

---

---

**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 September 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 October 29, 2013, 81,108,234 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 September 30, 2013 and December 31, 2012</a>	3
<a href="#">Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2013 and 2012</a>	4
<a href="#">Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 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>	26
<b>Part II — Other Information</b>	
<a href="#">Item 1A. Risk Factors</a>	26
<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)

	September 30, 2013	December 31, 2012
<b>ASSETS</b>		
Current Assets:		
Cash and Cash Equivalents	\$ 14,626	\$ 24,897
Marketable Securities	121,962	59,065
Accounts and Other Receivables	890	44
Prepaid and Other Current Assets	2,468	1,108
Total Current Assets	<u>139,946</u>	<u>85,114</u>
Property and Equipment, Net	8,814	7,205
Intangible Assets, Net	23,073	23,833
Other Assets	157	424
Goodwill	8,965	8,965
Total Assets	<u>\$ 180,955</u>	<u>\$ 125,541</u>
<b>LIABILITIES AND STOCKHOLDERS’ EQUITY</b>		
Current Liabilities:		
Accounts Payable	\$ 1,982	\$ 745
Accrued Expenses	13,807	10,960
Current Portion of Long-Term Liabilities	1,006	388
Current Portion of Term Loan	—	5,592
Total Current Liabilities	<u>16,795</u>	<u>17,685</u>
Term Loan, less Current Portion	—	5,746
Other Long-Term Liabilities	7,415	6,336
Total Liabilities	<u>24,210</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 September 30, 2013 and December 31, 2012	—	—
Common Stock, \$.001 Par Value; 297,000,000 Shares Authorized; 81,108,109 and 64,359,513 Shares Issued and Outstanding at September 30, 2013 and December 31, 2012, respectively	81	64
Additional Paid-In Capital	477,595	357,094

Accumulated Other Comprehensive Income	2,686	2,745
Accumulated Deficit	(323,617)	(264,129)
Total Stockholders' Equity	156,745	95,774
Total Liabilities and Stockholders' Equity	\$ 180,955	\$ 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		Nine Months Ended	
	September 30, 2013	September 30, 2012	September 30, 2013	September 30, 2012
<b>REVENUE:</b>				
Product Development and Licensing Agreements	\$ 40	\$ 28	\$ 117	\$ 103
Contracts and Grants	940	79	1,040	228
Product Royalties	—	3,006	2,334	7,224
Total Revenue	<u>980</u>	<u>3,113</u>	<u>3,491</u>	<u>7,555</u>
<b>OPERATING EXPENSE:</b>				
Research and Development	20,417	11,769	49,597	33,650
Royalty	—	3,006	2,334	7,224
General and Administrative	3,578	2,835	10,128	7,372
Amortization of Acquired Intangible Assets	254	254	760	836
Total Operating Expense	<u>24,249</u>	<u>17,864</u>	<u>62,819</u>	<u>49,082</u>
Operating Loss	(23,269)	(14,751)	(59,328)	(41,527)
Investment and Other Income, Net	142	105	682	436
Interest Expense	(13)	(381)	(842)	(1,225)
Net Loss	<u>\$ (23,140)</u>	<u>\$ (15,027)</u>	<u>\$ (59,488)</u>	<u>\$ (42,316)</u>
Basic and Diluted Net Loss Per Common Share (Note 3)	<u>\$ (0.29)</u>	<u>\$ (0.25)</u>	<u>\$ (0.76)</u>	<u>\$ (0.75)</u>
Shares Used in Calculating Basic and Diluted Net Loss per Share (Note 3)	<u>81,015</u>	<u>59,467</u>	<u>78,676</u>	<u>56,090</u>
<b>COMPREHENSIVE LOSS:</b>				
Net Loss	\$ (23,140)	\$ (15,027)	\$ (59,488)	\$ (42,316)
Other Comprehensive (Loss) Income:				
Foreign Currency Translation Adjustments	—	1	(3)	2
Unrealized Gain (Loss) on Marketable Securities	138	52	(56)	121
Comprehensive Loss	<u>\$ (23,002)</u>	<u>\$ (14,974)</u>	<u>\$ (59,547)</u>	<u>\$ (42,193)</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)

