Celldex Therapeutics, Inc. Form 10-Q August 10, 2015 Table of Contents

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

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

For the quarterly period ended June 30, 2015

OR

o 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.)

Perryville III Building, 53 Frontage Road, Suite 220, Hampton, New Jersey 08827

(Address of principal executive offices) (Zip Code)

(908) 200-7500

(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 x No o

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 x No o

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 X

Accelerated filer O

Non-accelerated filer O
(Do not check if a smaller reporting company)

Smaller reporting company O

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

As of July 28, 2015, 98,595,407 shares of common stock, \$.001 par value per share, were outstanding.

#### CELLDEX THERAPEUTICS, INC.

#### FORM 10-Q

#### Quarter Ended June 30, 2015

#### **Table of Contents**

	Page
Part I Financial Information	
Item 1. Unaudited Condensed Financial Statements	3
Condensed Balance Sheets at June 30, 2015 and December 31, 2014	3
Condensed Statements of Operations and Comprehensive Loss for the Three and Six Months Ended June 30, 2015 and 2014	4
Condensed Statements of Cash Flows for the Six Months Ended June 30, 2015 and 2014	5
Notes to Unaudited Condensed Financial Statements	6
Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3. Quantitative and Qualitative Disclosures About Market Risk	26
Item 4. Controls and Procedures	26
Part II Other Information	
Item 1A. Risk Factors	27
Item 6. Exhibits	28
<u>Signatures</u>	29
Exhibit Index	30
2	

#### PART I FINANCIAL INFORMATION

#### **Item 1. Unaudited Financial Statements**

#### CELLDEX THERAPEUTICS, INC.

#### CONDENSED BALANCE SHEETS

(Unaudited)

#### (In thousands, except share and per share amounts)

	June 30, 2015	December 31, 2014			
ASSETS	,	,			
Current Assets:					
Cash and Cash Equivalents	\$ 81,584	\$ 28,020			
Marketable Securities	252,408	173,023			
Accounts and Other Receivables	434	427			
Prepaid and Other Current Assets	5,115	3,515			
Total Current Assets	339,541	204,985			
Property and Equipment, Net	11,735	10,535			
Intangible Assets, Net	21,300	21,807			
Other Assets	1,676	1,722			
Goodwill	8,965	8,965			
Total Assets	\$ 383,217	\$ 248,014			
LIABILITIES AND STOCKHOLDERS EQUITY					
Current Liabilities:					
Accounts Payable	\$ 2,020	\$ 2,603			
Accrued Expenses	21,879	19,296			
Current Portion of Long-Term Liabilities	2,792	2,592			
Total Current Liabilities	26,691	24,491			
Other Long-Term Liabilities	10,648	11,863			
Total Liabilities	37,339	36,354			
Commitments and Contingent Liabilities					
Stockholders Equity:					
Convertible Preferred Stock, \$.01 Par Value; 3,000,000 Shares Authorized; No					
Shares Issued and Outstanding at June 30, 2015 and December 31, 2014					
Common Stock, \$.001 Par Value; 297,000,000 Shares Authorized; 98,548,319 and					
89,592,779 Shares Issued and Outstanding at June 30, 2015 and December 31,					
2014, respectively	99	90			
Additional Paid-In Capital	869,635	672,739			
Accumulated Other Comprehensive Income	2,436	2,590			
Accumulated Deficit	(526,292)	(463,759)			
Total Stockholders Equity	345,878	211,660			
Total Liabilities and Stockholders Equity	\$ 383,217	\$ 248,014			

See accompanying notes to unaudited condensed financial statements

#### CELLDEX THERAPEUTICS, INC.

#### CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

#### (In thousands, except per share amounts)

	Three Mo	nded	Six Months Ended				
	June 30, 2015		June 30, 2014		June 30, 2015		June 30, 2014
REVENUE:							
Product Development and Licensing Agreements	\$ 334	\$	200	\$	676	\$	235
Contracts and Grants	1,844		392		1,988		773
Total Revenue	2,178		592		2,664		1,008
OPERATING EXPENSE:							
Research and Development	26,490		24,100		51,615		51,169
General and Administrative	8,184		4,787		14,273		9,369
Amortization of Acquired Intangible Assets	254		254		507		507
Total Operating Expense	34,928		29,141		66,395		61,045
Operating Loss	(32,750)		(28,549)		(63,731)		(60,037)
Investment and Other Income, Net	391		275		1,198		1,860
Net Loss	\$ (32,359)	\$	(28,274)	\$	(62,533)	\$	(58,177)
Basic and Diluted Net Loss Per Common Share	\$ (0.33)	\$	(0.32)	\$	(0.65)	\$	(0.65)
Shares Used in Calculating Basic and Diluted							
Net Loss per Share	98,482		89,361		95,477		89,316
COMPREHENSIVE LOSS:							
Net Loss	\$ (32,359)	\$	(28,274)	\$	(62,533)	\$	(58,177)
Other Comprehensive (Loss) Income:							
Foreign Currency Translation Adjustments			(2)		15		(1)
Unrealized (Loss) Gain on Marketable Securities	(180)		80		(169)		81
Comprehensive Loss	\$ (32,539)	\$	(28,196)	\$	(62,687)	\$	(58,097)

See accompanying notes to unaudited condensed financial statements

#### CELLDEX THERAPEUTICS, INC.

#### CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

#### (In thousands)

		Six Mont	hs Ende	nded		
	J	une 30, 2015	June 30, 2014			
Cash Flows from Operating Activities:						
Net Loss	\$	(62,533)	\$	(58,177)		
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:						
Depreciation and Amortization		1,384		1,161		
Amortization of Intangible Assets		507		507		
Amortization and Premium of Marketable Securities		(1,228)		(1,436)		
Stock-Based Compensation Expense		4,808		2,761		
Non-Cash Expense		144				
Changes in Operating Assets and Liabilities:						
Accounts and Other Receivables		(7)		(36)		
Prepaid and Other Current Assets		(1,837)		(1,825)		
Other Assets		(98)		32		
Accounts Payable and Accrued Expenses		2,524		(1,033)		
Other Liabilities		(1,015)		5,315		
Net Cash Used in Operating Activities		(57,351)		(52,731)		
Cash Flows from Investing Activities:						
Sales and Maturities of Marketable Securities		86,345		50,587		
Purchases of Marketable Securities		(164,434)		(126,222)		
Acquisition of Property and Equipment		(3,108)		(1,094)		
Net Cash Used in Investing Activities		(81,197)		(76,729)		
Cash Flows from Financing Activities:						
Net Proceeds from Stock Issuances		188,840				
Proceeds from Issuance of Stock from Employee Benefit Plans		3,257		856		
Net Cash Provided by Financing Activities		192,097		856		
Effect of Exchange Rate Changes on Cash and Cash Equivalents		15		(1)		
Net Increase (Decrease) in Cash and Cash Equivalents		53,564		(128,605)		
Cash and Cash Equivalents at Beginning of Period		28,020		169,402		
Cash and Cash Equivalents at End of Period	\$	81,584	\$	40,797		
AL LI CLASSE						
Non-cash Investing Activities						
Acquisition of Property and Equipment included in Accounts Payable and Accrued	Ф	502				
Expenses	\$	503				

See accompanying notes to unaudited condensed financial statements

#### **Table of Contents**

#### CELLDEX THERAPEUTICS, INC.

#### **Notes to Unaudited Condensed Financial Statements**

June 30, 2015

#### (1) Basis of Presentation

The accompanying unaudited condensed 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). On December 31, 2014, the Company s wholly-owned subsidiary, Celldex Research Corporation, merged into Celldex Therapeutics, Inc. The unaudited condensed statement of operations and comprehensive loss and the statement of cash flows for the three and six months ended June 30, 2014 reflect the operations of the Company and its former 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, 2014, which are included in the Company s Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 24, 2015. 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 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, 2015.

At June 30, 2015, the Company had cash, cash equivalents and marketable securities of \$334.0 million. The Company incurred a loss of \$62.5 million for the six months ended June 30, 2015. Net cash used in operations for the six months ended June 30, 2015 was \$57.4 million. The Company believes that the cash, cash equivalents and marketable securities at June 30, 2015 will be sufficient to meet estimated working capital requirements and fund planned operations for at least the next twelve months.

