

---

---

**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 June 30, 2013

OR

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

Commission File Number: 000-15006

**CELLDEX THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

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

**No. 13-3191702**  
(I.R.S. Employer Identification No.)

**119 Fourth Avenue, Needham, Massachusetts 02494**  
(Address of principal executive offices) (Zip Code)

**(781) 433-0771**  
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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

As of July 29, 2013, 80,987,871 shares of common stock, \$.001 par value per share, were outstanding.

---

---

**Part I—Financial Information**

<a href="#">Item 1. Unaudited Financial Statements</a>	3
<a href="#">Condensed Consolidated Balance Sheets at June 30, 2013 and December 31, 2012</a>	3
<a href="#">Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Six Months Ended June 30, 2013 and 2012</a>	4
<a href="#">Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2013 and 2012</a>	5
<a href="#">Notes to Unaudited Condensed Consolidated Financial Statements</a>	6
<a href="#">Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</a>	12
<a href="#">Item 3. Quantitative and Qualitative Disclosures About Market Risk</a>	25
<a href="#">Item 4. Controls and Procedures</a>	25
<b>Part II — Other Information</b>	
<a href="#">Item 1A. Risk Factors</a>	25
<a href="#">Item 6. Exhibits</a>	27
<a href="#">Signatures</a>	28
<a href="#">Exhibit Index</a>	29

[Table of Contents](#)**PART I—FINANCIAL INFORMATION****Item 1. Unaudited Financial Statements**

**CELLDEX THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(Unaudited)**

(In thousands, except share and per share amounts)

	June 30, 2013	December 31, 2012
<b>ASSETS</b>		
Current Assets:		
Cash and Cash Equivalents	\$ 25,900	\$ 24,897
Marketable Securities	129,083	59,065
Accounts and Other Receivables	12	44
Prepaid and Other Current Assets	1,435	1,108
Total Current Assets	<u>156,430</u>	<u>85,114</u>
Property and Equipment, Net	7,338	7,205
Intangible Assets, Net	23,326	23,833
Other Assets	174	424
Goodwill	8,965	8,965
Total Assets	<u>\$ 196,233</u>	<u>\$ 125,541</u>
<b>LIABILITIES AND STOCKHOLDERS’ EQUITY</b>		
Current Liabilities:		
Accounts Payable	\$ 2,069	\$ 745
Accrued Expenses	9,904	10,960
Current Portion of Long-Term Liabilities	530	388
Current Portion of Term Loan	—	5,592
Total Current Liabilities	<u>12,503</u>	<u>17,685</u>
Term Loan, less Current Portion	—	5,746
Other Long-Term Liabilities	6,636	6,336
Total Liabilities	<u>19,139</u>	<u>29,767</u>
Commitments and Contingent Liabilities (Note 13)		
Stockholders’ Equity:		
Convertible Preferred Stock, \$.01 Par Value; 3,000,000 Shares Authorized; No Shares Issued and Outstanding at June 30, 2013 and December 31, 2012	—	—
Common Stock, \$.001 Par Value; 297,000,000 Shares Authorized; 80,977,696 and 64,359,513 Shares Issued and Outstanding at June 30, 2013 and December 31, 2012, respectively	81	64
Additional Paid-In Capital	474,942	357,094
Accumulated Other Comprehensive Income	2,548	2,745

Accumulated Deficit		(300,477)	(264,129)
Total Stockholders' Equity		177,094	95,774
Total Liabilities and Stockholders' Equity		\$ 196,233	\$ 125,541

See accompanying notes to unaudited condensed consolidated financial statements

3

[Table of Contents](#)

**CELLDEX THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
**(Unaudited)**

(In thousands, except per share amounts)

	Three Months Ended		Six Months Ended	
	June 30, 2013	June 30, 2012	June 30, 2013	June 30, 2012
<b>REVENUE:</b>				
Product Development and Licensing Agreements	\$ 47	\$ 40	\$ 77	\$ 75
Contracts and Grants	50	96	100	149
Product Royalties	—	1,873	2,334	4,218
Total Revenue	<u>97</u>	<u>2,009</u>	<u>2,511</u>	<u>4,442</u>
<b>OPERATING EXPENSE:</b>				
Research and Development	15,090	11,114	29,180	21,881
Royalty	—	1,873	2,334	4,218
General and Administrative	3,411	2,219	6,549	4,536
Amortization of Acquired Intangible Assets	254	291	507	583
Total Operating Expense	<u>18,755</u>	<u>15,497</u>	<u>38,570</u>	<u>31,218</u>
Operating Loss	(18,658)	(13,488)	(36,059)	(26,776)
Investment and Other Income, Net	161	126	540	331
Interest Expense	(519)	(411)	(829)	(844)
Net Loss	<u>\$ (19,016)</u>	<u>\$ (13,773)</u>	<u>\$ (36,348)</u>	<u>\$ (27,289)</u>
Basic and Diluted Net Loss Per Common Share (Note 3)	<u>\$ (0.24)</u>	<u>\$ (0.23)</u>	<u>\$ (0.47)</u>	<u>\$ (0.50)</u>
Shares Used in Calculating Basic and Diluted Net Loss per Share (Note 3)	<u>80,899</u>	<u>58,733</u>	<u>77,482</u>	<u>54,439</u>

<b>COMPREHENSIVE LOSS:</b>				
Net Loss	\$ (19,016)	\$ (13,773)	\$ (36,348)	\$ (27,289)
Other Comprehensive (Loss) Income:				
Foreign Currency Translation Adjustments	(1)	(1)	(3)	1
Unrealized (Loss) Gain on Marketable Securities	(140)	(39)	(194)	69
Comprehensive Loss	<u>\$ (19,157)</u>	<u>\$ (13,813)</u>	<u>\$ (36,545)</u>	<u>\$ (27,219)</u>

See accompanying notes to unaudited condensed consolidated financial statements

4

[Table of Contents](#)

**CELLDEX THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(Unaudited)**

(In thousands)

	Six Months Ended	
	June 30, 2013	June 30, 2012
<b>Cash Flows from Operating Activities:</b>		
Net Loss	\$ (36,348)	\$ (27,289)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation and Amortization	943	1,073
Amortization of Intangible Assets	507	583
Amortization and Premium of Marketable Securities	(1,949)	(157)
Realized Gain on Sales and Maturities of Marketable Securities	—	(6)
Gain on Sale or Disposal of Assets	(21)	(12)
Stock-Based Compensation Expense	1,384	1,088
Non-Cash Interest Expense	97	111
Changes in Operating Assets and Liabilities:		

Accounts and Other Receivables	32	109
Prepaid and Other Current Assets	(424)	(493)
Other Assets	250	(99)
Accounts Payable and Accrued Expenses	109	(993)
Other Liabilities	162	573
Net Cash Used in Operating Activities	<u>(35,258)</u>	<u>(25,512)</u>
<b>Cash Flows from Investing Activities:</b>		
Sales and Maturities of Marketable Securities	20,582	20,919
Purchases of Marketable Securities	(88,845)	(39,383)
Acquisition of Property and Equipment	(917)	(122)
Proceeds from Sale or Disposal of Assets	21	156
Net Cash Used in Investing Activities	<u>(69,159)</u>	<u>(18,430)</u>
<b>Cash Flows from Financing Activities:</b>		
Net Proceeds from Stock Issuances	114,187	51,957
Proceeds from Issuance of Stock from Employee Benefit Plans	2,294	—
Payments of Term Loan	(11,029)	(1,323)
Payments of Other Liabilities	(29)	(29)
Net Cash Provided by Financing Activities	<u>105,423</u>	<u>50,605</u>
Effect of Exchange Rate Changes on Cash and Cash Equivalents	<u>(3)</u>	<u>1</u>
Net Increase in Cash and Cash Equivalents	1,003	6,664
Cash and Cash Equivalents at Beginning of Period	24,897	11,899
Cash and Cash Equivalents at End of Period	<u>\$ 25,900</u>	<u>\$ 18,563</u>

See accompanying notes to unaudited condensed consolidated financial statements

[Table of Contents](#)

**CELLDEX THERAPEUTICS, INC.**  
**Notes to Unaudited Condensed Consolidated Financial Statements**  
**June 30, 2013**

**(1) Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared by Celldex Therapeutics, Inc. (the “Company” or “Celldex”) in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and reflect the operations of the Company and its wholly-owned subsidiary. All intercompany transactions have been eliminated in consolidation.

These interim financial statements do not include all the information and footnotes required by U.S. GAAP for annual financial statements and should be read in conjunction with the audited financial statements for the year ended December 31, 2012, which are included in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (“SEC”) on March 8, 2013. In the opinion of management, the interim financial statements reflect all normal recurring adjustments necessary to fairly state the Company’s financial position and results of operations for the interim periods presented. The year-end consolidated balance sheet data presented for comparative purposes was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for any future interim period or the fiscal year ending December 31, 2013.

At June 30, 2013, the Company had cash, cash equivalents and marketable securities of \$155.0 million and working capital of \$143.9 million. The Company incurred a loss of \$36.3 million for the six months ended June 30, 2013. Net cash used in operations for the six months ended June 30, 2013 was \$35.3 million. The Company believes that the cash, cash equivalents and marketable securities at June 30, 2013 will be sufficient to meet estimated working capital requirements and fund planned operations for at least the next twelve months.

During the next twelve months, the Company may take further steps to raise additional capital to meet its long-term liquidity needs. These capital raising activities may include, but may not be limited to, one or more of the following: the licensing of technology programs with existing or new collaborative partners, possible business combinations, issuance of debt, or the issuance of common stock or other securities via private placements or public offerings. While the Company continues to seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and the Company’s negotiating position in capital-raising efforts may worsen as existing resources are used. There is also no assurance that the Company will be able to enter into further collaborative relationships. Additional equity financing may be dilutive to the Company’s stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict the Company’s ability to operate as a business; and licensing or strategic collaborations may result in royalties or other terms which reduce the Company’s economic potential from products under development.

**(2) Significant Accounting Policies**

The significant accounting policies used in preparation of these condensed consolidated financial statements for the six months ended June 30, 2013 are consistent with those discussed in Note 2 to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2012, except for the adoption of new accounting standards during the first six months of 2013 as discussed below.

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

In January 2013, the Company adopted a new U.S. GAAP accounting standard which amended guidance applicable to annual impairment tests of indefinite-lived intangible assets. The amended guidance added an optional qualitative assessment for determining whether an indefinite-lived intangible asset is impaired. Prior to this guidance, companies were required to perform an annual impairment test that included a calculation of the fair value of the asset and a comparison of that fair value with its carrying value. If the carrying value exceeded the fair value, an impairment was recorded. The amended guidance allows a company the option to perform a qualitative assessment, considering both negative and positive evidence, regarding the potential impairment of the indefinite-lived intangible asset. If, based on the qualitative analysis, the company determines that it is more likely than not that the fair value of such an asset exceeds its carrying value, the company would be permitted to conclude that the indefinite-lived intangible asset was not impaired without a quantitative calculation of the fair value of the asset. Otherwise, the company would perform the

## [Table of Contents](#)

quantitative calculation of the fair value and the comparison with the carrying value. The Company's adoption of this new standard did not have a material effect on its operating results or financial position.

### (3) Net Loss Per Share

Basic net loss per common share is based upon the weighted-average number of common shares outstanding during the period, excluding restricted stock that has been issued but is not yet vested. Diluted net loss per common share is based upon the weighted-average number of common shares outstanding during the period plus additional weighted-average potentially dilutive common shares outstanding during the period when the effect is dilutive. The potentially dilutive common shares that have not been included in the net loss per common share calculations because the effect would have been anti-dilutive are as follows:

	Six months ended June 30,	
	2013	2012
Stock options	5,005,603	4,304,897
Restricted stock	12,000	12,000
	<u>5,017,603</u>	<u>4,316,897</u>

### (4) Comprehensive Loss

In January 2013, the Company adopted a new U.S. GAAP accounting standard which requires the Company to separately disclose, on a prospective basis, the change in each component of other comprehensive income (loss) relating to reclassification adjustments and current period other comprehensive income (loss). As the new guidance relates to presentation only, the adoption did not have a material impact on the Company's results of operations, financial position or cash flows. No amounts were reclassified out of accumulated other comprehensive income during the three or six months ended June 30, 2013. The changes in accumulated other comprehensive income (loss) by component for the three and six months ended June 30, 2013 are summarized below.

	Unrealized Gain (Loss) on Marketable Securities, net of tax		Foreign Currency Items (In thousands)		Total
	\$	\$	\$	\$	
Balance at March 31, 2013	\$ 102	\$ 2,587	\$ 2,587	\$ 2,689	
Other comprehensive income (loss) before reclassifications	(140)	(1)	(1)	(141)	
Amounts reclassified from other comprehensive income	—	—	—	—	
Net current-period other comprehensive income	(140)	(1)	(1)	(141)	
Balance at June 30, 2013	<u>\$ (38)</u>	<u>\$ 2,586</u>	<u>\$ 2,586</u>	<u>\$ 2,548</u>	
Balance at December 31, 2012	\$ 156	\$ 2,589	\$ 2,589	\$ 2,745	
Other comprehensive income (loss) before reclassifications	(194)	(3)	(3)	(197)	
Amounts reclassified from other comprehensive income	—	—	—	—	
Net current-period other comprehensive income	(194)	(3)	(3)	(197)	
Balance at June 30, 2013	<u>\$ (38)</u>	<u>\$ 2,586</u>	<u>\$ 2,586</u>	<u>\$ 2,548</u>	

### (5) Fair Value Measurements

The following tables set forth the Company's financial assets subject to fair value measurements:

	As of			
	June 30, 2013	Level 1	Level 2	Level 3
(In thousands)				
Money market funds and cash equivalents	\$ 22,709	\$ 22,709	—	—
Marketable securities	\$ 129,083	—	\$ 129,083	—
	<u>\$ 151,792</u>	<u>\$ 22,709</u>	<u>\$ 129,083</u>	<u>—</u>

	As of December 31, 2012	Level 1	Level 2	Level 3
	(In thousands)			
Money market funds and cash equivalents	\$ 18,688	\$ 18,688	—	—
Marketable securities	\$ 59,065	—	\$ 59,065	—
	<u>\$ 77,753</u>	<u>\$ 18,688</u>	<u>\$ 59,065</u>	<u>—</u>

There have been no transfers of assets or liabilities between the fair value measurement classifications. The Company's financial instruments consist mainly of cash and cash equivalents, marketable securities, short-term accounts receivable, accounts payable and debt obligations. The Company values its marketable securities utilizing independent pricing services which normally derive security prices from recently reported trades for identical or similar securities, making adjustments based on significant observable transactions. At each balance sheet date, observable market inputs may include trade information, broker or dealer quotes, bids, offers or a combination of these data sources. Short-term accounts receivable and accounts payable are reflected in the accompanying consolidated financial statements at cost, which approximates fair value due to the short-term nature of these instruments.

## (6) Marketable Securities

A summary of marketable securities is shown below:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(In thousands)			
<b>June 30, 2013</b>				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	\$ 34,189	\$ 15	\$ 5	\$ 34,199
Maturing after one year through three years	34,030	61	22	34,069
Total U.S. government and municipal obligations	<u>\$ 68,219</u>	<u>\$ 76</u>	<u>\$ 27</u>	<u>\$ 68,268</u>
Corporate debt securities				
Maturing in one year or less	\$ 33,336	\$ 10	\$ 32	\$ 33,314
Maturing after one year through three years	27,566	—	65	27,501
Total corporate debt securities	<u>\$ 60,902</u>	<u>\$ 10</u>	<u>\$ 97</u>	<u>\$ 60,815</u>
Total marketable securities	<u>\$ 129,121</u>	<u>\$ 86</u>	<u>\$ 124</u>	<u>\$ 129,083</u>
<b>December 31, 2012</b>				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	\$ 15,566	\$ 28	\$ —	\$ 15,594
Maturing after one year through three years	19,797	99	1	19,895
Total U.S. government and municipal obligations	<u>\$ 35,363</u>	<u>\$ 127</u>	<u>\$ 1</u>	<u>\$ 35,489</u>
Corporate debt securities				
Maturing in one year or less	\$ 17,353	\$ 23	\$ 4	\$ 17,372
Maturing after one year through three years	6,193	14	3	6,204
Total corporate debt securities	<u>\$ 23,546</u>	<u>\$ 37</u>	<u>\$ 7</u>	<u>\$ 23,576</u>
Total marketable securities	<u>\$ 58,909</u>	<u>\$ 164</u>	<u>\$ 8</u>	<u>\$ 59,065</u>

The marketable securities held by the Company were high investment grade and there were no marketable securities that the Company considered to be other-than-temporarily impaired as of June 30, 2013.

