Plan, the Committee shall make adjustments in accordance with such section in the number and kind of securities that may become vested under the Award. If any adjustment is made under Section 4.3 of the Plan and the Restricted Shares are not fully vested upon such event or prior thereto, the restrictions applicable to such Restricted Shares shall continue in effect with respect to any consideration, property or

other securities (the “**Restricted Property**” and, for the purposes of this Award Agreement, “Restricted Shares” shall include “Restricted Property”, unless the context otherwise requires) received in respect of such Restricted Shares. Such Restricted Property shall vest at such times and in such proportion as the Restricted Shares to which the Restricted Property is attributable vest, or would have vested pursuant to the terms hereof if such Restricted Shares had remained outstanding. To the extent that the Restricted Property includes any cash (other than regular cash dividends), such cash shall be invested, pursuant to policies established by the Committee, in interest bearing, FDIC-insured (subject to applicable insurance limits) deposits of a depository institution selected by the Committee, the earnings on which shall be added to and become a part of the Restricted Property.

**9. Notices.** Any notice to be given under the terms of this Award Agreement shall be in writing and addressed to the Company at its principal office to the attention of the Secretary, and to the Director at the Director’s last address reflected on the Company’s payroll records. Any notice shall be delivered in person or shall be enclosed in a properly sealed envelope, addressed as aforesaid, registered or certified, and deposited (postage and registry or certification fee prepaid) in a post office or branch post office regularly maintained by the United States Government. Any such notice shall be given only when received, but if the Director is no longer a member of the Board of Directors, shall be deemed to have been duly given five business days after the date mailed in accordance with the foregoing provisions of this Section 9.

**10. Plan.** The Award and all rights of the Director under this Award Agreement are subject to the terms and conditions of the provisions of the Plan, incorporated herein by reference. The Director agrees to be bound by the terms of the Plan and this Award Agreement. The Director acknowledges having read and understanding the Plan, the Prospectus for the Plan, and this Award Agreement. Unless otherwise expressly provided in other sections of this Award Agreement, provisions of the Plan that confer discretionary authority on the Board or the Committee do not (and shall not be deemed to) create any rights in the Director unless such rights are expressly set forth herein or are otherwise in the sole discretion of the Board or the Committee so conferred by appropriate action of the Board or the Committee under the Plan after the date hereof.

**11. Entire Agreement.** This Award Agreement and the Plan constitute the entire agreement and supersede all prior understandings and agreements, written or oral, of the parties hereto with respect to the subject matter hereof. The Plan may be amended pursuant to Section 10.1 of the Plan. This Award Agreement may be amended by the Committee from time to time. Any such amendment must be in writing and signed by the Company. Any such amendment that materially and adversely affects the Director’s rights under this Award Agreement requires the consent of the Director in order to be effective with respect to the Award. The Company may, however, unilaterally waive any provision hereof in writing to the extent such waiver does not adversely affect the interests of the Director hereunder, but no such waiver shall operate as or be construed to be a subsequent waiver of the same provision or a waiver of any other provision hereof.

**12. Counterparts.** This Award Agreement may be executed simultaneously in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.



**13. Section Headings.** The section headings of this Award Agreement are for convenience of reference only and shall not be deemed to alter or affect any provision hereof.

**14. Governing Law.** This Award Agreement shall be governed by and construed and enforced in accordance with the laws of the State of Washington without regard to conflict of law principles thereunder.

*[Remainder of page intentionally left blank]*

**IN WITNESS WHEREOF**, the Company has caused this Award Agreement to be executed on its behalf by a duly authorized officer and the Director has hereunto set his or her hand as of \_\_\_\_\_, 20\_\_.

**CELL THERAPEUTICS, INC.,**  
**a Washington corporation**

By: \_\_\_\_\_  
[Name]  
[Title]

**DIRECTOR**

\_\_\_\_\_  
*Signature*

\_\_\_\_\_  
*Print Name*

**STOCK POWER**

FOR VALUE RECEIVED and pursuant to that certain Director Restricted Stock Award Agreement between Cell Therapeutics, Inc., a Washington corporation (the "Company"), and the individual named below (the "Individual") dated as of \_\_\_\_\_, 20\_\_, the Individual, hereby sells, assigns and transfers to the Company, an aggregate \_\_\_\_\_ Shares of the Company, standing in the Individual's name on the books of the Company and represented by stock certificate number(s) \_\_\_\_\_ to which this instrument is attached, and hereby irrevocably constitutes and appoints \_\_\_\_\_ as his or her attorney in fact and agent to transfer such shares on the books of the Company, with full power of substitution in the premises.

Dated \_\_\_\_\_, \_\_\_\_\_

\_\_\_\_\_  
*Signature*

\_\_\_\_\_  
*Print Name*

*(Instruction: Please do not fill in any blanks other than the signature line. The purpose of the assignment is to enable the Company to exercise its sale/purchase option set forth in the Director Restricted Stock Award Agreement without requiring additional signatures on the part of the Individual.)*

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, James A. Bianco, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cell Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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):
  - (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: April 26, 2011

By: /s/ James A. Bianco, M.D.

James A. Bianco, M.D.  
Chief Executive Officer

**CERTIFICATION OF CHIEF FINANCIAL OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Louis A. Bianco, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cell Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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):
  - (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: April 26, 2011

By: /s/ Louis A. Bianco

Louis A. Bianco  
Executive Vice President,  
Finance and Administration

**CERTIFICATION OF CHIEF 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, James A. Bianco, 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 Cell Therapeutics, Inc., that, to my knowledge, the Quarterly Report of Cell Therapeutics, Inc. on Form 10-Q for the fiscal quarter ended March 31, 2011 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 Cell Therapeutics, Inc.

A signed original of this written statement required by Section 906 has been provided to Cell Therapeutics, Inc. and will be retained by Cell Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: April 26, 2011

By: /s/ James A. Bianco, M.D  
James A. Bianco, M.D.  
Chief Executive Officer

I, Louis A. Bianco, 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 Cell Therapeutics, Inc., that, to my knowledge, the Quarterly Report of Cell Therapeutics, Inc. on Form 10-Q for the fiscal quarter ended March 31, 2011 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 Cell Therapeutics, Inc.

A signed original of this written statement required by Section 906 has been provided to Cell Therapeutics, Inc. and will be retained by Cell Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: April 26, 2011

By: /s/ Louis A. Bianco  
Louis A. Bianco  
Executive Vice President,  
Finance and Administration