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

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**FORM 10-Q**

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

For the quarterly period ended June 30, 2016

OR

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

Commission File Number: **000-15006**

**CELLDEX THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

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

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

**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 July 31, 2016, 100,545,519 shares of common stock, \$.001 par value per share, were outstanding.

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### PART I—FINANCIAL INFORMATION

#### Item 1. Unaudited Financial Statements

**CELLEX THERAPEUTICS, INC.**  
**CONDENSED BALANCE SHEETS**  
**(Unaudited)**

(In thousands, except share and per share amounts)

	Consolidated June 30, 2016	December 31, 2015
<b>ASSETS</b>		
Current Assets:		
Cash and Cash Equivalents	\$ 32,482	\$ 72,108
Marketable Securities	187,646	217,781
Accounts and Other Receivables	1,116	970
Prepaid and Other Current Assets	7,538	4,077
Total Current Assets	<u>228,782</u>	<u>294,936</u>
Property and Equipment, Net	11,293	11,461
Intangible Assets, Net	20,287	20,794
Other Assets	1,879	1,428
Goodwill	8,965	8,965
Total Assets	<u>\$ 271,206</u>	<u>\$ 337,584</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts Payable	\$ 706	\$ 1,506
Accrued Expenses	14,937	24,316
Current Portion of Long-Term Liabilities	4,360	4,418
Total Current Liabilities	<u>20,003</u>	<u>30,240</u>
Other Long-Term Liabilities	16,494	17,239
Total Liabilities	<u>36,497</u>	<u>47,479</u>
Commitments and Contingent Liabilities		
Stockholders' Equity:		
Convertible Preferred Stock, \$.01 Par Value; 3,000,000 Shares Authorized; No Shares Issued and Outstanding at June 30, 2016 and December 31, 2015	—	—
Common Stock, \$.001 Par Value; 297,000,000 Shares Authorized; 99,394,537 and 98,685,595 Shares Issued and Outstanding at June 30, 2016 and December 31, 2015, respectively	99	99
Additional Paid-In Capital	889,468	878,655
Accumulated Other Comprehensive Income	2,723	2,307
Accumulated Deficit	(657,581)	(590,956)
Total Stockholders' Equity	<u>234,709</u>	<u>290,105</u>
Total Liabilities and Stockholders' Equity	<u>\$ 271,206</u>	<u>\$ 337,584</u>

See accompanying notes to unaudited condensed consolidated financial statements

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

(In thousands, except per share amounts)

	Consolidated Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Consolidated Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
<b>REVENUE:</b>				
Product Development and Licensing Agreements	\$ 604	\$ 334	\$ 1,057	\$ 676
Contracts and Grants	785	1,844	1,635	1,988
Total Revenue	<u>1,389</u>	<u>2,178</u>	<u>2,692</u>	<u>2,664</u>
<b>OPERATING EXPENSE:</b>				
Research and Development	25,711	26,490	53,158	51,615
General and Administrative	7,790	8,184	17,097	14,273
Amortization of Acquired Intangible Assets	254	254	507	507
Total Operating Expense	<u>33,755</u>	<u>34,928</u>	<u>70,762</u>	<u>66,395</u>
Operating Loss	(32,366)	(32,750)	(68,070)	(63,731)
Investment and Other Income, Net	414	391	1,445	1,198
Net Loss	<u>\$ (31,952)</u>	<u>\$ (32,359)</u>	<u>\$ (66,625)</u>	<u>\$ (62,533)</u>
Basic and Diluted Net Loss Per Common Share	<u>\$ (0.32)</u>	<u>\$ (0.33)</u>	<u>\$ (0.67)</u>	<u>\$ (0.65)</u>
Shares Used in Calculating Basic and Diluted Net Loss per Share	<u>98,817</u>	<u>98,482</u>	<u>98,753</u>	<u>95,477</u>
<b>COMPREHENSIVE LOSS:</b>				
Net Loss	\$ (31,952)	\$ (32,359)	\$ (66,625)	\$ (62,533)
Other Comprehensive (Loss) Income:				
Foreign Currency Translation Adjustments	—	—	—	15
Unrealized Gain (Loss) on Marketable Securities	36	(180)	416	(169)
Comprehensive Loss	<u>\$ (31,916)</u>	<u>\$ (32,539)</u>	<u>\$ (66,209)</u>	<u>\$ (62,687)</u>

See accompanying notes to unaudited condensed consolidated financial statements

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

(In thousands)

	Consolidated Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
<b>Cash Flows from Operating Activities:</b>		
Net Loss	\$ (66,625)	\$ (62,533)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation and Amortization	1,434	1,384
Amortization of Intangible Assets	507	507
Amortization and Premium of Marketable Securities, Net	612	(1,228)
Loss on Sale or Disposal of Assets	74	—
Stock-Based Compensation Expense	7,913	4,808
Non-Cash Expense	1,638	144
Changes in Operating Assets and Liabilities:		
Accounts and Other Receivables	(146)	(7)
Prepaid and Other Current Assets	(3,124)	(1,837)
Other Assets	—	(98)
Accounts Payable and Accrued Expenses	(10,212)	2,524
Other Liabilities	(803)	(1,015)
Net Cash Used in Operating Activities	<u>(68,732)</u>	<u>(57,351)</u>
<b>Cash Flows from Investing Activities:</b>		
Sales and Maturities of Marketable Securities	149,367	86,345
Purchases of Marketable Securities	(120,053)	(164,434)
Investment in Other	(1,801)	—
Acquisition of Property and Equipment	(1,307)	(3,108)
Net Cash Provided by (Used in) Investing Activities	<u>26,206</u>	<u>(81,197)</u>