## (7) Intangible Assets and Goodwill

Intangible assets, net of accumulated amortization, and goodwill are as follows:

	Estimated Life	June 30, 2013			December 31, 2012		
		Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
		(In thousands)					
Intangible Assets:							
IPR&D	Indefinite	\$ 11,800	—	\$ 11,800	\$ 11,800	—	\$ 11,800
Amgen Amendment	16 years	14,500	\$ (3,363)	11,137	14,500	\$ (2,915)	11,585
Core Technology	11 years	1,296	(907)	389	1,296	(848)	448
Total Intangible Assets		<u>\$ 27,596</u>	<u>\$ (4,270)</u>	<u>\$ 23,326</u>	<u>\$ 27,596</u>	<u>\$ (3,763)</u>	<u>\$ 23,833</u>
Goodwill	Indefinite	<u>\$ 8,965</u>	<u>—</u>	<u>\$ 8,965</u>	<u>\$ 8,965</u>	<u>—</u>	<u>\$ 8,965</u>

The IPR&D intangible asset was recorded in connection with the acquisition of CuraGen and relates to the development of CDX-011. At the date of acquisition and at June 30, 2013, CDX-011 had not yet reached technological feasibility nor did it have any alternative future use. The Company recently completed a randomized Phase 2b study of CDX-011 for the treatment of advanced breast cancer.

## (8) Term Loan

In December 2010, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with MidCap Financial, LLC pursuant to which the Company borrowed \$10 million (the "Term Loan") from MidCap. In March 2011, the Company amended the Loan Agreement and borrowed an additional \$5 million from General Electric Capital Corporation to increase the amount owed under the Term Loan to \$15 million. In March 2012, the Company amended the Loan Agreement to extend the maturity date from December 2013 to December 2014. In May 2013, the Company elected to prepay the Term Loan in full, pursuant to the terms of the Loan Agreement, as amended, and paid \$8.8 million in principal and \$0.7 million in interest, prepayment and final payment fees. The Company's obligations under the Loan Agreement had been secured by a first priority security interest in substantially all of its assets, other than its intellectual property. In connection with the repayment of the Term Loan and the termination of the Loan Agreement, those security interests were released. Interest expense on the Term Loan was \$0.5 million and \$0.8 million for the three and six months ended June 30, 2013 and \$0.4 million and \$0.8 million for the three and six months ended June 30, 2012, respectively.

## (9) Other Long-Term Liabilities

Other long-term liabilities include the following:

	June 30, 2013	December 31, 2012
	(In thousands)	
Deferred Rent	\$ 422	\$ 434
Net Deferred Tax Liability related to IPR&D	4,661	4,661
Deferred Income from Sale of Tax Benefits	1,630	1,118
Loan Payable	443	472
Other	10	39
Total	7,166	6,724
Less Current Portion	(530)	(388)
Long-Term Portion	<u>\$ 6,636</u>	<u>\$ 6,336</u>

In January 2013, 2012 and 2011, the Company received approval from the New Jersey Economic Development Authority and agreed to sell New Jersey tax benefits worth \$0.8 million, \$0.8 million and \$0.6 million to an independent third party for \$0.8 million, \$0.7 million and \$0.5 million, respectively. Under the agreement, the Company must maintain a base of operations in New Jersey for five years or the tax benefits must be paid back on a pro-rata basis based on the number of years completed. During the six months ended June 30, 2013 and 2012, the Company recorded \$0.2 million and \$0.1 million to other income related to the sale of these tax benefits, respectively.

## (10) Stockholders' Equity

In January 2011, the Company entered into a controlled equity offering sales agreement (the "Cantor Agreement") with Cantor Fitzgerald & Co. pursuant to which the Company could issue and sell up to 5,000,000 shares of its common stock from time to

## [Table of Contents](#)

time through Cantor, acting as agent. During the six months ended June 30, 2012, the Company issued 2,450,000 shares of common stock under the Cantor Agreement and raised \$8.5 million in net proceeds.

In September 2012, the Company and Cantor amended the Cantor Agreement (the "Cantor Amendment") to allow the Company to issue and sell additional shares of its common stock having an aggregate offering price of up to \$44.0 million. Under the Cantor Amendment, the Company will pay Cantor a fixed commission rate of 3.0% of the gross sales price per share of any common stock sold through Cantor. The Cantor Amendment terminates upon ten day notice by either Cantor or the Company. During the six months ended June 30, 2013, the Company issued 2,433,608 shares under the Cantor Amendment and raised \$17.1 million in net proceeds. At June 30, 2013, the Company had \$4.4 million remaining in aggregate offering price available under the Cantor Amendment.

During the six months ended June 30, 2012, the Company issued 12,075,000 shares of its common stock in an underwritten public offering, including the underwriter's exercise of their full over-allotment option to purchase an additional 1,575,000 shares of common stock. The net proceeds to the Company were \$43.4 million, after deducting underwriting fees and offering expenses.

During the six months ended June 30, 2013, the Company issued 13,800,000 shares of its common stock in an underwritten public offering, including the underwriter's exercise of their full over-allotment option to purchase an additional 1,800,000 shares of common stock. The net proceeds to the Company were \$97.0 million, after deducting underwriting fees and offering expenses.

## (11) Stock-Based Compensation

A summary of stock option activity for the six months ended June 30, 2013 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In Years)
Options Outstanding at December 31, 2012	5,349,810	\$ 5.98	7.0
Granted	38,750	\$ 13.01	
Exercised	(370,627)	\$ 6.17	
Canceled	(12,330)	\$ 6.64	
Options Outstanding at June 30, 2013	<u>5,005,603</u>	\$ 6.02	6.5
Options Vested and Expected to Vest at June 30, 2013	4,967,369	\$ 6.02	6.5
Options Exercisable at June 30, 2013	3,176,119	\$ 6.58	5.3
Shares Available for Grant under the 2008 Plan	3,313,661		



The weighted average grant-date fair value of stock options granted during the six months ended June 30, 2013 was \$8.31. Stock-based compensation expense for the three and six months ended June 30, 2013 and 2012 was recorded as follows:

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
	(In thousands)			
Research and development	\$ 422	\$ 284	\$ 863	\$ 679
General and administrative	254	164	521	409
Total stock-based compensation expense	\$ 676	\$ 448	\$ 1,384	\$ 1,088

The fair values of employee and director stock options granted during the three and six months ended June 30, 2013 and 2012 were valued using the Black-Scholes option-pricing model with the following assumptions:

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Expected stock price volatility	72%	71%	72%	70 - 71%
Expected option term	6.0 years	6.0 years	6.0 years	6.0 years
Risk-free interest rate	1.2 — 1.8%	0.9 — 1.3%	1.2 — 1.8%	0.9 — 1.4%
Expected dividend yield	None	None	None	None

10

[Table of Contents](#)

**(12) Income Taxes**

Massachusetts, New Jersey and Connecticut are the three states in which the Company primarily operates or has operated and has income tax nexus. The Company is not currently under examination by any jurisdictions for any tax year.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its net deferred tax assets, which are comprised principally of net operating loss carryforwards, capitalized R&D expenditures and R&D tax credit carryforwards. The Company has determined that it is more likely than not that it will not recognize the benefits of federal and state deferred tax assets and, as a result, a full valuation allowance was maintained at June 30, 2013 and December 31, 2012 against the Company's net deferred tax assets.

**(13) Commitments and Contingent Liabilities**

Except as set forth below, the significant commitments and contingencies at June 30, 2013 are consistent with those disclosed in Notes 13 and 15 to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2012.

On May 1, 2013, the Company entered into a lease agreement (the "Lease") with Crown Perryville, LLC., as Landlord, pursuant to which the Company will lease approximately 33,000 square feet of office space in Hampton, New Jersey for use as an office and laboratory. The Lease has a five-year, five-month term which will commence on the later of November 15, 2013 or the date on which the alterations are substantially complete and a Certificate of Occupancy is issued. The Company's obligation to pay rent commences five months after the lease commencement date. The annual rent obligations increase from \$0.4 million in the first year to \$0.5 million in the fifth year. The Lease includes two renewal options of five years each.

11

[Table of Contents](#)

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

**Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995:** This report on Form 10-Q contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "will," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our ability to successfully complete research and further development, including animal, preclinical and clinical studies, and commercialization of rindopepimut, CDX-011, and other drug candidates and the growth of the markets for those drug candidates;
- our ability to raise sufficient capital to fund our clinical studies and to meet our long-term liquidity needs, on terms acceptable to us, or at all. If we are unable to raise the funds necessary to meet our long-term liquidity needs, we may have to delay or discontinue the development of one or more programs, discontinue or delay on-going or anticipated clinical trials, license out programs earlier than expected, raise funds at significant discount or on other unfavorable terms, if at all, or sell all or part of our business;
- our ability to manage multiple clinical trials for a variety of drug candidates at different stages of development, including our Phase 3 trial for rindopepimut;



- the cost, timing, scope and results of ongoing safety and efficacy trials of rindopepimut, CDX-011, and other preclinical and clinical testing;
- our ability to fund and complete the development and commercialization of rindopepimut for North America internally;
- the ability to negotiate strategic partnerships, where appropriate, for our programs which may include rindopepimut outside North America;
- our ability to adapt our proprietary antibody-targeted technology, or APC Targeting Technology™, to develop new, safe and effective therapeutics for oncology and infectious disease indications;
- our ability to develop technological capabilities and expand our focus to broader markets for targeted immunotherapeutics;
- the availability, cost, delivery and quality of clinical and commercial grade materials produced by our own manufacturing facility or supplied by contract manufacturers and partners;
- the availability, cost, delivery and quality of clinical management services provided by our clinical research organization partners;
- the timing, cost and uncertainty of obtaining regulatory approvals for our drug candidates;
- our ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors;
- the validity of our patents and our ability to avoid intellectual property litigation, which can be costly and divert management time and attention; and
- the factors listed under the headings “Business,” “Risk Factors” and Management’s Discussion and Analysis of Financial Condition and Results of Operations” in the Company’s annual report on Form 10-K for the year ended December 31, 2012 and other reports that we file with the Securities and Exchange Commission.

[Table of Contents](#)

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith and we believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs or projections will result or be achieved or accomplished.

**OVERVIEW**

We are a biopharmaceutical company focused on the development and commercialization of several immunotherapy technologies for the treatment of cancer and other difficult-to-treat diseases. Our drug candidates are derived from a broad set of complementary technologies which have the ability to utilize the human immune system and enable the creation of therapeutic agents. We are using these technologies to develop targeted immunotherapeutics comprised of antibodies, adjuvants and monotherapies and antibody-drug conjugates that prevent or treat cancer and other diseases that modify undesirable activity by the body’s own proteins or cells.

Our lead drug candidates include rindopepimut (CDX-110) and CDX-011. Rindopepimut is a targeted immunotherapeutic in a pivotal Phase 3 study for the treatment of front-line glioblastoma and a Phase 2 study for the treatment of recurrent glioblastoma. CDX-011 is an antibody-drug conjugate for which we plan to initiate a randomized, accelerated approval study in patients with triple negative breast cancer that over-express GPNMB in the second half of 2013. We also have a number of earlier stage candidates in clinical development, including CDX-1135, a molecule that inhibits a part of the immune system called the complement system, CDX-1127, a therapeutic fully human monoclonal antibody for cancer indications, CDX-301, an immune cell mobilizing agent and dendritic cell growth factor and CDX-1401, an APC Targeting Technology™ program for cancer indications. Our drug candidates address market opportunities for which we believe current therapies are inadequate or non-existent.

We are building a fully integrated, commercial-stage biopharmaceutical company that develops important therapies for patients with unmet medical needs. Our program assets provide us with the strategic options to either retain full economic rights to our innovative therapies or seek favorable economic terms through advantageous commercial partnerships. This approach allows us to maximize the overall value of our technology and product portfolio while best ensuring the expeditious development of each individual product.

The following table includes the programs that we currently believe are significant to our business:

Product (generic)	Indication/Field	Partner	Status
<b>CLINICAL</b>			
CDX-110 (rindopepimut)	Front-line glioblastoma	—	Phase 3
CDX-011 (glembatumumab vedotin)	Metastatic breast cancer and melanoma	—	Phase 2b
CDX-110 (rindopepimut)	Recurrent glioblastoma	—	Phase 2
CDX-1135	Renal disease	—	Pilot
CDX-1127	Lymphoma/leukemia and solid tumors	—	Phase 1
CDX-301	Cancer, autoimmune disease and transplant	—	Phase 1
CDX-1401	Multiple solid tumors	—	Phase 1
<b>PRECLINICAL</b>			
CDX-014	Ovarian and renal cancer	—	Preclinical

The expenditures that will be necessary to execute our business plan are subject to numerous uncertainties. Completion of clinical trials may take several years or more, and the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product candidate.

It is not unusual for the clinical development of these types of product candidates to each take five years or more, and for total development costs to exceed \$100 million for each product candidate. We estimate that clinical trials of the type we generally conduct are typically completed over the following timelines:

Clinical Phase	Estimated Completion Period
Phase 1	1 - 2 Years
Phase 2	1 - 5 Years
Phase 3	1 - 5 Years

The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during the clinical trial protocol, including, among others, the following:

13

#### [Table of Contents](#)

- the number of patients that ultimately participate in the trial;
- the duration of patient follow-up that seems appropriate in view of results;
- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patient subjects; and
- the efficacy and safety profile of the product candidate.

We test potential product candidates in numerous preclinical studies for safety, toxicology and immunogenicity. We may then conduct multiple clinical trials for each product candidate. As we obtain results from trials, we may elect to discontinue or delay clinical trials for certain product candidates in order to focus our resources on more promising product candidates.

An element of our business strategy is to pursue the research and development of a broad portfolio of product candidates. This is intended to allow us to diversify the risks associated with our research and development expenditures. As a result, we believe our future capital requirements and our future financial success are not substantially dependent on any one product candidate. To the extent we are unable to maintain a broad range of product candidates, our dependence on the success of one or a few product candidates increases.

Regulatory approval is required before we can market our product candidates as therapeutic products. In order to proceed to subsequent clinical trial stages and to ultimately achieve regulatory approval, the regulatory agency must conclude that our clinical data is safe and effective. Historically, the results from preclinical testing and early clinical trials (through Phase 2) have often not been predictive of results obtained in later clinical trials. A number of new drugs and biologics have shown promising results in early clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

Furthermore, our business strategy includes the option of entering into collaborative arrangements with third parties to complete the development and commercialization of our product candidates. In the event that third parties take over the clinical trial process for one of our product candidates, the estimated completion date would largely be under control of that third party rather than us. We cannot forecast with any degree of certainty which proprietary products, if any, will be subject to future collaborative arrangements, in whole or in part, and how such arrangements would affect our development plan or capital requirements. Our programs may also benefit from subsidies, grants, contracts or government or agency-sponsored studies that could reduce our development costs.

As a result of the uncertainties discussed above, among others, it is difficult to accurately estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent it will receive cash inflows from the commercialization and sale of a product. Our inability to complete our research and development projects in a timely manner or our failure to enter into collaborative agreements, when appropriate, could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time to time in order to continue with our business strategy. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

During the past five years through December 31, 2012, we incurred an aggregate of \$156.3 million in research and development expenses. The following table indicates the amount incurred for each of our significant research programs and for other identified research and development activities during the six months ended June 30, 2013 and 2012. The amounts disclosed in the following table reflect direct research and development costs, license fees associated with the underlying technology and an allocation of indirect research and development costs to each program.

