
**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, 2012

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 30, 2012, 61,975,120 shares of common stock, \$.001 par value per share, were outstanding.

CELLDEX THERAPEUTICS, INC.

FORM 10-Q

Quarter Ended September 30, 2012

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Item 1. Unaudited Financial Statements**CELLDEX THERAPEUTICS, INC.**
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)**(In thousands, except share and per share amounts)**

	<u>September 30, 2012</u>	<u>December 31, 2011</u>
ASSETS		
Current Assets:		
Cash and Cash Equivalents	\$ 23,187	\$ 11,899
Marketable Securities	54,428	41,413
Accounts and Other Receivables	32	170
Prepaid and Other Current Assets	1,163	1,202
Total Current Assets	<u>78,810</u>	<u>54,684</u>
Property and Equipment, Net	7,566	9,093
Intangible Assets, Net	24,087	24,923
Other Assets	409	329
Goodwill	8,965	8,965
Total Assets	<u>\$ 119,837</u>	<u>\$ 97,994</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	\$ 1,281	\$ 935
Accrued Expenses	8,157	7,008
Current Portion of Long-Term Liabilities	399	219
Current Portion of Term Loan	5,294	6,136
Total Current Liabilities	<u>15,131</u>	<u>14,298</u>
Term Loan, less Current Portion	7,326	9,008
Other Long-Term Liabilities	6,365	5,966
Total Liabilities	<u>28,822</u>	<u>29,272</u>
Commitments and Contingent Liabilities		
Stockholders' Equity:		
Convertible Preferred Stock, \$.01 Par Value; 3,000,000 Shares Authorized; No Shares Issued and Outstanding at September 30, 2012 and December 31, 2011	—	—
Common Stock, \$.001 Par Value; 297,000,000 Shares Authorized; 60,807,350 and 44,210,636 Shares Issued and Outstanding at September 30, 2012 and December 31, 2011, respectively	61	44
Additional Paid-In Capital	335,501	271,032
Accumulated Other Comprehensive Income	2,775	2,652
Accumulated Deficit	(247,322)	(205,006)
Total Stockholders' Equity	<u>91,015</u>	<u>68,722</u>
Total Liabilities and Stockholders' Equity	<u>\$ 119,837</u>	<u>\$ 97,994</u>

See accompanying notes to unaudited condensed consolidated financial statements

CELLEX 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, 2012	September 30, 2011	September 30, 2012	September 30, 2011
REVENUE:				
Product Development and Licensing Agreements	\$ 28	\$ 40	\$ 103	\$ 65
Contracts and Grants	79	5	228	5
Product Royalties	3,006	2,318	7,224	6,761
Total Revenue	<u>3,113</u>	<u>2,363</u>	<u>7,555</u>	<u>6,831</u>
OPERATING EXPENSE:				
Research and Development	11,769	8,594	33,650	22,615
Royalty	3,006	2,318	7,224	6,761
General and Administrative	2,835	2,273	7,372	6,849
Amortization of Acquired Intangible Assets	254	656	836	1,622
Total Operating Expense	<u>17,864</u>	<u>13,841</u>	<u>49,082</u>	<u>37,847</u>
Operating Loss	(14,751)	(11,478)	(41,527)	(31,016)
Investment and Other Income, Net	105	144	436	307
Interest Expense	(381)	(438)	(1,225)	(1,358)
Net Loss	<u>\$ (15,027)</u>	<u>\$ (11,772)</u>	<u>\$ (42,316)</u>	<u>\$ (32,067)</u>
Basic and Diluted Net Loss Per Common Share (Note 3)	<u>\$ (0.25)</u>	<u>\$ (0.27)</u>	<u>\$ (0.75)</u>	<u>\$ (0.85)</u>
Shares Used in Calculating Basic and Diluted Net Loss per Share (Note 3)	<u>59,467</u>	<u>44,136</u>	<u>56,090</u>	<u>37,926</u>
COMPREHENSIVE LOSS:				
Net Loss	\$ (15,027)	\$ (11,772)	\$ (42,316)	\$ (32,067)
Other Comprehensive (Loss) Income:				
Foreign Currency Translation Adjustments	1	(3)	2	(8)
Unrealized Gain (Loss) on Marketable Securities	52	(117)	121	(89)
Comprehensive Loss	<u>\$ (14,974)</u>	<u>\$ (11,892)</u>	<u>\$ (42,193)</u>	<u>\$ (32,164)</u>

See accompanying notes to unaudited condensed consolidated financial statements

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

(In thousands)

	Nine Months Ended	
	September 30, 2012	September 30, 2011
Cash Flows from Operating Activities:		
Net Loss	\$ (42,316)	\$ (32,067)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation and Amortization	1,576	1,696
Amortization of Intangible Assets	836	1,622
Amortization and Premium of Marketable Securities	(420)	(96)
Realized (Gain) Loss on Sales and Maturities of Marketable Securities	(6)	5
Gain on Sale or Disposal of Assets	(74)	(58)
Stock-Based Compensation Expense	1,614	1,703
Non-Cash Interest Expense	169	250
Changes in Operating Assets and Liabilities:		
Accounts and Other Receivables	138	120
Prepaid and Other Current Assets	(8)	58
Other Assets	(80)	15
Accounts Payable and Accrued Expenses	1,495	556
Other Liabilities	620	(92)
Net Cash Used in Operating Activities	<u>(36,456)</u>	<u>(26,288)</u>
Cash Flows from Investing Activities:		
Sales and Maturities of Marketable Securities	45,432	38,353
Purchases of Marketable Securities	(57,900)	(48,217)
Acquisition of Property and Equipment	(193)	(403)
Proceeds from Sale or Disposal of Assets	218	68
Net Cash Used in Investing Activities	<u>(12,443)</u>	<u>(10,199)</u>
Cash Flows from Financing Activities:		
Net Proceeds from Stock Issuances	62,872	35,880
(Payments) Issuance of Term Loan	(2,646)	5,000
Payment of Convertible Subordinated Debt	—	(12,503)
Payments of Other Liabilities	(41)	(72)
Net Cash Provided by Financing Activities	<u>60,185</u>	<u>28,305</u>
Effect of Exchange Rate Changes on Cash and Cash Equivalents	<u>2</u>	<u>(8)</u>
Net Increase (Decrease) in Cash and Cash Equivalents	11,288	(8,190)
Cash and Cash Equivalents at Beginning of Period	11,899	21,287
Cash and Cash Equivalents at End of Period	<u>\$ 23,187</u>	<u>\$ 13,097</u>

See accompanying notes to unaudited condensed consolidated financial statements

CELLEX THERAPEUTICS, INC.
Notes to Unaudited Condensed Consolidated Financial Statements
September 30, 2012

(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, 2011, which are included in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (“SEC”) on March 8, 2012. 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, 2012.

