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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2015

OR

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

Commission File Number: 000-15006

CELLDEX THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**No. 13-3191702**
(State or other jurisdiction of incorporation or organization)	(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 ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

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

As of October 27, 2015, 98,645,692 shares of common stock, $.001 par value per share, were outstanding.

CELLDEX THERAPEUTICS, INC.

FORM 10-Q

Quarter Ended September 30, 2015

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PART I—FINANCIAL INFORMATION
Item 1. Unaudited Financial Statements

CELLDEX THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(Unaudited)

(In thousands, except share and per share amounts)

	September 30, 2015	December 31, 2014
ASSETS		
Current Assets:		
Cash and Cash Equivalents	$ 66,791	$ 28,020
Marketable Securities	237,819	173,023
Accounts and Other Receivables	527	427
Prepaid and Other Current Assets	4,119	3,515
Total Current Assets	309,256	204,985
Property and Equipment, Net	11,864	10,535
Intangible Assets, Net	21,047	21,807
Other Assets	1,500	1,722
Goodwill	8,965	8,965
Total Assets	$ 352,632	$ 248,014
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	$ 1,217	$ 2,603
Accrued Expenses	19,623	19,296
Current Portion of Long-Term Liabilities	2,795	2,592
Total Current Liabilities	23,635	24,491
Other Long-Term Liabilities	10,370	11,863
Total Liabilities	34,005	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 September 30, 2015 and December 31, 2014	—	—
Common Stock, $.001 Par Value; 297,000,000 Shares Authorized; 98,645,692 and 89,592,779 Shares Issued and Outstanding at September 30, 2015 and December 31, 2014, respectively	99	90
Additional Paid-In Capital	874,240	672,739
Accumulated Other Comprehensive Income	2,560	2,590
Accumulated Deficit	(558,272)	(463,759)
Total Stockholders' Equity	318,627	211,660
Total Liabilities and Stockholders' Equity	$ 352,632	$ 248,014

See accompanying notes to unaudited condensed financial statements

CELLDEX THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPRENHENSIVE LOSS
(Unaudited)

(In thousands, except per share amounts)

	Three Months Ended		Nine Months Ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
REVENUE:				
Product Development and Licensing Agreements	$ 377	$ 284	$ 1,053	$ 518
Contracts and Grants	649	817	2,636	1,591
Total Revenue	1,026	1,101	3,689	2,109
OPERATING EXPENSE:				
Research and Development	24,656	26,185	76,271	77,355
General and Administrative	8,487	5,004	22,761	14,373
Amortization of Acquired Intangible Assets	254	254	760	760
Total Operating Expense	33,397	31,443	99,792	92,488
Operating Loss	(32,371)	(30,342)	(96,103)	(90,379)
Investment and Other Income, Net	391	2,260	1,590	4,121
Net Loss	$ (31,980)	$ (28,082)	$ (94,513)	$ (86,258)
Basic and Diluted Net Loss Per Common Share (Note 3)	$ (0.32)	$ (0.31)	$ (0.98)	$ (0.97)
Shares Used in Calculating Basic and Diluted Net Loss per Share (Note 3)	98,568	89,404	96,518	89,346
COMPREHENSIVE LOSS:				
Net Loss	$ (31,980)	$ (28,082)	$ (94,513)	$ (86,258)
Other Comprehensive (Loss) Income:				
Foreign Currency Translation Adjustments	—	(3)	15	(4)
Unrealized Gain (Loss) on Marketable Securities	124	(121)	(45)	(40)
Comprehensive Loss	$ (31,856)	$ (28,206)	$ (94,543)	$ (86,302)

See accompanying notes to unaudited condensed financial statements

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

(In thousands)