	Six Months Ended June 30,	
	2013	2012
	(In thousands)	
Rindopepimut	\$ 17,743	\$ 10,956
CDX-011	2,778	1,853
CDX-1135	794	4,577
CDX-1127	4,524	2,020
CDX-301	260	839
CDX-1401	318	710
CDX-014	508	320
Other Programs	2,255	606
<b>Total R&amp;D Expense</b>	<b>\$ 29,180</b>	<b>\$ 21,881</b>

14

**Clinical Development Programs***Rindopepimut*

Our lead clinical development program, rindopepimut, is a targeted immunotherapeutic that targets the tumor-specific molecule, epidermal growth factor receptor variant III, or EGFRvIII. EGFRvIII is a mutated form of the epidermal growth factor receptor, or EGFR, that is only expressed in cancer cells and not in normal tissue and can directly contribute to cancer cell growth. EGFRvIII is expressed in approximately 30% of glioblastoma, or GB, tumors, also referred to as glioblastoma multiforme, or GBM, the most common and aggressive form of brain cancer. Rindopepimut is composed of the EGFRvIII peptide linked to a carrier protein called Keyhole Limpet Hemocyanin, or KLH, and administered together with the adjuvant GM-CSF. The Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, have both granted orphan drug designation for rindopepimut for the treatment of EGFRvIII expressing GB. The FDA has also granted Fast Track designation.

The Phase 2a study of rindopepimut referred to as ACTIVATE was led by collaborating investigators at the Brain Center at Duke Comprehensive Cancer Center in Durham, North Carolina and at M.D. Anderson Cancer Center in Houston, Texas and enrolled 18 evaluable GB patients. An extension of the Phase 2a study referred to as ACT II evaluated 22 additional GB patients treated in combination with the current standard of care, maintenance temozolomide, or TMZ, at the same two institutions.

We initiated ACT III, a Phase 2b/3 randomized study of rindopepimut combined with standard of care, TMZ, versus standard of care alone in patients with GB in over 30 sites throughout the United States. In December 2008, we announced an amendment to convert the ACT III study to a single-arm Phase 2 clinical trial in which all patients were to receive rindopepimut in combination with TMZ. The decision, which followed the recommendation of the Independent Data Monitoring Committee, was based on the observation that the majority of patients randomized to the control (standard of care) arm withdrew from this open-label study after being randomized to the control arm. Patients participating in the control arm of the study were offered the option to receive treatment with rindopepimut. Under this amendment, the ACT III study provided for a multi-center, non-randomized dataset for rindopepimut in patients with newly diagnosed GB.

In November 2012, we announced three-year survival data for each of our three Phase 2 studies in rindopepimut, ACT III, ACT II and ACTIVATE. The median overall survival, or OS, in ACT III was 24.6 months from diagnosis (21.8 months from study entry) and OS was 26% at three years. The median OS in ACT II was 24.4 months from diagnosis (20.5 months from study entry) and OS was 23% at three years. The median OS in ACTIVATE was 24.6 months from diagnosis (20.4 months from study entry) and OS was 33% at three years. In addition we also announced data from a retrospective analysis of EGFRvIII expression status and associated clinical outcome in the Phase 3 Radiation Therapy Oncology Group's, or RTOG, 0525 study. This analysis was conducted by The University of Texas MD Anderson Cancer Center in cooperation with RTOG to provide an assessment of the prognosis for patients with EGFRvIII-positive disease contemporary with the ACT III data. Across three Phase 2 studies of rindopepimut, survival data remains consistent and suggests a continuing survival benefit in comparison to independent control datasets (see chart below) at the median and at three years.

**Rindopepimut Overall Survival (OS) in EGFRvIII-Positive Glioblastoma vs Independent Control Datasets****Rindopepimut Phase 2 Studies (all data from study entry)**

	<b>Medium (months)</b>	<b>OS at 3 years</b>
ACT III (n=65)	21.8	26%
ACT II (n=22)	20.5	23%
ACTIVATE (n=18)	20.4	33%

**Independent Control Datasets (all data from study entry)**

MD Anderson EGFRvIII-positive patients matched(1) to ACTIVATE patient population (n=17) (contemporary with ACTIVATE)	12.2(2)	6%
Radiation Therapy Oncology Group (RTOG) 0525 study—all EGFRvIII- positive patients (n=142) (contemporary with ACT III)	15.1	18%
RTOG 0525 study—all EGFRvIII-positive patients treated with standard dose temozolomide (n=62) (contemporary with ACT III)	14.2	7%
RTOG 0525 study—EGFRvIII-positive patients matched(1) to ACT III/IV patient population (n=29) (contemporary with ACT III)	16.0	13%

(1) Controls are closely matched to rindopepimut patient criteria including gross total resection of patient tumor and ~3 months without disease progression at time of study entry

(2) In order to provide comparable timeframes across datasets, data have been estimated assuming study entry at three months from diagnosis.

In December 2011, we initiated ACT IV, a pivotal, randomized, double-blind, controlled Phase 3 study of rindopepimut in patients with surgically resected, EGFRvIII-positive GB. Patients are randomized after the completion of surgery and standard chemoradiation treatment. The treatment regime includes a rindopepimut priming phase post-radiation followed by an adjuvant TMZ phase and a rindopepimut maintenance therapy phase. Patients are treated until disease progression or intolerance to therapy. The primary objective of the study is to determine whether rindopepimut plus adjuvant GM-CSF improves the overall survival of patients with newly diagnosed EGFRvIII-positive GB after Gross Total Resection, or GTR, when compared to treatment with TMZ and a control injection of KLH. KLH is a component of rindopepimut and was selected due to its ability to generate a similar injection site reaction to that observed with rindopepimut. ACT IV will enroll up to 440 patients at over 150 centers worldwide to recruit approximately 374 patients with GTR to be

included in the primary analysis. We expect to complete patient accrual by the end of 2013 and anticipate receiving data 18 to 24 months after completing accrual. We anticipate ACT IV to cost over \$60 million during its duration.

In December 2011, we also initiated ReACT, a Phase 2 study of rindopepimut in combination with Avastin® in patients with recurrent EGFRvIII-positive GB. ReACT will enroll approximately 95 patients in a first or second relapse of GB following receipt of standard therapy and will be conducted at approximately 25 sites across the United States. Approximately 70 patients who have yet to receive Avastin will be randomized to receive either rindopepimut and Avastin or a control injection of KLH and Avastin in a blinded fashion. Another 25 patients who are refractory to Avastin having received Avastin in either the frontline or recurrent setting with subsequent progression will receive rindopepimut plus Avastin in a single treatment arm. We expect to report data from this study at the Society for Neuro-Oncology (SNO) Annual Meeting in November 2013.

In addition, researchers at Stanford University are conducting an investigator sponsored, pilot trial of rindopepimut in pediatric patients with pontine glioma. Patient enrollment is ongoing for this trial.

#### Glebatumumab Vedotin (CDX-011)

CDX-011 is an antibody-drug conjugate, or ADC, that consists of a fully-human monoclonal antibody, CR011, linked to a potent cell-killing drug, monomethyl-auristatin E, or MMAE. The CR011 antibody specifically targets glycoprotein NMB, referred to as GPNMB, that is expressed in a variety of human cancers including breast cancer and melanoma. The ADC technology, comprised of MMAE and a stable linker system for attaching it to CR011, was licensed from Seattle Genetics, Inc. The ADC is designed to be stable in the bloodstream. Following intravenous administration, CDX-011 targets and binds to GPNMB and upon internalization into the targeted cell, CDX-011 is designed to release MMAE from CR011 to produce a cell-killing effect. The FDA has granted Fast Track designation to CDX-011 for the treatment of advanced, refractory/resistant GPNMB-expressing breast cancer.

**Treatment of Breast Cancer:** In June 2008, an open-label, multi-center Phase 1/2 study was initiated of CDX-011 administered intravenously once every three weeks to patients with locally advanced or metastatic breast cancer who had received prior therapy (median of seven prior regimens). The study began with a bridging phase to confirm the maximum tolerated dose, or MTD, and then expanded into a Phase 2 open-label, multi-center study.

The study confirmed the safety of CDX-011 at the pre-defined maximum dose level (1.88 mg/kg) in 6 patients. An additional 28 patients were enrolled in an expanded Phase 2 cohort (for a total of 34 treated patients at 1.88 mg/kg, the Phase 2 dose) to evaluate the PFS rate at 12 weeks. As previously seen in melanoma patients, the 1.88 mg/kg dose was well tolerated in this patient population with the most common adverse events of rash, alopecia, and fatigue. The primary activity endpoint, which called for at least 5 of 25 (20%) patients in the Phase 2 study portion to be progression-free at 12 weeks, was met as 9 of 26 (35%) evaluable patients were progression-free at 12 weeks.

For all patients treated at the maximum dose level, tumor shrinkage was seen in 62% (16/26) and median PFS was 9.1 weeks. A subset of 10 patients had “triple negative disease,” a more aggressive breast cancer subtype that carries a high risk of relapse and reduced survival as well as limited therapeutic options due to lack of over-expression of HER2/neu, estrogen and progesterone receptors. In these patients, 78% (7/9) had some tumor shrinkage, 12-week PFS rate was 70% (7/10), and median PFS was 17.9 weeks. Tumor samples from a subset of patients across all dose groups were analyzed for GPNMB expression. The tumor samples from most patients showed evidence of stromal and/or tumor cell expression of GPNMB.

In December 2011, we completed enrollment of EMERGE, a randomized, multi-center Phase 2b study of CDX-011 in 122 patients with heavily pre-treated, advanced, GPNMB positive breast cancer. Patients were randomized (2:1) to receive either CDX-

#### [Table of Contents](#)

011 or single-agent Investigator’s Choice, or IC, chemotherapy. Patients randomized to receive IC were allowed to cross over to receive CDX-011 following disease progression. Activity endpoints included response rate, PFS and OS.

In December 2012, we announced final results, as shown below, from the EMERGE study which suggested that CDX-011 induces significant response rates compared to currently available therapies in patient subsets with advanced, refractory breast cancers with GPNMB over-expression (expression in greater than 25% of tumor cells) and in patients with triple negative breast cancer. The overall survival, or OS, and progression free survival, or PFS, of patients treated with CDX-011 was also observed to be greatest in patients with triple negative breast cancer who also over-express GPNMB and all patients with GPNMB over-expression.

#### EMERGE: Overall Response Rate and Disease Control Data

	All Patients		Triple Negative		On target effect clearly demonstrated in targeted patient populations			
					GPNMB Over-Expression		Triple Negative and GPNMB Over-Expression	
	CDX-011 (n=81)	IC (n=36)	CDX-011 (n=27)	IC (n=9)	CDX-011 (n=25)	IC (n=8)	CDX-011 (n=12)	IC (n=4)
Response	16%	14%	19%	0%	32%	13%	33%	0%
Disease Control Rate	57%	53%	67%	33%	64%	38%	75%	25%

Responses per RECIST 1.1; IC = Investigator’s Choice; CDX-011 arm includes 15 patients who crossed over to receive CDX-011 treatment after progression on IC. Analysis of best response excludes patients who discontinued from study without evaluable post-baseline radiographic imaging (n=15 for CDX-011 arm; n=5 for IC arm).

#### EMERGE: Overall Survival (OS) and Progression Free Survival (PFS) Data

	All Patients		Triple Negative		On target effect clearly demonstrated in targeted patient populations			
					GPNMB Over-Expression		Triple Negative and GPNMB Over-Expression	
	CDX-011	IC	CDX-011	IC	CDX-011	IC	CDX-011	IC

Median OS (months)	7.5	7.4	6.9	6.5	10.0	5.7	10.0	5.5
	p=0.24		p=0.30		p=0.18		p=0.003	
Median PFS (months)	2.1	2.0	2.3	1.6	2.7	1.5	3.0	1.5
	p=0.38		p=0.43		p=0.14		p=0.008	

Analyses include all treated patients. Patients who initially received Investigator's Choice (IC) and subsequently crossed over to receive CDX-011 (n=15) are included in the PFS analysis for each treatment. These patients, with a median OS of 12.5 months, are assigned to the IC arm only for OS analysis. Median OS for the remaining IC patients who did not cross over is 5.4 months. When cross over patients are removed, median OS in patients with GPNMB over-expression is 10.0 months for CDX-011 vs 5.2 months for IC (p=0.05) and median OS in triple negative patients with GPNMB over-expression is 10.0 months for CDX-011 vs 5.2 months for IC (p=0.009).

In December 2012, we had our end of Phase 2b meeting with the FDA for our CDX-011 program. Based on this meeting, we intend to initiate METRIC, a randomized, accelerated approval study of CDX-011 in patients with triple negative breast cancer that over-express GPNMB in the second half of 2013. METRIC will be conducted in approximately 100 sites, primarily across the United States with additional sites in Canada and Australia.

**Treatment of Metastatic Melanoma:** In 2009, we completed enrollment of 117 patients in a Phase 1/2 open-label, multi-center, dose escalation study to evaluate the safety, tolerability and pharmacokinetics of CDX-011 for patients with un-resectable Stage III or Stage IV melanoma who had failed no more than one prior line of cytotoxic therapy. The MTD was determined to be 1.88 mg/kg administered intravenously once every three weeks. The study achieved its primary activity objective with an ORR in the Phase 2 cohort of 15% (5/34). Median PFS was 3.9 months. CDX-011 was generally well tolerated, with the most frequent treatment-related adverse events being rash, fatigue, hair loss, pruritus, diarrhea and neuropathy. In the subset of patients with tumor biopsies, high levels of tumor expression of GPNMB appeared to correlate with favorable outcome. In the seven patients whose tumors were found to express high amounts of GPNMB, and who were treated at the maximum tolerated doses across all dosing schedules, median

## [Table of Contents](#)

PFS was 4.9 months. The development of rash, which may be associated with the presence of GPNMB in the skin also seemed to correlate with greater PFS.

We intend to initially focus our resources on advancing CDX-011 for the treatment of breast cancer while pursuing further development of CDX-011 in melanoma and other indications that are known to express GPNMB.

### CDX-1135

CDX-1135 is a molecule that inhibits a part of the human immune system called the complement system. The complement system is a series of proteins that are important initiators of the body's acute inflammatory response against disease, infection and injury. Excessive complement activation also plays a role in some persistent inflammatory conditions. CDX-1135 is a soluble form of naturally occurring Complement Receptor 1 that has been shown to inhibit the activation of the complement cascade in animal models and in human clinical trials. In preclinical studies, CDX-1135 has been shown to inhibit both the classical and alternative pathways of complement activation.

Dense Deposit Disease, or DDD, is a rare and devastating disease that is caused by uncontrolled activation of the alternative pathway of complement and leads to progressive kidney damage in children. There is currently no treatment for patients with DDD and about half progress to end-stage renal disease within 10 years. Because DDD recurs in virtually all patients who receive a kidney transplant, transplantation is not a viable option for these patients. In animal models of DDD, CDX-1135 treatment showed evidence of reversal of kidney damage.

Initial experience under an investigator sponsored IND indicated that CDX-1135 limits complement abnormalities in DDD. In 2011, we completed process development activities and in 2011 and 2012 we manufactured multiple runs of cGMP clinical drug product at our Fall River manufacturing facility in preparation for our upcoming pilot study. We dosed the first of a small number of DDD patients in our pilot study of CDX-1135 to determine the appropriate dose and regimen for further clinical development based on safety, tolerability and biological activity. We expect preliminary data by the end of 2013.