**Cash Flows from Financing Activities:**

Net Proceeds from Stock Issuances	2,551	188,840
Proceeds from Issuance of Stock from Employee Benefit Plans	349	3,257
Net Cash Provided by Financing Activities	<u>2,900</u>	<u>192,097</u>
Effect of Exchange Rate Changes on Cash and Cash Equivalents	<u>—</u>	<u>15</u>
Net (Decrease) Increase in Cash and Cash Equivalents	(39,626)	53,564
Cash and Cash Equivalents at Beginning of Period	72,108	28,020
Cash and Cash Equivalents at End of Period	<u>\$ 32,482</u>	<u>\$ 81,584</u>
<i>Non-cash Investing Activities</i>		
Acquisition of Property and Equipment included in Accounts Payable and Accrued Expenses	\$ 108	503

See accompanying notes to unaudited condensed consolidated financial statements

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**CELLDEX THERAPEUTICS, INC.**  
**Notes to Unaudited Condensed Consolidated Financial Statements**  
**June 30, 2016**

**(1) Basis of Presentation**

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

These interim financial statements do not include all the information and footnotes required by U.S. GAAP for annual financial statements and should be read in conjunction with the audited financial statements for the year ended December 31, 2015, which are included in the Company’s Annual Report on Form 10-K/A filed with the Securities and Exchange Commission (“SEC”) on February 25, 2016. 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, 2016.

At June 30, 2016, the Company had cash, cash equivalents and marketable securities of \$220.1 million. The Company incurred a loss of \$66.6 million for the six months ended June 30, 2016. Net cash used in operations for the six months ended June 30, 2016 was \$68.7 million. The Company believes that the cash, cash equivalents and marketable securities at June 30, 2016 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 consolidated financial statements for the six months ended June 30, 2016 are consistent with those discussed in Note 2 to the financial statements in our Annual Report on Form 10-K/A for the year ended December 31, 2015, except for the adoption of new accounting standards during the first six months of 2016 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 February 2016, the FASB issued a new U.S. GAAP accounting standard which requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The new standard will be effective for the Company on January 1, 2019. The Company is currently evaluating the potential impact that this standard may have on the Company’s financial statements.

In March 2016, the FASB issued a new U.S. GAAP accounting standard which involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The new standard will be effective for the Company on January 1, 2017. The Company is currently evaluating the potential impact that this standard may have on the Company's financial statements.

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In June 2016, the FASB issued a new U.S. GAAP accounting standard which changes the impairment model for most financial assets and certain other instruments. Under the new standard, entities holding financial assets and net investment in leases that are not accounted for at fair value through net income to be presented at the net amount expected to be collected. An allowance for credit losses will be a valuation account that will be deducted from the amortized cost basis of the financial asset to present the net carrying value at the amount expected to be collected on the financial asset. The new standard will be effective for the Company on January 1, 2020. The adoption of this standard is not expected to have a material impact on the Company's financial statements.

**(3) Net Loss Per Share**

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

	Six months ended June 30,	
	2016	2015
Stock options	10,260,073	8,121,183
Restricted stock	60,000	40,000
	<u>10,320,073</u>	<u>8,161,183</u>

**(4) Comprehensive Loss**

The changes in Accumulated Other Comprehensive Income by component for the three and six months ended June 30, 2016 are summarized below. No amounts were reclassified out of accumulated other comprehensive income during the three or six months ended June 30, 2016.

	Unrealized Gain (Loss) on Marketable Securities, net of tax	Foreign Currency Items (In thousands)	Total
	Balance at March 31, 2016	\$ 91	\$ 2,596
Other comprehensive income before reclassifications	36	—	36
Amounts reclassified from other comprehensive income	—	—	—
Net current-period other comprehensive income	36	—	36
Balance at June 30, 2016	<u>\$ 127</u>	<u>\$ 2,596</u>	<u>\$ 2,723</u>
Balance at December 31, 2015	\$ (289)	\$ 2,596	\$ 2,307
Other comprehensive income before reclassifications	416	—	416
Amounts reclassified from other comprehensive income	—	—	—
Net current-period other comprehensive income	416	—	416
Balance at June 30, 2016	<u>\$ 127</u>	<u>\$ 2,596</u>	<u>\$ 2,723</u>

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**(5) Fair Value Measurements**

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

	As of June 30, 2016	Level 1	Level 2	Level 3
		(In thousands)		
Money market funds and cash equivalents	\$ 25,116	\$ —	\$ 25,116	\$ —
Marketable securities	187,646	—	187,646	—
	<u>\$ 212,762</u>	<u>\$ —</u>	<u>\$ 212,762</u>	<u>\$ —</u>
	As of December 31, 2015	Level 1	Level 2	Level 3
	(In thousands)			
Money market funds and cash equivalents	\$ 59,831	\$ —	\$ 59,831	\$ —
Marketable securities	217,781	—	217,781	—
	<u>\$ 277,612</u>	<u>\$ —</u>	<u>\$ 277,612</u>	<u>\$ —</u>

There have been no transfers of assets or liabilities between the fair value measurement classifications. The Company's financial instruments consist mainly of cash and cash equivalents, marketable securities, short-term accounts receivable 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 consolidated financial statements at cost, which approximates fair value due to the short-term nature of these instruments.