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

#### (2) Significant Accounting Policies

The significant accounting policies used in preparation of these condensed financial statements for the six months ended June 30, 2015 are consistent with those discussed in Note 2 to the financial statements in our Annual Report on Form 10-K for the year ended December 31, 2014, except for the adoption of new accounting standards during the first six months of 2015 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 May 2014, the FASB issued a new U.S. GAAP accounting standard that creates modifications to various other revenue accounting standards for specialized transactions and industries. The new U.S. GAAP accounting standard is intended to conform revenue accounting principles with a concurrently issued new standard under International Financial Reporting Standards, as well as, to enhance disclosures related to disaggregated revenue information. In July 2015, the FASB voted to defer the amendments in this update apply public business entities for the annual period ending after December 15, 2017. The amendment allows for two methods

6

#### **Table of Contents**

of adoption, a full retrospective method or a modified retrospective approach with the cumulative effect recognized at the date of initial application. The Company will further study the implications of this standard in order to evaluate the expected impact on the financial statements.

In April 2015, the FASB issued amendments that provide guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. The new guidance does not change the accounting for a customer s accounting for service contracts. The standard update is effective for fiscal years beginning after December 15, 2015 and interim periods within those years. Early adoption is permitted. The standard allows for adoption retrospectively or prospectively to all arrangements entered into or materially modified after the effective date. The amendment is not expected to have a material impact on our financial statements.

In August 2014, the FASB issued a new U.S. GAAP accounting standard that provides guidance about management s responsibility to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern and to provide related footnote disclosures. The new accounting standard requires management to assess an entity s ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. The new accounting standard is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company does not expect the adoption of this standard to have a material impact on the financial statements.

#### (3) Net Loss Per Share

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

	Six months ended	June 30,
	2015	2014
Stock options	8,121,183	6,961,766
Restricted stock	40,000	12,000
	8,161,183	6,973,766

#### (4) Comprehensive Loss

The changes in Accumulated Other Comprehensive Income by component for the three and six months ended June 30, 2015 are summarized below. No amounts were reclassified out of accumulated other comprehensive income during the three or six months ended June 30, 2015.

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

	(L Ma	alized Gain Loss) on rketable ies, net of tax	Cur	Foreign rency Items housands)	Total		
Balance at March 31, 2015	\$	20	\$	2,596	\$	2,616	
Other comprehensive loss before reclassifications		(180)				(180)	
Amounts reclassified from other comprehensive income							
Net current-period other comprehensive loss		(180)				(180)	
Balance at June 30, 2015	\$	(160)	\$	2,596	\$	2,436	
Balance at December 31, 2014	\$	9	\$	2,581	\$	2,590	
Other comprehensive income (loss) before reclassifications		(169)		15		(154)	
Amounts reclassified from other comprehensive income							
Net current-period other comprehensive income (loss)		(169)		15		(154)	
Balance at June 30, 2015	\$	(160)	\$	2,596	\$	2,436	

#### (5) Fair Value Measurements

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

	As of June 30, 2015	Level 1 (In thousands)	Level 2	Level 3
Money market funds and cash equivalents	\$ 68,641	\$ \$	68,641	\$
Marketable securities	252,408		252,408	
	\$ 321.049	\$ \$	321.049	\$

	]	As of December 31, 2014	Level 1 (In thousands)	Level 2	Level 3
Money market funds and cash equivalents	\$	18,677	\$ \$	18,677	\$
Marketable securities		173,023		173,023	
	\$	191,700	\$ \$	191,700	\$

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 and accounts payable. 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 financial statements at cost, which approximates fair value due to the short-term nature of these instruments.

#### (6) Marketable Securities

A summary of marketable securities is shown below:

	Amortized Cost		Gross Unrealized Gains (In tho		thousand	Gross Unrealized Losses s)	Fair Value		
June 30, 2015									
Marketable securities									
U.S. government and municipal obligations									
Maturing in one year or less	\$	56,882	\$	22	\$	(3)	\$	56,901	
Maturing after one year through three years		12,120		30	)	(53)		12,097	
Total U.S. government and municipal									
obligations	\$	69,002	\$	52	\$	(56)	\$	68,998	
Corporate debt securities									
Maturing in one year or less	\$	120,267	\$	12	\$	(92)	\$	120,187	

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

Maturing after one year through three years	63,299	9	(85)	63,223
Total corporate debt securities	\$ 183,566	\$ 21	\$ (177)	\$ 183,410
Total marketable securities	\$ 252,568	\$ 73	\$ (233)	\$ 252,408
December 31, 2014				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	\$ 44,580	\$ 30	\$ (6)	\$ 44,604
Maturing after one year through three years	16,108	49	(1)	16,156
Total U.S. government and municipal				
obligations	\$ 60,688	\$ 79	\$ (7)	\$ 60,760
Corporate debt securities				
Maturing in one year or less	\$ 89,636	\$ 6	\$ (37)	\$ 89,605
Maturing after one year through three years	22,690	3	(35)	22,658
Total corporate debt securities	\$ 112,326	\$ 9	\$ (72)	\$ 112,263
Total marketable securities	\$ 173,014	\$ 88	\$ (79)	\$ 173,023

#### Table of Contents

The marketable securities held by the Company were high investment grade and there were no marketable securities that the Company considered to be other-than-temporarily impaired as of June 30, 2015. Marketable securities include \$1.6 million and \$1.4 million in accrued interest at June 30, 2015 and December 31, 2014, respectively.

#### (7) Intangible Assets and Goodwill

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

	Estimated Life	Cost	Ac	ne 30, 2015 cumulated nortization	(In	Net thousands)	Cost	A	ember 31, 2014 ccumulated mortization	Net
Intangible Assets:										
IPR&D	Indefinite	\$ 11,800	\$		\$	11,800	\$ 11,800	\$		\$ 11,800
Amgen Amendment	16 years	14,500		(5,156)		9,344	14,500		(4,708)	9,792
Core Technology	11 years	1,296		(1,140)		156	1,296		(1,081)	215
Total Intangible										
Assets		\$ 27,596	\$	(6,296)	\$	21,300	\$ 27,596	\$	(5,789)	\$ 21,807
Goodwill	Indefinite	\$ 8,965	\$		\$	8,965	\$ 8,965	\$		\$ 8,965

The IPR&D intangible asset was recorded in connection with the acquisition of CuraGen and relates to the development of glembatumumab vedotin. At the date of acquisition and at June 30, 2015, glembatumumab vedotin had not yet reached technological feasibility nor did it have any alternative future use. Glembatumumab vedotin is in a randomized, Phase 2b study for the treatment of triple negative breast cancer and a Phase 2 study for the treatment of metastatic melanoma.

#### (8) Other Long-Term Liabilities

Other long-term liabilities include the following:

	June	30, 2015 (In thou	cember 31, 2014	
Deferred Rent	\$	432	\$	482
Net Deferred Tax Liability related to IPR&D	Ψ	4,661	Ψ	4,661
Deferred Income from Sale of Tax Benefits		3,417		4,015
Deferred Revenue		4,930		5,297
Total		13,440		14,455
Less Current Portion		(2,792)		(2,592)
Long-Term Portion	\$	10,648	\$	11,863

In December 2014, January 2014, January 2013, January 2012 and January 2011, the Company received approval from the New Jersey Economic Development Authority and agreed to sell New Jersey tax benefits worth \$1.9 million, \$1.1 million, \$0.8 million, \$0.8 million and \$0.6 million to an independent third party for \$1.8 million, \$1.0 million, \$0.8 million, \$0.7 million and \$0.5 million, respectively. Under the agreement, the Company must maintain a base of operations in New Jersey for five years or the tax benefits must be paid back on a pro-rata basis based on the number of years completed. During the six months ended June 30, 2015 and 2014, the Company recorded \$0.6 million and \$0.4 million to other income related to the sale of these tax benefits, respectively.

In September 2013, the Company entered into an agreement with Rockefeller University pursuant to which the Company performs research and development services for Rockefeller. The agreement included an upfront payment of \$1.3 million which is being recognized as revenue over the three year term of the agreement. The Company bills Rockefeller quarterly for actual time and direct costs incurred and recorded \$1.5 million and \$1.6 million in revenue related to the Rockefeller agreement during the three and six months ended June 30, 2015 and \$0.4 million and \$0.7 million during the three and six months ended June 30, 2014, respectively.

In May 2014, the Company entered into a clinical trial collaboration with Bristol-Myers Squibb Company (BMS) to evaluate the safety, tolerability and preliminary efficacy of varillumab and Opdivo®, BMS s PD-1 immune checkpoint inhibitor, in a Phase 1/2 study. Under the terms of this clinical trial collaboration, BMS made a one-time payment to the Company of \$5.0 million and BMS and the Company amended the terms of the Company s existing license agreement with Medarex (a subsidiary of BMS) related to the Company s CD27 program whereby certain future milestone payments were waived and future royalty rates were reduced that may have been due from the Company to Medarex. In return, BMS was granted a time-limited right of first negotiation if the Company wishes to out-license varlilumab. The companies also agreed to work exclusively with each other to explore anti-PD-1

#### Table of Contents

antagonist antibody and anti-CD27 agonist antibody combination regimens. The clinical trial collaboration provides that the companies will share development costs and that the Company will be responsible for conducting the ongoing Phase 1/2 study.