### CDX-1127

CDX-1127 is a human monoclonal antibody that targets CD27, a potentially important target for immunotherapy of various cancers. We have entered into license agreements with the University of Southampton, UK for intellectual property related to uses of anti-CD27 antibodies and with Medarex (now a subsidiary of the Bristol-Myers Squibb Company) for access to the UltiMab technology to develop and commercialize human antibodies to CD27. CD27 acts downstream from CD40 and may provide a novel way to regulate the immune responses. CD27 is a co-stimulatory molecule on T cells and is over-expressed in certain lymphomas and leukemias. CDX-1127 is an agonist antibody designed to have two potential therapeutic mechanisms. CDX-1127 has been shown to activate immune cells that can target and eliminate cancerous cells in tumor-bearing mice and to directly kill or inhibit the growth of CD27 expressing lymphomas and leukemias in vitro and in vivo. Both mechanisms have been seen even at low doses in appropriate preclinical models.

In November 2011, we initiated an open label, dose-escalating Phase 1 study of CDX-1127 in patients with selected malignant solid tumors or hematologic cancers at multiple clinical sites in the United States. The Phase 1 study is designed to test five escalating doses of CDX-1127 to determine a Phase 2 dose for further development based on safety, tolerability, potential activity and immunogenicity. The study will accrue approximately 30 patients in each of the two arms, either selected refractory or relapsed solid tumors or lymphomas or leukemias known to express CD27. Patients will have received all appropriate prior therapies for their specific disease. The trial design incorporates both single dosing and multiple dosing regimens at each dose level. Enrollment has completed in the Phase 1 portion of the solid tumor arm and CDX-1127 was determined to be well tolerated to date, including at the highest dose level. Expansion cohorts were initiated to enroll patients with metastatic melanoma and renal cell carcinoma. We continue to enroll patients in the dose escalation portion of the lymphoma and leukemia arm and we also plan to initiate an expansion cohort of this arm. We anticipate reporting data from the solid tumor dose escalation portion of the study and the corresponding expansion cohorts by the end of 2013 and from the hematologic dose escalation arm in 2014.

### CDX-301



CDX-301 is a FMS-like tyrosine kinase 3 ligand, or Flt3L, stem cell mobilizer and dendritic cell growth factor. We licensed CDX-301 from Amgen Inc. in March 2009. CDX-301 is a potent hematopoietic cytokine that stimulates the expansion and differentiation of hematopoietic progenitor and stem cells. CDX-301 has demonstrated a unique capacity to increase the number of circulating dendritic cells in both laboratory and clinical studies. In addition, CDX-301 has shown impressive results in models of cancer, infectious diseases and inflammatory/autoimmune diseases. We believe CDX-301 may hold significant opportunity for synergistic development in combination with other proprietary molecules in our portfolio.

In February 2013, we announced final results from our dose-escalating Phase 1 study of CDX-301 in 30 healthy subjects in collaboration with Rockefeller University. The Phase 1 study evaluated seven different dosing regimens of CDX-301 to determine the

[Table of Contents](#)

appropriate dose for further development based on safety, tolerability, and biological activity. The data from the study were consistent with previous clinical experience and demonstrated that CDX-301 was well-tolerated and can effectively mobilize hematopoietic stem cell populations in healthy volunteers. Based on the safety profile and the increases observed for CD34+ stem cells and dendritic cells, we plan to initiate a pilot study in hematopoietic stem cell transplant in the second half of 2013.

*CDX-1401*

CDX-1401, developed from our APC Targeting Technology, is a fusion protein consisting of a fully human monoclonal antibody with specificity for the dendritic cell receptor, DEC-205, linked to the NY-ESO-1 tumor antigen. In humans, NY-ESO-1 has been detected in 20 - 30% of all melanoma, lung, esophageal, liver, gastric, prostate, ovarian and bladder cancers, thus representing a broad opportunity. This product is intended to selectively deliver the NY-ESO-1 antigen to dendritic cells for generating robust immune responses against cancer cells expressing NY-ESO-1. We are developing CDX-1401 for the treatment of malignant melanoma and a variety of solid tumors which express the proprietary cancer antigen NY-ESO-1, which we licensed from the Ludwig Institute for Cancer Research in 2006. Preclinical studies have shown that CDX-1401 is effective for activation of human T cell responses against NY-ESO-1.

In October 2012, we announced results from a dose-escalating, multi-center, Phase 1 study that evaluated three different doses of CDX-1401 in combination with toll-like receptor agonists poly-ICLC or Hiltonol™ and/or R848 or resiquimod. In total, the study enrolled 45 patients with advanced malignancies that had progressed after any available curative and/or salvage therapies. 60% of patients had confirmed NY-ESO expression in archived tumor sample. Thirteen patients maintained stable disease for up to 13.4 months with a median of 6.7 months. Treatment was well-tolerated and there were no dose limiting toxicities. Humoral responses were elicited in both NY-ESO-1 positive and negative patients. NY-ESO-1-specific T cell responses were absent or low at baseline, but increased post-vaccination in 53% of evaluable patients, including both CD4 and/or CD8 T cell responses. Robust immune responses were observed with CDX-1401 with resiquimod and Poly ICLC alone and in combination. The study has identified a well-tolerated and immunogenic regimen to take forward into the future studies and we expect that a study sponsored by the Cancer Immunotherapy Trials Network of the National Cancer Institute will be initiated in 2013.

**Preclinical Programs**

*CDX-014*

CDX-014 is a fully-human monoclonal ADC that targets TIM-1, a molecule that is highly expressed on renal and ovarian cancers with minimal expression in normal tissues. The antibody, CDX-014, is linked to MMAE using Seattle Genetics' proprietary technology. The ADC is designed to be stable in the bloodstream, but to release MMAE upon internalization into TIM-1-expressing tumor cells, resulting in a targeted cell-killing effect. CDX-014 has shown potent activity in preclinical models of ovarian and renal cancer. We are conducting proof-of-concept studies in 2013 to optimize the drug candidate to move into future manufacturing and IND-enabling studies.

**CRITICAL ACCOUNTING POLICIES**

Our critical accounting policies are more fully described in Note 2 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2012 and there have been no material changes to such critical accounting policies. We believe our most critical accounting policies include accounting for business combinations, revenue recognition, impairment of long-lived assets, research and development expenses and stock-based compensation expense.

[Table of Contents](#)

**RESULTS OF OPERATIONS**

*Three Months Ended June 30, 2013 compared with Three Months Ended June 30, 2012*

	Three Months Ended June 30,		Increase/ (Decrease) \$	Increase/ (Decrease) %
	2013	2012		
	(In thousands)			
Revenue:				
Product Development and Licensing Agreements	\$ 47	\$ 40	\$ 7	18%
Contracts and Grants	50	96	(46)	(48)%
Product Royalties	—	1,873	(1,873)	(100)%
<b>Total Revenue</b>	<b>\$ 97</b>	<b>\$ 2,009</b>	<b>\$ (1,912)</b>	<b>(95)%</b>
Operating Expense:				
Research and Development	15,090	11,114	3,976	36%
Royalty	—	1,873	(1,873)	(100)%
General and Administrative	3,411	2,219	1,192	54%

Amortization of Acquired Intangible Assets	254	291	(37)	(13)%
Total Operating Expense	18,755	15,497	3,258	21%
Operating Loss	(18,658)	(13,488)	5,170	38%
Investment and Other Income, Net	161	126	35	28%
Interest Expense	(519)	(411)	108	26%
Net Loss	\$ (19,016)	\$ (13,773)	\$ 5,243	38%

#### Net Loss

The \$5.2 million increase in net loss for the three months ended June 30, 2013 compared to the three months ended June 30, 2012 was primarily the result of an increase in research and development and general and administrative expenses.

#### Revenue

The \$1.9 million decrease in product royalty revenue for the three months ended June 30, 2013 compared to the three months ended June 30, 2012 was related to our retained interests in Rotarix<sup>®</sup> net royalties which were not sold to Paul Royalty Fund II, L.P., or PRF, and which is equal to the amount payable to Cincinnati Children's Hospital Medical Center, or CCH, and recognized in royalty expense by us. Our agreement with GlaxoSmithKline plc, or Glaxo, terminated automatically upon the expiration of the last relevant patent right covered by the Glaxo agreement. We do not expect additional Rotarix royalty revenue.

#### Research and Development Expense

Research and development expenses consist primarily of (i) personnel expenses, (ii) laboratory supply expenses relating to the development of our technology, (iii) facility expenses, and (iv) product development expenses associated with our product candidates as follows:

	Three Months Ended June 30,		Increase/ (Decrease) \$	Increase/ (Decrease) %
	2013	2012		
	(In thousands)			
Personnel	\$ 3,835	\$ 3,211	\$ 624	19%
Laboratory Supplies	929	573	356	62%
Facility	1,142	1,159	(17)	(1)%
Product Development	8,569	5,692	2,877	51%

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The \$0.6 million increase in personnel expenses for the three months ended June 30, 2013 compared to the three months ended June 30, 2012 was primarily due to higher headcount. We expect personnel expenses to increase over the next twelve months as we plan to continue to increase our headcount, primarily to support our rindopepimut and CDX-011 programs.

Laboratory supply expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The \$0.4 million increase in laboratory supply expense for the three months ended June 30, 2013 compared to the three months ended June 30, 2012 was primarily due to higher manufacturing supply purchases. We expect supply expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

#### [Table of Contents](#)

Facility expenses include depreciation, amortization, utilities, rent, maintenance, and other related expenses incurred at our facilities. Facility expenses for the three months ended June 30, 2013 were relatively consistent as compared to the three months ended June 30, 2012. We expect facility expenses to increase over the next twelve months primarily related to the amortization of leasehold improvements being made at our new facility in Hampton, New Jersey.

Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing. The \$2.9 million increase in product development expenses for the three months ended June 30, 2013 compared to the three months ended June 30, 2012 was primarily the result of an increase in clinical trial costs and contract manufacturing of \$1.8 million and \$1.1 million, respectively, primarily due to our rindopepimut program. We expect product development expenses to increase over the next twelve months primarily due to the increase in clinical trial and contract manufacturing expenses related to our rindopepimut and CDX-011 programs, although there may be fluctuations on a quarterly basis.

#### Royalty Expense

Royalty expenses include product royalty and sublicense royalty fees on our out-licensed programs. The \$1.9 million decrease in royalty expenses for the three months ended June 30, 2013 compared to the three months ended June 30, 2012 was due to a decrease in Rotarix<sup>®</sup> related royalty fees. Our retained interests in Rotarix<sup>®</sup> net royalties which were not sold to PRF are recorded as product royalty revenue and a corresponding amount that is payable to CCH is recorded as royalty expense. The Glaxo agreement terminated automatically upon the expiration of the last relevant patent right covered by the Glaxo agreement. We do not expect any more Rotarix royalty expense related to the Glaxo agreement.

#### General and Administrative Expense

The \$1.2 million increase in general and administrative expenses for the three months ended June 30, 2013 compared to the three months ended June 30, 2012 was primarily due to higher headcount, professional services and rindopepimut-related commercial planning costs. We expect general and administrative expense to increase over the next twelve months primarily due to increased commercial planning efforts, although there may be fluctuations on a quarterly basis.

#### Amortization Expense



Amortization expenses for the three months ended June 30, 2013 were relatively consistent compared to the three months ended June 30, 2012. We expect amortization expense of acquired intangible assets to remain relatively consistent over the next twelve months.

#### Investment and Other Income, Net

Investment and other income, net for the three months ended June 30, 2013 was relatively consistent as compared to the three months ended June 30, 2012. We anticipate investment income to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

#### Interest Expense

The \$0.1 million increase in interest expense for the three months ended June 30, 2013 compared to the three months ended June 30, 2012 was due to our election in May 2013 to prepay the Term Loan in full, pursuant to the terms of our Loan Agreement. We anticipate interest expense to decrease over the next twelve months due to the repayment of the Term Loan.

### [Table of Contents](#)

#### Six Months Ended June 30, 2013 compared with Six Months Ended June 30, 2012

	Six Months Ended June 30,		Increase/ (Decrease) \$	Increase/ (Decrease) %
	2013	2012		
	(In thousands)			
<b>Revenue:</b>				
Product Development and Licensing Agreements	\$ 77	\$ 75	\$ 2	3%
Contracts and Grants	100	149	(49)	(33)%
Product Royalties	2,334	4,218	(1,884)	(45)%
<b>Total Revenue</b>	<b>\$ 2,511</b>	<b>\$ 4,442</b>	<b>\$ (1,931)</b>	<b>(43)%</b>
<b>Operating Expense:</b>				
Research and Development	29,180	21,881	7,299	33%
Royalty	2,334	4,218	(1,884)	(45)%
General and Administrative	6,549	4,536	2,013	44%
Amortization of Acquired Intangible Assets	507	583	(76)	(13)%
<b>Total Operating Expense</b>	<b>38,570</b>	<b>31,218</b>	<b>7,352</b>	<b>24%</b>
Operating Loss	(36,059)	(26,776)	9,283	35%
Investment and Other Income, Net	540	331	209	63%
Interest Expense	(829)	(844)	(15)	(2)%
<b>Net Loss</b>	<b>\$ (36,348)</b>	<b>\$ (27,289)</b>	<b>\$ 9,059</b>	<b>33%</b>

#### Net Loss

The \$9.1 million increase in net loss for the six months ended June 30, 2013 compared to the six months ended June 30, 2012 was primarily the result of an increase in research and development and general and administrative expenses.

#### Revenue

The \$1.9 million decrease in product royalty revenue for the six months ended June 30, 2013 compared to the six months ended June 30, 2012 was related to our retained interests in Rotarix<sup>®</sup> net royalties which were not sold to PRF and which is equal to the amount payable to CCH and recognized in royalty expense by us.

#### Research and Development Expense

	Six Months Ended June 30,		Increase/ (Decrease) \$	Increase/ (Decrease) %
	2013	2012		
	(In thousands)			
Personnel	\$ 7,618	\$ 6,638	\$ 980	15%
Laboratory Supplies	1,641	961	680	71%
Facility	2,259	2,301	(42)	(2)%
Product Development	16,384	10,677	5,707	53%

The \$1.0 million increase in personnel expenses for the six months ended June 30, 2013 compared to the six months ended June 30, 2012 was primarily due to higher headcount.

The \$0.7 million increase in laboratory supply expense for the six months ended June 30, 2013 compared to the six months ended June 30, 2012 was primarily due to higher manufacturing supply purchases.

Facility expenses for the six months ended June 30, 2013 were relatively consistent as compared to the six months ended June 30, 2012.

The \$5.7 million increase in product development expenses for the six months ended June 30, 2013 compared to the six months ended June 30, 2012 was primarily the result of an increase in clinical trial costs and contract manufacturing of \$4.0 million and \$1.6 million, respectively, primarily due to our rindopepimut program.

#### Royalty Expense

The \$1.9 million decrease in royalty expenses for the six months ended June 30, 2013 compared to the six months ended June 30, 2012 was due to a decrease in Rotarix® related royalty fees.

---

[Table of Contents](#)

*General and Administrative Expense*

The \$2.0 million increase in general and administrative expenses for the six months ended June 30, 2013 compared to the six months ended June 30, 2012 was primarily due to higher headcount, professional service and rindopepimut-related commercial planning costs.

*Amortization Expense*

The \$0.1 million decrease in amortization expenses for the six months ended June 30, 2013 compared to the six months ended June 30, 2012 was due to certain intangible assets becoming fully amortized during 2012.

*Investment and Other Income, Net*

The \$0.2 million increase in investment and other income, net for the six months ended June 30, 2013 compared to the six months ended June 30, 2012 was primarily due to us recognizing \$0.2 million and \$0.1 million in other income related to the sale of New Jersey tax benefits during the six months ended June 30, 2013 and 2012, respectively.

*Interest Expense*

Interest expense for the six months ended June 30, 2013 was relatively consistent as compared to the six months ended June 30, 2012.

**LIQUIDITY AND CAPITAL RESOURCES**

Our cash equivalents are highly liquid investments with a maturity of three months or less at the date of purchase and consist primarily of investments in money market mutual funds with commercial banks and financial institutions. We maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances. We invest our excess cash balances in marketable securities including municipal bond securities, U.S. government agency securities, and high-grade corporate bonds that meet high credit quality standards, as specified in our investment policy. Our investment policy seeks to manage these assets to achieve our goals of preserving principal and maintaining adequate liquidity.