	Nine Months Ended	
	September 30, 2013	September 30, 2012
<b>Cash Flows from Operating Activities:</b>		
Net Loss	\$ (59,488)	\$ (42,316)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation and Amortization	1,422	1,576
Amortization of Intangible Assets	760	836
Amortization and Premium of Marketable Securities	(1,232)	(420)
Realized Gain on Sales and Maturities of Marketable Securities	—	(6)
Gain on Sale or Disposal of Assets	(21)	(74)
Stock-Based Compensation Expense	3,400	1,614

Non-Cash Interest Expense	97	169
<b>Changes in Operating Assets and Liabilities:</b>		
Accounts and Other Receivables	(846)	138
Prepaid and Other Current Assets	(1,457)	(8)
Other Assets	267	(80)
Accounts Payable and Accrued Expenses	2,954	1,495
Other Liabilities	1,432	620
Net Cash Used in Operating Activities	<u>(52,712)</u>	<u>(36,456)</u>
<b>Cash Flows from Investing Activities:</b>		
Sales and Maturities of Marketable Securities	30,679	45,432
Purchases of Marketable Securities	(92,400)	(57,900)
Acquisition of Property and Equipment	(1,901)	(193)
Proceeds from Sale or Disposal of Assets	21	218
Net Cash Used in Investing Activities	<u>(63,601)</u>	<u>(12,443)</u>
<b>Cash Flows from Financing Activities:</b>		
Net Proceeds from Stock Issuances	114,187	62,872
Proceeds from Issuance of Stock from Employee Benefit Plans	2,931	—
Payments of Term Loan	(11,029)	(2,646)
Payments of Other Liabilities	(44)	(41)
Net Cash Provided by Financing Activities	<u>106,045</u>	<u>60,185</u>
Effect of Exchange Rate Changes on Cash and Cash Equivalents	<u>(3)</u>	<u>2</u>
Net (Decrease) Increase in Cash and Cash Equivalents	(10,271)	11,288
Cash and Cash Equivalents at Beginning of Period	24,897	11,899
Cash and Cash Equivalents at End of Period	<u>\$ 14,626</u>	<u>\$ 23,187</u>

See accompanying notes to unaudited condensed consolidated financial statements

[Table of Contents](#)

**CELLDEX THERAPEUTICS, INC.**  
**Notes to Unaudited Condensed Consolidated Financial Statements**  
**September 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 September 30, 2013, the Company had cash, cash equivalents and marketable securities of \$136.6 million and working capital of \$123.2 million. The Company incurred a loss of \$59.5 million for the nine months ended September 30, 2013. Net cash used in operations for the nine months ended September 30, 2013 was \$52.7 million. The Company believes that the cash, cash equivalents and marketable securities at September 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 nine months ended September 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 nine months of 2013 as discussed below.

#### Recent Accounting Pronouncements

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 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.

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

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 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:

	Three and Nine Months Ended September 30,	
	2013	2012
Stock options	6,077,377	5,351,999
Restricted stock	9,000	9,000
	<u>6,086,377</u>	<u>5,360,999</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 nine months ended September 30, 2013. The changes in accumulated other comprehensive income (loss) by component for the three and nine months ended September 30, 2013 are summarized below.

	Unrealized Gain (Loss) on Marketable Securities, net of tax		Foreign Currency Items (In thousands)		Total
	\$	\$	\$	\$	
Balance at June 30, 2013	\$ (38)	\$ 2,586	\$ 2,586	\$ 2,548	
Other comprehensive income (loss) before reclassifications	138	—	—	138	
Amounts reclassified from other comprehensive income	—	—	—	—	
Net current-period other comprehensive income	138	—	—	138	
Balance at September 30, 2013	<u>\$ 100</u>	<u>\$ 2,586</u>	<u>\$ 2,586</u>	<u>\$ 2,686</u>	
Balance at December 31, 2012	\$ 156	\$ 2,589	\$ 2,589	\$ 2,745	
Other comprehensive income (loss) before reclassifications	(56)	(3)	(3)	(59)	
Amounts reclassified from other comprehensive income	—	—	—	—	
Net current-period other comprehensive income	(56)	(3)	(3)	(59)	
Balance at September 30, 2013	<u>\$ 100</u>	<u>\$ 2,586</u>	<u>\$ 2,586</u>	<u>\$ 2,686</u>	

#### (5) Fair Value Measurements

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

	As of September 30, 2013			
	Level 1	Level 2	Level 3	
	(In thousands)			
Money market funds and cash equivalents	\$ 11,580	\$ 11,580	—	—

Marketable securities	\$	121,962	—	\$	121,962	—
	\$	133,542	\$	11,580	\$	121,962

7

[Table of Contents](#)