## (6) Marketable Securities

A summary of marketable securities is shown below:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
(In thousands)				
<b>June 30, 2016</b>				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	\$ 63,618	\$ 63	\$ —	\$ 63,681
Maturing after one year through three years	5,382	21	—	5,403
Total U.S. government and municipal obligations	<u>\$ 69,000</u>	<u>\$ 84</u>	<u>\$ —</u>	<u>\$ 69,084</u>
Corporate debt securities				
Maturing in one year or less	\$ 115,497	\$ 47	\$ (10)	\$ 115,534
Maturing after one year through three years	3,022	6	—	3,028
Total corporate debt securities	<u>\$ 118,519</u>	<u>\$ 53</u>	<u>\$ (10)</u>	<u>\$ 118,562</u>
Total marketable securities	<u>\$ 187,519</u>	<u>\$ 137</u>	<u>\$ (10)</u>	<u>\$ 187,646</u>
<b>December 31, 2015</b>				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	\$ 48,871	\$ 4	\$ (20)	\$ 48,855
Maturing after one year through three years	15,940	24	(57)	15,907
Total U.S. government and municipal obligations	<u>\$ 64,811</u>	<u>\$ 28</u>	<u>\$ (77)</u>	<u>\$ 64,762</u>
Corporate debt securities				
Maturing in one year or less	\$ 129,327	\$ 2	\$ (141)	\$ 129,188
Maturing after one year through three years	23,932	1	(102)	23,831
Total corporate debt securities	<u>\$ 153,259</u>	<u>\$ 3</u>	<u>\$ (243)</u>	<u>\$ 153,019</u>
Total marketable securities	<u>\$ 218,070</u>	<u>\$ 31</u>	<u>\$ (320)</u>	<u>\$ 217,781</u>

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The marketable securities held by the Company were high investment grade and there were no marketable securities that the Company considered to be other-than-temporarily impaired as of June 30, 2016. Marketable securities include \$0.8 million and \$1.5 million in accrued interest at June 30, 2016 and December 31, 2015, respectively.

## (7) Intangible Assets and Goodwill

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

	Estimated Life	June 30, 2016			December 31, 2015		
		Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
(In thousands)							
Intangible Assets:							
IPR&D	Indefinite	\$ 11,800	\$ —	\$ 11,800	\$ 11,800	\$ —	\$ 11,800
Amgen Amendment	16 years	14,500	(6,053)	8,447	14,500	(5,605)	8,895
Core Technology	11 years	1,296	(1,256)	40	1,296	(1,197)	99
Total Intangible Assets		<u>\$ 27,596</u>	<u>\$ (7,309)</u>	<u>\$ 20,287</u>	<u>\$ 27,596</u>	<u>\$ (6,802)</u>	<u>\$ 20,794</u>
Goodwill	Indefinite	<u>\$ 8,965</u>	<u>\$ —</u>	<u>\$ 8,965</u>	<u>\$ 8,965</u>	<u>\$ —</u>	<u>\$ 8,965</u>

The IPR&D intangible asset was recorded in connection with the acquisition of CuraGen and relates to the development of glembatumumab vedotin. At the date of acquisition and at June 30, 2016, glembatumumab vedotin had not yet reached technological feasibility nor did it have any alternative future use. Glembatumumab vedotin is in a randomized, Phase 2b study for the treatment of triple negative breast cancer and a Phase 2 study for the treatment of metastatic melanoma.

## (8) Other Assets

In April 2016, the Company entered into a research and collaboration agreement with an undisclosed private company to access novel technologies and paid \$3.5 million to support research activities and make an investment in the private company. At June 30, 2016, the Company has recorded \$1.8 million to other assets related to this investment and \$1.7 million was initially recorded to prepaid and other current assets and will be amortized over the term of the agreement.

## (9) Other Long-Term Liabilities

Other long-term liabilities include the following:

	June 30, 2016	December 31, 2015
	(In thousands)	
Deferred Rent	\$ 401	\$ 409
Net Deferred Tax Liability related to IPR&D	4,661	4,661
Deferred Income from Sale of Tax Benefits	11,620	12,219
Deferred Revenue	4,172	4,368
Total	20,854	21,657
Less Current Portion	(4,360)	(4,418)
Long-Term Portion	\$ 16,494	\$ 17,239

In November 2015, December 2014, January 2014, January 2013 and January 2012, the Company received approval from the New Jersey Economic Development Authority and agreed to sell New Jersey tax benefits of \$9.8 million, \$1.9 million, \$1.1 million, \$0.8 million and \$0.8 million to an independent third party for \$9.2 million, \$1.8 million, \$1.0 million, \$0.8 million and \$0.7 million, respectively. Under the agreement, the Company must maintain a base of operations in New Jersey for five years or the tax benefits must be paid back on a pro-rata basis based on the number of years completed. During the six months ended June 30, 2016 and 2015, the Company recorded \$0.6 million and \$0.6 million to other income related to the sale of these tax benefits, respectively.

## (10) 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.

In May 2016, the Company entered into an agreement with Cantor Fitzgerald & Co. to allow the Company to issue and sell shares of its common stock having an aggregate offering price of up to \$60.0 million from time to time through Cantor, acting as agent. Subject to the terms and conditions of the agreement, Cantor will sell shares from time to time based upon the Company's instructions, including any price, time or size limits specified by the Company. Under the agreement, the Company pays Cantor a fixed commission rate of 3.0% of the gross sales price per share of any common stock sold through Cantor, as agent. In June and July 2016, the Company issued 593,111 and 1,109,536 shares under the

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agreement and raised \$2.7 million and \$5.0 million in net proceeds, respectively. At July 31, 2016, the Company had \$52.0 million remaining in aggregate gross offering price available under the agreement.