The use of our cash flows for operations has primarily consisted of salaries and wages for our employees, facility and facility-related costs for our offices, laboratories and manufacturing facility, fees paid in connection with preclinical studies, clinical studies, contract manufacturing, laboratory supplies and services, consulting, legal and other professional fees. To date, the primary sources of cash flows from operations have been payments received from our collaborative partners and from government entities. The timing of any new collaboration agreements, government contracts or grants and any payments under these agreements, contracts or grants cannot be easily predicted and may vary significantly from quarter to quarter.

At June 30, 2013, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of \$155.0 million. Our working capital at June 30, 2013 was \$143.9 million. We incurred a loss of \$36.3 million for the six months ended June 30, 2013. Net cash used in operations for the six months ended June 30, 2013 was \$35.3 million. We believe that the cash, cash equivalents and marketable securities at June 30, 2013 are sufficient to fund planned operations through 2015.

During the next twelve months, we may take further steps to raise additional capital to meet our long-term liquidity needs. Our capital raising activities may include, but may not be limited to, one or more of the following: the licensing of technology programs with existing or new collaborative partners, possible business combinations, issuance of debt, or the issuance of common stock or other securities via private placements or public offerings. While we continue to seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and our negotiating position in capital-raising efforts may worsen as existing resources are used. There is also no assurance that we will be able to enter into further collaborative relationships. Additional equity financing may be dilutive to our stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business; and licensing or strategic collaborations may result in royalties or other terms which reduce our economic potential from products under development.

*Operating Activities*

Net cash used in operating activities was \$35.3 million for the six months ended June 30, 2013 compared to \$25.5 million for the six months ended June 30, 2012. The increase in net cash used in operating activities was primarily due to an increase in net loss of \$9.1 million and changes in working capital. We expect that cash used in operations will continue to increase over the next twelve months primarily related to costs incurred on our rindopepimut and CDX-011 programs, although there may be fluctuations on a quarterly basis.

---

[Table of Contents](#)

We have incurred and will continue to incur significant costs in the area of research and development, including preclinical and clinical trials, as our product candidates are developed. We plan to spend significant amounts to progress our current product candidates through the clinical trial and commercialization process as well as to develop additional product candidates. As our product candidates progress through the clinical trial process, we may be obligated to make significant milestone payments.

*Investing Activities*

Net cash used in investing activities was \$69.2 million for the six months ended June 30, 2013 compared to \$18.4 million for the six months ended June 30, 2012. The increase in net cash used in investing activities was primarily due to net purchases of marketable securities for the six months ended June 30, 2013 of \$68.3 million as compared to \$18.5 million for the six months ended June 30, 2012. We expect that cash provided by investing activities will increase over the next twelve months as we fund our operations through the net proceeds from the sale and maturity of marketable securities, cash provided by financing activities and/or new partnerships, although there may be significant fluctuations on a quarterly basis.

#### *Financing Activities*

Net cash provided by financing activities was \$105.4 million for the six months ended June 30, 2013 compared to \$50.6 million for the six months ended June 30, 2012. Net proceeds from stock issuances, including stock issued pursuant to employee benefit plans, were \$116.5 million during the six months ended June 30, 2013 compared to \$52.0 million for the six months ended June 30, 2012. We paid \$11.0 million in principal payments on our Term Loan during the six months ended June 30, 2013 compared to \$1.3 million for the six months ended June 30, 2012.

In May 2013, pursuant to the terms of our Loan Agreement, we elected to prepay our Term Loan in full and paid \$8.8 million in principal and \$0.7 million in interest, prepayment and final payment fees. The Term Loan would have otherwise matured in December 2014. By prepaying the term loan in May 2013, we saved approximately \$0.5 million in interest costs (net of prepayment fees) which would have been payable over the remaining term of the loan. Our obligations under the Loan Agreement had been secured by a first priority security interest in substantially all of its assets, other than its intellectual property. In connection with the repayment of the Term Loan and the termination of the Loan Agreement, those security interests were released.

#### *Equity Offerings*

In April 2010, we filed a shelf registration statement with the Securities and Exchange Commission to register for sale any combination of the types of securities described in the shelf registration statement up to a dollar amount of \$150 million. The shelf registration went effective on April 22, 2010. In December 2012, we filed a new shelf registration statement with the Securities and Exchange Commission to register for sale any combination of the types of securities described in the new shelf registration statement up to a dollar amount of \$200 million. The new shelf registration went effective on January 16, 2013.

In January 2011, we entered into a controlled equity offering sales agreement with Cantor Fitzgerald & Co. pursuant to which we could issue and sell up to 5,000,000 shares of our common stock from time to time through Cantor, acting as agent. During the six months ended June 30, 2012, we issued 2,425,000 shares of common stock under the Cantor agreement and raised \$8.5 million in net proceeds.

In September 2012, we amended the Cantor agreement to allow us to issue and sell additional shares of our common stock having an aggregate offering price of up to \$44.0 million. Under the Cantor amendment, we will pay Cantor a fixed commission rate of 3.0% of the gross sales price per share of any common stock sold through Cantor. The Cantor amendment terminates upon ten day notice by either Cantor or us. During the six months ended June 30, 2013, we issued 2,433,608 shares under the Cantor amendment and raised \$17.1 million in net proceeds. At June 30, 2013, we had \$4.4 million remaining in aggregate offering price available under the Cantor amendment.

During the six months ended June 30, 2012, we issued 12,075,000 shares of our common stock in an underwritten public offering, including the underwriter's exercise of their full over-allotment option to purchase an additional 1,575,000 shares of common stock. The net proceeds to us were \$43.4 million, after deducting underwriting fees and offering expenses.

During the six months ended June 30, 2013, we issued 13,800,000 shares of our common stock in an underwritten public offering, including the underwriter's exercise of their full over-allotment option to purchase an additional 1,800,000 shares of common stock. The net proceeds to us were \$97.0 million, after deducting underwriting fees and offering expenses.

---

#### [Table of Contents](#)

### **AGGREGATE CONTRACTUAL OBLIGATIONS**

Except as set forth below, the disclosures relating to our contractual obligations reported in our Annual Report on Form 10-K for the year ended December 31, 2012 which was filed with the SEC on March 8, 2013 have not materially changed since we filed that report.

In May 2013, we entered into a lease agreement (the "Lease") with Crown Perryville, LLC., as Landlord, pursuant to which we will lease approximately 33,000 square feet of office space in Hampton, New Jersey for use as an office and laboratory. The Lease has a five-year, five-month term which will commence on the later of November 15, 2013 or the date on which the alterations are substantially complete and a Certificate of Occupancy is issued. Our obligation to pay rent commences five months after the lease commencement date. The annual rent obligations increase from \$0.4 million in the first year to \$0.5 million in the fifth year. The Lease includes two renewal options of five years each.

In May 2013, we elected to prepay the Term Loan in full, pursuant to the terms of the Loan Agreement, and paid \$8.8 million in principal and \$0.7 million in interest, prepayment and final payment fees.

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

#### *Interest Rate Risk*

We own financial instruments that are sensitive to market risk as part of our investment portfolio. Our investment portfolio is used to preserve our capital until it is used to fund operations, including our research and development activities. None of these market-risk sensitive instruments are held for trading purposes. We invest our cash primarily in money market mutual funds. These investments are evaluated quarterly to determine the fair value of the portfolio. From time to time, we invest our excess cash balances in marketable securities including municipal bond securities, U.S. government agency securities, and high-grade corporate bonds that meet high credit quality standards, as specified in our investment policy. Our investment policy seeks to manage these assets to achieve our goals of preserving principal and maintaining adequate liquidity. Because of the short-term nature of these investments, we do not believe we have material exposure due to market risk. The impact to our financial position and results of operations from likely changes in interest rates is not material.

We do not utilize derivative financial instruments. The carrying amounts reflected in the consolidated balance sheet of cash and cash equivalents, accounts receivables and accounts payable approximates fair value at June 30, 2013 due to the short-term maturities of these instruments.

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

##### *Evaluation of Disclosure Controls and Procedures.*

As of June 30, 2013, we evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2013. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within time periods specified by the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

##### *Changes in Internal Control Over Financial Reporting.*

There were no changes in our internal control over financial reporting during the three months ended June 30, 2013 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**

None.

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

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2012, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K may not be the only risks

25

---

#### [Table of Contents](#)

facing the Company. Additional risks and uncertainties not currently known to the Company or that the Company currently deems to be immaterial also may materially adversely affect the Company’s business, financial condition and/or operating results.

There were no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 8, 2013.

26

---

#### [Table of Contents](#)

<b>Item 6.</b>	<b>Exhibits</b>
3.1	Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company’s Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
3.2	Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company’s Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
3.3	Second Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.2 of the Company’s Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
3.4	Third Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company’s Quarterly Report on Form 10-Q, filed May 10, 2002 with the Securities and Exchange Commission.
3.5	Fourth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company’s Current Report on Form 8-K, filed on March 11, 2008 with the Securities and Exchange Commission.
3.6	Fifth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.2 of the Company’s Current Report on Form 8-K, filed on March 11, 2008 with the Securities and Exchange Commission.
3.7	Sixth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.7 of the Company’s Quarterly Report on Form 10-Q, filed November 10, 2008 with the Securities and Exchange Commission.
4.3	Amendment No. 2 to Shareholder Rights Agreement dated November 5, 2004, between the Company and Computershare Trust Company, N.A. (formerly EquiServe Trust Company, N.A.), as Rights Agent, incorporated by reference to Exhibit 10.1 of the Company’s Registration Statement on Form 8-A1G/A, filed on March 7, 2008 with the Securities and Exchange Commission.
10.1	Lease Agreement, by and between the Company and Crown Perryville, LLC, dated May 1, 2013, incorporated by reference to Exhibit 10.1 of the Company’s Registration Statement on Form 8-A1G/A, filed on March 7, 2008 with the Securities and Exchange Commission.
10.2	Amendment dated March 6, 2013 to Celldex Therapeutics, Inc. 2004 Employee Stock Purchase Plan, incorporated by reference to Exhibit 10.1 of the Company’s Quarterly Report on Form 10-Q, filed on May 3, 2013 with the Securities and Exchange Commission.
*10.3	Master Services Agreement dated May 6, 2013 by and between the Company and PPD Development, LLC
*31.1	Certification of President and Chief Executive Officer
*31.2	Certification of Senior Vice President and Chief Financial Officer
**32.1	Section 1350 Certifications
101.1+	XBRL Instance Document.

101.2+	XBRL Taxonomy Extension Schema Document.
101.3+	XBRL Taxonomy Extension Calculation Linkbase Document.
101.4+	XBRL Taxonomy Extension Definition Linkbase Document.
101.5+	XBRL Taxonomy Extension Label Linkbase Document.
101.6+	XBRL Taxonomy Extension Presentation Linkbase Document.

\* Filed herewith.

\*\* Furnished herewith.

+ The XBRL information is being furnished and not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any registration statement under the Securities Act of 1933, as amended.

[Table of Contents](#)

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**CELLEX THERAPEUTICS, INC.**

BY:

/s/ ANTHONY S. MARUCCI

Anthony S. Marucci  
President and Chief Executive Officer  
(Principal Executive Officer)

Dated: August 6, 2013

/s/ AVERY W. CATLIN

Avery W. Catlin  
Senior Vice President, Treasurer and Chief Financial Officer  
(Principal Financial and Accounting Officer)

Dated: August 6, 2013

[Table of Contents](#)

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
3.1	Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
3.2	Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
3.3	Second Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.2 of the Company's Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
3.4	Third Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q, filed May 10, 2002 with the Securities and Exchange Commission.
3.5	Fourth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K, filed on March 11, 2008 with the Securities and Exchange Commission.
3.6	Fifth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K, filed on March 11, 2008 with the Securities and Exchange Commission.
3.7	Sixth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.7 of the Company's Quarterly Report on Form 10-Q, filed November 10, 2008 with the Securities and Exchange Commission.
4.3	Amendment No. 2 to Shareholder Rights Agreement dated November 5, 2004, between the Company and Computershare Trust Company, N.A. (formerly EquiServe Trust Company, N.A.) as Rights Agent, incorporated by reference to Exhibit 10.1 of the Company's Registration Statement on Form 8-A1G/A, filed on March 7, 2008 with the Securities and Exchange Commission.
10.1	Lease Agreement, by and between the Company and Crown Perryville, LLC, dated May 1, 2013, incorporated by reference to Exhibit 10.1 of the Company's Registration Statement on Form 8-A1G/A, filed on March 7, 2008 with the Securities and Exchange Commission.
10.2	Amendment dated March 6, 2013 to Celldex Therapeutics, Inc. 2004 Employee Stock Purchase Plan, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed June 13, 2013 with the Securities and Exchange Commission.
*10.3	Master Services Agreement dated May 6, 2013 by and between the Company and PPD Development, LLC
*31.1	Certification of President and Chief Executive Officer
*31.2	Certification of Senior Vice President and Chief Financial Officer
**32.1	Section 1350 Certifications
101.1+	XBRL Instance Document.
101.2+	XBRL Taxonomy Extension Schema Document.
101.3+	XBRL Taxonomy Extension Calculation Linkbase Document.
101.4+	XBRL Taxonomy Extension Definition Linkbase Document.
101.5+	XBRL Taxonomy Extension Label Linkbase Document.
101.6+	XBRL Taxonomy Extension Presentation Linkbase Document.

- 
- \* Filed herewith.
  - \*\* Furnished herewith.
  - + The XBRL information is being furnished and not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any registration statement under the Securities Act of 1933, as amended.

## MASTER SERVICES AGREEMENT

**THIS MASTER SERVICES AGREEMENT** (the “**Agreement**”) is made and entered into as of May 6, 2013 (the “**Effective Date**”) by and between **PPD DEVELOPMENT, LLC**, a Delaware limited liability company, with its principal executive offices located at 929 North Front Street, Wilmington, North Carolina 28401 (“**PPD**”) and Celldex Therapeutics Inc., a corporation with its principal executive offices located at 119 Fourth Avenue, Needham, MA 02494 (“**Sponsor**”).

WHEREAS, Sponsor is engaged in the development, manufacture, distribution and sale of pharmaceutical products; and

WHEREAS, PPD is a clinical research organization engaged in the business of managing clinical research programs and providing clinical development and other related services; and

WHEREAS, Sponsor may wish to retain the services of PPD from time to time to perform clinical development services in connection with certain clinical research programs Sponsor is conducting (individually, a “**Project**”), in which case the terms and conditions for each such Project shall be set forth in a project addendum to be attached to this Agreement and incorporated herein by reference (individually, a “**Project Addendum**” and collectively, the “**Project Addenda**”); and

WHEREAS, PPD is willing to provide such services to Sponsor in accordance with the terms and conditions of this Agreement and the attached Project Addenda.

NOW, THEREFORE, for good and valuable consideration contained herein, the exchange, receipt and sufficiency of which are acknowledged, the parties agree as follows:

### 1. SERVICES.

1.1 Services to be Provided by PPD. PPD hereby agrees to provide to Sponsor the services identified and described in the Services section of each Project Addendum attached to this Agreement (the “**Services**”). PPD and its Agents (and Affiliates if applicable pursuant to Section 13.11) shall perform the Services for each Project set forth in the applicable Project Addendum in compliance with (i) the protocol for the Project (“**Protocol**”), which may be attached to and as amended or updated from time to time by written agreement of the parties, and made a part of the applicable Project Addendum, (ii) the terms and conditions of this Agreement, (iii) the terms and conditions of the applicable Project Addendum, (iv) PPD’s standard operating procedures (“**SOPs**”), which have been approved by Sponsor, and (v) all applicable laws, rules and regulations including in strict accordance with: all applicable federal, national, regional and local statutes, rules, guidelines, and regulations (“**Applicable Law**”), including without limitation;

(i) the United States Food, Drug and Cosmetic Act, as amended, and any and all rules and regulations promulgated there under (the “**Act**”), Title 21 Code of Federal Regulations (“**CFR**”) Parts 50, 56 and 312, and any other applicable FDA regulations or guidance documents;

(ii) European Commission Directive 2001/20 EC; and

(iii) ICH guidelines and Good Clinical Practices;

Sponsor agrees that PPD is responsible only for those Services set forth on a properly executed Project Addendum which is signed by authorized representatives of both parties to this Agreement.