	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	—
	\$ 77,753	\$ 18,688	\$ 59,065	—

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>September 30, 2013</b>				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	\$ 50,900	\$ 32	\$ (3)	\$ 50,929
Maturing after one year through three years	14,104	63	(2)	14,165
Total U.S. government and municipal obligations	\$ 65,004	\$ 95	\$ (5)	\$ 65,094
Corporate debt securities				
Maturing in one year or less	\$ 36,001	\$ 13	\$ (4)	\$ 36,010
Maturing after one year through three years	20,857	9	(8)	20,858
Total corporate debt securities	\$ 56,858	\$ 22	\$ (12)	\$ 56,868
Total marketable securities	\$ 121,862	\$ 117	\$ (17)	\$ 121,962
<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	\$ 35,363	\$ 127	\$ (1)	\$ 35,489
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	\$ 23,546	\$ 37	\$ (7)	\$ 23,576
Total marketable securities	\$ 58,909	\$ 164	\$ (8)	\$ 59,065

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 September 30, 2013.

8

[Table of Contents](#)

**(7) Intangible Assets and Goodwill**

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

Estimated Life	September 30, 2013			December 31, 2012			
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net	
	(In thousands)						
<b>Intangible Assets:</b>							
IPR&D	Indefinite	\$ 11,800	—	\$ 11,800	\$ 11,800	—	\$ 11,800
Amgen Amendment	16 years	14,500	(3,587)	10,913	14,500	(2,915)	11,585
Core Technology	11 years	1,296	(936)	360	1,296	(848)	448
Total Intangible Assets		\$ 27,596	\$ (4,523)	\$ 23,073	\$ 27,596	\$ (3,763)	\$ 23,833
Goodwill	Indefinite	\$ 8,965	—	\$ 8,965	\$ 8,965	—	\$ 8,965

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

The Company performed an annual impairment test of the IPR&D and goodwill assets as of July 1, 2013 and concluded that the IPR&D and goodwill assets were not impaired.

## (8) Term Loan

In May 2013, the Company elected to prepay its Term Loan with MidCap Financial, LLC and General Electric Capital Corporation in full, pursuant to the terms of its 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 collateralized 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 and \$0.8 million for the three and nine months ended September 30, 2013 and \$0.4 million and \$1.2 million for the three and nine months ended September 30, 2012, respectively.

## (9) Other Long-Term Liabilities

Other long-term liabilities include the following:

	September 30, 2013	December 31, 2012
	(In thousands)	
Deferred Rent	\$ 404	\$ 434
Net Deferred Tax Liability related to IPR&D	4,661	4,661
Deferred Income from Sale of Tax Benefits	1,630	1,118
Deferred Revenue	1,237	—
Loan Payable	428	472
Other	61	39
<b>Total</b>	<b>8,421</b>	<b>6,724</b>
Less Current Portion	(1,006)	(388)
<b>Long-Term Portion</b>	<b>\$ 7,415</b>	<b>\$ 6,336</b>

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 nine months ended September 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.

In September 2013, the Company entered into an agreement with Rockefeller University pursuant to which the Company will perform research and development services for Rockefeller. The agreement includes an approved project plan for the development

## [Table of Contents](#)

services of \$4.8 million and a term of three years. The agreement included an upfront payment of \$1.3 million which is being recognized as revenue over the term of the agreement. The Company will bill Rockefeller quarterly for actual time and direct costs incurred and record those amounts to revenue in the quarter the services are performed. The Company recorded \$0.9 million in revenue related to the Rockefeller agreement during the three months ended September 30, 2013.

## (10) Stockholders' Equity

In January 2011, the Company entered into a controlled equity offering sales agreement with Cantor Fitzgerald & Co. (the "Cantor Agreement") pursuant to which the Company could issue and sell up to 5,000,000 shares of its common stock from time to time through Cantor, acting as agent. During the nine months ended September 30, 2012, the Company issued 4,425,000 shares of common stock under the Cantor Agreement and raised \$19.0 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 nine months ended September 30, 2013, the Company issued 2,433,608 shares under the Cantor Amendment and raised \$17.1 million in net proceeds. At September 30, 2013, the Company had \$4.4 million remaining in aggregate offering price available under the Cantor Amendment.