The Company has determined that its performance obligations under the BMS agreement, which primarily include performing research and development, supplying varillumab and participating in the joint development committee, should be accounted for as a single unit of accounting and estimated that its performance period under the BMS agreement would be 5 years. Accordingly, the \$5.0 million up-front payment was initially recorded as deferred revenue and is being recognized as revenue on a straight-line basis over the estimated 5-year performance period using the Contingency Adjusted Performance Model ( CAPM ). The BMS agreement also provides for BMS to reimburse the Company for 50% of the external costs incurred by the Company in connection with the clinical trial. These BMS payments will be recognized as revenue under the CAPM. The Company recorded \$0.3 million and \$0.6 million in revenue related to the BMS agreement during the three and six months ended June 30, 2015, respectively, and \$0.2 million and \$0.2 million during the three and six months ended June 30, 2014, respectively.

#### (9) Stockholders Equity

In March 2015, the Company issued 8,337,500 shares of its common stock in an underwritten public offering resulting in net proceeds to the Company of \$188.8 million, after deducting underwriting fees and offering expenses.

#### (10) Stock-Based Compensation

A summary of stock option activity for the six months ended June 30, 2015 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In Years)
Options Outstanding at December 31, 2014	7,015,350	\$ 9.34	6.6
Granted	1,734,650	\$ 25.41	
Exercised	(574,554)	\$ 5.55	
Canceled	(54,263)	\$ 14.41	
Options Outstanding at June 30, 2015	8,121,183	\$ 13.00	7.1
Options Vested and Expected to Vest at June 30, 2015	8,059,516	\$ 12.94	7.1
Options Exercisable at June 30, 2015	4,247,785	\$ 7.95	5.4
Shares Available for Grant under the 2008 Plan	5.905.772		

The weighted average grant-date fair value of stock options granted during the six months ended June 30, 2015 was \$15.63. Stock-based compensation expense for the three and six months ended June 30, 2015 and 2014 was recorded as follows:

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

	Three months ended June 30,		Six months ended June 30,				
		2015	2014		2015		2014
			(In tho	usands)			
Research and development	\$	1,244	\$ 747	\$	2,512	\$	1,338
General and administrative		1,283	764		2,296		1,423
Total stock-based compensation expense	\$	2,527	\$ 1,511	\$	4,808	\$	2,761

The fair values of employee and director stock options granted during the three and six months ended June 30, 2015 and 2014 were valued using the Black-Scholes option-pricing model with the following assumptions:

	Three months ended June 30,		Six months end	led June 30,
	2015	2014	2015	2014
Expected stock price volatility	67%	72%	67 - 69%	71 - 72%
Expected option term	6.0 years	6.0 years	6.0 years	6.0 years
Risk-free interest rate	2.2%	2.2%	1.8 - 2.2%	2.2%
Expected dividend yield	None	None	None	None

#### Table of Contents

#### (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 June 30, 2015 and December 31, 2014 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. contempl estimate. point to, target, potential and other simila continue, plan, project, predict, could. intend, expressions of the future.

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

- our ability to successfully complete research and further development, including animal, preclinical and clinical studies, and, if we obtain regulatory approval, commercialization of Rintega® (also referred to as rindopepimut and CDX-110), glembatumumab vedotin (also referred to as CDX-011), and other drug candidates and the growth of the markets for those drug candidates;
- our ability to raise sufficient capital to fund our clinical studies and to meet our long-term liquidity needs, on terms acceptable to us, or at all. If we are unable to raise the funds necessary to meet our long-term liquidity needs, we may have to delay or discontinue the development of one or more programs, discontinue or delay on-going or anticipated clinical trials, license out programs earlier than expected, raise funds at significant discount or on other unfavorable terms, if at all, or sell all or part of our business;
- our ability to manage multiple clinical trials for a variety of drug candidates at different stages of development, including ACT IV and ReACT for Rintega and METRIC for glembatumumab vedotin;
- the cost, timing, scope and results of ongoing safety and efficacy trials of Rintega, glembatumumab vedotin, and other preclinical and clinical testing;

Edgar Filing: Gelidex Therapeutics, Inc Form 10-Q
• our ability to fund and complete the development and, if we obtain regulatory approval, to commercialize Rintega in North America and Europe ourselves;
• the availability, cost, delivery and quality of clinical and commercial grade materials produced by our own manufacturing facility or supplied by contract manufacturers, suppliers and partners, who may be the sole source of supply;
• the 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;
• our ability to negotiate strategic partnerships, where appropriate, for our programs, which may include, Rintega outside of North America and Europe, glembatumumab vedotin and varlilumab (also referred to as CDX-1127);
• our ability to develop technological capabilities, including identification of novel and clinically important targets, exploiting our existing technology platforms to develop new product candidates and expand our focus to broader markets for our existing targeted immunotherapeutics;
• our ability to adapt our proprietary antibody-targeted technology, or APC Targeting Technology , to develop new, safe and effective therapeutics for oncology and infectious disease indications;
• the availability, cost, delivery and quality of clinical management services provided by our clinical research organization partners;
• our ability to protect our intellectual property rights, including the ability to successfully defend patent oppositions filed against a European patent related to technology we use in varlilumab, 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, 2014 and other reports that we file with the Securities and Exchange Commission.

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

#### **OVERVIEW**

We are a biopharmaceutical company focused on the development and commercialization of several immunotherapy technologies for the treatment of cancer and other difficult-to-treat diseases. Our drug candidates are derived from a broad set of complementary technologies which have the ability to utilize the human immune system and enable the creation of therapeutic agents. We are using these technologies to develop targeted immunotherapeutics comprised of protein-based molecules such as vaccines, antibodies and antibody-drug conjugates that are used to treat specifics types of cancer or other diseases.

Our latest stage drug candidate, Rintega (also referred to as rindopepimut and CDX-110) is a therapeutic vaccine that completed enrollment in December 2014 to a pivotal Phase 3 study in front-line glioblastoma in patients that express a specific cancer marker known as EGFRvIII. This Phase 3 study completed its first interim analysis at 50% of events (deaths) in June 2015, and an independent Data Safety and Monitoring Board recommended that the study continue as planned. Updated results from a randomized, Phase 2 study of Rintega added to the standard of care for the treatment of recurrent glioblastoma were presented in May 2015. A statistically significant overall survival benefit and the emergence of a long-term survival benefit were observed. The primary endpoint of the study, progression-free survival at six months (PFS6), was met. In February 2015, the U.S. Food and Drug Administration, or FDA, granted Rintega Breakthrough Therapy Designation for the treatment of adult patients with EGFRvIII-positive glioblastoma. Glembatumumab vedotin (also referred to as CDX-011) is a targeted antibody-drug conjugate in a randomized, Phase 2b study for the treatment of triple negative breast cancer and a Phase 2 study for the treatment of metastatic melanoma. Varlilumab (also referred to as CDX-1127) is an immune modulating antibody that is designed to enhance a patient s immune response against their cancer. We established proof of concept in a Phase 1 study with varlilumab, which has allowed several combination studies to begin in various indications. We also have a number of earlier stage drug candidates in clinical development, including CDX-1401, a targeted immunotherapeutic aimed at antigen presenting cells, or APC, for cancer indications and CDX-301, an immune cell mobilizing agent and dendritic cell growth factor. Our drug candidates address market opportunities for which we believe current therapies are inadequate or non-existent.

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

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

Product (generic)	Indication/Field	Partner	Status
CLINICAL			
Rintega	Front-line glioblastoma		Phase 3
Glembatumumab vedotin	Metastatic breast cancer		Phase 2b
Rintega	Recurrent glioblastoma		Phase 2
Glembatumumab vedotin	Metastatic melanoma		Phase 2
Varlilumab	Lymphoma/leukemia and solid tumors		Phase 1
Varlilumab	Multiple solid tumors		Phase 1/2
CDX-1401	Multiple solid tumors		Phase 1
CDX-301	Allogeneic Hematopoietic Stem Cell Transplantation		Phase 2
PRECLINICAL			
CDX-014	Ovarian and renal cancer		Preclinical

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

#### Table of Contents

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

	Estimated
	Completion
Clinical Phase	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. To the extent we are unable to maintain a broad range of product candidates, our dependence on the success of one or a few product candidates increases.