## (11) Stock-Based Compensation

A summary of stock option activity for the six months ended June 30, 2016 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In Years)
Options Outstanding at December 31, 2015	8,110,239	\$ 13.13	6.7
Granted	2,291,250	\$ 4.86	
Exercised	(37,942)	\$ 2.93	
Canceled	(103,474)	\$ 15.92	
Options Outstanding at June 30, 2016	10,260,073	\$ 11.29	7.0
Options Vested and Expected to Vest at June 30, 2016	10,175,654	\$ 11.30	7.0
Options Exercisable at June 30, 2016	5,558,678	\$ 10.20	5.3
Shares Available for Grant under the 2008 Plan	3,542,107		

The weighted average grant-date fair value of stock options granted during the six months ended June 30, 2016 was \$3.23. Stock-based compensation expense for the three and six months ended June 30, 2016 and 2015 was recorded as follows:

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
	(In thousands)			
Research and development	\$ 2,008	\$ 1,244	\$ 3,824	\$ 2,512
General and administrative	1,965	1,283	4,089	2,296
Total stock-based compensation expense	\$ 3,973	\$ 2,527	\$ 7,913	\$ 4,808

The fair values of employee and director stock options granted during the three and six months ended June 30, 2016 and 2015 were valued using the Black-Scholes option-pricing model with the following assumptions:

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Expected stock price volatility	77%	67%	70 - 77%	67 - 69%
Expected option term	6.0 years	6.0 years	6.0 years	6.0 years
Risk-free interest rate	1.5%	2.2%	1.5 - 1.6%	1.8 - 2.2%
Expected dividend yield	None	None	None	None

## (12) Revenue



In May 2014, the Company entered into a clinical trial collaboration with 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

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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 \$0.6 million and \$1.0 million in revenue related to the BMS agreement during the three and six months ended June 30, 2016, respectively, and \$0.3 million and \$0.6 million during the three and six months ended June 30, 2015, respectively.

*Rockefeller University (Rockefeller)*

In September 2013, the Company entered into an agreement, as amended, with Rockefeller pursuant to which the Company performs research and development services for Rockefeller. The Company bills Rockefeller quarterly for actual time and direct costs incurred and records those amounts to revenue in the quarter the services are performed. The Company recorded \$0.4 million and \$0.8 million in revenue related to the Rockefeller agreement during the three and six months ended June 30, 2016 and \$1.5 million and \$1.6 million during the three and six months ended June 30, 2015, respectively.

**(13) Income Taxes**

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

The Company has evaluated the positive and negative evidence bearing upon the realizability of its net deferred tax assets, which are comprised principally of net operating loss carryforwards, capitalized R&D expenditures and R&D tax credit carryforwards. The Company has determined that it is more likely than not that it will not recognize the benefits of federal and state deferred tax assets and, as a result, a full valuation allowance was maintained at June 30, 2016 and December 31, 2015 against the Company's net deferred tax assets.

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**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 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 negotiate strategic partnerships, where appropriate, for our programs, which may include, glembatumumab vedotin and varlilumab (also referred to as CDX-1127);



- our ability to manage multiple clinical trials for a variety of drug candidates at different stages of development;
- the cost, timing, scope and results of ongoing safety and efficacy trials of glembatumumab vedotin, and other preclinical and clinical testing;
- the cost, timing, and uncertainty of obtaining regulatory approvals for our drug candidates;
- 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;
- our ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors;
- 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/A for the year ended December 31, 2015 and other reports that we file with the Securities and Exchange Commission.

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

**OVERVIEW**

We are a biopharmaceutical company focused on the development and commercialization of several immunotherapy technologies for the treatment of cancer and other difficult-to-treat diseases. Our 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 specific types of cancer or other diseases.

Our latest stage drug candidate, 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 APCs, for cancer indications, CDX-301, an immune cell mobilizing agent and dendritic cell growth factor, and CDX-014, an antibody drug conjugate targeting TIM-1. 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 reflects our current clinical pipeline.

Product (generic)	Indication/Field	Partner	Status
Glembatumumab vedotin	Triple negative breast cancer	—	Phase 2b
Glembatumumab vedotin	Metastatic melanoma	—	Phase 2
Varlilumab	Multiple solid tumors (with nivolumab)	—	Phase 2
Varlilumab	Metastatic melanoma (with ipilimumab)	—	Phase 1
Varlilumab	Renal cell carcinoma (with sunitinib)	—	Phase 1
Varlilumab	Multiple solid tumors (with atezolizumab)	—	Phase 1
CDX-1401	Multiple solid tumors	—	Phase 2
CDX-301	Multiple indications	—	Phase 1
CDX-014	Renal cell carcinoma	—	Phase 1

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;

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- 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, 2015, we incurred an aggregate of \$351.8 million in research and development expenses. The following table indicates the amount incurred for each of our significant research programs and for other identified research and development activities during the six months ended June 30, 2016 and 2015. The amounts disclosed in the following table reflect direct research and development costs, license fees associated with the underlying technology and an allocation of indirect research and development costs to each program.