During the nine months ended September 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 nine months ended September 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 nine months ended September 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	1,233,500	\$ 16.31	
Exercised	(491,165)	\$ 5.83	
Canceled	(14,768)	\$ 7.00	
Options Outstanding at September 30, 2013	<u>6,077,377</u>	\$ 8.09	7.0
Options Vested and Expected to Vest at September 30, 2013	6,008,723	\$ 8.04	7.0
Options Exercisable at September 30, 2013	3,435,954	\$ 6.50	5.4
Shares Available for Grant under the 2008 Plan	2,121,349		

10

## [Table of Contents](#)

The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2013 was \$10.47. Stock-based compensation expense for the three and nine months ended September 30, 2013 and 2012 was recorded as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
	(In thousands)			
Research and development	\$ 1,326	\$ 330	\$ 2,190	\$ 1,010
General and administrative	690	195	1,210	604
Total stock-based compensation expense	<u>\$ 2,016</u>	<u>\$ 525</u>	<u>\$ 3,400</u>	<u>\$ 1,614</u>

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

	Three Months Ended September 30,		Nine Months Ended September 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	1.9 - 2.0%	1.2 - 1.3%	1.2 - 2.0%	0.9 - 1.4%
Expected dividend yield	None	None	None	None

## (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 September 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 September 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, if we obtain regulatory approval, commercialization of rindopepimut (referred to as CDX-110), glembatumumab vedotin (referred to as glemba or 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 ACT IV and ReACT for rindopepimut and METRIC for glemba;
- the cost, timing, scope and results of ongoing safety and efficacy trials of rindopepimut, glemba, and other preclinical and clinical testing;
- our ability to fund and complete the development and, if we obtain regulatory approval, commercialization of rindopepimut and glemba for North America internally;
- the ability to negotiate strategic partnerships, where appropriate, for our programs which may include rindopepimut and glemba 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, suppliers and partners, who may be the sole source of supply;
- 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;

## [Table of Contents](#)

- 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.

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 (referred to as CDX-110) and glembatumumab vedotin (referred to as glemba or 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. Glemba 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 by year-end 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>			
Rindopepimut	Front-line glioblastoma	—	Phase 3
Glembatumumab vedotin	Metastatic breast cancer and melanoma	—	Phase 2b
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:

13

## [Table of Contents](#)

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:

- 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 nine months ended September 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.

[Table of Contents](#)

	Nine Months Ended September 30,	
	2013	2012
	(In thousands)	
Rindopepimut	\$ 28,144	\$ 17,396
Glembatumumab vedotin	7,695	3,437
CDX-1135	1,103	6,321
CDX-1127	6,944	3,043
CDX-301	344	1,143
CDX-1401	497	827
CDX-014	706	612
Other Programs	4,164	871
<b>Total R&amp;D Expense</b>	<b>\$ 49,597</b>	<b>\$ 33,650</b>

**Clinical Development Programs***Rindopepimut (CDX-110)*

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.

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

	Medium (months)	OS at 3 years
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)	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 regimen 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. We continue to actively enroll newly diagnosed patients with GB in ACT IV.

In December 2011, we also initiated ReACT, a Phase 2 study of rindopepimut in combination with Avastin<sup>®</sup> in patients with recurrent EGFRvIII-positive GB. ReACT was initially planned to enroll approximately 95 patients in a first or second relapse of GB following receipt of standard therapy at approximately 25 sites across the United States. In August 2013, we announced that we decided to add an expansion cohort of approximately 75 patients to better characterize the potential activity of rindopepimut in this refractory patient population. This decision was based on early evidence of anti-tumor activity, including stable disease, tumor shrinkage and investigator-reported response. As amended, the ReACT study will now enroll approximately 170 patients across three groups. 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 100 patients, including the expansion cohort of 75 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. Study endpoints include 6 month progression free survival rate, objective response rate, overall survival and safety and tolerability.

We expect to report data from the ReACT study at the Society for Neuro-Oncology Annual Meeting and provide a rindopepimut program update in November 2013.