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

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

As a result of the uncertainties discussed above, among others, it is difficult to accurately estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we 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, 2014, we incurred an aggregate of \$279.3 million in research and development expenses. The following table indicates the amount incurred for each of our significant research programs and for other identified research and development activities during the six months ended June 30, 2015 and 2014. The amounts disclosed in the following table reflect direct research and development costs, license fees associated with the underlying technology and an allocation of indirect research and development costs to each program.

#### Table of Contents

Six Months Ended June 30, 2015 2014 (In thousands) \$ 24,241 25,917 Rintega \$ Glembatumumab vedotin 8,895 14,799 Varlilumab 8,182 4,433 CDX-1401 1,790 2,058 CDX-301 920 581 CDX-014 3,909 1,815 Other Programs 3,678 1,566 Total R&D Expense \$ 51,615 \$ 51,169

#### **Clinical Development Programs**

#### Rintega

Rintega is an epidermal growth factor receptor variant III, or EGFRvIII, specific vaccine for glioblastoma multiforme, or GBM. EGFRvIII is a mutated form of the epidermal growth factor receptor, or EGFR, that is only expressed in cancer cells and not in normal tissue and can directly contribute to cancer cell growth. EGFRvIII is expressed in approximately 30% of GBM tumors, the most common and aggressive form of brain cancer. Rintega 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 Rintega for the treatment of EGFRvIII expressing GBM. The FDA has also granted Fast Track designation. In February 2015, the FDA granted Rintega Breakthrough Therapy Designation for the treatment of adult patients with EGFRvIII-positive glioblastoma.

The Phase 2a study of Rintega 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 GBM patients. An extension of the Phase 2a study referred to as ACT II evaluated 22 additional GBM patients treated in combination with the current standard of care, maintenance temozolomide, or TMZ, at the same two institutions.

The Phase 2b study of Rintega referred to as ACT III combined Rintega with standard of care, TMZ, in patients with newly diagnosed GBM. The ACT III study provided for a multi-center, non-randomized dataset for Rintega in 65 patients at over 30 sites throughout the United States.

In November 2013, we announced the four- and five-year survival data from the 105 patients enrolled in the three Phase 2 Rintega clinical studies (ACTIVATE, ACT II and ACT III) in EGFRvIII-positive GBM. Across these three Phase 2 studies of Rintega, survival data remains consistent and suggests a continuing survival benefit in comparison to independent control datasets (see chart below) at the median and at all other time points evaluated.

#### Phase 2 Frontline Long-term Overall Survival Assessments

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

	Median, Years (95% CI)	2-year rate	3-year rate	4-year rate	5-year rate
Phase 2 Rintega studies (n=105)	2.1 (1.8, 2.4)	51%	30%	18%	14%
Matched historical control (n=17)(1)	1.3 (0.9, 1.7)	6%	6%	0%	0%

<sup>(1)</sup> Patients treated at M.D. Anderson contemporaneously to ACTIVATE, matched for major eligibility requirements, including EGFRvIII- positive GBM, gross total resection and no disease progression through chemoradiation treatment.

The pooled overall long-term survival results continue to be consistent with the ACT III Phase 2 study (18% for 4-years and 14% for 5-years).

In December 2011, we initiated ACT IV, a pivotal, randomized, double-blind, controlled Phase 3 study of Rintega in patients with surgically resected, EGFRvIII-positive GBM. Patients were randomized after the completion of surgery and standard chemoradiation treatment. The treatment regimen includes a Rintega priming phase post-radiation followed by an adjuvant phase where Rintega is dosed along with TMZ and a Rintega maintenance therapy phase. Patients are treated until disease progression or intolerance to therapy. The primary objective of the study is to determine whether Rintega plus adjuvant GM-CSF improves the overall survival of patients with newly diagnosed EGFRvIII-positive GBM with minimal residual disease post resection and traditional chemo-radiation when compared to treatment with TMZ and a control injection of KLH. KLH is a component of Rintega and was selected due to its ability to generate a similar injection site reaction to that observed with Rintega.

In December 2014, enrollment was completed in the ACT IV study. In total, over 4,800 tissue samples from GBM patients were submitted for EGFRvIII evaluation from more than 200 clinical trial sites across 22 countries and, consistent with prior studies, 30% were positive for the EGFRvIII mutation. The study enrolled 745 patients to reach the required 374 patients with minimal residual disease (assessed by central review) needed for analysis of the primary overall survival endpoint. All patients, including patients with disease that exceed this threshold, will be included in a secondary analysis of overall survival as well as analyses of progression-free survival, safety and tolerability, and quality of life. The timing of the overall survival primary endpoint data is event-driven. The study design requires interim analyses to be conducted by an independent Data Safety and Monitoring Board (DSMB) at 50% and 75% of events (deaths). The first interim analysis occurred in June 2015 and the DSMB recommended continuation of the study as planned. The second interim analysis is currently expected in late 2015 or early 2016, and the final data are expected by the end of 2016; although our expectations regarding the timing for the second interim analysis and final data read out may change based on event rates.

In December 2011, we also initiated ReACT, a Phase 2 study of Rintega in combination with Avastin® in patients with recurrent EGFRvIII-positive GBM. This study completed enrollment in 2014 and includes 3 groups. Group 1 consists of 72 patients who had not previously received Avastin and were randomized to receive either Rintega and Avastin or a control injection of KLH and Avastin in a blinded fashion. Group 2 includes 25 patients who are refractory to Avastin having received Avastin in either the frontline or recurrent setting with subsequent progression and who received Rintega plus Avastin in a single treatment arm. In August 2013, we announced the addition of an expansion cohort of up to 75 patients, called Group 2C, to better characterize the potential activity of Rintega in this refractory patient population. This decision was based on early evidence of anti-tumor activity, including stable disease, tumor shrinkage and investigator-reported response. In total, Group 2C enrolled 28 patients. The primary endpoint is six month progression-free survival rate (PFS-6) for groups 1 and 2 and objective response rate (ORR) for group 2C. Other study endpoints include PFS-6, ORR, PFS, overall survival, or OS and safety and tolerability.

In May 2015, we reported the following updated data from Group 1 of the ReACT study. These data were adjudicated by an independent review committee (IRC) blinded to treatment group assignment and included study results through March 2015 for both intent to treat (ITT) and per protocol (PP) populations; tumor responses were evaluated in accordance with Response Assessment in Neuro-Oncology (RANO) criteria. The IRC analyses are statistically equivalent with and confirm previously reported results. The primary endpoint of the study, progression-free survival at six months (PFS6), was met, and a clear advantage was demonstrated across multiple, clinically important endpoints including overall survival (OS), long-term progression-free survival, objective response rate (ORR) and need for steroids. We continue to follow patients for long-term survival and expect to update these numbers by year-end at an appropriate scientific conference.

#### **Updated Data**

- **PFS6:** The primary endpoint of the study, PFS6, was met. In the ITT population, 28% of patients on the Rintega arm were progression free at six months compared to 16% of patients on the control arm (p=0.1163). In the PP population, 30% of patients on the Rintega arm were progression free at six months compared to 12% of patients on the control arm (p=0.0310).
- Survival: The ITT population OS demonstrated a statistically significant benefit (p=0.0386) with a hazard ratio of 0.57 (0.33, 0.98) in favor of the Rintega treated patients. Median OS was 11.6 months for patients treated with Rintega compared to 9.3 months for control patients. The PP population OS demonstrated a statistically significant benefit (p=0.0244) with a hazard ratio of 0.53 (0.30, 0.93) in favor of the Rintega treated patients. Median OS was 10.9 months for patients treated with Rintega compared to 8.5 months for control patients.
- Response Rate: Nine out of 30 evaluable ITT patients (30%) on the Rintega arm experienced a confirmed objective response versus six out of 34 evaluable patients (18%) on the control arm. Nine out of 29 evaluable PP patients (31%) on the Rintega arm experienced a confirmed objective response versus five out of 32 evaluable patients (16%) on the control arm. Five patients on the Rintega arm experienced durable responses greater than six months, and three of these patients experienced durable responses greater than one year (range of 14.8+ to 18.4+ months). In contrast, only one

patient on the control arm experienced a durable response greater than six months, and none experienced a response greater than one year.