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	Six Months Ended June 30,	
	2016	2015
	(In thousands)	
Glembatumumab vedotin	\$ 12,097	\$ 8,895
Varlilumab	15,559	8,182
CDX-1401	3,039	1,790
CDX-301	2,643	920
CDX-014	1,882	3,909
Rintega	13,640	24,241
Other Programs	4,298	3,678
Total R&D Expense	\$ 53,158	\$ 51,615

## Clinical Development Programs

Glebatumumab 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, melanoma, non-small cell lung cancer, uveal melanoma and osteosarcoma, among others. 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, glebatumumab vedotin targets and binds to gpNMB, and upon internalization into the targeted cell, glebatumumab vedotin is designed to release MMAE from CR011 to produce a cell-killing effect. The FDA has granted Fast Track designation to glebatumumab vedotin for the treatment of advanced, refractory/resistant gpNMB-expressing breast cancer. A companion diagnostic is in development for certain indications, and we expect that, if necessary, such a companion diagnostic must be approved by the FDA or certain other foreign regulatory agencies before glebatumumab vedotin may be commercialized in those indications.

**Treatment of Metastatic Breast Cancer:** The Phase 1/2 study of glebatumumab 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). Results were published in the *Journal of Clinical Oncology* in September 2014. 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 glebatumumab 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 progression-free survival (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, neuropathy 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 27 (33%) evaluable patients were progression-free at 12 weeks. For all patients treated at the maximum dose level, 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, 12-week PFS rate was 60% (6/10), and median PFS was 17.9 weeks. Tumor samples from a subset of patients across all dose groups were analyzed for gpNMB expression. The tumor samples from most patients showed evidence of stromal and/or tumor cell expression of gpNMB.

The EMERGE study was a randomized, multi-center Phase 2b study of glebatumumab vedotin in 124 patients with heavily pre-treated, advanced, gpNMB-positive breast cancer. Results from EMERGE were published in the *Journal of Clinical Oncology* in April 2015. Patients were randomized (2:1) to receive either glebatumumab vedotin or single-agent Investigator’s Choice, or IC, chemotherapy. Patients randomized to receive IC were allowed to cross over to receive glebatumumab vedotin following disease progression. Activity endpoints included response rate, PFS and overall survival (OS). The final results, as shown below, suggested that glebatumumab vedotin induces significant response rates compared to currently available therapies in patient subsets with advanced, refractory breast cancers with high gpNMB 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 glebatumumab vedotin was also observed to be greatest in patients with triple negative breast cancer who also have high gpNMB expression and all patients with high gpNMB expression.

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**EMERGE: Overall Response Rate and Disease Control Data (Intent-to-Treat Population)**

	High gpNMB Expression		Triple Negative and gpNMB Over-Expression	
	Glebatumumab Vedotin (n=23)	Investigator Choice (n=11)	Glebatumumab Vedotin (n=10)	Investigator Choice (n=6)
Response	30%	9%	40%	0%
Disease Control Rate	65%	27%	90%	17%

Responses per RECIST 1.1; IC = Investigator’s Choice

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

	High gpNMB Expression		Triple Negative and gpNMB Over-Expression	
	Glebatumumab Vedotin	Investigator Choice	Glebatumumab Vedotin	Investigator Choice
Median PFS (months)	2.8 p=0.18	1.5	3.5 p=0.0017	1.5
Median OS (months)	10.0 p=0.31	5.7	10.0 p=0.003	5.5

In December 2013, we initiated METRIC, a randomized, controlled Phase 2b study of glebatumumab vedotin in patients with triple negative breast cancer that over-express gpNMB. Clinical trial sites are open to enrollment across the U.S., Canada, Australia and the European Union. The METRIC protocol was amended in late 2014 based on feedback from clinical investigators conducting the study that the eligibility criteria for study entry were limiting their ability to enroll patients they felt were clinically appropriate. 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. The amendment 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 U.S. 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 U.S. and Europe dependent upon data review.

**Treatment of Metastatic Melanoma:** The Phase 1/2 open-label, multi-center, dose escalation study evaluated the safety, tolerability and pharmacokinetics of glebatumumab vedotin in 117 patients with unresectable stage III or 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 overall response rate (ORR) in the Phase 2 cohort of 15% (5/34). Median PFS was 3.3 months for patients treated with the Phase 2 MTD. Glebatumumab vedotin was generally well tolerated, with the most frequent treatment-related adverse events being rash, fatigue, alopecia, pruritus, diarrhea and nausea. A nonsignificant trend toward prolonged PFS was seen for patients with tumors expressing higher levels of gpNMB. 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, single-agent, open label Phase 2 study of glebatumumab vedotin in patients with unresectable stage III or IV melanoma (n=60) and enrollment has been completed. We recently amended the protocol to add a second cohort of patients to a glebatumumab vedotin and varlilumab combination arm to assess the potential clinical benefit of the combination and to explore varlilumab's potential biologic and immunologic effect when combined with an ADC. This additional cohort is open to enrollment. The primary endpoint of each cohort is ORR. Secondary endpoints include analyses of PFS, duration of response, OS, retrospective investigation of whether the anticancer activity of glebatumumab vedotin is dependent upon the degree of gpNMB expression in tumor tissue and safety of both the monotherapy and combination regimen. We plan to present data from the single-agent cohort at the European Society for Medical Oncology (ESMO) Congress in October 2016.