At September 30, 2012, the Company had cash, cash equivalents and marketable securities of \$77.6 million; working capital of \$63.7 million; and a Term Loan balance of \$12.6 million. The Company incurred a loss of \$42.3 million for the nine months ended September 30, 2012. Net cash used in operations for the nine months ended September 30, 2012 was \$36.5 million. The Company believes that the cash, cash equivalents and marketable securities at September 30, 2012 will be sufficient to meet estimated working capital requirements and fund planned operations for at least the next twelve months.

The Company raised net proceeds of \$62.9 million during the nine months ended September 30, 2012 from the issuance of its common stock. 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. If the Company is unable to raise the funds necessary to meet its long-term liquidity needs, it 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 a part of the Company.

(2) Significant Accounting Policies

The significant accounting policies used in preparation of these condensed consolidated financial statements for the nine months ended September 30, 2012 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, 2011, except for the adoption of new accounting standards during the first nine months of 2012 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 2012, the Company adopted a new U.S. GAAP accounting standard which amended the guidance on the annual testing of goodwill for impairment. The amended guidance allows companies to assess qualitative factors to determine if it is more likely than not that goodwill might be impaired and whether it is necessary to perform the two-step goodwill impairment test required under U.S. GAAP. The Company’s adoption of this new standard did not have a material effect on its operating results or financial position.

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In January 2012, the Company adopted a new U.S. GAAP accounting standard which clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. The Company's adoption of this standard did not have a material impact on its operating results or financial position.

In July 2012, the FASB issued amended guidance applicable to annual impairment tests of indefinite-lived intangible assets. The FASB 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. This amended guidance will be effective for annual impairment tests performed by the Company for fiscal years beginning on January 1, 2013.

(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:

	Nine months ended September 30,	
	2012	2011
Stock options	5,351,999	4,535,137
Restricted stock	9,000	9,000
	<u>5,360,999</u>	<u>4,544,137</u>

(4) Fair Value Measurements

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

	As of			
	September 30, 2012	Level 1	Level 2	Level 3
	(In thousands)			
Money market funds and cash equivalents	\$ 18,278	\$ 18,278	—	—
Marketable securities	\$ 54,428	—	\$ 54,428	—
	<u>\$ 72,706</u>	<u>\$ 18,278</u>	<u>\$ 54,428</u>	<u>—</u>

	As of			
	December 31, 2011	Level 1	Level 2	Level 3
	(In thousands)			
Money market funds and cash equivalents	\$ 11,038	\$ 11,038	—	—
Marketable securities	\$ 41,413	—	\$ 41,413	—
	<u>\$ 52,451</u>	<u>\$ 11,038</u>	<u>\$ 41,413</u>	<u>—</u>

There have been no transfers of assets or liabilities between the fair value measurement classifications. The Company's financial instruments consist mainly of cash and cash equivalents, marketable securities, short-term accounts receivable, accounts payable and debt obligations. The Company values its marketable securities utilizing independent pricing services which normally derive security prices from recently reported trades for identical or similar securities, making adjustments based on significant observable transactions. At each balance sheet date, observable market inputs may include trade information, broker or dealer quotes, bids, offers or a combination of these data sources. Short-term accounts receivable and accounts payable are reflected in the accompanying consolidated financial statements at cost, which approximates fair value due to the short-term nature of these instruments. Our Term Loan is valued based on level 2 inputs. Based on these calculations, the fair value approximates the carrying value of the Term Loan and note payable at September 30, 2012.

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(5) Marketable Securities

A summary of marketable securities is shown below:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
(In thousands)				
September 30, 2012				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	\$ 12,338	\$ 28	\$ 2	\$ 12,364
Maturing after one year through three years	17,297	114	1	17,410
Total U.S. government and municipal obligations	<u>\$ 29,635</u>	<u>\$ 142</u>	<u>\$ 3</u>	<u>\$ 29,774</u>
Corporate debt securities				
Maturing in one year or less	\$ 17,817	\$ 39	\$ 3	\$ 17,853
Maturing after one year through three years	6,790	13	2	6,801
Total corporate debt securities	<u>\$ 24,607</u>	<u>\$ 52</u>	<u>\$ 5</u>	<u>\$ 24,654</u>
Total marketable securities	<u>\$ 54,242</u>	<u>\$ 194</u>	<u>\$ 8</u>	<u>\$ 54,428</u>
December 31, 2011				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	\$ 19,993	\$ 20	\$ —	\$ 20,013
Maturing after one year through three years	10,808	122	6	10,924
Total U.S. government and municipal obligations	<u>\$ 30,801</u>	<u>\$ 142</u>	<u>\$ 6</u>	<u>\$ 30,937</u>
Corporate debt securities				
Maturing in one year or less	\$ 5,817	\$ 3	\$ 4	\$ 5,816
Maturing after one year through three years	4,730	2	72	4,660
Total corporate debt securities	<u>\$ 10,547</u>	<u>\$ 5</u>	<u>\$ 76</u>	<u>\$ 10,476</u>
Total marketable securities	<u>\$ 41,348</u>	<u>\$ 147</u>	<u>\$ 82</u>	<u>\$ 41,413</u>

The marketable securities held by the Company were high investment grade and there were no marketable securities that the Company considered to be other-than-temporarily impaired as of September 30, 2012.

(6) Intangible Assets and Goodwill

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

	Estimated Life	September 30, 2012			December 31, 2011		
		Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
(In thousands)							
Intangible Assets:							
IPR&D	Indefinite	\$ 11,800	—	\$ 11,800	\$ 11,800	—	\$ 11,800
Amgen Amendment	16 years	14,500	\$ (2,691)	11,809	14,500	\$ (2,018)	12,482
Core Technology	11 years	1,296	(818)	478	1,948	(1,307)	641
Total Intangible Assets		<u>\$ 27,596</u>	<u>\$ (3,509)</u>	<u>\$ 24,087</u>	<u>\$ 28,248</u>	<u>\$ (3,325)</u>	<u>\$ 24,923</u>
Goodwill	Indefinite	<u>\$ 8,965</u>	<u>—</u>	<u>\$ 8,965</u>	<u>\$ 8,965</u>	<u>—</u>	<u>\$ 8,965</u>

(7) Term Loan

In December 2010, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with MidCap Financial, LLC (MidCap) pursuant to which the Company borrowed \$10 million (the "Term Loan") from MidCap. In March 2011, as the Company had anticipated, the Company amended the Loan Agreement and borrowed an additional \$5 million from General Electric Capital Corporation (GECC) (collectively with MidCap, the "Lenders") to increase the amount owed under the Term Loan to \$15 million. No additional advances are available under the Loan Agreement. The Term Loan accrues interest at a fixed annual interest rate equal to the greater of (i) the sum of (A) the LIBOR Rate (as defined in the Loan Agreement) plus (B) 6.25%; or (ii) a minimum rate of 9.50%. In September 2011, the Company exercised an option to extend the interest-only period by 6 months from October 1, 2011 to April 1, 2012. In March 2012, the Company amended the Loan Agreement to extend the maturity date from December 2013 to December 2014 in return for an upfront fee of \$25,000 and an additional fee of \$37,500 (the "Final Payment Fee")

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due upon repayment of the Term Loan in full. The Company is accreting the Final Payment Fee ratably over the amended term of the Term Loan to interest expense.