- Steroid Use: Further emphasizing the level of disease control, 56% of patients on the Rintega arm who were on steroids at the start of treatment were able to stop steroids during treatment versus 42% on the control arm, and 44% of patients on the Rintega arm were able to stop steroids for at least two months during treatment versus only 21% on the control arm. Six patients on the Rintega arm were able to stop steroids for more than six months, and of these, three were able to stop for more than one year versus none on the control arm for either time point.
- **Immune Response:** Rapid generation of anti-EGFRvIII humoral response correlated with longer survival, though even those with slower development of immune responses benefitted. No patient in the control arm had detectable EGFRvIII specific antibody response. This effect is consistent with Rintega s proposed mechanism of action as a targeted immunotherapeutic vaccine.
- Other: Subgroup analyses, including performance status, steroid use and recent resection, favor Rintega treatment. Rintega was very well tolerated without additive toxicity to Avastin. In Group 2/2C, evidence of rare but prominent tumor regression was reported with an 11% objective response rate observed in this heavily pretreated, refractory patient population.

Glembatumumab Vedotin

Glembatumumab vedotin is an antibody-drug conjugate, or ADC, that consists of a fully-human monoclonal antibody, CR011, linked to a potent cell-killing drug, monomethyl-auristatin E, or MMAE. The CR011 antibody specifically targets glycoprotein NMB, referred to as gpNMB, that is over-expressed in a variety of 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. and is the same as that used in the marketed product Adcetris®. The ADC is designed to be stable in the bloodstream. Following intravenous administration, glembatumumab vedotin targets and binds to gpNMB and upon internalization into the targeted cell, glembatumumab vedotin is designed to release MMAE from CR011 to produce a cell-killing effect. The FDA has granted Fast Track designation to glembatumumab vedotin for the treatment of advanced, refractory/resistant gpNMB-expressing breast cancer.

**Treatment of Breast Cancer:** The Phase 1/2 study of glembatumumab vedotin administered intravenously once every three weeks evaluated 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 glembatumumab vedotin 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. The 1.88 mg/kg dose was well tolerated in this patient population with the most

common adverse events of rash, alopecia, and fatigue. The primary activity endpoint, which called for at least 5 of 25 (20%) patients in the Phase 2 study portion to be progression-free at 12 weeks, was met as 9 of 26 (35%) evaluable patients were progression-free at 12 weeks.

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

In December 2012, we announced final results from the EMERGE study, a randomized, multi-center Phase 2b study of glembatumumab vedotin in 122 patients with heavily pre-treated, advanced, gpNMB positive breast cancer. Patients were randomized (2:1) to receive either glembatumumab vedotin or single-agent Investigator s Choice, or IC, chemotherapy. Patients randomized to receive IC were allowed to cross over to receive glembatumumab vedotin following disease progression. Activity endpoints included response rate, PFS and OS. The final results, as shown below, suggested that glembatumumab vedotin induces significant response rates compared to currently available therapies in patient subsets with advanced, refractory breast cancers with gpNMB over-expression (expression in at least 25% of tumor cells) and in patients with triple negative breast cancer. The OS and PFS of patients treated with glembatumumab vedotin was also observed to be greatest in patients with triple negative breast cancer who also over-express gpNMB and all patients with gpNMB over-expression.

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

	gpNMB Over-I	Expression	Triple N and gp Over-Ex <sub>l</sub>	NMB
	glembatumumab vedotin (n=25)	Investigator Choice (n=8)	glembatumumab vedotin (n=12)	Investigator Choice (n=4)
Response	32%	13%	33%	0%
Disease Control Rate	64%	38%	75%	25%

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

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

	gpNM Over-Expi		Triple N and gp Over-Exp	NMB
	glembatumumab vedotin	Investigator Choice	glembatumumab vedotin	Investigator Choice
Median PFS (months)	2.7 p=0.14	1.5	3.0 p=0.008	1.5

When cross over patients are removed, median OS in patients with gpNMB over-expression is 10.0 months for glembatumumab vedotin vs 5.2 months for IC (p=0.05) and median OS in triple negative patients with gpNMB over-expression is 10.0 months for glembatumumab vedotin vs 5.2 months for IC (p=0.009).

In December 2013, we initiated METRIC, a randomized, controlled Phase 2b study of glembatumumab vedotin in patients with triple negative breast cancer that over-express gpNMB. To-date, 95 sites are open to enrollment across the United States, Canada and Australia. The study was originally designed to obtain accelerated approval. Feedback from clinical investigators conducting the study indicated that the eligibility criteria for study entry were limiting their ability to enroll patients they felt were clinically appropriate on study. In addition, we had spoken to country-specific members of the European Medicines Agency, or EMA, and believed a significant opportunity existed to expand the study into the EU. Based on these factors, in the fourth quarter of 2014, we amended the METRIC study and expanded patient entry criteria to position it for full marketing approval with global regulators, including the EMA, and to support improved enrollment in the study. The primary endpoint of the study is PFS as PFS is an established endpoint for full approval registration studies in this patient population in both the US and the EU. The sample size (n=300) and the secondary endpoint of OS remained unchanged. We implemented these changes in parallel to regulatory discussions to maintain momentum at open clinical trial sites. Since implementation, both the FDA and central European regulatory authorities have reviewed the protocol design and we believe the METRIC study could support marketing approval in both the US and Europe dependent upon data review. Based on current projections, we believe enrollment will be completed in the second half of 2016.

Treatment of Metastatic Melanoma: The Phase 1/2 open-label, multi-center, dose escalation study evaluated the safety, tolerability and pharmacokinetics of glembatumumab vedotin in 117 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. Glembatumumab vedotin 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.

In December 2014, we initiated a single arm, open-label Phase 2 study of glembatumumab vedotin in patients with unresectable Stage III or IV melanoma. The study is expected to include approximately 10 sites in the United States and will enroll approximately 60 patients. The primary objective is to evaluate the anticancer activity of glembatumumab vedotin in advanced melanoma as measured by the ORR. Secondary endpoints include analyses of PFS, duration of response, OS, retrospective investigation of whether the anticancer activity of glembatumumab vedotin is dependent upon the degree of gpNMB expression in tumor tissue and safety.

#### **Table of Contents**

We have completed the assay optimization and validation for a Phase 2 study in squamous cell lung cancer and expect the study will commence in the second half of 2015. We have also entered into a Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute, or NCI, under which NCI will sponsor two studies of glembatumumab vedotin one in uveal melanoma and one in pediatric osteosarcoma.

Varlilumab

Varlilumab, a fully human monoclonal agonist antibody, binds and activates CD27, a critical co-stimulatory molecule in the immune activation cascade, primarily by stimulating T cells to attack cancer cells. Restricted expression and regulation of CD27 enables varlilumab specifically to activate T cells, resulting in an enhanced immune response with a favorable safety profile. Varlilumab has also been shown to directly kill or inhibit the growth of CD27 expressing lymphomas and leukemias *in vitro* and *in vivo*. We have entered into license agreements with the University of Southampton, UK for intellectual property to use anti-CD27 antibodies and with Medarex (now a subsidiary of the Bristol-Myers Squibb Company, or BMS) for access to the UltiMab technology to develop and commercialize human antibodies to CD27.

We are conducting an open label Phase 1 study of varlilumab in patients with selected malignant solid tumors or hematologic cancers at multiple clinical sites in the United States. Initial dose escalation cohorts were conducted to determine an optimal dose for future study and, to date, no maximum tolerated dose has been reached. The lymphoid malignancies dose escalation arm has completed enrollment (n=24) and a new cohort has been added to include evaluation of T cell malignancies. An expansion cohort has also been added at 0.3mg/kg dosed once every three weeks in patients with Hodgkin Lymphoma (n=15). The solid tumor arm, which included patients with various solid tumors, completed dose escalation in 2013. Two expansion cohorts were subsequently added at 3 mg/kg dosed weekly in metastatic melanoma (n=16) and renal cell carcinoma (n=15) to better characterize clinical activity and further define the safety profile in preparation for combination studies.

We presented updated data from this Phase 1 study in November 2014. Varlilumab was very well tolerated and induced immunologic activity in patients that is consistent with both its mechanism of action and preclinical models. A total of 86 patients have been dosed in the study. 55 patients have been dosed in dose escalation cohorts (various solid and hematologic B-cell tumors) and 31 patients have been dosed in the expansion cohorts (melanoma and RCC) at 3 mg/kg. In both the solid tumor and hematologic dose-escalations, the pre-specified maximum dose level (10 mg/kg) was reached without identification of a maximum tolerated dose. The majority of adverse events, or AEs, related to treatment have been mild to moderate (Grade 1/2) in severity, with only three serious AEs related to treatment reported. No significant immune-mediated adverse events (colitis, hepatitis, etc.) typically associated with check-point blockade have been observed. Two patients experienced objective responses including a complete response in Hodgkin Lymphoma and a partial response in renal cell carcinoma. Thirteen patients experienced stable disease with a range of 3-30.7+ months to-date. Based on the results observed in hematologic malignancies, an expansion cohort has been added to enroll up to 15 patients with Hodgkin Lymphoma and an abbreviated dose escalation in T cell hematologic malignancies is ongoing.