**Treatment of Other Indications:** We have entered into a collaborative relationship with PrECOG, LLC, which represents a research network established by the Eastern Cooperative Oncology Group (ECOG), under which PrECOG, LLC, is conducting an open-label Phase 1/2 study in patients with unresectable stage IIIB or IV, gpNMB-expressing, advanced or metastatic squamous cell carcinoma (SCC) of the lung, who have progressed on prior platinum-based chemotherapy. This study opened to enrollment in April 2016. The study includes a brief dose-escalation phase followed by a two-stage Phase 2 portion (Simon two-stage design). The Phase 1, dose-escalation portion of the study will assess the safety and tolerability of glebatumumab vedotin at the current dose of 1.9 mg/kg and then 2.2 mg/kg in order to determine whether higher dosing is feasible in this population. The first stage of the Phase 2 portion will enroll approximately 20 patients, and if at least two patients achieve a partial response or complete response, a second stage may enroll an additional 15 patients. The primary objective of the Phase 2 portion of the study is to assess the anti-tumor

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efficacy of glebatumumab vedotin in squamous cell lung cancer as measured by ORR. Secondary objectives of the study include analyses of safety and tolerability and further assessment of anti-tumor activity across a broad range of endpoints.

We have also entered into a Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute, or NCI, under which NCI is sponsoring two studies of glebatumumab vedotin—one in uveal melanoma and one in osteosarcoma. Both studies are currently open to enrollment. The uveal melanoma study is a single arm, open label study in patients with locally recurrent or metastatic uveal melanoma. The primary outcome measure is ORR. Secondary outcome measures include change in gpNMB expression on tumor tissue via immunohistochemistry, safety, OS and PFS. The osteosarcoma study is a single arm, open label, evaluation of adolescent and adult patients with recurrent or refractory osteosarcoma. The co-primary objectives are to determine whether glebatumumab vedotin therapy either increases the disease control rate at 4 months in patients with recurrent measurable osteosarcoma as compared to historical experience and/or whether glebatumumab vedotin therapy produces an objective response rate greater than 20% in patients without previous eribulin (eribulin mesylate) treatment. Secondary outcome measures include safety, pharmacokinetics and the relation of gpNMB expression as measured by immunohistochemistry to clinical response.

## *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.

**Single-agent Phase 1 Study:** 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 U.S. 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 0.3 mg/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, or RCC, (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 90 patients have been dosed in the study. 56 patients have been dosed in dose escalation cohorts (various solid and hematologic B-cell tumors), and 34 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 checkpoint blockade have been observed. Two patients experienced significant objective responses including a complete response in Hodgkin lymphoma (continues at 33.1+ months) and a partial response in renal cell carcinoma of 24.7+ months. Thirteen patients experienced stable disease with a range of 3-41.4+ months (as of April 2016) 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.

**Phase 1/2 Varlilumab/Opdivo® Combination Study:** In May 2014, we entered into a clinical trial collaboration with Bristol-Myers Squibb to evaluate the safety, tolerability and preliminary efficacy of varlilumab and Opdivo, Bristol-Myers Squibb's PD-1 immune checkpoint inhibitor, in a Phase 1/2 study. Under the terms of this clinical trial collaboration, Bristol-Myers Squibb 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 Bristol-Myers Squibb) 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, Bristol-Myers Squibb 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 2015 and is being conducted in adult patients with multiple solid tumors to assess the safety and tolerability of varlilumab at varying doses when administered with Opdivo followed by a Phase 2 expansion to

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evaluate the activity of the combination in disease specific cohorts. The Phase 1 dose escalation portion of the study, conducted in patients with solid tumors, has completed enrollment (n=36) and primarily enrolled patients with colorectal and ovarian cancer.

Data were presented from the Phase 1 portion of the varlilumab and nivolumab study in a poster at the American Association for Cancer Research (AACR) Annual Meeting 2016 in April. The primary objective of the Phase 1 portion of the study was to evaluate the safety and tolerability of the combination. The combination showed acceptable tolerability and safety across all dose levels without any evidence of increased autoimmunity or inappropriate immune activation. Marked changes in the tumor microenvironment including increased infiltrating CD8+ T cells and increased PD-L1 expression, which have been shown to correlate with a greater magnitude of treatment effect from checkpoint inhibitors in other clinical studies were observed. Additional favorable immune biomarkers, such as increase in inflammatory chemokines and decrease in T regulatory cells, were also noted. In a subset of patients (n=17) on study who had both pre- and post-tumor biopsies available, preliminary evidence suggest a correlation between biomarker data and stable disease or better in seven of these patients (4 ovarian cancer, 2 colorectal cancer, 1 squamous cell carcinoma of the head and neck). All dose levels of the combination therapy showed acceptable tolerability and safety, without identification of a maximum tolerated dose. In the Phase 2 portion of the study, varlilumab will be administered at 3 mg/kg, which is based upon cumulative data across multiple studies.

The Phase 2 portion of the study opened to enrollment in April 2016. A protocol amendment was recently finalized to include additional arms evaluating alternate dosing schedules in both renal cell carcinoma and squamous cell head and neck cancer. A cohort in non-small cell lung cancer was removed prior to enrolling any patients to accommodate the addition of these new arms. As amended, the overall study size has increased and includes cohorts in colorectal cancer (n=18), ovarian cancer (n=18), head and neck squamous cell carcinoma (n=48), renal cell carcinoma (n=75) and glioblastoma (n=20). The primary objective of the Phase 2 cohorts will be ORR, except glioblastoma, where the primary objective is the rate of 12-month overall survival. 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.

**Phase 1/2 Varlilumab/Atezolizumab Combination Study:** 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. The Phase 1 portion of the study is being conducted in multiple tumor types, and the primary outcome is safety and tolerability. The Phase 2 portion of the study will be conducted in RCC, and the primary outcome is ORR. Secondary outcome measures include safety and tolerability, pharmacokinetics, immunogenicity and further assessment of anti-tumor activity across a broad range of endpoints. The Phase 1 portion of the study, which opened to enrollment in December 2015, has completed enrollment. We anticipate the Phase 2 portion of the study in RCC will be initiated in the third quarter of 2016. Under the terms of this agreement, Roche is providing study drug, and we are responsible for conducting and funding the study.