	Nine Months Ended	
	September 30, 2015	**September 30, 2014**
Cash Flows from Operating Activities:		
Net Loss	$ (94,513)	$ (86,258)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation and Amortization	2,151	1,764
Amortization of Intangible Assets	760	760
Amortization and Premium of Marketable Securities, Net	(501)	(754)
Realized Gain on Sales and Maturities of Marketable Securities	—	(11)
Stock-Based Compensation Expense	8,677	4,719
Non-Cash Expense	216	—
Changes in Operating Assets and Liabilities:		
Accounts and Other Receivables	(100)	(2,416)
Prepaid and Other Current Assets	(478)	(1,428)
Other Assets	6	49
Accounts Payable and Accrued Expenses	(70)	(740)
Other Liabilities	(1,290)	4,992
Net Cash Used in Operating Activities	(85,142)	(79,323)
Cash Flows from Investing Activities:		
Sales and Maturities of Marketable Securities	129,349	89,215
Purchases of Marketable Securities	(193,815)	(146,159)
Acquisition of Property and Equipment	(4,469)	(1,766)
Net Cash Used in Investing Activities	(68,935)	(58,710)
Cash Flows from Financing Activities:		
Net Proceeds from Stock Issuances	188,840	—
Proceeds from Issuance of Stock from Employee Benefit Plans	3,993	1,160
Net Cash Provided by Financing Activities	192,833	1,160
Effect of Exchange Rate Changes on Cash and Cash Equivalents	15	(4)
Net Increase (Decrease) in Cash and Cash Equivalents	38,771	(136,877)
Cash and Cash Equivalents at Beginning of Period	28,020	169,402
Cash and Cash Equivalents at End of Period	$ 66,791	$ 32,525
Non-cash Investing Activities		
Acquisition of Property and Equipment included in Accounts Payable and Accrued Expenses	38	—

See accompanying notes to unaudited condensed financial statements

CELLDEX THERAPEUTICS, INC.
Notes to Unaudited Condensed Financial Statements
September 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 nine months ended September 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 condensed 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 September 30, 2015, the Company had cash, cash equivalents and marketable securities of $304.6 million. The Company incurred a loss of $94.5 million for the nine months ended September 30, 2015. Net cash used in operations for the nine months ended September 30, 2015 was $85.1 million. The Company believes that the cash, cash equivalents and marketable securities at September 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 nine months ended September 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 nine 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 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:

	Nine Months Ended September 30,	
	2015	2014
Stock options	8,098,128	6,999,421
Restricted stock	29,750	9,000
	8,127,878	7,008,421

(4) Comprehensive Loss

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

	Unrealized Gain (Loss) on Marketable Securities, net of tax	Foreign Currency Items	Total
		(In thousands)	
Balance at June 30, 2015	$ (160)	$ 2,596	$ 2,436
Other comprehensive income before reclassifications	124	—	124
Amounts reclassified from other comprehensive income	—	—	—
Net current-period other comprehensive income	124	—	124
Balance at September 30, 2015	$ (36)	$ 2,596	$ 2,560
Balance at December 31, 2014	$ 9	$ 2,581	$ 2,590
Other comprehensive (loss) income before reclassifications	(45)	15	(30)
Amounts reclassified from other comprehensive income	—	—	—
Net current-period other comprehensive income	(45)	15	(30)
Balance at September 30, 2015	$ (36)	$ 2,596	$ 2,560

(5) Fair Value Measurements

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

	As of September 30, 2015	Level 1	Level 2	Level 3
		(In thousands)		
Money market funds and cash equivalents	$ 54,692	$ —	$ 54,692	$ —
Marketable securities	237,819	—	237,819	—
	$ 292,511	$ —	$ 292,511	$ —

	As of December 31, 2014	Level 1	Level 2	Level 3
		(In thousands)		
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	Gross Unrealized Losses	Fair Value
		(In thousands)		
September 30, 2015				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	$ 43,379	$ 21	$ (2)	$ 43,398
Maturing after one year through three years	22,921	54	(45)	22,930
Total U.S. government and municipal obligations	$ 66,300	$ 75	$ (47)	$ 66,328
Corporate debt securities				
Maturing in one year or less	$ 135,613	$ 24	$ (89)	$ 135,548
Maturing after one year through three years	35,942	21	(20)	35,943
Total corporate debt securities	$ 171,555	$ 45	$ (109)	$ 171,491
Total marketable securities	$ 237,855	$ 120	$ (156)	$ 237,819
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