1.2 Project Addendum. In the event that the parties hereto shall reach agreement with respect to the provision of Services for a Project, PPD and Sponsor shall execute a Project Addendum evidencing such Services. Each Project Addendum shall be in writing and signed by authorized representatives of both parties and attached to this Agreement and incorporated into and made a part of this Agreement by reference, and each such Project Addendum and this Agreement shall constitute the entire agreement for the applicable Project. To the extent any terms set forth in a Project Addendum conflict with the terms set forth in this Agreement, the terms of this Agreement shall control unless otherwise specifically set forth in the Project Addendum. PPD shall report in accordance with any specific reporting obligations set forth in

a Project Addendum to Sponsor regarding progress under each Project Addendum including provision of all data, work products, incidents and results relating to the Services.

### 1.3 Sponsor and PPD Cooperation.

Sponsor will reasonably cooperate with PPD in providing information to PPD, taking action and executing documents, as appropriate, to achieve the objectives of this Agreement. Sponsor acknowledges and agrees that PPD’s performance under this Agreement is dependent on Sponsor’s timely and effective reasonable cooperation with PPD. Accordingly, Sponsor acknowledges that any delay by Sponsor may result in PPD being released from an obligation or schedule deadline or in Sponsor having to pay extra fees in order for PPD to meet a specific obligation or deadline despite the delay. PPD agrees to reasonably cooperate with Sponsor and provide Sponsor a reasonable time to respond to PPD’s requests to achieve the objectives of this Agreement. Sponsor shall comply with all Applicable Laws governing the performance of its obligations hereunder and the subject matter of this Agreement, including without limitation, Sponsor’s Property (as defined below).

1.4 Serious Adverse Event and Medical Management Plan. Notwithstanding anything to the contrary herein, in the event PPD and Sponsor agree in writing upon a serious adverse event and medical management plan relating to a specific Project (“**SMMP**”), the parties shall comply with the terms and conditions of any such SMMP. In the event of any conflict between the terms and conditions of the SMMP and the relevant Project Addendum, the terms and conditions of the SMMP shall control. Sponsor shall be responsible for any additional costs associated with compliance with the SMMP. Costs associated with compliance with the SMMP shall be agreed to in a Project Addendum or amendment thereto.

1.5 Patient Enrollment. Enrollment numbers are good faith estimates and PPD shall exercise reasonable diligence and efforts to meet such enrollment estimates in accordance with any mutually agreed upon estimated time-lines.

1.6 Final Protocol. The parties agree that Sponsor shall be solely responsible for the final review, approval and adoption of the Protocol and PPD shall not be liable for such Protocol.



## 2. COMPENSATION AND PAYMENT.

2.1 Charges for Services. Sponsor shall pay PPD for all Services performed under this Agreement and any Project Addendum (“**Direct Fees**”) in accordance with the rates for such Services set forth in such Project Addendum which shall be inclusive of any and all applicable taxes unless expressly stated otherwise; with the exception of taxes required to be added to invoicing issued by PPD as required by local regulations, such as VAT or GST in Australia. Sponsor shall also reimburse PPD for all out-of-pocket expenses incurred in connection with the performance of the Services with respect to a Project, including, without limitation, investigator grants and fees, reasonable travel expenses, shipping and postage costs, copying and printing fees, copyright fees, third party drug storage and distribution fees, required Institutional Review Board or similar board or committee fees, and other “pass through” expenses reasonably expected to be incurred in connection with performing the Services (collectively, the “**Pass Through Costs**”) and agreed in advance in writing with Sponsor through inclusion in the relevant Project Addendum and subject to production of reasonable documentary proof of such expenditure if requested by Sponsor. All Pass Through Costs invoiced to Sponsor will be at actual cost with no mark-up for administration or overhead. Except as otherwise expressly provided in a Project Addendum, PPD shall submit to Sponsor for each Project a monthly invoice describing the Services performed on such Project, the Direct Fees due for such Services, and all Pass Through Costs paid by PPD and identifying the relevant Project and Project Addendum. Sponsor shall pay each undisputed invoice within thirty (30) days of receipt of said invoice. If payment is not received by PPD within such thirty-day period, PPD shall provide notice to Sponsor in writing of such unpaid invoice. In the event that Sponsor disputes one or

2

more items in an invoice, Sponsor will notify PPD in writing within ten (10) working days of receipt of the invoice and such notice shall contain a reasonably specific description of the item(s) being disputed and the basis therefor. PPD will respond to Sponsor in writing within ten (10) working days of receipt of the notification. The parties shall use good faith efforts to resolve the dispute within sixty (60) days of receipt of the invoice. If PPD and Sponsor resolve said dispute Sponsor shall pay the disputed amount within thirty (30) days of resolution of said dispute. PPD shall have no obligation to pay subcontractor costs or investigator grant payments to any subcontractor or investigator site (the “**Site**”) for conduct of services related to a Project until PPD has received payment of such Pass Through Costs from Sponsor. Notwithstanding anything to the contrary contained herein, Sponsor acknowledges and agrees that certain vendor and subcontractor contracts, including without limitation, contracts for investigator meetings and patient recruitment services, must be advanced and paid up front by Sponsor. PPD shall be under no obligation to incur any such vendor or subcontractor fees until such fees are received from Sponsor. In addition, in certain circumstances, PPD may require investigator grants to be advanced by Sponsor at the timeframes mutually agreed upon by the parties.

2.2 Payment after Termination. Upon termination of any Project Addendum or this Agreement pursuant to Section 3 below, Sponsor shall pay PPD all Direct Fees and Pass Through Costs for all Services, and any portion of Services, performed through the termination date within thirty (30) days of the termination date where feasible for PPD to calculate the final costs associated with Services performed within such a timescale, but in no case longer than sixty (60) days. In addition, Sponsor shall reimburse PPD for all future non-cancelable obligations to third parties (where such obligations were created and agreed as a result of a Project being authorized by the Sponsor). Any funds held by PPD which shall be determined to be unearned shall be returned to Sponsor within ninety (90) days following conclusion of the Project. Notwithstanding the foregoing, certain Services of PPD require greater utilization of resources at the outset such that compensation for such Services based on a percentage of milestones completed prior to PPD fully completing the milestones would work to the detriment of PPD. Accordingly, the parties agree that in the event of early termination, at PPD’s sole but reasonable discretion, PPD shall be entitled to compensation for all completed and partially completed Services on a time and materials basis for work actually conducted by PPD up to the date of termination.

2.3 Pre-Execution Services. In the event Sponsor requests PPD to begin providing the Services for a Project prior to the execution by Sponsor of a Project Addendum or other mutually agreed upon writing, Sponsor agrees that PPD shall be compensated for Services performed at Sponsor’s request in accordance with the PPD Proposal for Services.

2.4 Payments. Unless otherwise set forth in a Project Addendum, all payments to PPD under this Agreement or any Project Addendum shall be made as follows:

If made by check, payment mailed to:

PPD Development, LLC  
26361 Network Place  
Chicago, IL 60673-1263  
Tax ID# 74-2325267

Overnight Address:  
JPMorgan Chase  
131 S. Dearborn, 6th Floor  
Chicago, IL 60603  
Attn: PPD Development, LLC/Box 26361

If made by wire transfer, payment wired to:

JPMorgan Chase  
Acct: 500002360  
R/T Number: 021000021 (ACH & Wire)  
SWIFT/BIC: CHASUS33  
Beneficiary: PPD Development, LLC

3

Any changes to the payee information set forth above require a writing signed by PPD’s treasurer or chief financial officer.

## 3. TERM AND TERMINATION.

3.1 Term. The term of this Agreement shall commence on the Effective Date and shall continue for a period of three (3) years unless extended by mutual written agreement by the parties. Each Project Addendum shall be effective upon the date signed by the last signatory thereto and shall terminate

upon (i) the completion of the Services to be provided thereunder, and (ii) PPD's receipt of all Direct Fees, Pass Through Costs, and any other payments due to PPD related to the Services provided thereunder, unless earlier terminated in accordance with this Section 3.

3.2 Early Termination. Subject to Section 3.4, any Project Addendum may be terminated individually, or this Agreement may be terminated in its entirety, with or without cause by Sponsor upon thirty (30) days prior written notice. PPD may terminate any Project Addendum upon Sponsor's breach of this Agreement upon thirty (30) days prior written notice provided that such breach was not remedied by Sponsor within the afore-mentioned thirty (30) day prior notice period.

3.3 Insolvency. Either party hereto may terminate this Agreement immediately upon the occurrence of an "Insolvency Event" with respect to the other party. For purposes of this Agreement, "**Insolvency Event**" shall mean (1) a party or any of its Affiliates shall commence a voluntary proceeding seeking liquidation, reorganization or other relief with respect to itself or its debts under any bankruptcy, insolvency or other similar law or seeking the appointment of a trustee, receiver, liquidator, custodian or other similar official of it or any substantial part of its property, or shall consent to any such relief or to the appointment of or taking possession by any such official in an involuntary case or other proceeding commenced against it, or shall make a general assignment for the benefit of creditors, or shall fail generally to pay its debts as they become due, or shall take any action to authorize any of the foregoing; (2) an involuntary case or other proceeding shall be commenced against a party or any of its Affiliates seeking liquidation, reorganization or other relief with respect to it or its debts under bankruptcy, insolvency or other similar law or seeking the appointment of a trustee, receiver, liquidator, custodian or other similar official of it or any substantial part of its property, and such involuntary case or other proceeding shall remain undismissed and unstayed for a period of sixty (60) days; or (3) an order for relief shall be entered against a party or any of its subsidiaries under the federal bankruptcy laws now or hereafter in effect.

3.4 Effect of Termination. The termination of this Agreement in its entirety by either party shall automatically terminate all Project Addenda, unless otherwise agreed in writing. In the event that a Project Addendum extends past the termination of this Agreement, the terms and conditions of the Agreement shall extend only for such period of time as is necessary for completion of the Services and any related obligations under such Project Addendum.

3.5 Wind Down. Upon the termination of this Agreement or a Project Addendum, PPD shall cooperate with Sponsor to provide for an orderly wind-down of the Services provided by PPD hereunder. PPD shall cooperate with Sponsor, at Sponsor's reasonable request, to develop and begin implementing a wind-down plan for the Services including, where appropriate, the transition to new service provider(s) designated by Sponsor. Sponsor shall reimburse PPD for all reasonable costs associated with the transition to a new services provider(s). In connection with any termination or expiration of this Agreement, PPD shall return to Sponsor all copies of all materials, data, work product, specimens, reports and all other property of Sponsor under this Agreement, in accordance with Section 5.6 and 10.2 of the Agreement.

4

---

3.6 Provisions Surviving Termination. The obligations of the parties contained in Sections 2, 3.4, 3.5, 3.6, 5, 6, 7, 8, 9, 10.2, 13.2, 13.3, 13.6, 13.7, 13.8, 13.11, and 13.12 hereof and herein shall survive termination of this Agreement.

#### 4. PERSONNEL.

4.1 Project Management. The Services with respect to each Project shall be performed by PPD under the direction of the person identified as the Project Manager in the applicable Project Addendum or such other person acceptable to Sponsor and mutually agreed to in writing (email is sufficient) as PPD may from time to time designate as the Project Manager, such Sponsor acceptance of the designated Project Manager not to be unreasonably withheld or delayed in all instances. PPD shall provide Sponsor with a list of functional area leads and copies of their curriculum vitae (e-mail is acceptable) for prior approval by Sponsor (such approval by Sponsor shall not be unreasonably withheld or delayed) before commencing the Services under any Project Addendum. In the event that any of the functional area leads will be replaced or become unavailable during the term of a Project Addendum, PPD shall provide Sponsor the name of the substitute and a copy of the substitute's curriculum vitae for approval (such approval by Sponsor shall not be unreasonably withheld or delayed) prior to commencing services under a Project Addendum (e-mail notification is acceptable).

4.2 Covenant Not to Interfere. Neither party will solicit for employment any employee of the other party during the active term of this Agreement. As used in this section "solicit" means the initiation by a party or its agent of a contact with any of the other party's then current employees who are performing services under this Agreement for the purpose of offering employment to such employees, but shall not include the circumstance where any such employee initiates a contact with the other party for the purpose of obtaining employment whether in response to a general advertisement of employment or where such contact is initiated by a third party who was not instructed to contact such employee by the hiring party.

4.3 Personnel Retention. In the event of delays in the performance of the Project, i.e., after PPD is authorized to commence work, which are beyond the control of PPD, and where Sponsor desires in writing for PPD to keep PPD Project personnel assigned to the Project, in addition to any other sums payable to PPD hereunder, Sponsor agrees that Sponsor shall pay a personnel fee calculated on an FTE-day basis. Said personnel fees shall be invoiced by PPD on a monthly basis, and shall be due and payable by Sponsor within 30 days of receipt of an undisputed invoice in accordance with Section 2.1.

#### 5. CONFIDENTIALITY.

5.1 Sponsor Confidential Information. PPD and its Affiliates shall treat all information obtained from Sponsor (including, without limitation, information regarding Sponsor's business, services, methodologies, marketing strategies, business plans and proposals, employees and personnel, standard operating procedures, prices and rates, technology, tools, programs and software programs; scientific or technical information including any experimental results, trade secret, invention, idea, procedure, formulation, process, formula or data; any information relating to Sponsor drug products and proposed drug products; current or proposed studies on Sponsor products; prior research and results of studies on Sponsor's drug products; and reports and decisions resulting from clinical trials on Sponsor's drug products) and all Sponsor Property (as defined in Section 7.2) ("**Sponsor Confidential Information**") as the confidential and exclusive property of Sponsor.

5.2 PPD Confidential Information. Sponsor shall treat all information obtained from PPD or any of PPD's Affiliates including, without limitation, any PPD bids or proposals, standard operating procedures, personnel information, all PPD Property (as defined below) and any revisions, improvements or enhancements thereto ("**PPD Confidential Information**") as the confidential and exclusive property of PPD. For avoidance of doubt PPD Confidential Information excludes Sponsor Property. In addition, any affiliate of Sponsor receiving information from PPD or any PPD Affiliate shall be bound by these confidentiality obligations. Further, any information disclosed, obtained, or observed by Sponsor or any

affiliate of Sponsor during an audit of PPD or an Affiliate of PPD, or the facilities of either, with the exception of Sponsor Confidential Information, shall be treated as confidential by Sponsor in accordance with the terms contained herein.

5.3 Use of Sponsor Confidential Information and PPD Confidential Information. Each party shall use the other's Confidential Information solely for the purposes contemplated by this Agreement and for no other purpose without the prior written consent of the other party. Neither party shall publish, disseminate or otherwise disclose Confidential Information of the other to any third party without first obtaining the written consent of such other party. Each party shall restrict the dissemination of the other's Confidential Information with its organization to only those persons who have a need to know, and shall ensure that all of its directors, officers, employees, agents, representatives and advisors (collectively, "**Agents**") are aware of this Agreement and bound by the terms of confidentiality stated herein.

5.4 Exceptions to Confidential Information. The above provisions of confidentiality shall not apply to that part of disclosing party's Confidential Information which the receiving party is able to demonstrate by documentary evidence: (i) was in the receiving party's possession prior to receipt from the disclosing party other than as a result of the receiving party's breach of any legal obligation or is independently developed by the receiving party; (ii) was in the public domain at the time of receipt from disclosing party; (iii) subsequently becomes a part of the public domain through no fault of the receiving party or its Agents; or (iv) is lawfully received by the receiving party from a third party having a right of further disclosure.