**Phase 1/2 Varlilumab/Yervoy® +/- CDX-1401 Combination Study:** In April 2015, we initiated a Phase 1/2 safety pilot and expansion study examining the combination of varlilumab and Yervoy in patients with stage III or IV metastatic melanoma. In the Phase 2 portion of the study, patients with tumors that express NY-ESO-1 will also receive CDX-1401. The Phase 1 portion of the study will assess the safety and tolerability of varlilumab at varying doses when administered with Yervoy 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 Yervoy. The primary objective for both cohorts is objective response rate up to 24 weeks. 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.

**Phase 1/2 Varlilumab/Sutent® Combination Study:** 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. We believe that the Phase 1 portion of the study will complete enrollment in the next few months and that the Phase 2 portion of the study will initiate by year-end 2016.

**Treatment of Other Indications:** 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.

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*CDX-1401*

CDX-1401, developed from our APC Targeting Technology, is an NY-ESO-1-antibody fusion protein for immunotherapy in multiple solid tumors. CDX-1401, 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% to 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. Results were published in *Science Translational Medicine* in April 2014. Sixty percent 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 56% 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 Yervoy or an investigational checkpoint inhibitor, and six of these patients had objective tumor regression. Six patients with melanoma received Yervoy 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 Yervoy. 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. We are currently developing a follow on program that will better assess the impact of CDX-1401 activity on response to subsequent checkpoint inhibitor therapy in these diseases.

The Phase 1 study identified a well-tolerated and immunogenic regimen to take forward into future studies. 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.

In addition to our sponsored studies, CDX-1401's potential activity is also being explored in investigator sponsored and collaborative studies. A Phase 2 study of CDX-1401 in combination with CDX-301 is being conducted in metastatic melanoma by the Cancer Immunotherapy Trials Network under a CRADA with the Cancer Therapy Evaluation Program of the NCI. This study was designed to determine if CDX-1401 works better with or without CDX-301 in melanoma. The primary outcome measure of the study is immune response to NY-ESO-1. Secondary outcome measures include analysis and characterization of peripheral blood mononuclear cells (dendritic cells, T cells, natural killer cells, etc.), additional immune monitoring, safety and clinical outcomes (survival and time to tumor recurrence). Enrollment is now complete and initial results were presented in June at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting. The data confirmed that CDX-1401 is effective at driving NY-ESO-1 immunity and further demonstrated the value of CDX-301 as a combination agent for enhancing tumor specific immune responses. Based on results to date, plans for additional studies are being considered, including a targeted study in NY-ESO-1 positive disease to determine if these enhanced immune responses can translate to improved clinical outcomes.

Additionally, a Phase 1/2b multi-arm study of the IDO1 inhibitor epacadostat (INCB024360) in combination with CDX-1401 and Hiltonol<sup>®</sup> is being conducted in patients in remission with ovarian, fallopian tube or primary peritoneal cancer by the Roswell Park Cancer Institute. Celldex is providing CDX-1401 and Hiltonol in support of this study. Patients' tumors must have expressed NY-ESO-1 or the LAGE-1 antigen to be eligible for the study. Primary outcome measures include identifying a maximum tolerated dose determined by the incidence of dose limiting toxicities and progression free survival. Secondary outcome measures include additional safety analyses and immune monitoring.

### 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

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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 (HSC) populations in healthy volunteers. In December 2013, we announced data from a preclinical combination study of CDX-301 and Mozobil<sup>®</sup> (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<sup>®</sup>, 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. Related donors of patients with hematological malignancies requiring hematopoietic stem cell transplant are administered CDX-301 for 5 or 7 days alone or in combination with Mozobil to mobilize CD34+ stem cells. The primary efficacy endpoint of the study is determine if treatment of the donor results in the collection of  $\geq 2$  million CD34+ HSCs/kg recipient body weight in  $\leq 2$  leukopoiesis collections. Other key endpoints are the safety of the treatment regimen in the donor and clinical outcomes in the recipient, including stem cell engraftment, graft-versus-host disease, immune reconstitution and relapse. Preliminary results from this Phase 2 study were presented at the annual meeting of the American Society for Blood and Marrow Transplantation in February 2016. These preliminary data from three donor/patient pairs showed that CDX-301 given as a single agent was well tolerated and effective at mobilizing hematopoietic stem cells in healthy donors. The stem cell graft contained notable increases in naive lymphocytes and plasmacytoid dendritic cells consistent with preclinical data suggesting a possible better outcome. Recipients experienced successful engraftment in an expected time frame. Given that hematopoietic stem cell transplantation is outside of our core focus, in an effort to prioritize human and capital resources, we announced in May of 2016 that we have decided not to advance CDX-301 in this particular indication at this time.

In June, at the 2016 ASCO Annual Meeting, initial results from a Phase 2 study of CDX-1401 in combination with CDX-301 in metastatic melanoma were presented that further demonstrated the value of CDX-301 as a combination agent for enhancing tumor specific immune responses. Based on

these results, plans for additional studies are being considered. The Phase 2 study was conducted by the Cancer Immunotherapy Trials Network under a CRADA with the Cancer Therapy Evaluation Program of the NCI.