#### *Glembatumumab Vedotin (glemba or CDX-011)*

Glemba 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, glemba targets and binds to GPNMB and upon internalization into

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

the targeted cell, glemba is designed to release MMAE from CR011 to produce a cell-killing effect. The FDA has granted Fast Track designation to glemba 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 glemba 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 glemba 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 glemba in 122 patients with heavily pre-treated, advanced, GPNMB positive breast cancer. Patients were randomized (2:1) to receive either glemba or single-agent Investigator’s Choice, or IC, chemotherapy. Patients randomized to receive IC were allowed to cross over to receive glemba 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 glemba 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 glemba 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	Triple Negative

	Over-Expression								and GPNMB Over-Expression			
	CDX-011		IC		CDX-011		IC		CDX-011		IC	
	(n=81)	(n=36)	(n=27)	(n=9)	(n=25)	(n=8)	(n=12)	(n=4)	(n=12)	(n=4)		
Response	16%	14%	19%	0%	32%	13%	33%	0%	33%	33%	0%	
Disease Control Rate	57%	53%	67%	33%	64%	38%	75%	25%	75%	25%		

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

[Table of Contents](#)

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

	On target effect clearly demonstrated in targeted patient populations							
	All Patients		Triple Negative		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 glemba (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 glemba 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 glemba 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 glemba program. Based on this meeting, we intend to initiate METRIC, a randomized, accelerated approval study of glemba in patients with triple negative breast cancer that over-express GPNMB in the fourth quarter 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 glemba 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. Glemba 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 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 glemba for the treatment of breast cancer while pursuing further development of glemba 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 pilot study. We initiated 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 anticipate presenting a program update in February 2014.

[Table of Contents](#)

**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. In July 2013, the United States Patent and Trademark Office issued a patent to the University of Southampton, that we have exclusive license to under our license agreement, which broadly supports CDX-1127. The patent includes 18 claims covering various methods of treating cancer using agonistic anti-human CD27 antibodies and relates, among other things, directly to our CD27 antibody program and therapeutic uses of CDX-1127.

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. In November 2013 at the Society for Immunotherapy of Cancer (SITC) Annual Meeting, we reported data from our ongoing Phase 1 dose-escalation study. The results suggest a favorable safety profile with no evidence of immune related toxicities. Clear biologic activity and promising signs of clinical activity were demonstrated in an advanced, refractory patient population including a complete response in Hodgkin disease, two additional patients with significant tumor shrinkage and eight patients with stable disease or better (PFS range of 3.0 to 14+ months). No maximum tolerated dose was reached to date and immune monitoring data in patients confirmed CDX-1127's mechanism of action. After we complete the dose-escalation study and corresponding expansion cohorts, we intend to initiate additional studies of CDX-1127, with an initial focus on combination studies.

#### *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 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 clinical study of CDX-301 in hematopoietic stem cell transplant in early 2014.

#### *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

---

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

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. We are planning a collaborative Phase 2 study of CDX-1401 in combination with CDX-301 in malignant melanoma. This study will be conducted under a cooperative research and development agreement with the Cancer Immunotherapy Trials Network and the Cancer Therapy Evaluation Program of the National Cancer Institute.

#### **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.

## RESULTS OF OPERATIONS

### Three Months Ended September 30, 2013 compared with Three Months Ended September 30, 2012

	Three Months Ended September 30,		Increase/ (Decrease) \$	Increase/ (Decrease) %
	2013	2012		
(In thousands)				
<b>Revenue:</b>				
Product Development and Licensing Agreements	\$ 40	\$ 28	\$ 12	43%
Contracts and Grants	940	79	861	1,090%
Product Royalties	—	3,006	(3,006)	(100)%
<b>Total Revenue</b>	<b>\$ 980</b>	<b>\$ 3,113</b>	<b>\$ (2,133)</b>	<b>(69)%</b>
<b>Operating Expense:</b>				
Research and Development	20,417	11,769	8,648	73%
Royalty	—	3,006	(3,006)	(100)%
General and Administrative	3,578	2,835	743	26%
Amortization of Acquired Intangible Assets	254	254	—	n/a
<b>Total Operating Expense</b>	<b>24,249</b>	<b>17,864</b>	<b>6,385</b>	<b>36%</b>
Operating Loss	(23,269)	(14,751)	8,518	58%
Investment and Other Income, Net	142	105	37	35%
Interest Expense	(13)	(381)	(368)	(97)%
<b>Net Loss</b>	<b>\$ (23,140)</b>	<b>\$ (15,027)</b>	<b>\$ 8,113</b>	<b>54%</b>

#### Net Loss

The \$8.1 million increase in net loss for the three months ended September 30, 2013 compared to the three months ended September 30, 2012 was primarily the result of an increase in research and development expenses.