The marketable securities held by the Company were high investment grade and there were no marketable securities that the Company considered to be other-than-temporarily impaired as of September 30, 2015. Marketable securities include $1.2 million and $1.4 million in accrued interest at September 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	September 30, 2015 Cost	September 30, 2015 Accumulated Amortization	September 30, 2015 Net	December 31, 2014 Cost	December 31, 2014 Accumulated Amortization	December 31, 2014 Net
		(In thousands)					
Intangible Assets:							
IPR&D	Indefinite	$ 11,800	—	$ 11,800	$ 11,800	—	$ 11,800
Amgen Amendment	16 years	14,500	$ (5,381)	9,119	14,500	$ (4,708)	9,792
Core Technology	11 years	1,296	(1,168)	128	1,296	(1,081)	215
Total Intangible Assets		$ 27,596	$ (6,549)	$ 21,047	$ 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 September 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.

The Company performed an annual impairment test of the IPR&D and goodwill assets as of July 1, 2015 and concluded that the IPR&D and goodwill assets were not impaired.

(8) Other Long-Term Liabilities

Other long-term liabilities include the following:

	September 30, 2015	December 31, 2014
	(In thousands)	
Deferred Rent	$ 399	$ 482
Net Deferred Tax Liability related to IPR&D	4,661	4,661
Deferred Income from Sale of Tax Benefits	3,417	4,015
Deferred Revenue	4,688	5,297
Total	13,165	14,455
Less Current Portion	(2,795)	(2,592)
Long-Term Portion	$ 10,370	$ 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 nine months ended September 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 term of the agreement. The Company bills Rockefeller quarterly for actual time and direct costs incurred and recorded $0.5 million and $2.1 million in revenue related to the Rockefeller agreement during the three and nine months ended September 30, 2015 and $0.8 million and $1.5 million during the three and nine months ended September 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 varlilumab 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

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 varlilumab 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 $1.0 million in revenue related to the BMS agreement during the three and nine months ended September 30, 2015, respectively, and $0.3 million and $0.4 million during the three and nine months ended September 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 nine months ended September 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	1,806,650	$ 25.05	
Exercised	(660,658)	$ 5.68	
Canceled	(63,214)	$ 15.32	
Options Outstanding at September 30, 2015	8,098,128	$ 13.10	6.9
Options Vested and Expected to Vest at September 30, 2015	8,045,278	$ 13.04	6.9
Options Exercisable at September 30, 2015	4,480,232	$ 8.25	5.3
Shares Available for Grant under the 2008 Plan	5,842,723		

The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2015 was $15.41 per share. Stock-based compensation expense for the three and nine months ended September 30, 2015 and 2014 was recorded as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands)			
Research and development	$ 1,715	$ 977	$ 4,228	$ 2,315
General and administrative	2,153	981	4,449	2,404
Total stock-based compensation expense	$ 3,868	$ 1,958	$ 8,677	$ 4,719

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

	Three Months Ended September 30,		Nine Months Ended September 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	1.9%	2.1 - 2.2%	1.8 - 2.2%	2.1 - 2.2%
Expected dividend yield	None	None	None	None

(11) Income Taxes

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

The Company has evaluated the positive and negative evidence bearing upon the realizability of its net deferred tax assets, which are comprised principally of net operating loss carryforwards, capitalized R&D expenditures and R&D tax credit carryforwards. The Company has determined that it is more likely than not that it will not recognize the benefits of federal and state deferred tax assets and, as a result, a full valuation allowance was maintained at September 30, 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," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future.

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

- our ability to successfully complete research and further development, including animal, preclinical and clinical studies, and, if we obtain regulatory approval, commercialization of 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;

- the cost, timing, and uncertainty of obtaining regulatory approvals for our drug candidates;

- 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 management services provided by our clinical research organization partners;

- 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;

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

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

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

- 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 nine months ended September 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.