5.5 Disclosure Required by Law. The non-disclosure obligations pursuant to this Agreement shall not apply to Confidential Information that a receiving party is required to disclose pursuant to any judicial action, order of the court or other governmental agency; provided, however, that the receiving party shall make all reasonable efforts to notify the disclosing party prior to the disclosure of Confidential Information and allow the disclosing party the opportunity to contest and avoid such disclosure, and further provided that the receiving party shall disclose only that portion of such Confidential Information (and solely for such purpose) that it is legally required to disclose.

5.6 Return of Information. Upon termination or expiration of this Agreement or at the disclosing party's earlier written request, the receiving party shall return, and shall cause its Agents and Affiliates to return, all documentary, electronic or other tangible forms of Confidential Information provided by the disclosing party including, without limitation, any and all copies thereof, or, at the disclosing party's request, destroy all or such parts of the disclosing party's Confidential Information as the disclosing party shall direct. Notwithstanding the foregoing, the receiving party may retain copies of such of the disclosing party's Confidential Information as is reasonably necessary for regulatory and business archival purposes, subject to the ongoing obligation to maintain the confidentiality of such information.

5.7 Remedy. Each party agrees that its obligations hereunder are necessary and reasonable in order to protect the other party and the other party's business, and expressly agrees that monetary damages would be inadequate to compensate the other party for any breach of the terms of this Agreement. Accordingly, each party agrees and acknowledges that any such violation or threatened violation will cause irreparable injury to the other party, and that, in addition to any other remedies that may be available, in law, in equity or otherwise, the other party shall be entitled to seek injunctive relief against the threatened breach of this Agreement or a Project Addendum or the continuation of any such breach.

## 6. DATA PRIVACY.

6.1 Definitions. For the purpose of this Section 6, 'Personal Data', 'Process/Processing', 'Data Controller', 'Data Processor' and 'Data Subject' shall have the same meaning as in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ("Directive 95/46/EC") as implemented in the law of any EU Member State which is applicable to the provision of the Services or as defined in the law of any other country which is applicable to the provision

of the Services (including, as applicable, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules, 45 C.F.R. Parts 160-164, and the Health Information Technology for Economic and Clinical Health Act (HITECH), P.L. No. 111-005, Part I, Title XIII, Subpart D, 13401-13409, and state privacy laws) (collectively referred to as the "Applicable Data Privacy Laws").

6.2 Compliance. Each party warrants to the other that it will Process the Personal Data in compliance with all Applicable Data Privacy Laws.

6.3 Data Processing. The Sponsor and PPD acknowledge that the Sponsor is the Data Controller and PPD is the Data Processor with respect to the Processing of Personal Data relating to the Services provided under this Agreement. In the event that the Services are performed by any PPD Affiliate then such PPD Affiliate shall be a sub-Processor. PPD shall Process the Personal Data only in accordance with written instructions from the Sponsor or as may be required or permitted by Applicable Law including the Applicable Data Privacy Laws. (The instructions may be specific instructions or instructions of a general nature as set out in this Agreement, a Project Addendum, Protocol, SOP or SMMP or as otherwise notified by the Sponsor to PPD during the Term).

6.4 Representative. If Sponsor needs to appoint a representative to comply with Applicable Data Privacy Law in any EU Member State pursuant to Article 4 of Directive 95/46/EC and PPD is willing to provide such services to Sponsor, Sponsor and PPD shall enter into a mutually acceptable agreement for such representative purposes. Unless and until such an agreement is entered into, PPD shall not be deemed to be a representative under any Applicable Data Privacy Law.

6.5 Security. PPD and its Affiliates and Agents as applicable shall implement appropriate technical and organisational measures to protect the Personal Data as required by ICH-GCP and Applicable Data Privacy Laws.

6.6 Data Privacy Requests. PPD shall promptly notify the Sponsor in writing if it or its Affiliates and Agents as applicable receives any communication with regard to data privacy relating to the Services from a Data Subject, a privacy authority or other regulatory authority, and provide the Sponsor with cooperation and assistance in relation to any such communication. PPD shall be entitled to charge the Sponsor for such assistance, at its usual hourly rate, unless the communication relates to a breach or violation by PPD or a PPD Affiliate or Agent of its obligations under this Section 6. However, PPD and Sponsor recognize that any fees charged to the requesting party must comply with Applicable Data Privacy Laws.

6.7 Security Breaches. If PPD becomes aware of any breach of an Applicable Data Privacy Law relating to the Services, then it shall promptly notify the Sponsor and, if requested, assist the Sponsor in meeting any obligations under Applicable Data Privacy Law to notify Data Subjects, regulatory authorities or other required parties. PPD shall not respond directly to any Data Subjects, privacy authority or regulatory authority without obtaining the express written consent of Sponsor, unless otherwise required by Applicable Law. PPD shall be entitled to charge the Sponsor for such assistance, at its usual hourly rate, unless PPD or a PPD Affiliate was responsible for such breach.

6.8 Data transfers. PPD shall only Process or otherwise transfer Personal Data outside the European Economic Area (member states of the European Union plus, Norway, Iceland & Liechtenstein) as set out in this Agreement, any Project Addendum, Protocol, SOP or SMMP or with the prior consent of the Sponsor.

## 7. INTELLECTUAL PROPERTY.

7.1 No License. The delivery of any information to a party hereto, shall not be deemed to grant the receiving party any right or license under any patent or patent application or to any know-how, technology or invention of the disclosing party except as expressly stated herein. PPD hereby grants and will grant to Sponsor a non-exclusive, fully-paid up, compensation-free, irrevocable (except in the event of material breach), perpetual world-wide license to use any PPD Property which is incorporated into a

7

---

deliverable under the Project Addendum to the extent reasonably necessary for Sponsor to utilize the deliverables as contemplated by the Project Addendum and for commercialization of the relevant Project. Unless prior approved in writing by PPD, Sponsor shall not sublicense or transfer this license hereby granted (or to be granted) to any other party except that Sponsor may sublicense or transfer this license to a *bona fide* development or commercialization partner in respect of the relevant Project upon due notice to PPD provided that in no event shall any such transferee or sub licensee of Sponsor be PPD's direct competitor.

7.2 Sponsor Property. Subject to Section 7.3 below, PPD hereby assigns to Sponsor all rights PPD or its Agents or Affiliates may have or may acquire in any information, data, results, any invention, technology, know-how, discovery, improvement, works, products or other intellectual property relating to a Project drug or Protocol and which is (i) a direct and sole result of PPD's or its Agents' or Affiliates' provision of the Services or (ii) specifically set forth as a deliverable under a Project Addendum (collectively, "Sponsor Property"). The parties hereby agree, for the avoidance of any doubt, that all Sponsor Property, is the exclusive property of Sponsor. Sponsor shall be free to use Sponsor Property without restriction, subject to Applicable Law and PPD shall assist Sponsor, at Sponsor's sole cost and expense, in obtaining or extending protection therefor. PPD warrants that it has and will continue to have valid agreements with all of its Affiliates and Agents to effect the terms of this Section 7.2. PPD shall promptly disclose in writing to Sponsor full details of any and all such Sponsor Property. PPD agrees to (as is reasonably necessary) execute and have executed assignments of all Sponsor Property (and any and all rights therein) to Sponsor. PPD further agrees, at Sponsor's sole cost and expense, to execute other documents that may be reasonably necessary or helpful to Sponsor, or at PPD's sole but reasonable discretion, which may relate to any litigation or interference and/or controversy in connection therewith. PPD acknowledges that Sponsor has the exclusive right to file patent applications and own patents in connection with the Sponsor Property.

7.3 PPD Property. PPD possesses certain inventions, processes, technology, know-how, trade secrets, improvements, other intellectual property and assets, including, without limitation, those related to business or product plans or proposals, marketing strategies, standard operating procedures, data, composition of matter, research, experimental results, personnel data, financial information and conditions, pricing information, customer information, supplier/vendor information, raw materials, data collection and data management processes, laboratory analyses, analytical, biotechnology and clinical methods, procedures and techniques, computer technical expertise and software (including code) which have been independently developed without the benefit of any information provided by Sponsor (collectively, "**PPD Property**"). Sponsor and PPD agree that any PPD Property or revisions, improvements or enhancements thereto which are developed without the benefit of any Sponsor Property or Sponsor Confidential Information shall be the sole and exclusive property of PPD, and Sponsor shall have no rights, title and interest to such PPD Property.

7.4 Work for Hire. The parties expressly agree that any and all Sponsor Property which represents original works of authorship, reports, data, technical information, communications, materials, and/or concepts and plans made, conceived or written by PPD or its Affiliates or Agents as a result of Services performed for Sponsor pursuant to this Agreement is and shall be a work for hire as defined under 17 USC §101 or equivalent provisions and shall belong exclusively to Sponsor, including, without limitation, exclusive rights to Sponsor to use and obtain copyrights therein.

## 8. INDEMNIFICATION.

8.1 Sponsor Indemnity. Sponsor shall indemnify, defend, and hold harmless PPD, PPD Affiliates (as that term is defined in Section 13.11), and their Agents ("**PPD Indemnitees**") from and against any and all damages, liabilities, losses, fines, penalties, settlement amounts, costs and expenses of any kind or nature whatsoever, including, without limitation, reasonable attorneys' fees, expert witness fees, court costs, , incurred in connection with any claim, demand, action, proceeding, investigation or hearing (collectively, a "**Claim**") directly or indirectly relating to or arising from this Agreement or any Services provided by PPD Indemnitees hereunder, including but not limited to, Project related services

8

---

provided by PPD at the request of Sponsor yet prior to finalization of the relevant Project Addendum; provided however, that Sponsor shall have no obligation of indemnity hereunder with respect to any Claim which arose from the negligence, intentional misconduct or material breach of this Agreement or any Project Addendum on the part of PPD or its Agents or Affiliates.

8.2 PPD Indemnity. PPD shall indemnify, defend and hold harmless Sponsor and its Agents from and against any and all damages, liabilities, losses, fines, penalties, settlement amounts, cost and expenses of any kind or nature whatsoever, including, without limitation, reasonable attorney's fees, expert witnesses and court costs, incurred in connection with any Claim arising from the negligence, intentional misconduct, or material breach of this Agreement of PPD or its Agents or Affiliates; provided however, that PPD shall have no obligation of indemnity hereunder with respect to any Claim which arose from the negligence, intentional misconduct or material breach of this Agreement on the part of Sponsor or its Agents or Affiliates.

8.3 Indemnification Procedure. Each indemnified party shall give the indemnifying party prompt notice of any Claim for which indemnification is sought hereunder. The indemnifying party shall have the right to control the defense and settlement of a Claim, provided the indemnifying party shall act reasonably and in good faith with respect to all matters relating to the settlement or disposition of the Claim, and the indemnified party shall reasonably cooperate in the investigation, defense and settlement of such Claim. Any indemnified party shall have the right to participate in, but not control, the defense and settlement of a Claim and to employ separate legal counsel of its own choice; provided, however, that such employment shall be at the indemnified party's own expense, unless (i) the employment thereof has been specifically authorized by the indemnifying party, or (ii) the indemnifying party has failed to assume the defense and employ counsel (in which case the indemnified party shall control the defense and settlement of such Claim); provided however that the defense or settlement under this Section 8.3 (ii) shall not act as a waiver of rights to indemnification and shall not excuse the indemnifying party from its obligations hereunder and, all reasonable costs and expenses incurred by the Party claiming indemnification shall be subject to indemnity by the indemnifying Party. The costs and expenses, including reasonable fees and disbursements of counsel, incurred by any indemnified party in connection with any Claim shall be reimbursed on a monthly basis by the indemnifying party subject to refund in the event the indemnifying party is ultimately held not to be obligated to indemnify the indemnified party. Neither party will enter into any settlement agreement that attributes fault or negligence to the other party, requires any payment by the other party, or restricts the future actions or activities of the other party, without the other party's prior written consent, which shall not be unreasonably withheld.

## 9. LIMITATION OF LIABILITY.

**NEITHER PARTY SHALL BE LIABLE FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT (OR THE TERMINATION HEREOF) OR ANY PROJECT ADDENDUM, INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS OR ANTICIPATED SALES.**

**TO THE FULLEST EXTENT PERMITTED BY LAW, AND NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT OR ANY PROJECT ADDENDUM, THE TOTAL LIABILITY, IN THE AGGREGATE, OF PPD AND ITS AGENTS, AND ANY OF THEM, TO SPONSOR AND ANYONE CLAIMING BY OR THROUGH SPONSOR, FOR ANY AND ALL CLAIMS, LOSSES, COSTS OR DAMAGES, INCLUDING WITHOUT LIMITATION, ATTORNEYS' FEES AND COSTS AND EXPERT-WITNESS FEES AND COSTS OF ANY NATURE WHATSOEVER OR CLAIMS EXPENSES RESULTING FROM OR IN ANY WAY RELATED TO THIS AGREEMENT OR ANY PROJECT ADDENDUM FROM ANY CAUSE OR CAUSES SHALL NOT EXCEED TWO TIMES THE TOTAL DIRECT FEES RECEIVED BY PPD UNDER THE APPLICABLE PROJECT ADDENDUM, WHICH IS THE SUBJECT OF THE CLAIM, UNLESS AND TO THE EXTENT SUCH CLAIMS, LOSSES, COSTS OR DAMAGES ARE CAUSED BY THE GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT OF PPD OR ITS AFFILIATES OR AGENTS.**

9

---

## 10. RECORD STORAGE.

10.1 Record Maintenance during Project. During the term of this Agreement, PPD shall maintain all materials, documents and all other data obtained or generated by PPD in the course of providing the Services hereunder, including all computerized records and files in accordance with Applicable Law and Sponsor's instructions. PPD shall cooperate with any reasonable internal review or audit by Sponsor and make available to Sponsor for examination and duplication, during normal business hours and at mutually agreeable times, all documentation, data and information relating to a Project.

10.2 Record Maintenance after Expiration or Termination. Upon the expiration or termination of the Services other than for Sponsor's breach of required payment hereunder, all materials and all other data and information obtained or generated by PPD in the course of providing the Services hereunder (collectively, the "**Records**") shall, at Sponsor's option, be (i) delivered to Sponsor at its expense and risk, to its offices identified herein in such form as is then currently in the possession of PPD, (ii) securely retained by PPD for Sponsor for a period of three (3) years after the expiration or termination of the Services, or (iii) disposed of at Sponsor's expense, as directed by written request of Sponsor, unless the Records are otherwise required to be stored or maintained by PPD under Applicable Law. If PPD is required or requested to maintain and/or store the Records for a period beyond three (3) years after the termination or expiration of the Services, Sponsor shall reimburse PPD for its maintenance and storage costs. In no event shall PPD dispose of Records without first giving Sponsor sixty (60) days prior written notice of its intent to dispose of the Records and allowing Sponsor the opportunity to take control of such Records. PPD shall be entitled at its expense to retain copies of the Records reasonably necessary for regulatory purposes or to demonstrate the satisfaction of its obligations hereunder, all subject to the confidentiality obligations set forth in Section 5 above.

## 11. REGULATORY.

11.1 PPD hereby certifies that it has not been debarred, and has not been convicted of a crime which could lead to debarment, under the Generic Drug Enforcement Act of 1992. PPD further certifies that it has never been debarred and, none of its employees, Affiliates, has ever been 1) debarred 2) threatened to be debarred or 3) to its knowledge, indicted for a crime or otherwise engaged in conduct for which a person can be debarred, under the Food, Drug and Cosmetic Act or any other Applicable Law. PPD agrees that it will promptly notify Sponsor in the event of any such debarment, conviction, threat or indictment related to the performance of Services hereunder. If PPD or any of its Agents or Affiliates or subcontractors (as defined in Section 13.1) who perform Services for a Project is debarred or receives notice of an action or threat of action of debarment, PPD shall immediately notify Sponsor of same. The debarment of PPD or any of its Agents or subcontractors (as defined in section 13.1) (which are providing services to Sponsor on a Project under this Agreement) or Affiliates that remains in place for a period of at least thirty (30) days shall be deemed to be a material breach of this Agreement, unless, with respect to the debarment of an Agent or subcontractor (as defined in Section 13.1) which is providing services to Sponsor hereunder, PPD is able to replace the Agent or subcontractor (as defined in Section 13.1) within such 30-day period, in which case the debarment of the replaced Agent or subcontractor (as defined in section 13.1) shall not be a material breach of this Agreement. PPD hereby further certifies that it shall include a similar debarment provision to that set out in Section 11.1 above in contracts with subcontractors (as defined in Section 13.1) and shall not knowingly utilize any debarred subcontractors (as defined in section 13.1) when providing Services pursuant to this Agreement and any Project Addendum.