Interest on the Term Loan is payable monthly and principal is due, as amended, in 34 equal consecutive monthly installments commencing on April 1, 2012. All unpaid principal and accrued interest with respect to the Term Loan is due and payable on the earlier of (A) December 30, 2014 or (B) the date that the Term Loan otherwise becomes due and payable under the terms of the Loan Agreement. The Company may prepay all, but not less than all, of the Term Loan subject to a prepayment premium of 1% in year three and 2% in year two of the original principal amount of the Term Loan. There is no prepayment premium if the loan is paid off early in year four. The Company is also obligated to make a payment fee of \$0.5 million (the "Payment Fee") upon the earlier of (A) December 30, 2013 or (B) upon repayment of the Term Loan in full prior to December 30, 2013. The Company is accreting the Payment Fee ratably over the original term of the Term Loan to interest expense.

The obligations of the Company under the Loan Agreement are secured by a first priority lien upon and security interest in substantially all of the Company's existing and after-acquired assets, excluding its intellectual property assets. Under the Loan Agreement, the Company is subject to specified affirmative and negative covenants customary for financings of this type. The Loan Agreement provides that, upon the occurrence of certain specified events of default customary for financings of this type, the Company's obligations under the Loan Agreement may be automatically accelerated, whereupon the Company's obligations under the Loan Agreement shall be immediately due and payable. At September 30, 2012, the Company believes it is in compliance with the Loan Agreement.

Interest expense on the Term Loan including the accretion of the Payment Fee and Final Payment Fee and amortization of the deferred financing costs was \$0.4 million and \$1.2 million for the three and nine months ended September 30, 2012 and \$0.4 million and \$1.2 million for the three and nine months ended September 30, 2011, respectively.

(8) Other Long-Term Liabilities

Other long-term liabilities include the following:

	September 30, 2012	December 31, 2011
	(In thousands)	
Deferred Rent	\$ 434	\$ 435
Net Deferred Tax Liability	4,661	4,661
Deferred Income from Sale of Tax Benefits	1,118	510
Loan Payable	486	527
Other	65	52
Total	6,764	6,185
Less Current Portion	(399)	(219)
Long-Term Portion	\$ 6,365	\$ 5,966

In January 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 and \$0.6 million to an independent third party for \$0.7 million and \$0.5 million, respectively. Under the agreement, the Company must maintain a base of operations in NJ 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, 2012, the Company recorded \$0.1 million to other income related to the sale of these tax benefits.

(9) Stockholders' Equity

In January 2011, the Company entered into a controlled equity offering sales agreement (the "Cantor Agreement") with Cantor Fitzgerald & Co. ("Cantor") 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 year ended December 31, 2011, the Company issued 575,000 shares of common stock under the Cantor Agreement and raised \$2.2 million in net proceeds, after deducting commission and offering expenses. In January 2012, the Company issued 2,450,000 shares of common stock under the Cantor Agreement and raised \$8.5 million in net proceeds. During the three months ended September 30, 2012, the Company issued the remaining 1,975,000 shares available to be sold under the Cantor Agreement and raised \$10.6 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 from time to time through Cantor, acting as agent. 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, as agent. The Cantor Amendment terminates upon ten day notice by either Cantor or the Company. In September and October 2012, the Company issued 57,100 and 1,167,770 shares

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under the Cantor Amendment and raised \$0.3 million and \$7.0 million in net proceeds, respectively. At October 30, 2012, the Company had \$36.4 million remaining in aggregate offering price available under the Cantor Amendment.

During February and March 2012, the Company issued a total of 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.

(10) Stock-Based Compensation

At September 30, 2012, the 2008 Stock Option and Incentive Plan allowed for a maximum of 7,400,000 shares of common stock to be issued for grants of Stock Options and other Awards made prior to March 7, 2018 and grants of Incentive Stock Options made prior to October 20, 2017.

A summary of stock option activity for the nine months ended September 30, 2012 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In Years)
Options Outstanding at December 31, 2011	4,459,034	\$ 6.08	6.9
Granted	1,115,700	\$ 5.84	
Exercised	(21,679)	\$ 2.61	
Canceled	(201,056)	\$ 8.22	
Options Outstanding at September 30, 2012	<u>5,351,999</u>	\$ 5.97	7.2
Options Vested and Expected to Vest at September 30, 2012	5,273,241	\$ 5.98	7.1
Options Exercisable at September 30, 2012	3,190,776	\$ 6.77	5.9
Shares Available for Grant under the 2008 Plan	3,380,865		

The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2012 was \$3.67. Stock-based compensation expense for the three and nine months ended September 30, 2012 and 2011 was recorded as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
	(In thousands)			
Research and development	\$ 330	\$ 327	\$ 1,010	\$ 1,032
General and administrative	195	243	604	671
Total stock-based compensation expense	<u>\$ 525</u>	<u>\$ 570</u>	<u>\$ 1,614</u>	<u>\$ 1,703</u>

The fair values of employee stock options granted during the three and nine months ended September 30, 2012 and 2011 were valued using the Black-Scholes option-pricing model with the following assumptions:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Expected stock price volatility	71%	70%	70 - 71%	68 - 70%
Expected option term	6.0 years	6.0 years	6.0 years	6.0 years
Risk-free interest rate	1.2 - 1.3%	1.9 - 2.5%	0.9 - 1.4%	1.9 - 2.9%
Expected dividend yield	None	None	None	None

(11) 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, 2012 and December 31, 2011 against the Company's net deferred tax assets.

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 raise sufficient capital to fund our clinical studies to meet our long-term liquidity needs, on terms acceptable to us, or at all;
- our ability to successfully complete research and further development, including animal, preclinical and clinical studies, and commercialization of rindopepimut, CDX-011, CDX-1127, and other drug candidates and the growth of the markets for those drug candidates;
- our ability to manage multiple clinical trials for a variety of drug candidates at different stages of development, including our Phase 3 trial for rindopepimut;
- the cost, timing, scope and results of ongoing safety and efficacy trials of rindopepimut, CDX-011, CDX-1127 and other preclinical and clinical testing;
- our ability to fund and complete the development and commercialization of rindopepimut for North America internally and to find a strategic partner to commercialize rindopepimut outside of North America;
- the ability to negotiate strategic partnerships, where appropriate, for our lead programs, including CDX-011 and CDX-1127, as well as for our non-core programs;
- the strategies and business plans of our partners, such as GlaxoSmithKline's plans with respect to Rotarix[®] and Vaccine Technologies' plans concerning the CholeraGarde[®] (Peru-15) and ETEC E. coli vaccines, which are not within our control, and our ability to maintain strong, mutually beneficial relationships with these partners;
- our ability to adapt our proprietary antibody-targeted vaccine technology, or APC Targeting Technology[™], to develop new, safe and effective vaccines against oncology and infectious disease indications;
- our ability to develop technological capabilities and expand our focus to broader markets for vaccines;
- the availability, cost, delivery and quality of clinical and commercial grade materials produced by our own manufacturing facility or supplied by contract manufacturers and partners;
- the availability, cost, delivery and quality of clinical management services provided by our clinical research organization partners;
- the timing, cost and uncertainty of obtaining regulatory approvals for our drug candidates;
- our ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors;
- the validity of our patents and our ability to avoid intellectual property litigation, which can be costly and divert management time and attention; and
- the factors listed under the headings "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's annual report on Form 10-K for the year ended December 31, 2011 and other reports that we file with the Securities and Exchange Commission.