	Nine Months Ended September 30,	
	2015	2014
	(In thousands)	
Rintega	$ 34,139	$ 39,846
Glembatumumab vedotin	13,907	20,948
Varlilumab	12,480	6,721
CDX-1401	2,820	3,379
CDX-301	1,658	910
CDX-014	4,782	2,220
Other Programs	6,485	3,331
Total R&D Expense	$ 76,271	$ 77,355

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

	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%

(1) 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. We anticipate that ACT IV will reach the required number of events to perform the second interim analysis in late 2015 and that the analysis will occur in early 2016. Final data from ACT IV are expected by the end of 2016; although our expectations regarding the timing for the 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 in this study and will present an update on overall survival and long-term survival in a podium presentation at the 20th Annual Scientific Meeting of the Society for Neuro-Oncology (SNO) on Friday, November 20th.

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-Expression		Triple Negative and gpNMB Over-Expression	
	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

	gpNMB Over-Expression		Triple Negative and gpNMB Over-Expression	
	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
Median OS (months)	10.0 p=0.18	5.7	10.0 p=0.003	5.5

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. Clinical trial sites are open to enrollment across the United States, Canada and Australia and trial expansion into the European Union is underway with enrollment planned to open in early 2016. 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.

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 first quarter of 2016. 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.

Patient treatment is complete in the 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 no maximum tolerated dose was reached. The lymphoid malignancies dose escalation arm completed enrollment (n=24) and a new cohort was added to include evaluation of T cell malignancies. An expansion cohort was also added at 0.3mg/kg dosed once every three weeks in patients with Hodgkin Lymphoma (n= up to 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 3-36.2+ months to-date. Based on the results observed in hematologic malignancies, an expansion cohort in up to 15 patients with Hodgkin Lymphoma and an abbreviated dose escalation in T cell hematologic malignancies were added and are now closed to enrollment. Any incremental data updates from this study will be included in future scientific presentations/publications.

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 varlilumab 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 varlilumab. 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 in patients with advanced breast and ovarian cancers. Under the terms of the clinical trial collaboration, the Phase 1b trial was conducted and funded by Oncothyreon. Oncothyreon recently completed evaluation of two dosing cohorts in the study. Preliminary data from these two cohorts did not demonstrate sufficient activity to move forward with the program and Oncothyreon does not plan to enroll additional patients in the Phase 1b trial. Varlilumab biomarker analyses from peripheral blood samples from this study are consistent with prior experience including an increase in activated T cells and natural killer cells and a decrease in regulatory T cells.

In March 2015, we entered into a clinical trial collaboration with Roche to evaluate the safety, tolerability and preliminary efficacy of varlilumab and atezolizumab (anti-PDL1), Roche's investigational cancer immunotherapy in a Phase 1/2 study in renal cell carcinoma (RCC). 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 open to enrollment in the fourth quarter 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 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.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 Network under a CRADA with the Cancer Therapy Evaluation Program of the NCI and enrollment is now complete.

As described above, 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.

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.

RESULTS OF OPERATIONS

Three Months Ended September 30, 2015 compared with Three Months Ended September 30, 2014

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2015	2014	$	%
	(In thousands)			
Revenue:				
Product Development and Licensing Agreements	$ 377	$ 284	$ 93	33%
Contracts and Grants	649	817	(168)	(21)%
Total Revenue	$ 1,026	$ 1,101	$ (75)	(7)%
Operating Expense:				
Research and Development	24,656	26,185	(1,529)	(6)%
General and Administrative	8,487	5,004	3,483	70%
Amortization of Acquired Intangible Assets	254	254	—	0%
Total Operating Expense	33,397	31,443	1,954	6%
Operating Loss	(32,371)	(30,342)	2,029	7%
Investment and Other Income, Net	391	2,260	(1,869)	(83)%
Net Loss	$ (31,980)	$ (28,082)	$ 3,898	14%

Net Loss

The $3.9 million increase in net loss for the three months ended September 30, 2015 compared to the three months ended September 30, 2014 was primarily the result of an increase in general and administrative expenses and a decrease in investment and other income, partially offset by a decrease in research and development expenses.