In May 2014, we entered into a clinical trial collaboration with Bristol-Myers Squibb Company, or BMS, to evaluate the safety, tolerability and preliminary efficacy of varillumab and Opdivo®, BMS s PD-1 immune checkpoint inhibitor, in a Phase 1/2 study. Under the terms of this clinical trial collaboration, BMS made a one-time payment to us of \$5.0 million and the companies amended the terms of our existing license agreement with Medarex (a subsidiary of BMS) related to our CD27 program whereby certain future milestone payments were waived and future royalty rates were reduced that may have been due from us to Medarex. In return, BMS was granted a time-limited right of first negotiation if we wish to out-license varillumab. The companies also agreed to work exclusively with each other to explore anti-PD-1 antagonist antibody and anti-CD27 agonist antibody combination regimens. The clinical trial collaboration provides that the companies will share development costs and that we will be responsible for conducting the Phase 1/2 study.

The Phase 1/2 study was initiated in January of 2015 and is being conducted in adult patients with advanced non-small cell lung cancer, metastatic melanoma, colorectal cancer, ovarian cancer, and head and neck squamous cell carcinoma. The Phase 1 dose-escalation portion of the study will assess the safety and tolerability of varlilumab at varying doses when administered with Opdivo. Following dose escalation, a Phase 2 portion of the study will include five disease specific cohorts. The primary objective of the Phase 2 study is overall response rate. Secondary objectives include pharmacokinetics assessments, determining the immunogenicity of varlilumab when given in combination with Opdivo and further assessing the anti-tumor activity of combination treatment.

In May 2014, we also entered into a clinical trial collaboration with Oncothyreon Inc. to evaluate the safety, tolerability and preliminary efficacy of varlilumab and ONT-10, Oncothyreon s therapeutic vaccine targeting the tumor-associated antigen MUC1, in a Phase 1b study. Under the terms of the clinical trial collaboration, the Phase 1b trial will be conducted and funded by Oncothyreon. Both companies will jointly own the data from the trial and will make any plans for potential future development of the combination therapy together. The Phase 1b study was initiated in November 2014 and is being conducted in up to 42 patients with advanced breast or ovarian cancer. The primary objective of the trial is to determine the safety and tolerability of the combined therapy. Additional

#### Table of Contents

objectives include evaluations of the impact of combination treatment on MUC1-specific humoral and cellular immune responses, T-cell activation markers and levels of regulatory T- cells, and anti-tumor effects.

In March 2015, we entered into a clinical trial collaboration with Roche to evaluate the safety, tolerability and preliminary efficacy of varillumab and MPDL3280A (anti-PDL1), Roche s investigational cancer immunotherapy in a Phase 1/2 study in renal cell carcinoma. Under the terms of this agreement, Roche will provide study drug and we will be responsible for conducting and funding the study, which is expected to begin in the second half of 2015.

In April 2015, we initiated a Phase 1/2 safety pilot and expansion study examining the combination of varlilumab and Yervoy® in patients with Stage III or IV metastatic melanoma. In the Phase 2 portion of the study, patients with tumors that express NY-ESO-1 will also receive CDX-1401. The Phase 1 portion of the study will assess the safety and tolerability of varlilumab at varying doses when administered with ipilimumab to identify a recommended dose for the Phase 2 portion of the study. The Phase 2 study will include two cohorts one comprised of patients who are NY-ESO-1 positive and one comprised of patients who are NY-ESO-1 negative. Patients who are NY-ESO-1 positive will also receive CDX-1401 (with poly-ICLC at 2 mg given as an adjuvant) in addition to varlilumab and ipilimumab. The primary objective for both cohorts is objective response rate up to 24 weeks (ORR6). Secondary objectives for the Phase 2 study include safety and tolerability, immunogenicity, pharmacokinetics and further assessment of anti-tumor activity across a broad range of endpoints.

In May 2015, we initiated a Phase 1/2 safety and tolerability study examining the combination of varlilumab and sunitinib (Sutent®) in patients with metastatic clear cell renal cell carcinoma. The Phase 1 portion of the study will assess the safety and tolerability of varlilumab at varying doses when administered with sunitinib to identify a recommended dose for the Phase 2 portion of the study. The primary objective of the Phase 2 portion of the study is to assess the preliminary anti-tumor efficacy of the varlilumab/sunitinib combination measured by the overall response rate. Secondary objectives include safety and tolerability, pharmacokinetics, immunogenicity and further assessment of anti-tumor activity across a broad range of endpoints.

Efforts are underway to finalize designs and plans for additional Phase 2 combination studies of varlilumab, including but not limited to a Phase 1/2 study of varlilumab plus a MEK pathway agent, followed sequentially by a checkpoint inhibitor, for patients with B-Raf mutated metastatic melanoma. In addition to our sponsored studies and clinical trial collaborations, we anticipate that varlilumab s potential activity will also be explored in investigator sponsored studies at various academic institutions.

CDX-1401

CDX-1401, developed from our APC Targeting Technology, is an antibody-based NY-ESO-1-specific therapeutic vaccine for multiple solid tumors. The vaccine, which is administered with an adjuvant, is composed of the cancer-specific antigen NY-ESO-1 fused to a fully human antibody that binds to DEC-205 for efficient delivery to dendritic cells. Delivery of tumor-specific proteins directly to dendritic cells in vivo elicits potent, broad, anti-tumor immune responses across populations with different genetic backgrounds. 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. 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.

We have completed a Phase 1 study of CDX-1401 which assessed the safety, immunogenicity and clinical activity of escalating doses of CDX-1401 with TLR agonists (resiquimod and/or Poly ICLC) in 45 patients with advanced malignancies refractory to all available 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. Long-term patient follow up suggested that treatment with CDX-1401 may predispose patients to better outcomes on subsequent therapy with checkpoint inhibitors. Of the 45 patients in the Phase 1 study, eight went on to receive subsequent therapy of either ipilimumab or an investigational checkpoint inhibitor and six of these patients had objective tumor regression. Six patients with melanoma received ipilimumab within three months of treatment with CDX-1401 and four (67%) had objective tumor responses, including one complete response, which compares favorably to the overall response rate of 11% previously reported in metastatic melanoma patients treated with single-agent ipilimumab. In addition, two patients with non-small cell lung cancer received an investigational checkpoint blockade within two months of completing treatment with CDX-1401 and both achieved partial responses.

The Phase 1 study identified a well-tolerated and immunogenic regimen to take forward into future studies. A Phase 2 study of CDX-1401 in combination with CDX-301 in metastatic melanoma is being conducted by the Cancer Immunotherapy Trials

#### Table of Contents

Network under a CRADA with the Cancer Therapy Evaluation Program of the NCI and is ongoing. As described above, in April 2015, we initiated a Phase 1/2 safety pilot and expansion study examining the combination of varillumab and Yervoy® in patients with Stage III or IV metastatic melanoma. In the Phase 2 portion of the study, patients with tumors that express NY-ESO-1 will also receive CDX-1401.

CDX-301

CDX-301, a recombinant FMS-like tyrosine kinase 3 ligand, or Flt3L, is a potent hematopoietic cytokine that uniquely expands dendritic cells and hematopoietic stem cells in combination with other agents to potentiate the anti-tumor response. Depending on the setting, cells expanded by CDX-301 promote either enhanced or permissive immunity. CDX-301 is in clinical development for multiple cancers, in combination with vaccines, adjuvants, and other treatments that release tumor antigens. We licensed CDX-301 from Amgen Inc. in March 2009 and believe CDX-301 may hold significant opportunity for synergistic development in combination with other proprietary molecules in our portfolio.

In February 2013, we announced final results from our dose-escalating Phase 1 study of CDX-301 in 30 healthy subjects in collaboration with Rockefeller University. The Phase 1 study evaluated seven different dosing regimens of CDX-301 to determine the appropriate dose for further development based on safety, tolerability, and biological activity. The data from the study were consistent with previous clinical experience and demonstrated that CDX-301 was well-tolerated and can effectively mobilize hematopoietic stem cell populations in healthy volunteers. In December 2013, we announced data from a preclinical combination study of CDX-301and Mozobil® (Plerixafor injection, formerly AMD3100) demonstrating that the combination of these agents significantly increases hematopoietic stem cell mobilization in mice. The data demonstrate a novel potent cell mobilization regimen combining CDX-301 and Mozobil®, which may have significant potential for use in autologous and allogeneic hematopoietic stem cell transplantation. Based on the safety profile and the clinical and preclinical data to date, we initiated a pilot clinical study of CDX-301 for the mobilization and transplantation of allogeneic hematopoietic stem cells in patients with hematological malignancies undergoing hematopoietic stem cell transplantation. The study will explore the utility of CDX-301 alone and in combination with Mozobil®. In addition to our sponsored studies and clinical trial collaborations, we anticipate that CDX-301 s potential activity will also be explored in investigator sponsored studies at various academic institutions.