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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 lead drug candidates include rindopepimut (CDX-110), an immunotherapeutic vaccine in a pivotal Phase 3 study for the treatment of front-line glioblastoma and a Phase 2 study for the treatment of recurrent glioblastoma, CDX-011, an antibody-drug conjugate which recently completed a randomized Phase 2b study for the treatment of advanced breast cancer and CDX-1127, a therapeutic human antibody in a Phase 1 study for cancer indications. We have additional clinical and preclinical programs, including CDX-1401, an APC Targeting Technology™ program, CDX-301, an immune cell mobilizing agent and dendritic cell growth factor and CDX-1135, a molecule that inhibits a part of the immune system called the complement system. Our drug candidates address market opportunities for which we believe current therapies are inadequate or non-existent.

Generally our strategy is to develop and demonstrate proof-of-concept for our drug candidates before leveraging their value through partnerships or, in appropriate situations, continuing late stage development through commercialization ourselves. Demonstrating proof-of-concept for a drug candidate generally involves bringing it through Phase 1 clinical trials and one or more Phase 2 clinical trials so that we are able to demonstrate, based on human trials, good safety data for the drug candidate and some data indicating its effectiveness. We thus leverage the value of our technology portfolio through corporate, governmental and non-governmental 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. Our current collaborations include the commercialization of an oral human rotavirus vaccine. We are exploring potential development and commercialization collaborations for certain drug candidates such as CDX-011 and CDX-1127. Furthermore, while we plan to retain the rights to develop and commercialize rindopepimut in North America, we are exploring potential partnership opportunities to commercialize rindopepimut outside of North America.

Our products 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. A number of our immunotherapeutic and antibody-drug conjugate drug candidates are in various stages of clinical trials. We expect that a large percentage of our research and development expenses will be incurred in support of our current and future clinical trial programs.

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

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

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. Our estimates that clinical trials of the type we generally conduct are typically completed over the following timelines:

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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 or vaccine 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, biologics and vaccines 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, we are unable to 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, 2011, we incurred an aggregate of \$118.8 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, 2012 and 2011. 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.

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	Nine Months Ended September 30,	
	2012	2011
	(In thousands)	
Rindopepimut	\$ 17,396	\$ 4,249
CDX-011	3,437	3,593
CDX-1127	3,043	4,800
CDX-1401	827	1,888
CDX-301	1,143	856
CDX-1135	6,321	3,553
CDX-014	612	347
Other Programs	871	3,329
Total R&D Expense	<u>\$ 33,650</u>	<u>\$ 22,615</u>

Clinical Development Programs

Rindopepimut (CDX-110)

Our lead clinical development program, rindopepimut, is an immunotherapeutic vaccine 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 has been shown by polymerase chain reaction analysis to be expressed in approximately 31% of glioblastoma, or GB, tumors, also referred to as glioblastoma multiforme, or GBM, the most common and aggressive form of brain cancer. The rindopepimut vaccine 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 and the FDA has also granted Fast Track designation.

In April 2008, we and Pfizer Inc. entered into a License and Development Agreement under which Pfizer was granted an exclusive worldwide license to rindopepimut. This agreement provided for reimbursement by Pfizer of all costs incurred by us in connection with the collaboration since the effective date. In November 2010, the agreement was terminated and all rights to rindopepimut were returned to us. Pfizer did not provide a reason for termination. Since the termination of this agreement, Pfizer is no longer funding the development of rindopepimut.

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 2010, we announced complete data for the primary endpoint of the 65 patients enrolled to receive rindopepimut in combination with maintenance TMZ in the ACT III study. The data showed that 43 of 65 patients (66%) were progression-free at 5.5 months after entry into the study. Taking into account the 3 to 3.5 months required to complete pre-study chemoradiation and enter into the study, the 5.5 month time point in ACT III corresponds to approximately 8.5 months after diagnosis. The ACTIVATE and ACT II trials, which were conducted in two leading centers, reported progression-free rates at 8.5 months after diagnosis of 70% and 80%, respectively, and similar results were seen in the ACT III trial, which enrolled patients in over 25 centers in the United States.

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The following table summarizes the progression free survival, or PFS, and overall survival, or OS, rates from clinical trials of rindopepimut as compared to matched historical controls and the standard of care, or SOC.

	Median PFS from diagnosis (months)	Median OS from diagnosis (months)	OS at 24 months
ACT III (n=65)	12.3(1)	24.6	52%
ACT II (n=22)	15.3	24.4	50%
ACTIVATE (n=18)	14.2	24.6	50%
Matched historical control (n=17)(2)	6.4	15.2	6%
Standard of care radiation/TMZ (n=287)(3)	6.9	14.6	27%

- (1) Change in median PFS not statistically significant from ACTIVATE and ACT II.
- (2) Sampson, et al. J. Clin. Oncol. 2010 Nov 1, 28(31), 4722-9. Historical controls were treated at M.D. Anderson and matched for eligibility (EGFRvIII-positive, Karnofsky performance status greater-than or equal to 80%, complete resection, radiation/TMZ and without progression through approximately 3 months post-diagnosis).
- (3) Stupp, et al. N. Engl. J. Med. 2005, 352, 987-96.

Importantly, rindopepimut showed a similar benefit in patients whether or not they expressed MGMT, an active DNA repair gene that has been shown to limit the benefit from TMZ treatment. In ACT III, the number of patients who were expected to be resistant to the TMZ chemotherapy appeared to do better with vaccination than the numbers observed in the historical data. Patients who have an unmethylated MGMT generally have a worse outcome presumably because they do not gain much benefit from TMZ as reported in the literature. Patients with a methylated MGMT promoter in their tumor do not express MGMT and have a more favorable outcome to TMZ treatment. Patients with methylated tumors (n=25) that were treated with the rindopepimut regimen experienced a median PFS of 17.5 months, which compares favorably with the published data from the SOC of radiation plus TMZ of 10.3 months. Patients with unmethylated tumors (n=40) that were treated with the rindopepimut regimen experienced a median PFS of 11.2 months, which compared favorably to the PFS with SOC of 5.3 months in this patient population. Thus, rindopepimut would appear to benefit both methylated and unmethylated MGMT patients. We expect to present updated overall survival data from the Phase 2 ACT III, ACT II and ACTIVATE studies at the Society for Neuro-Oncology meeting in November 2012.