Revenue

The $0.1 million increase in product development and licensing agreements revenue for the three months ended September 30, 2015 compared to the three months ended September 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 $0.2 million decrease in contracts and grants revenue for the three months ended September 30, 2015 compared to the three months ended September 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 Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2015	2014	$	%
	(In thousands)			
Personnel	$ 7,872	$ 5,425	$ 2,447	45%
Laboratory Supplies	1,160	856	304	36%
Facility	1,487	1,258	229	18%
License Fees	624	304	320	105%
Product Development	11,930	16,956	(5,026)	(30)%

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 September 30, 2015 compared to the three months ended September 30, 2014 was primarily due to increased headcount and higher stock-based compensation of $0.7 million. 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 varlilumab programs.

Laboratory supply expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The $0.3 million increase in laboratory supply expense for the three months ended September 30, 2015 compared to the three months ended September 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 $0.2 million increase in facility expenses for the three months ended September 30, 2015 compared to the three months ended September 30, 2014 was primarily due to an increase in rent and 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. The $0.3 million increase in license fee expenses for the three months ended September 30, 2015 compared to the three months ended September 30, 2014 was due to the further development of our drug candidates. We expect license fee expense may increase over the next twelve months as our drug candidates reach achievement of certain development, regulatory and/or commercial milestones, 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 $5.0 million decrease in product development expenses for the three months ended September 30, 2015 compared to the three months ended September 30, 2014 was primarily due to a $5.5 million decrease in ACT IV costs. Increases in glembatumumab vedotin and varlilumab clinical trial costs of $0.9 million and $0.9 million, respectively, were largely offset by decreases in contract manufacturing costs of $1.6 million. We expect product development expenses to increase over the next twelve months primarily due to increases in our glembatumumab vedotin and varlilumab programs, although there may be fluctuations on a quarterly basis.

General and Administrative Expense

The $3.5 million increase in general and administrative expenses for the three months ended September 30, 2015 compared to the three months ended September 30, 2014 was primarily due to higher headcount, stock-based compensation of $1.2 million and a $1.1 million increase in Rintega and glembatumumab vedotin commercial planning costs as we prepare for potential product launches. 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.

Amortization Expense

Amortization expenses for the three months ended September 30, 2015 were relatively consistent compared to the three months ended September 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 $1.9 million decrease in investment and other income, net for the three months ended September 30, 2015 compared to the three months ended September 30, 2014 was primarily due to other income of $2.0 million received in 2014 in connection with our

TopoTarget agreement. We anticipate investment income to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Nine Months Ended September 30, 2015 compared with Nine Months Ended September 30, 2014

	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2015	2014	$	%
	(In thousands)			
Revenue:				
Product Development and Licensing Agreements	$ 1,053	$ 518	$ 535	103%
Contracts and Grants	2,636	1,591	1,045	66%
Total Revenue	$ 3,689	$ 2,109	$ 1,580	75%
Operating Expense:				
Research and Development	76,271	77,355	(1,084)	(1)%
General and Administrative	22,761	14,373	8,388	58%
Amortization of Acquired Intangible Assets	760	760	—	0%
Total Operating Expense	99,792	92,488	7,304	8%
Operating Loss	(96,103)	(90,379)	5,724	6%
Investment and Other Income, Net	1,590	4,121	(2,531)	(61)%
Net Loss	$ (94,513)	$ (86,258)	$ 8,255	10%

Net Loss

The $8.3 million increase in net loss for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily the result of an increase in general and administrative expenses.

Revenue

The $0.5 million increase in product development and licensing agreements revenue for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily related to our BMS agreement. The $1.0 million increase in contracts and grants revenue for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily related to our Rockefeller University agreement.

Research and Development Expense

	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2015	2014	$	%
	(In thousands)			
Personnel	$ 21,644	$ 14,717	$ 6,927	47%
Laboratory Supplies	3,589	2,525	1,064	42%
Facility	4,255	3,817	438	11%
License Fees	833	2,988	(2,155)	(72)%
Product Development	41,387	49,979	(8,592)	(17)%

The $6.9 million increase in personnel expenses for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily due to increased headcount and higher stock-based compensation of $1.9 million.