### **Preclinical Programs**

CDX-014

CDX-014 is a fully-human monoclonal ADC that targets T-cell immunoglobulin and mucin domain 1, or TIM-1, a molecule that is upregulated in several cancers, including renal cell and ovarian carcinomas. TIM-1 is associated with kidney injury and the shedding of its ectodomain is a predictive biomarker for tumor progression. TIM-1 has very restricted expression in healthy tissues, making it a promising target for antibody mediated therapy. The TIM-1 antibody is linked to MMAE using Seattle Genetics proprietary technology. The ADC is designed to be stable in the bloodstream, but to release MMAE upon internalization into TIM-1-expressing tumor cells, resulting in a targeted cell-killing effect. CDX-014 has shown potent activity in preclinical models of ovarian and renal cancer. We expect to complete manufacturing and IND-enabling studies by the end of 2015 to support the initiation of Phase 1 clinical studies in renal cell carcinoma and potentially other TIM-1 expressing tumors in 2016.

## CRITICAL ACCOUNTING POLICIES

Our critical accounting policies are more fully described in Note 2 to our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2014 and there have been no material changes to such critical accounting policies. We believe our most critical accounting policies include accounting for revenue recognition, impairment of long-lived assets, research and development expenses and stock-based compensation expense.

#### Table of Contents

#### RESULTS OF OPERATIONS

#### Three Months Ended June 30, 2015 compared with Three Months Ended June 30, 2014

	Three Months Ended June 30,				Increase/ (Decrease)	Increase/ (Decrease)	
		2015		2014		\$	%
				(In thousand	ds)		
Revenue:							
Product Development and Licensing							
Agreements	\$	334	\$	200	\$	134	67%
Contracts and Grants		1,844		392		1,452	370%
Total Revenue	\$	2,178	\$	592	\$	1,586	268%
Operating Expense:							
Research and Development		26,490		24,100		2,390	10%
General and Administrative		8,184		4,787		3,397	71%
Amortization of Acquired Intangible Assets		254		254			0%
Total Operating Expense		34,928		29,141		5,787	20%
Operating Loss		(32,750)		(28,549)		4,201	15%
Investment and Other Income, Net		391		275		116	42%
Net Loss	\$	(32,359)	\$	(28,274)	\$	4,085	14%

#### Net Loss

The \$4.1 million increase in net loss for the three months ended June 30, 2015 compared to the three months ended June 30, 2014 was primarily the result of an increase in research and development and general and administrative expenses, partially offset by an increase in contracts and grants revenue.

#### Revenue

The \$0.1 million increase in product development and licensing agreements revenue for the three months ended June 30, 2015 compared to the three months ended June 30, 2014 was primarily related to our BMS agreement. In May 2014, we entered into a clinical trial collaboration with BMS whereby BMS made a one-time payment to us of \$5.0 million which we are recognizing as revenue along with BMS s 50% share of the clinical trial cost over our estimated performance period of five years. The \$1.5 million increase in contracts and grants revenue for the three months ended June 30, 2015 compared to the three months ended June 30, 2014 was primarily related to our Rockefeller University agreement pursuant to which we perform research and development services for Rockefeller.

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, (iv) license fees and (v) product development expenses associated with our product candidates as follows:

		Three Moi Jun	nths End	led		ncrease/ Decrease)	Increase/ (Decrease)
	2	015		2014		\$	%
				(In thous	ands)		
Personnel	\$	7,227	\$	4,831	\$	2,396	50%
Laboratory Supplies		1,264		845		419	50%
Facility		1,423		1,358		65	5%
License Fees		54		74		(20)	(27)%
Product Development		14.922		15.871		(949)	(6)%

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The \$2.4 million increase in personnel expenses for the three months ended June 30, 2015 compared to the three months ended June 30, 2014 was primarily due to higher stock-based compensation of \$0.5 million and increased headcount. We expect personnel expenses to increase over the next twelve months as we plan to continue to increase our headcount, primarily to support our Rintega, glembatumumab vedotin and varillumab programs.

#### **Table of Contents**

Laboratory supply expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The \$0.4 million increase in laboratory supply expense for the three months ended June 30, 2015 compared to the three months ended June 30, 2014 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 increase in facility expenses for the three months ended June 30, 2015 compared to the three months ended June 30, 2014 was primarily due to an increase in depreciation and amortization expense. We expect facility expenses to increase over the next twelve months as a result of us leasing addition space at our headquarters in Hampton, NJ.

License fee expenses include annual license maintenance fees and milestone payments due upon the achievement of certain development, regulatory and/or commercial milestones. License fee expenses for the three months ended June 30, 2015 were relatively consistent compared to the three months ended June 30, 2014. We expect license fee expense 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 \$0.9 million decrease in product development expenses for the three months ended June 30, 2015 compared to the three months ended June 30, 2014 was primarily the result of a decrease in contract manufacturing costs of \$2.1 million, partially offset by increases in clinical trial and contract research costs of \$0.8 million and \$0.3 million, respectively. We expect product development expenses to remain relatively consistent over the next twelve months as continued decreases in ACT IV costs are offset by increases in our glembatumumab vedotin and varlilumab programs, although there may be fluctuations on a quarterly basis.

General and Administrative Expense

The \$3.4 million increase in general and administrative expenses for the three months ended June 30, 2015 compared to the three months ended June 30, 2014 was primarily due to higher commercial personnel-related expenses as we prepare for potential product launch and an increase in Rintega and glembatumumab vedotin commercial planning costs. We expect general and administrative expense to increase over the next twelve months primarily due to increased commercial planning efforts for Rintega and glembatumumab vedotin, although there may be fluctuations on a quarterly basis.

Amortization Expense

Amortization expenses for the three months ended June 30, 2015 were relatively consistent compared to the three months ended June 30, 2014. We expect amortization expense of acquired intangible assets to remain relatively consistent over the next twelve months.

Investment and Other Income, Net

The \$0.1 million increase in investment and other income, net for the three months ended June 30, 2015 compared to the three months ended June 30, 2014 was primarily due to higher cash and investment balances. We anticipate investment and other income to remain relatively consistent over the next twelve months.

## Table of Contents

#### Six Months Ended June 30, 2015 compared with Six Months Ended June 30, 2014

	Six Mon Jun	ths Ende	d		Increase/ (Decrease)	Increase/ (Decrease)
	2015		2014		\$	%
			(In thousa	nds)		
Revenue:						
Product Development and Licensing						
Agreements	\$ 676	\$	235	\$	441	188%
Contracts and Grants	1,988		773		1,215	157%
Total Revenue	\$ 2,664	\$	1,008	\$	1,656	164%
Operating Expense:						
Research and Development	51,615		51,169		446	1%
General and Administrative	14,273		9,369		4,904	52%
Amortization of Acquired Intangible Assets	507		507			0%
Total Operating Expense	66,395		61,045		5,350	9%
Operating Loss	(63,731)		(60,037)		3,694	6%
Investment and Other Income, Net	1,198		1,860		(662)	(36)%
Net Loss	\$ (62,533)	\$	(58,177)	\$	4,356	7%

Net Loss

The \$4.4 million increase in net loss for the six months ended June 30, 2015 compared to the six months ended June 30, 2014 was primarily the result of an increase in general and administrative expenses, partially offset by an increase in contracts and grants revenue.

#### Revenue

The \$0.4 million increase in product development and licensing agreements revenue for the six months ended June 30, 2015 compared to the six months ended June 30, 2014 was primarily related to our BMS agreement. The \$1.2 million increase in contracts and grants revenue for the six months ended June 30, 2015 compared to the six months ended June 30, 2014 was primarily related to our Rockefeller University agreement.

### Research and Development Expense

	Six Mont June	ed			Increase/ (Decrease)	Increase/ (Decrease)
	2015	2014	(In thous	ands)	\$	%
Personnel	\$ 13,773	\$	9,292	\$	4,481	48%
Laboratory Supplies	2,429		1,669		760	46%
Facility	2,768		2,559		209	8%
License Fees	209		2,683		(2,474)	(92)%

Product Development	29,457	33,024	(3,567)	(11)%
---------------------	--------	--------	---------	-------

The \$4.5 million increase in personnel expenses for the six months ended June 30, 2015 compared to the six months ended June 30, 2014 was primarily due to higher stock-based compensation of \$1.2 million and increased headcount.