In December 2011, we initiated ACT IV, a pivotal, randomized, double-blind, controlled Phase 3 study of rindopepimut in patients with surgically resected, EGFRvIII-positive GB. Patients are randomized after the completion of surgery and standard chemoradiation treatment. The treatment regime includes a vaccine priming phase post-radiation followed by an adjuvant TMZ phase and a vaccine 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 the rindopepimut vaccine. ACT IV will enroll up to 440 patients at over 150 centers worldwide to recruit approximately 374 patients with GTR to be included in the primary analysis. Our targeted patient accrual is 24 months and another 18 to 24 months of follow-up. In early 2013, we anticipate initiating a parallel, randomized, double-blind, controlled Phase 2 study in western Europe to optimize accrual of the pivotal (registration) study and to further support potential future commercial efforts in this region, assuming rindopepimut is approved by the EMA. We anticipate these two studies to cost over \$60 million during their duration.

In December 2011, we also initiated ReACT, a Phase 2 study of rindopepimut in combination with Avastin® in patients with recurrent EGFRvIII-positive GB. ReACT will enroll approximately 95 patients in a first or second relapse of GB following receipt of standard therapy and will be conducted at approximately 20 sites across the United States. Approximately 70 patients who have yet to receive Avastin will be randomized to receive either rindopepimut and Avastin or a control injection of KLH and Avastin in a blinded fashion. Another 25 patients who are refractory to Avastin having received Avastin in either the frontline or recurrent setting with subsequent progression will receive rindopepimut plus Avastin in a single treatment arm. We expect preliminary data from this study to be available in the second half of 2013.

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

Glembatumumab Vedotin (CDX-011)

CDX-011 is an antibody-drug conjugate, or ADC, that consists of a fully-human monoclonal antibody, CR011, linked to a potent cell-killing drug, monomethyl-auristatin E, or MMAE. The CR011 antibody specifically targets glycoprotein NMB, or

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GPNMB, that is expressed in a variety of human cancers including breast cancer and melanoma. The ADC technology, comprised of MMAE and a stable linker system for attaching it to CR011, was licensed from Seattle Genetics, Inc. The ADC is designed to be stable in the bloodstream. Following intravenous administration, CDX-011 targets and binds to GPNMB and upon internalization into the targeted cell, CDX-011 is designed to release MMAE from CR011 to produce a cell-killing effect. The FDA has granted Fast Track designation to CDX-011 for the treatment of advanced, refractory/resistant GPNMB-expressing breast cancer.

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

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

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

In December 2011, we completed enrollment of EMERGE, a randomized, multi-center Phase 2b study of CDX-011 in patients with heavily pre-treated, advanced, GPNMB-positive breast cancer. Patients were randomized (2:1) to receive either CDX-011 or single-agent “Investigator’s Choice” chemotherapy. Patients randomized to receive Investigator’s Choice, or IC, were allowed to cross over to CDX-011 following disease progression. Patients on the CDX-011 arm had a median of six prior regimens for metastatic disease while patients in the IC arm had a median of five prior regimens. Activity endpoints include response rate, or RR, and PFS.

In May 2012, we announced preliminary results from the EMERGE study which suggested that CDX-011 induces significant response rates compared to currently available therapies in patient subsets with advanced, refractory breast cancers with high GPNMB expression (expression in $\geq 25\%$ of tumor cells) and in patients with triple negative breast cancer. In the high GPNMB expressing patient population (n=25), treatment with CDX-011 resulted in a 32% overall response rate, or ORR, (including confirmed and unconfirmed responses), whereas treatment with IC (n=8) resulted in a 13% ORR. In patients with triple negative breast cancer across all levels of GPNMB expression where treatment options are extremely limited, CDX-011 resulted in ORR of 21% (n=24) whereas treatment with IC resulted in ORR of 0% (n=9). In patients with triple negative breast cancer who also highly express GPNMB, CDX-011 resulted in ORR of 36% (n=11) whereas treatment with IC resulted in ORR of 0% (n=3). In patients with high GPNMB in the CDX-011 arm, a trend of improvement in PFS was observed. In patients with both triple negative breast cancer and high GPNMB expression, a statistically significant PFS benefit was observed (p=0.0032). Mature data from the EMERGE study is expected to be presented at the San Antonio Breast Cancer Symposium in December 2012.

In 2009, Formatech, Inc., a third party contract manufacturer was engaged by us for the aseptic filling of one lot of our CDX-011 product candidate being used in our ongoing Phase 2b study. The CDX-011 lot from Formatech has passed all of the sterility testing performed during drug release and in subsequent stability studies. At the end of January 2012, we were notified by the FDA that because significant Good Manufacturing Practice, or cGMP, violations were uncovered during inspection of Formatech, our Phase 2b study for CDX-011 was being placed on partial clinical hold. The FDA uncovered these findings during their inspections of the Formatech facility between August to October 2010 and July to August 2011. These inspections began approximately one year after the CDX-011 drug product was filled at Formatech. Specifically, the FDA requested that no new patients be treated with CDX-011. However, patients already undergoing treatment with CDX-011 in the EMERGE study could continue treatment using vials of CDX-011 from the lot filled by Formatech, after such patients were informed of the potential risk and consented to continued participation in the study. The FDA also agreed that patients in the IC arm of the study who became eligible to receive CDX-011 at the time of progression, could receive an older lot of CDX-011 until such time that the material was exhausted or expired. We completed patient treatment in the EMERGE study and this partial clinical hold did not significantly impact the conduct or analysis of the Phase 2b study for purposes of determining next steps in our future development of CDX-011. With respect to future clinical trials, the FDA has converted the partial clinical hold to a clinical hold pending successful completion of reprocessing of the CDX-011 manufactured at Formatech or submission of an alternate cGMP manufacturing site for future lots of CDX-011. The FDA has agreed in concept that we could reprocess the remaining available vials of CDX-011 manufactured at Formatech at another cGMP contract

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manufacturer in order to lift the clinical hold. This reprocessing activity is currently underway. The FDA's final decision regarding the acceptability of this reprocessing will be made upon review of data concerning the stability and sterility of the reprocessed vials of CDX-011. If we are unsuccessful at reprocessing the available drug product or if FDA does not approve the use of these reprocessed vials, we will need to manufacture new drug product for subsequent clinical studies for CDX-011, which may cause a delay in the initiation of a subsequent trial with CDX-011.