The $1.1 million increase in laboratory supply expense for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily due to higher manufacturing supply purchases.

The $0.4 million increase in facility expenses for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily due to an increase in depreciation and amortization expense

The $2.2 million decrease in license fee expenses for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily due to the one-time $2.5 million milestone incurred and paid to Seattle Genetics in 2014 as a result of the METRIC study initiation.

The $8.6 million decrease in product development expenses for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily due to a $9.0 million decrease in ACT IV costs. Increases in glembatumumab vedotin and varlilumab clinical trial costs of $1.4 million and $2.3 million, respectively, and contract research of $1.0 million were largely offset by decreases in contract manufacturing costs of $3.4 million.

General and Administrative Expense

The $8.4 million increase in general and administrative expenses for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily due to higher headcount, stock-based compensation of $2.0 million and a $3.3 million increase in Rintega and glembatumumab vedotin commercial planning costs as we prepare for potential product launches.

Amortization Expense

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

Investment and Other Income, Net

The $2.5 million decrease in investment and other income, net for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily due to other income of $3.0 million received in 2014 in connection with our TopoTarget agreement.

LIQUIDITY AND CAPITAL RESOURCES

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

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

At September 30, 2015, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of $304.6 million. We incurred a loss of $94.5 million for the nine months ended September 30, 2015. Net cash used in operations for the nine months ended September 30, 2015 was $85.1 million. We believe that the cash, cash equivalents and marketable securities at September 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 $85.1 million for the nine months ended September 30, 2015 compared to $79.3 million for the nine months ended September 30, 2014. The increase in net cash used in operating activities was primarily due to an increase in net loss of $8.3 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 $68.9 million for the nine months ended September 30, 2015 compared to $58.7 million for the nine months ended September 30, 2014. The increase in net cash used in investing activities was primarily due to net purchases of marketable securities for the nine months ended September 30, 2015 of $64.5 million as compared to $56.9 million for the nine months ended September 30, 2014. We expect that cash provided by investing activities will increase over the next twelve months as we fund our operations through the net proceeds from the sale and maturity of marketable securities, cash provided by financing activities and/or new partnerships, although there may be significant fluctuations on a quarterly basis.

Financing Activities

Net cash provided by financing activities was $192.8 million for the nine months ended September 30, 2015 compared to $1.2 million for the nine months ended September 30, 2014. Net proceeds from stock issuances, including stock issued pursuant to employee benefit plans, were $192.8 million during the nine months ended September 30, 2015 compared to $1.2 million for the nine months ended September 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

Interest Rate Risk

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

We do not utilize derivative financial instruments. The carrying amounts reflected in the balance sheet of cash and cash equivalents, accounts receivables and accounts payable approximates fair value at September 30, 2015 due to the short-term maturities of these instruments.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

As of September 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 September 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.

Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting during the three months ended September 30, 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.
*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 herewith.
** Furnished herewith.

Table of Contents

SIGNATURES

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

CELLDEX THERAPEUTICS, INC.

BY:

/s/ ANTHONY S. MARUCCI

Dated: November 5, 2015

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

/s/ AVERY W. CATLIN

Dated: November 5, 2015

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

EXHIBIT INDEX

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*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 herewith.
** Furnished herewith.

Exhibit 31.1

CERTIFICATION

I, Anthony S. Marucci, certify that:

1. I have reviewed this report on Form 10-Q of Celldex Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2015

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

Exhibit 31.2

CERTIFICATION

I, Avery W. Catlin, certify that:

1. I have reviewed this report on Form 10-Q of Celldex Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2015

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

Exhibit 32.1

SECTION 1350 CERTIFICATIONS

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

Date: November 5, 2015	By:	/s/ ANTHONY S. MARUCCI
	Name:	Anthony S. Marucci
	Title:	President and Chief Executive Officer
Date: November 5, 2015	By:	/s/ AVERY W. CATLIN
	Name:	Avery W. Catlin
	Title:	Senior Vice President and Chief Financial Officer

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