#### Revenue

The \$3.0 million decrease in product royalty revenue for the three months ended September 30, 2013 compared to the three months ended September 30, 2012 was related to our retained interests in Rotarix® 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

### [Table of Contents](#)

expiration of the last relevant patent right covered by the Glaxo agreement. We do not expect additional Rotarix royalty revenue. The \$0.9 million increase in contracts and grants revenue for the three months ended September 30, 2013 compared to the three months ended September 30, 2012 was primarily related to our Rockefeller University agreement pursuant to which we perform research and development services for Rockefeller. The agreement includes an approved project plan for the development services of \$4.8 million and a term of three years.

#### 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 September 30,		Increase/ (Decrease) \$	Increase/ (Decrease) %
	2013	2012		
(In thousands)				
Personnel	\$ 4,999	\$ 3,285	\$ 1,714	52%
Laboratory Supplies	968	543	425	78%
Facility	1,110	1,104	6	1%
Product Development	12,447	5,966	6,481	109%

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The \$1.7 million increase in personnel expenses for the three months ended September 30, 2013 compared to the three months ended September 30, 2012 was primarily due to higher stock-based compensation of \$1.0 million and increased 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 glemba 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 September 30, 2013 compared to the three months ended September 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.

Facility expenses include depreciation, amortization, utilities, rent, maintenance, and other related expenses incurred at our facilities. Facility expenses for the three months ended September 30, 2013 were relatively consistent as compared to the three months ended September 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 future headquarters 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 \$6.5 million increase in product development expenses for the three months ended September 30, 2013 compared to the three months ended September 30, 2012 was primarily the result of an increase in clinical trial costs and contract manufacturing of \$3.1 million and \$3.3 million, respectively, primarily related to our rindopepimut and glemba programs. 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 glemba 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 \$3.0 million decrease in royalty expenses for the three months ended September 30, 2013 compared to the three months ended September 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 \$0.7 million increase in general and administrative expenses for the three months ended September 30, 2013 compared to the three months ended September 30, 2012 was primarily due to higher stock-based compensation of \$0.5 million and increased

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

headcount. We expect general and administrative expense to increase over the next twelve months primarily due to increased commercial planning efforts for rindopepimut and glemba, although there may be fluctuations on a quarterly basis.

#### Amortization Expense

Amortization expenses for the three months ended September 30, 2013 were relatively consistent compared to the three months ended September 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 September 30, 2013 was relatively consistent as compared to the three months ended September 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 \$0.4 million decrease in interest expense for the three months ended September 30, 2013 compared to the three months ended September 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 remain relatively consistent over the next twelve months.

#### Nine Months Ended September 30, 2013 compared with Nine Months Ended September 30, 2012

	Nine Months Ended September 30,		Increase/ (Decrease) \$	Increase/ (Decrease) %
	2013	2012		
(In thousands)				
<b>Revenue:</b>				
Product Development and Licensing Agreements	\$ 117	\$ 103	\$ 14	14%
Contracts and Grants	1,040	228	812	356%
Product Royalties	2,334	7,224	(4,890)	(68)%
<b>Total Revenue</b>	<b>\$ 3,491</b>	<b>\$ 7,555</b>	<b>\$ (4,064)</b>	<b>(54)%</b>
<b>Operating Expense:</b>				
Research and Development	49,597	33,650	15,947	47%
Royalty	2,334	7,224	(4,890)	(68)%
General and Administrative	10,128	7,372	2,756	37%
Amortization of Acquired Intangible Assets	760	836	(76)	(9)%
<b>Total Operating Expense</b>	<b>62,819</b>	<b>49,082</b>	<b>13,737</b>	<b>28%</b>
Operating Loss	(59,328)	(41,527)	17,801	43%
Investment and Other Income, Net	682	436	246	56%
Interest Expense	(842)	(1,225)	(383)	(31)%
<b>Net Loss</b>	<b>\$ (59,488)</b>	<b>\$ (42,316)</b>	<b>\$ 17,172</b>	<b>41%</b>

#### Net Loss

The \$17.2 million increase in net loss for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 was primarily the result of an increase in research and development and general and administrative expenses.

#### Revenue

The \$4.9 million decrease in product royalty revenue for the nine months ended September 30, 2013 compared to the nine months ended September 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. The \$0.8 million increase in contracts and grants revenue for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 was related to our Rockefeller University agreement.