Treatment of Metastatic Melanoma: In 2009, we completed enrollment of 117 patients in a Phase 1/2 open-label, multi-center, dose escalation study to evaluate the safety, tolerability and pharmacokinetics of CDX-011 for patients with un-resectable Stage III or Stage IV melanoma who had failed no more than one prior line of cytotoxic therapy. The MTD was determined to be 1.88 mg/kg administered intravenously once every three weeks. The study achieved its primary activity objective with an ORR in the Phase 2 cohort of 15% (5/34). Median PFS was 3.9 months. CDX-011 was generally well tolerated, with the most frequent treatment-related adverse events being rash, fatigue, hair loss, pruritus, diarrhea and neuropathy. In the subset of patients with tumor biopsies, high levels of tumor expression of GPNMB appeared to correlate with favorable outcome. In the seven patients whose tumors were found to express high amounts of GPNMB, and who were treated at the maximum tolerated doses across all dosing schedules, median PFS was 4.9 months. The development of rash, which may be associated with the presence of GPNMB in the skin also seemed to correlate with greater PFS.

We intend to initially focus our resources on advancing CDX-011 for the treatment of breast cancer while pursuing further development of CDX-011 in melanoma through collaborations and investigator sponsored studies.

CDX-1127

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

In November 2011, we initiated an open label, dose-escalating Phase 1 study of CDX-1127 in patients with selected malignant solid tumors or hematologic cancers at multiple clinical sites in the United States. The Phase 1 study is designed to test five escalating doses of CDX-1127 to determine a Phase 2 dose for further development based on safety, tolerability, potential activity and immunogenicity. The study will accrue approximately 30 patients in each of the two arms, either selected refractory or relapsed solid tumors or lymphomas or leukemias known to express CD27. Patients will have received all appropriate prior therapies for their specific disease. The trial design incorporates both single dosing and multiple dosing regimens at each dose level. We expect to complete enrollment in the solid tumor arm by the end of 2012 and in the lymphoma and leukemia arm in the first half of 2013.

CDX-1401

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

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

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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 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 January 2012, we initiated a dose-escalating Phase 1 study of CDX-301 in approximately 30 healthy subjects in collaboration with Rockefeller University. The Phase 1 study will evaluate seven different dosing regimens of CDX-301 to determine the appropriate dose for further development based on safety, tolerability, and biological activity. Patient accrual and treatment are complete and we expect to present preliminary results from the Phase 1 study at the American Society of Hematology Annual Meeting in December 2012.

Preclinical Programs

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 GMP clinical drug product at our Fall River manufacturing facility in preparation for our Phase 2 pilot study. We are planning to initiate a Phase 2 pilot study of CDX-1135 in a small number of DDD patients to determine the appropriate dose and regimen for further clinical development based on safety, tolerability and biological activity in the fourth quarter of 2012.

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.

Marketed Products

Rotavirus is a major cause of diarrhea and vomiting in infants and children. In 1997, we licensed our oral rotavirus strain to GlaxoSmithKline plc and Glaxo assumed responsibility for all subsequent clinical trials and all other development activities. Glaxo gained approval for its rotavirus vaccine, Rotarix, in Mexico in July 2004, which represented the first in a series of worldwide approvals and commercial launches for the product leading up to the approval in Europe in 2006 and in the U.S. in 2008. We licensed-in our rotavirus strain in 1995 and owe a license fee of 30% to Cincinnati Children's Hospital Medical Center, or CCH, on net royalties received from Glaxo. We are obligated to maintain a license with CCH with respect to the Glaxo agreement. The term of the Glaxo agreement is through the expiration of the last of the relevant patents covered by the agreement. The last relevant patent is scheduled to expire in December 2012. No additional milestone payments are due from Glaxo under the agreement.

In May 2005, we entered into an agreement whereby an affiliate of Paul Royalty Fund II, L.P., or PRF, purchased a 70% interest in the milestone payments and net royalties that we will receive on the development and worldwide sales of Rotarix. We have received a total of \$60 million in milestone payments under the PRF agreement. No additional milestone payments are due from PRF under the agreement. The PRF agreement terminates in December 2012.

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, 2011 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, 2012 compared with Three Months Ended September 30, 2011

	Three Months Ended September 30,		Increase/ (Decrease) \$	Increase/ (Decrease) %
	2012	2011		
(In thousands)				
Revenue:				
Product Development and Licensing Agreements	\$ 28	\$ 40	\$ (12)	(30)%
Contracts and Grants	79	5	74	1,480%
Product Royalties	3,006	2,318	688	30%
Total Revenue	\$ 3,113	\$ 2,363	\$ 750	32%
Operating Expense:				
Research and Development	11,769	8,594	3,175	37%
Royalty	3,006	2,318	688	30%
General and Administrative	2,835	2,273	562	25%
Amortization of Acquired Intangible Assets	254	656	(402)	(61)%
Total Operating Expense	17,864	13,841	4,023	29%
Operating Loss	(14,751)	(11,478)	3,273	29%
Investment and Other Income, Net	105	144	(39)	(27)%
Interest Expense	(381)	(438)	(57)	(13)%
Net Loss	\$ (15,027)	\$ (11,772)	\$ 3,255	28%

Net Loss

The \$3.3 million increase in net loss for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 was primarily the result of an increase in research and development and general and administrative expenses, partially offset by a decrease in amortization expense on acquired intangible assets.

Revenue

The \$0.1 million increase in contracts and grants revenue for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 was due to an APC Targeting Technology-based HIV vaccine being funded through a Small Business Innovation Research, or SBIR, grant in collaboration with Rockefeller University. The \$0.7 million increase in product royalty revenue for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 was related to our retained interests in Rotarix[®] net royalties which were not sold to PRF and which is equal to the amount payable to CCH and recognized in royalty expense by us.

Research and Development Expense

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:

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	Three Months Ended September 30,		Increase/ (Decrease) \$	Increase/ (Decrease) %
	2012	2011		
	(In thousands)			
Personnel	\$ 3,285	\$ 3,123	\$ 162	5%
Laboratory Supplies	543	388	155	40%
Facility	1,104	1,196	(92)	(8)%
Product Development	5,966	2,810	3,156	112%

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The \$0.2 million increase in personnel expenses for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 was primarily due to higher headcount. We expect personnel expenses to increase over the next twelve months, although there may be fluctuations on a quarterly basis.

Laboratory supply expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The \$0.2 million increase in laboratory supply expense for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 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. The \$0.1 million decrease in facility expenses for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 was primarily due to lower depreciation and amortization expenses. We expect facility expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing. The \$3.2 million increase in product development expenses for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 was primarily the result of an increase in clinical trial costs of \$3.2 million primarily due to our rindopepimut program, including the ACT IV and ReACT studies. We expect product development expenses to increase over the next twelve months due to the increase in clinical trial expenses related to our rindopepimut program, 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 \$0.7 million increase in royalty expenses for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 was due to an increase in Rotarix[®] related royalty fees. Our retained interests in Rotarix[®] 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.

General and Administrative Expense

The \$0.6 million increase in general and administrative expenses for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 was primarily due to higher headcount, consulting and rindopepimut-related commercialization expenses. We expect general and administrative expense to increase over the next twelve months due to increased commercialization efforts, although there may be fluctuations on a quarterly basis.