The \$0.8 million increase in laboratory supply expense for the six months ended June 30, 2015 compared to the six months ended June 30, 2014 was primarily due to higher manufacturing supply purchases.

The \$0.2 million increase in facility expenses for the six months ended June 30, 2015 compared to the six months ended June 30, 2014 was primarily due to an increase in depreciation and amortization expense.

The \$2.5 million decrease in license fee expenses for the six months ended June 30, 2015 compared to the six months ended June 30, 2014 was due to the one-time \$2.5 million milestone incurred and paid to Seattle Genetics during the six months ended June 30, 2014 as a result of the METRIC initiation.

#### **Table of Contents**

The \$3.6 million decrease in product development expenses for the six months ended June 30, 2015 compared to the six months ended June 30, 2014 was primarily the result of a decrease in clinical trial costs and contract manufacturing of \$2.3 million and \$1.9 million, respectively, partially offset by increases in contract research costs of \$0.6 million.

General and Administrative Expense

The \$4.9 million increase in general and administrative expenses for the six months ended June 30, 2015 compared to the six months ended June 30, 2014 was primarily due to higher commercial personnel-related expenses as we prepare for potential product launch and an increase in Rintega and glembatumumab vedotin commercial planning costs.

Amortization Expense

Amortization expenses for the six months ended June 30, 2015 was relatively consistent as compared to the six months ended June 30, 2014.

Investment and Other Income. Net

The \$0.7 million decrease in investment and other income, net for the six months ended June 30, 2015 compared to the six months ended June 30, 2014 was primarily due to \$1.0 million received in February 2014 in connection with our TopoTarget agreement and us recognizing \$0.6 million and \$0.4 million in other income related to the sale of New Jersey tax benefits during the six months ended June 30, 2015 and 2014, respectively.

#### LIQUIDITY AND CAPITAL RESOURCES

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

The use of our cash flows for operations has primarily consisted of salaries and wages for our employees, facility and facility-related costs for our offices, laboratories and manufacturing facility, fees paid in connection with preclinical studies, clinical studies, contract manufacturing, laboratory supplies and services, consulting, legal and other professional fees. To date, the primary sources of cash flows from operations have been payments received from our collaborative partners and from government entities. The timing of any new collaboration agreements,

government contracts or grants and any payments under these agreements, contracts or grants cannot be easily predicted and may vary significantly from quarter to quarter.

At June 30, 2015, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of \$334.0 million. We incurred a loss of \$62.5 million for the six months ended June 30, 2015. Net cash used in operations for the six months ended June 30, 2015 was \$57.4 million. We believe that the cash, cash equivalents and marketable securities at June 30, 2015 are sufficient to meet estimated working capital requirements and fund planned operations through 2017, however, this could be impacted by our clinical data results from our Rintega program and their impact on our pace of commercial manufacturing and the rate of expansion of our commercial operations.

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 may seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and our negotiating position in capital-raising efforts may worsen as existing resources are used. There is also no assurance that we will be able to enter into further collaborative relationships. Additional equity financing may be dilutive to our stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business; and licensing or strategic collaborations may result in royalties or other terms which reduce our economic potential from products under development.

**Operating Activities** 

Net cash used in operating activities was \$57.4 million for the six months ended June 30, 2015 compared to \$52.7 million for the six months ended June 30, 2014. The increase in net cash used in operating activities was primarily due to an increase in net loss

#### Table of Contents

of \$4.4 million and changes in working capital. We expect that cash used in operating activities will increase over the next twelve months primarily related to costs incurred on our Rintega, glembatumumab vedotin and varlilumab programs.

We have incurred and will continue to incur significant costs in the area of research and development, including preclinical and clinical trials, as our drug candidates are developed. We plan to spend significant amounts to progress our current drug candidates through the clinical trial and commercialization process as well as to develop additional drug candidates. As our drug 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 \$81.2 million for the six months ended June 30, 2015 compared to \$76.7 million for the six months ended June 30, 2014. The increase in net cash used in investing activities was primarily due to net purchases of marketable securities for the six months ended June 30, 2015 of \$78.1 million as compared to \$75.6 million for the six months ended June 30, 2014.

Financing Activities

Net cash provided by financing activities was \$192.1 million for the six months ended June 30, 2015 compared to \$0.9 million for the six months ended June 30, 2014. During the six months ended June 30, 2015, we issued 8,337,500 shares of our common stock in an underwritten public offering resulting in net proceeds to us of \$188.8 million, after deducting underwriting fees and offering expenses. Net proceeds from stock issuances pursuant to employee benefit plans, were \$3.3 million during the six months ended June 30, 2015 compared to \$0.9 million for the six months ended June 30, 2014.

#### AGGREGATE CONTRACTUAL OBLIGATIONS

The disclosures relating to our contractual obligations reported in our Annual Report on Form 10-K for the year ended December 31, 2014 which was filed with the SEC on February 24, 2015 have not materially changed since we filed that report.

#### Item 3. Quantitative and Qualitative Disclosures about Market 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 balance sheet of cash and cash equivalents, accounts receivables and accounts payable approximates fair value at June 30, 2015 due to the short-term maturities of these instruments.

### Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

As of June 30, 2015, we evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act )). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2015. 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.

Table	$\alpha f$	Contents

Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting during the three months ended June 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II OTHER INFORMATION

### 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, 2014, 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.

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 February 24, 2015.

## Table of Contents

Item 6.	Exhibits
3.1	Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company s Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
3.2	Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company s Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
3.3	Second Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.2 of the Company s Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
3.4	Third Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company s Quarterly Report on Form 10-Q, filed May 10, 2002 with the Securities and Exchange Commission.
3.5	Fourth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company s Current Report on Form 8-K, filed on March 11, 2008 with the Securities and Exchange Commission.
3.6	Fifth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.2 of the Company s Current Report on Form 8-K, filed on March 11, 2008 with the Securities and Exchange Commission.
3.7	Sixth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.7 of the Company s Quarterly Report on Form 10-Q, filed November 10, 2008 with the Securities and Exchange Commission.
10.1	Celldex Therapeutics, Inc. 2008 Stock Option and Incentive Plan, as amended and restated effective June 10, 2015, incorporated by reference to Exhibit 10.1 to the Company s current report on Form 8-K, filed on June 11, 2015 with the Securities and Exchange Commission.
*10.2	First Amendment to Lease Agreement between the Company and Crown Perryville, LLC dated as of June 17, 2015.
*10.3	Employment Agreement, dated as of July 1, 2015, by and between the Company and Richard Wright.
*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	XBRL Instance Document.
*101	XBRL Taxonomy Extension Schema Document.
*101	XBRL Taxonomy Extension Calculation Linkbase Document.
*101	XBRL Taxonomy Extension Definition Linkbase Document.
*101	XBRL Taxonomy Extension Label Linkbase Document.
*101	XBRL Taxonomy Extension Presentation Linkbase Document.

<sup>\*</sup> Filed herewith.

<sup>\*\*</sup> Furnished herewith.

## Table of Contents

Dated: August 10, 2015

#### **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.

### CELLDEX THERAPEUTICS, INC.

BY:

/s/ ANTHONY S. MARUCCI Dated: August 10, 2015

Anthony S. Marucci

President and Chief Executive Officer

(Principal Executive Officer)

/s/ AVERY W. CATLIN

Avery W. Catlin

Senior Vice President, Treasurer and Chief Financial Officer

(Principal Financial and Accounting Officer)

29

## Table of Contents

## EXHIBIT INDEX

Exhibit	
No.	Description
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
10.1	Commission.
10.1	Celldex Therapeutics, Inc. 2008 Stock Option and Incentive Plan, as amended and restated effective June 10, 2015, incorporated
	by reference to Exhibit 10.1 to the Company s current report on Form 8-K, filed on June 11, 2015 with the Securities and Exchange Commission.
*10.2	First Amendment to Lease Agreement between the Company and Crown Perryville, LLC dated as of June 17, 2015
*10.3	Employment Agreement, dated as of July 1, 2015, by and between the Company and Richard Wright
*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	XBRL Instance Document.
*101	XBRL Taxonomy Extension Schema Document.
*101	XBRL Taxonomy Extension Calculation Linkbase Document.
*101	XBRL Taxonomy Extension Definition Linkbase Document.
*101	XBRL Taxonomy Extension Label Linkbase Document.
*101	XBRL Taxonomy Extension Presentation Linkbase Document.
*	Filed benevith
**	Filed herewith. Furnished herewith.
	- WILLIAM INVESTIGATION