[Table of Contents](#)

*Research and Development Expense*

	Nine Months Ended September 30,		Increase/ (Decrease) \$	Increase/ (Decrease) %
	2013	2012		
	(In thousands)			
Personnel	\$ 12,617	\$ 9,923	\$ 2,694	27%
Laboratory Supplies	2,609	1,504	1,105	73%
Facility	3,369	3,405	(36)	(1)%
Product Development	28,831	16,642	12,189	73%

The \$2.7 million increase in personnel expenses for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 was primarily due to higher stock-based compensation of \$1.2 million and increased headcount.

The \$1.1 million increase in laboratory supply expense for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 was primarily due to higher manufacturing supply purchases.

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

The \$12.2 million increase in product development expenses for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 was primarily the result of an increase in clinical trial costs and contract manufacturing of \$7.1 million and \$5.0 million, respectively, primarily related to our rindopepimut and glemba programs.

*Royalty Expense*

The \$4.9 million decrease in royalty expenses for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 was due to a decrease in Rotarix<sup>®</sup> related royalty fees.

*General and Administrative Expense*

The \$2.8 million increase in general and administrative expenses for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 was primarily due to higher stock-based compensation of \$0.6 million, increased headcount and rindopepimut-related commercial planning costs.

*Amortization Expense*

The \$0.1 million decrease in amortization expenses for the nine months ended September 30, 2013 compared to the nine months ended September 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 nine months ended September 30, 2013 was primarily due to higher levels of cash, cash equivalents and marketable securities compared to the nine months ended September 30, 2012 and us recognizing \$0.2 million and \$0.1 million in other income related to the sale of New Jersey tax benefits during the nine months ended September 30, 2013 and 2012, respectively.

*Interest Expense*

The \$0.4 million decrease in interest expense for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 was primarily due to our election in May 2013 to prepay the Term Loan in full, pursuant to the terms of our Loan Agreement.

**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.

[Table of Contents](#)

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 September 30, 2013, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of \$136.6 million. Our working capital at September 30, 2013 was \$123.2 million. We incurred a loss of \$59.5 million for the nine months ended September 30, 2013. Net cash used in operations for the nine months ended September 30, 2013 was \$52.7 million. We believe that the cash, cash equivalents and marketable securities at September 30, 2013 are sufficient to fund planned operations into late 2015. Expected cash burn has increased as a result of our recent expansion of the ReACT study, the planned initiation of the METRIC study and our substantial expansion of manufacturing activities with our commercial suppliers to support our pivotal studies in rindopepimut and glemba.

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 \$52.7 million for the nine months ended September 30, 2013 compared to \$36.5 million for the nine months ended September 30, 2012. The increase in net cash used in operating activities was primarily due to an increase in net loss of \$17.2 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 glemba programs, although there may be fluctuations on a quarterly basis.

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 \$63.6 million for the nine months ended September 30, 2013 compared to \$12.4 million for the nine months ended September 30, 2012. The increase in net cash used in investing activities was primarily due to net purchases of marketable securities for the nine months ended September 30, 2013 of \$61.7 million as compared to \$12.5 million for the nine months ended September 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 \$106.0 million for the nine months ended September 30, 2013 compared to \$60.2 million for the nine months ended September 30, 2012. Net proceeds from stock issuances, including stock issued pursuant to employee benefit plans, were \$117.1 million during the nine months ended September 30, 2013 compared to \$62.9 million for the nine months ended September 30, 2012. We paid \$11.0 million in principal payments on our Term Loan during the nine months ended September 30, 2013 compared to \$2.6 million for the nine months ended September 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.

---

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

#### *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 nine months ended September 30, 2012, we issued 4,425,000 shares of common stock under the Cantor agreement and raised \$19.0 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 nine months ended September 30, 2013, we issued 2,433,608 shares under the Cantor amendment and raised \$17.1 million in net proceeds. At September 30, 2013, we had \$4.4 million remaining in aggregate offering price available under the Cantor amendment.

During the nine months ended September 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 nine months ended September 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.

## **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 September 30, 2013 due to the short-term maturities of these instruments.

## [Table of Contents](#)

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

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

As of September 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 September 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 September 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 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.

[Table of Contents](#)

Item 6.	Exhibits
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.
*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)

/s/ AVERY W. CATLIN

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

Dated: November 8, 2013

Dated: November 8, 2013

[Table of Contents](#)

**EXHIBIT INDEX**

Exhibit

Description

<u>No.</u>	
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.
*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.

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: November 8, 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: November 8, 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: November 8, 2013

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

Date: November 8, 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.

---