Amortization Expense

The \$0.4 million decrease in amortization expenses for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 was due to certain intangible assets becoming fully amortized during 2011. 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, 2012 was relatively consistent as compared to the three months ended September 30, 2011. We anticipate investment income to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

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Interest Expense

The \$0.1 million decrease in interest expense for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 was due to the decrease in our Term Loan balance. We anticipate interest expense to decrease over the next twelve months as we continue to make monthly principal payments on our Term Loan.

Nine Months Ended September 30, 2012 compared with Nine Months Ended September 30, 2011

	Nine Months Ended September 30,		Increase/ (Decrease) \$	Increase/ (Decrease) %
	2012	2011		
(In thousands)				
Revenue:				
Product Development and Licensing Agreements	\$ 103	\$ 65	\$ 38	58%
Contracts and Grants	228	5	223	4,460%
Product Royalties	7,224	6,761	463	7%
Total Revenue	\$ 7,555	\$ 6,831	\$ 724	11%
Operating Expense:				
Research and Development	33,650	22,615	11,035	49%
Royalty	7,224	6,761	463	7%
General and Administrative	7,372	6,849	523	8%
Amortization of Acquired Intangible Assets	836	1,622	(786)	(48)%
Total Operating Expense	49,082	37,847	11,235	30%
Operating Loss	(41,527)	(31,016)	10,511	34%
Investment and Other Income, Net	436	307	129	42%
Interest Expense	(1,225)	(1,358)	(133)	(10)%
Net Loss	\$ (42,316)	\$ (32,067)	\$ 10,249	32%

Net Loss

The \$10.2 million increase in net loss for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was primarily the result of an increase in research and development expense, partially offset by a decrease in amortization expense on acquired intangible assets.

Revenue

The \$0.2 million increase in contract and grant revenue for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was due to an APC Targeting Technology-based HIV vaccine being funded through a SBIR grant in collaboration with Rockefeller University. The \$0.5 million increase in product royalty revenue for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was related to our retained interests in Rotarix[®] net royalties which were not sold to PRF and which is equal to the amount payable to CCH and recognized in royalty expense by us.

Research and Development Expense

	Nine Months Ended September 30,		Increase/ (Decrease) \$	Increase/ (Decrease) %
	2012	2011		
(In thousands)				
Personnel	\$ 9,923	\$ 9,505	\$ 418	4%
Laboratory Supplies	1,504	1,508	(4)	—
Facility	3,405	3,567	(162)	(5)%
Product Development	16,642	5,898	10,744	182%

The \$0.4 million increase in personnel expenses for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was primarily due to higher headcount.

Laboratory supply expense for the nine months ended September 30, 2012 was relatively consistent as compared to the nine months ended September 30, 2011.

The \$0.2 million decrease in facility expenses for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was primarily due to lower depreciation and amortization expenses.

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The \$10.7 million increase in product development expenses for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was primarily the result of an increase in clinical trial costs of \$11.1 million primarily due to our rindopepimut program, including the ACT IV and ReACT studies.

Royalty Expense

The \$0.5 million increase in royalty expenses for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was due to an increase in Rotarix[®] related royalty fees.

General and Administrative Expense

The \$0.5 million increase in general and administrative expenses for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was due to higher headcount, consulting, rindopepimut-related commercialization and investor relations expenses, partially offset by lower insurance and professional service expenses.

Amortization Expense

The \$0.8 million decrease in amortization expenses for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was due to certain intangible assets becoming fully amortized during 2011.

Investment and Other Income, Net

The \$0.1 million increase in investment and other income, net for the nine months ended September 30, 2012 was due to higher levels of cash, cash equivalents and marketable securities as compared to the nine months ended September 30, 2011 and \$0.1 million in other income related to the sale of New Jersey tax benefits recorded during the nine months ended September 30, 2012.

Interest Expense

The \$0.1 million decrease in interest expense for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was primarily due to a decrease in our Term Loan balance.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2012, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of \$77.6 million. Our working capital at September 30, 2012 was \$63.7 million. At September 30, 2012, our Term Loan balance was \$12.6 million. We incurred a loss of \$42.3 million for the nine months ended September 30, 2012. Net cash used in operations for the nine months ended September 30, 2012 was \$36.5 million. We believe that the cash, cash equivalents and marketable securities at September 30, 2012 are sufficient to meet estimated working capital requirements and fund planned operations for at least the next twelve months.

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

The use of our cash flows for operations has primarily consisted of salaries and wages for our employees, facility and facility-related costs for our offices, laboratories and manufacturing facility, fees paid in connection with preclinical studies, clinical studies, contract manufacturing, laboratory supplies and services, consulting, legal and other professional fees. To date, and for the foreseeable future, 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.

We raised net proceeds of \$62.9 million during the nine months ended September 30, 2012 from the issuance of our common stock. 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

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result in royalties or other terms which reduce our economic potential from products under development. 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.

Operating Activities

Net cash used in operating activities was \$36.5 million for the nine months ended September 30, 2012 compared to \$26.3 million for the nine months ended September 30, 2011. The increase in net cash used in operating activities was primarily due to an increase in net loss of \$10.2 million. We expect that cash used in operations will continue to increase in over the next twelve months primarily related to costs incurred on our rindopepimut program.

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 \$12.4 million for the nine months ended September 30, 2012 compared to \$10.2 million for the nine months ended September 30, 2011. 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, 2012 of \$12.5 million as compared to \$9.9 million for the nine months ended September 30, 2011. 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 \$60.2 million for the nine months ended September 30, 2012 compared to \$28.3 million for the nine months ended September 30, 2011. Net proceeds from stock issuances were \$62.9 million during the nine months ended September 30, 2012 compared to \$35.9 million for the nine months ended September 30, 2011. In February 2011, we paid \$12.5 million to satisfy all outstanding principal related to the CuraGen Debt. We paid \$2.6 million in principal payments on our Term Loan during the nine months ended September 30, 2012.

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 filing up to a dollar amount of \$150 million. The shelf registration went effective on April 22, 2010.

In January 2011, we entered into a controlled equity offering sales agreement (the "Cantor Agreement") with Cantor Fitzgerald & Co. ("Cantor") 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 year ended December 31, 2011, we issued 575,000 shares of common stock under the Cantor Agreement and raised \$2.2 million in net proceeds, after deducting commission and offering expenses. In January 2012, we issued 2,450,000 shares of common stock under the Cantor Agreement and raised \$8.5 million in net proceeds. During the three months ended September 30, 2012, we issued the remaining 1,975,000 shares available to be sold under the Cantor Agreement and raised \$10.6 million in net proceeds.

In September 2012, we and Cantor amended the Cantor Agreement (the "Cantor Amendment") to allow us to issue and sell additional shares of our common stock having an aggregate offering price of up to \$44.0 million from time to time through Cantor, acting as agent. 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, as agent. The Cantor Amendment terminates upon ten day notice by either Cantor or us. In September and October 2012, we issued 57,100 and 1,167,770 shares under the Cantor Amendment and raised \$0.3 million and \$7.0 million in net proceeds, respectively. At October 30, 2012, we had \$36.4 million remaining in aggregate offering price available under the Cantor Amendment.