11.2 In the event any Applicable Law governing any Services is amended, revised or revoked during the term of this Agreement, the parties will discuss the effect (if any) of such change on the Agreement and/or on Services being provided under this Agreement together with any financial implications and will document any required changes to any Project Addendum by written Amendment executed by both parties.

11.3 During the term of this Agreement and for a period of one year thereafter, Sponsor or its designee (provided that such designee is not considered by PPD to be a competitor of PPD) may, upon

reasonable advance notice that is mutually agreeable by the parties, during regular business hours and at Sponsor's sole cost and expense, audit PPD's or Affiliates' records, facilities or procedures related to PPD's or Affiliates' provision of the Services. Such designee shall, in advance of such audit, execute a mutually agreeable confidentiality and non-disclosure agreement with PPD. Sponsor agrees to hold such records and procedures in confidence, in accordance with Section 5 of this Agreement. Audits shall be conducted by Sponsor on site at PPD or its Affiliate, in a manner designed to cause the least interruption to PPD's or its Affiliate's business operations. Sponsor may perform quality assurance audits of the work performed hereunder, documentation and record-keeping procedures and storage facilities to determine that the Services are being conducted in accordance with this Agreement and the relevant Project Addendum. The parties will discuss any audit findings as soon as reasonably practicable following the audit.

11.4 PPD shall promptly notify Sponsor of any impending inspection or audit by the FDA or other federal, state, or foreign government authority ("Regulatory Authority") which directly relates to the Services. In the event that PPD receives from a Regulatory Authority a notice of inspection (hereinafter "Notice") which directly relates to any Services under this Agreement, PPD shall (i) promptly notify Sponsor of the Notice; (ii) keep Sponsor informed of the progress of the inspection; and (iii) provide a copy to Sponsor of any project documents directly related to the Services produced to such Regulatory Authority. Notwithstanding the foregoing, in the event any Regulatory Authority issues any findings or commences an enforcement action (e.g. FDA 483) to PPD directly related to the Services provided hereunder or if any of PPD's practices/procedures which are directly impactful upon the Services provided hereunder are found to be objectionable by a regulatory authority, PPD shall promptly notify Sponsor of any such findings or enforcement action.

## 12. CURRENCY MANAGEMENT.

12.1 Direct Fees. All Direct Fees owed to PPD for Services performed under this Agreement or any Project Addendum shall generally be invoiced to and paid by Sponsor in the "**Contract Currency**", which shall be defined as the currency, or currencies, designated in any budget or payment schedule set forth in a Project Addendum. However, any Services performed outside the United States shall be invoiced to and paid by Sponsor in the local currency where such Services are performed with any Services performed in Europe being invoiced to and paid by Sponsor in British pounds or Euros.

In special circumstances, PPD may invoice Sponsor in United States dollars ("USD") for Services performed outside the United States. In such cases, PPD shall specify in the proposal and the contract the estimated exchange rate or rates ("**Exchange Rate**") used to prepare the budget or payment schedule for such Project Addendum. This Exchange Rate will be the one used for the preparation of each invoice for Services and payment by the Sponsor. The "Spot Rate" for purposes of reconciliation, shall mean the actual spot rate in the Wall Street Journal at the close of the day before the date on which the invoice is raised. At the conclusion of each calendar year, a reconciliation shall be undertaken. PPD shall compare the USD total of the invoices billed to Sponsor that year at the Exchange Rate with the USD total of those same invoices when converted using the Spot Rates. In the event the comparison demonstrates that the difference in such amounts is five percent (5%) or more and is greater than USD \$50,000 such difference shall be invoiced or credited, as the case may be, to Sponsor. The reconciliation invoice or credit note will be issued by PPD in USD. The process of reconciliation is not cumulative but shall be conducted on a calendar year basis and completed by the end of March in the subsequent year.

12.2 Pass Through Costs. Where PPD incurs Pass Through Costs in a currency other than the Contract Currency, PPD shall, for Sponsor invoicing and payment purposes, convert such costs to the Contract Currency based on an average reasonable market exchange rate between the local currency and the Contract Currency for the month in which such costs were incurred.

12.3 Investigator Fees. PPD shall pay investigator fees in the currency specified in the investigator agreements. For Sponsor invoicing and payment purposes, PPD shall convert all investigator fees that are to be paid in a currency other than the Contract Currency to the Contract

Currency. The conversion to the Contract Currency shall be based on an average reasonable market exchange rate between the currency specified in an investigator agreement and the Contract Currency for the month prior to the month the Sponsor invoice is raised. All amounts invoiced to Sponsor will be based upon an accrual of costs owed to investigators. At the end of the project a reconciliation will be completed between the estimated exchange rate used for the purposes of billing on the basis of the accrued costs versus the exchange rate when the actual payment is made to the sites, and any variation will be billed or credited to the Sponsor as applicable.

## 13. MISCELLANEOUS.

13.1 Independent Contractor Relationship. The parties hereto are independent contractors, and nothing contained in this Agreement is intended, and shall not be construed, to place the parties in the relationship of partners, principal and agent, employer/employee or joint venturer. Neither party shall have any right, power or authority to bind or obligate the other, nor shall either hold itself out as having such right, power or authority.

13.2 Publicity. Neither party shall mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other party (or any abbreviation or adaptation thereof) in any publication, press release, promotional material or other form of publicity without the prior written approval of the other party in each instance. The restrictions imposed by this Section shall not prohibit a party from making any disclosure identifying the other party that is required by any Applicable Law.

13.3 Publication. PPD and Affiliates may not publish any articles or make any presentations relating to the Services provided to Sponsor hereunder with respect to a Project or referring to data, information or materials generated as part of the Services without the prior written consent of Sponsor. Neither party will issue any press release or statement regarding this Agreement or the Services, written or oral, to the communications media or any third party without the prior written consent of the other.

13.4 Insurance. Sponsor and PPD will each undertake to purchase and maintain insurance of such types and amounts reasonably adequate to cover any liabilities arising out of its obligations hereunder (including but not limited to that required by Applicable Law). Sponsor further undertakes to purchase and maintain insurance of such types and amounts reasonably adequate (including but not limited to that required by law) to cover any liabilities arising in relation to all clinical trials contracted to PPD pursuant to this Agreement.

Sponsor and PPD will each undertake, upon request, to provide the other party a certificate (or certificates) of insurance setting forth the liability limits, exclusions and deductibles of the insurance such party is required to carry pursuant to this Agreement.

13.5 **Force Majeure.** If either party shall be delayed, hindered, or prevented from the performance of any act required hereunder by reason of strike, lockouts, labor troubles, restrictive governmental or judicial orders or decrees, riots, insurrection, war, acts of God, inclement weather, or other cause beyond such party's reasonable control (each, a "**Disability**"), then performance of such act shall be excused for the length of time necessary to cure such Disability and resume performance. A party shall not be liable for any delays resulting from a Disability, and any affected timelines shall be extended for a period at least equal to that of the Disability. The party incurring the Disability shall provide notice to the other of the commencement and termination of the Disability.

13.6 **Notices.** Any notice required or permitted to be given hereunder by either party hereto shall be in writing and shall be deemed given on the date delivered if delivered (i) personally, (ii) on the first business day after the date sent if sent by recognized overnight courier, (iii) on the date transmitted if sent via facsimile (with confirmation of receipt generated by the transmitting machine), or (iv) on the second business day after the date deposited if mailed by certified mail, return receipt requested, postage prepaid. All notices to each party shall be sent to the address for said party set forth in the applicable Project Addendum. If no address is provided in the Project Addendum, then notices shall be sent to the following address:

12

---

If to PPD: PPD Development, LLC  
929 North Front Street  
Wilmington, North Carolina 28401  
Attention: CEO  
Tel: (910) 251-0081  
Fax: (910) 558-5820

If to Sponsor: Celldex Therapeutics, Inc.  
119 Fourth Avenue  
Needham, MA 02494  
Tel: (781) 433-0771  
Fax: (781) 433-0262  
Attention: CEO, CFO and CCO

Either party may change its notice address by notice to the other party hereto in the form and manner provided in this Section 13.6.

13.7 **Governing Law.** This Agreement and the rights and obligations of the parties hereunder shall be governed by and construed in accordance with the laws of the State of New Jersey without reference to its conflicts of laws provisions. The parties hereby consent to the jurisdiction of the state and federal courts sitting in the State of New Jersey, and any Courts of Appeal there from, in connection with any dispute arising in connection with this Agreement or the provision of Services hereunder.

13.8 **Severability.** If any provision of this Agreement or any Project Addendum is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of any party hereto under this Agreement or such Project Addendum will not be materially or adversely affected thereby, (a) such provision will be fully severable, (b) this Agreement or such Project Addendum will be construed and enforced as if such illegal, invalid or unenforceable provision had never compromised a part hereof, (c) the remaining provisions of this Agreement or such Project Addendum will remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision or by its severance here from, and (d) in lieu of such illegal, invalid or unenforceable provision, there will be added automatically as a part of this Agreement or such Project Addendum, a legal, valid and enforceable provision as similar in terms as to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the parties herein.

13.9 **Waiver.** Any term or condition of this Agreement or a Project Addendum may be waived at any time by the party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the party waiving such term or condition. No waiver by any party hereto of any term or condition of this Agreement or a Project Addendum, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement or such Project Addendum on any future occasion.

13.10 **Amendments.** No amendment, change or modification to this Agreement or any Project Addendum shall be effective unless in writing and executed by the parties hereto.

13.11 **Assignment and Subcontracting.** This Agreement and any Project Addendum may not be assigned by either party without the prior written consent of the other party; provided, however, that (i) a party hereto may assign this Agreement or a Project Addendum hereunder with prompt notice but without the requirement for consent to a successor-in-interest to the party's business to which this Agreement relates and (ii) PPD may assign this Agreement or a Project Addendum or subcontract all or part of the Services to be performed hereunder to PPD Affiliates, provided that such Affiliates are bound by all applicable terms of this Agreement and the relevant Project Addendum or Addenda. "PPD Affiliates" shall mean entities which can provide the Services and which controls, is controlled by or is under common

13

---

control with PPD or PPD's parent company Pharmaceutical Product Development, LLC. In the event the Services shall be performed by a PPD Affiliate, such PPD Affiliate may be the contracting party to any Project Addendum for the Services. PPD shall notify Sponsor of the intention to subcontract or delegate its obligation to perform any portion of the Services under a Project Addendum to a subcontractor. PPD shall be responsible and retain primary liability for the performance of all obligations of PPD under this Agreement and any breach thereof by PPD or subcontractors selected and managed by PPD. When used in this Agreement, the term "**subcontractor**" shall mean and refer to any third party to whom PPD has subcontracted or delegated PPD's obligation to perform any portion of the Services hereunder (but shall exclude Affiliates of PPD and any third party vendor whose expenses are considered a Pass Through Cost).



13.12 Construction. Except where the context otherwise requires, wherever used the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the parties and no rule of strict construction shall be applied against either party hereto.

13.13 MedDRA and WHODrug Dictionary License. The parties acknowledge that MedDRA and Uppsala Monitoring Centre product licenses are required by all parties who wish to distribute or receive MedDRA or WHODrug dictionary terminology. Each party represents and warrants that it possesses a current MedDRA and/or Uppsala Monitoring Centre product license as required. In the event Sponsor requests that PPD perform services which require PPD to distribute MedDRA terminology or WHODrug dictionary to third parties, Sponsor shall be responsible for ensuring that all such third parties possess the necessary MedDRA and/or Uppsala Monitoring Centre product licenses.

13.14 Counterparts and Electronic Signatures. This Agreement or any Project Addendum hereunder may be executed in counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument. Each party may execute this Agreement or any Project Addendum by facsimile transmission or in Portable Document Format sent by electronic means. Signatures of authorized signatories of the parties transmitted by facsimile or sent by electronic means in Portable Document Format shall be deemed to be original signatures, shall be valid and binding, and, upon delivery, shall constitute due execution of this Agreement or any Project Addendum hereunder.

13.15 Representative. With regard to any Project conducted under this Agreement, Sponsor represents and warrants that it shall not name any PPD employee, contractor, or other PPD representative on Line 15 of Form FDA 1571. Sponsor acknowledges and understands that if Sponsor desires that any PPD employee, contractor, or other PPD representative be named as the Senior Medical Officer in Canada on Line 87 of Form HC/SC 3011 or in any similar capacity for clinical trials conducted in other countries, Sponsor must first submit such a request to PPD in writing for the performance of services pursuant to such naming, including, without limitation, responsibility for review and evaluation of information relevant to the safety of the Study Drug. If PPD agrees to perform such services, the parties shall enter into good faith negotiations and enter into either a separate agreement or written amendment to the applicable Project Addendum prior to PPD initiating the services.

13.16 Entire Agreement. This Agreement constitutes the entire agreement between the parties and supersedes all prior negotiations, representations or agreements, either written or oral, with respect to the subject matter hereof.

## 14. WARRANTIES

14.1 Each party warrants the following:

14

---

(a) that it is authorized to enter into this Agreement and that the terms of this Agreement are not (and shall not become) inconsistent with or constitute a violation of any contracted or other legal obligation to which it is subject; and

(b) that in performing under this Agreement it shall (i) conduct business in compliance with all Applicable Laws,; and (ii) shall not achieve business results by illegal act or unethical conduct.

(c) that it and its Affiliates as applicable have all necessary or appropriate qualifications, authorizations, licenses and permits to perform the Services under this Agreement.

14.2 PPD warrants that (a) it is not currently involved in any material litigation, and is unaware of any pending litigation proceedings, relating to its or its Affiliates' Services provided in a clinical trial for any third party; and (b) it has not within the past ten (10) years received any warnings from the FDA or other Regulatory Authority relating to services it has provided to third parties during the conduct of a clinical trial.

IN WITNESS WHEREOF, this Agreement has been executed and delivered by the parties hereto by their duly authorized officers as of the date first above written.

**PPD DEVELOPMENT, LLC**

**CELLDEX THERAPEUTICS, INC.**

By: /s/ William J. Sharbaugh

By: /s/ Anthony S. Marucci

Name: William J. Sharbaugh

Name: Anthony S. Marucci

Title: Chief Operating Officer

Title: President & CEO

15

---

CERTIFICATION

I, Anthony S. Marucci, certify that:

1. I have reviewed this report on Form 10-Q of Celldex 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 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.

Date: August 6, 2013

By: /s/ ANTHONY S. MARUCCI  
Name: Anthony S. Marucci  
Title: President and Chief Executive Officer

---

CERTIFICATION

I, Avery W. Catlin, certify that:

1. I have reviewed this report on Form 10-Q of Celldex 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 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.

Date: August 6, 2013

By: /s/ AVERY W. CATLIN  
Name: Avery W. Catlin  
Title: Senior Vice President and Chief Financial Officer

---

SECTION 1350 CERTIFICATIONS

Pursuant to 18 U.S.C. §1350 as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, the undersigned officers of Celldex Therapeutics, Inc. (the "Company") hereby certify that to their knowledge and in their respective capacities that the Company's quarterly report on Form 10-Q to which this certification is attached (the "Report"), fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 6, 2013

By: /s/ ANTHONY S. MARUCCI  
Name: Anthony S. Marucci  
Title: President and Chief Executive Officer

Date: August 6, 2013

By: /s/ AVERY W. CATLIN  
Name: Avery W. Catlin  
Title: Senior Vice President and Chief Financial Officer

This certification shall not be deemed "filed" for any purpose, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act. A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Celldex Therapeutics, Inc. and will be retained by Celldex Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

---