During February and March 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.

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Term Loan

On December 30, 2010, we entered the Loan Agreement with MidCap pursuant to which we borrowed \$10 million from MidCap. In March 2011, we amended the Loan Agreement and borrowed an additional \$5 million from GECC to increase the amount owed under the Term Loan to \$15 million. No additional advances are available under the Loan Agreement. The Term Loan accrues interest at a fixed annual interest rate equal to the greater of (i) the sum of (A) the LIBOR Rate (as defined in the Loan Agreement) plus (B) 6.25%; or (ii) a minimum rate of 9.50%. In September 2011, we exercised an option to extend the interest-only period by 6 months from October 1, 2011 to April 1, 2012. In March 2012, we amended the Loan Agreement to extend the maturity date from December 2013 to December 2014 in return for an upfront fee of \$25,000 and an additional fee of \$37,500 due upon repayment of the Term Loan in full.

Interest on the Term Loan is payable monthly and principal is due, as amended, in 34 equal consecutive monthly installments commencing on April 1, 2012. All unpaid principal and accrued interest with respect to the Term Loan is due and payable on the earlier of (A) December 30, 2014 or (B) the date that the Term Loan otherwise becomes due and payable under the terms of the Loan Agreement. We may prepay all, but not less than all, of the Term Loan subject to a prepayment premium of 1% in year three and 2% in year two of the original principal amount of the Term Loan. There is no prepayment premium if the loan is paid off early in year four. We are also obligated to make a payment of \$0.5 million (Payment Fee) upon the earlier of (A) December 30, 2013 or (B) upon repayment of the Term Loan in full prior to December 30, 2013.

Our obligations under the Loan Agreement are secured by a first priority lien upon and security interest in substantially all of our existing and after-acquired assets, excluding our intellectual property assets. Under the Loan Agreement, we are subject to specified affirmative and negative covenants customary for financings of this type. The Loan Agreement provides that, upon the occurrence of certain specified events of default customary for financings of this type, our obligations under the Loan Agreement may be automatically accelerated, whereupon our obligations under the Loan Agreement shall be immediately due and payable. At September 30, 2012, we believe we are in compliance with the Loan Agreement.

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, 2011 which was filed with the SEC on March 8, 2012 have not materially changed since we filed that report.

In June 2012, we notified the landlord of our Phillipsburg, New Jersey property that we were exercising our right within our lease agreement to terminate the lease early in November 2013.

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, 2012 due to the short-term maturities of these instruments.

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Foreign Currency Risk

All of our revenues and most of our expenses are denominated in U.S. dollars and as a result, we have not experienced significant foreign currency transaction gains and losses to date. We have conducted some transactions in foreign currencies during the nine months ended September 30, 2012, primarily related to clinical trial activities outside the U.S., and we expect to continue to do so. Our primary exposure is to fluctuations in the Euro, British Pound, Australian Dollar and Brazilian Real. We do not anticipate that foreign currency transaction gains or losses will be significant at our current level of operations. We have not engaged in foreign currency hedging to date.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

As of September 30, 2012, 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, 2012. 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, 2012 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, 2011, 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.

Except as set forth below, there were no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 8, 2012.

Our long term success depends heavily on our ability to fund and complete research and development activities for, and to commercialize, our lead drug candidate, rindopepimut, which we are developing internally.

While in the past we have typically focused on developing and demonstrating proof-of-concept for our product candidates by bringing such candidates through Phase 1 and one or more Phase 2 clinical trials, and then leveraging their value through partnerships, we have decided to fund and complete the research and development activities for rindopepimut ourselves. We plan to commercialize rindopepimut ourselves in North America and to find a partner to commercialize rindopepimut outside of North America. Therefore, we must allocate a significant portion of our time, personnel and financial resources to the development of rindopepimut. We initiated ACT IV, our pivotal Phase 3 clinical trial of rindopepimut, in December 2011. While we are targeting two years for patient accrual, it could take up to three years to enroll all the patients, and another 18 to 24 months of follow-up. We plan to initiate a parallel Phase 2 study in western Europe. We anticipate these two studies to cost over \$60 million during their duration. Our management team lacks significant experience in completing Phase 3 clinical trials and bringing a drug through commercialization. If we face delays, difficulties or unanticipated costs in completing the development of rindopepimut, we will need substantial additional financing. Further, even if we complete the development of rindopepimut and gain marketing approvals from the FDA and comparable foreign regulatory authorities in a timely manner, we cannot be sure that rindopepimut will be commercially successful in the pharmaceutical market. If the results of clinical trials of rindopepimut, the anticipated or actual timing of marketing approvals for rindopepimut, or the market acceptance of rindopepimut, if approved, do not meet the expectations of investors or public market analysts, the market price of our common stock would likely decline.

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Item 6. Exhibits

- 2.1 Agreement and Plan of Merger, dated as of May 28, 2009, by and among Celldex Therapeutics, Inc., CuraGen Corporation and Cottrell Merger Sub, Inc. incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K filed May 29, 2009 with the Securities and Exchange Commission.
- 3.1 Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
- 3.2 Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
- 3.3 Second Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.2 of the Company's Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
- 3.4 Third Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q, filed May 10, 2002 with the Securities and Exchange Commission.
- 3.5 Fourth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K, filed on March 11, 2008 with the Securities and Exchange Commission.
- 3.6 Fifth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K, filed on March 11, 2008 with the Securities and Exchange Commission.
- 3.7 Sixth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.7 of the Company's Quarterly Report on Form 10-Q, filed November 10, 2008 with the Securities and Exchange Commission.
- 4.3 Amendment No. 2 to Shareholder Rights Agreement dated November 5, 2004, between the Company and Computershare Trust Company, N.A. (formerly EquiServe Trust Company, N.A.), as Rights Agent, incorporated by reference to Exhibit 10.1 of the Company's Registration Statement on Form 8-A1G/A, filed on March 7, 2008 with the Securities and Exchange Commission.
- 10.1 Amendment No. 1 to Sales Agreement, dated January 6, 2011, between Celldex Therapeutics, Inc. and Cantor Fitzgerald & Co., dated September 20, 2012 incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed September 24, 2012 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.

SIGNATURES

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

CELLEX THERAPEUTICS, INC.

BY:

/s/ ANTHONY S. MARUCCI

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

Dated: November 2, 2012

/s/ AVERY W. CATLIN

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

Dated: November 2, 2012

EXHIBIT INDEX

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of May 28, 2009, by and among Celldex Therapeutics, Inc., CuraGen Corporation and Cottrell Merger Sub, Inc. incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K filed May 29, 2009 with the Securities and Exchange Commission.
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.
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* 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 2, 2012

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 2, 2012

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 2, 2012

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

Date: November 2, 2012

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.