In addition to our sponsored studies and clinical trial collaborations, CDX-301's potential activity is also being explored in investigator sponsored studies at various academic institutions. This includes a Phase 1/2 study of CDX-301 and Hiltonol in combination with low-dose radiotherapy in patients with low-grade B-cell lymphomas conducted by the Icahn School of Medicine at Mount Sinai. The primary outcome of the study is objective response rate. Secondary outcome measures include safety and tumor specific immune response.

#### CDX-014

CDX-014 is a fully-human monoclonal ADC that targets T cell immunoglobulin and mucin domain 1, or TIM-1. TIM-1 expression is upregulated in several cancers, most notably renal cell and ovarian carcinomas, and is associated with a more malignant phenotype of renal cell carcinoma (RCC) and 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. In July 2016, we announced that enrollment had opened in a Phase 1/2 study of CDX-014 to patients with both clear cell and papillary RCC. The Phase 1 dose-escalation portion of the study will evaluate cohorts of patients receiving increasing doses of CDX-014 to determine the maximum tolerated dose and a recommended dose for Phase 2 study. The Phase 2 portion of the study will enroll approximately 25 patients to assess the anti-tumor activity of CDX-014 at the recommended dose in advanced renal cell carcinoma as measured by objective response rate. Secondary objectives include safety and tolerability, pharmacokinetics, immunogenicity and additional measures of anti-tumor activity.

#### Rintega

On March 7, 2016, we announced that our Phase 3 study of Rintega<sup>®</sup> in patients with newly diagnosed EGFRvIII-positive glioblastoma was being discontinued. This decision was made based on the outcome of a preplanned interim analysis conducted by an independent Data Safety and Monitoring Board (DSMB). The DSMB determined that continuation of the study would not result in reaching statistical significance for the primary endpoint of the study, overall survival in patients with minimal residual disease, as both the Rintega arm and the control arm were performing on par with each other. In the ACT IV study, Rintega performed

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consistently with prior Phase 2 studies but the control arm significantly outperformed expectations (Hazard ratio = 0.99; median OS: Rintega 20.4 months vs. control 21.1 months). Based on this recommendation, we discontinued the study. Study closure activities are substantially complete, and we continue to anticipate that we will not incur substantial additional costs related to Rintega at this time. We are in the process of conducting a thorough review of the data, and plan to present the ACT IV results at the Society for Neuro-Oncology Annual Meeting in November of 2016. All patients on the Rintega arm of the ACT IV study, prior Phase 2 studies and existing compassionate use recipients have been offered ongoing access to Rintega on a compassionate use basis.

#### 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/A for the year ended December 31, 2015 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 June 30, 2016 compared with Three Months Ended June 30, 2015

	Three Months Ended June 30,		Increase/ (Decrease) \$	Increase/ (Decrease) %
	2016	2015		
	(In thousands)			
Revenue:				
Product Development and Licensing Agreements	\$ 604	\$ 334	\$ 270	81%
Contracts and Grants	785	1,844	(1,059)	(57)%
Total Revenue	\$ 1,389	\$ 2,178	\$ (789)	(36)%
Operating Expense:				
Research and Development	25,711	26,490	(779)	(3)%
General and Administrative	7,790	8,184	(394)	(5)%
Amortization of Acquired Intangible Assets	254	254	—	0%
Total Operating Expense	33,755	34,928	(1,173)	(3)%
Operating Loss	(32,366)	(32,750)	(384)	(1)%
Investment and Other Income, Net	414	391	23	6%
Net Loss	\$ (31,952)	\$ (32,359)	\$ (407)	(1)%

#### Net Loss

The \$0.4 million decrease in net loss for the three months ended June 30, 2016 compared to the three months ended June 30, 2015 was primarily the result of a decrease in research and development and general and administrative expenses, partially offset by a decrease in contracts and grants revenue.

#### Revenue

The \$0.3 million increase in product development and licensing agreements revenue for the three months ended June 30, 2016 compared to the three months ended June 30, 2015 was primarily related to our BMS agreement. In May 2014, we entered into a clinical trial collaboration with BMS whereby



BMS made a one-time payment to us of \$5.0 million which we are recognizing as revenue along with BMS's 50% share of the clinical trial cost over our estimated performance period of five years. The \$1.1 million decrease in contracts and grants revenue for the three months ended June 30, 2016 compared to the three months ended June 30, 2015 was primarily related to our Rockefeller University agreement pursuant to which we perform research and development services for Rockefeller.

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*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 June 30,		Increase/ (Decrease) \$	Increase/ (Decrease) %
	2016	2015		
	(In thousands)			
Personnel	\$ 8,779	\$ 7,227	\$ 1,552	21%
Laboratory Supplies	877	1,264	(387)	(31)%
Facility	1,391	1,423	(32)	(2)%
License Fees	386	54	332	615%
Product Development	12,246	14,922	(2,676)	(18)%

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The \$1.6 million increase in personnel expenses for the three months ended June 30, 2016 compared to the three months ended June 30, 2015 was primarily due to higher stock-based compensation of \$0.8 million and increased headcount. We expect personnel expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Laboratory supply expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The \$0.4 million decrease in laboratory supply expense for the three months ended June 30, 2016 compared to the three months ended June 30, 2015 was primarily due to lower manufacturing supply purchases. We expect supply expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Facility expenses include depreciation, amortization, utilities, rent, maintenance, and other related expenses incurred at our facilities. Facility expenses for the three months ended June 30, 2016 were consistent with the three months ended June 30, 2015. We expect facility expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

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 June 30, 2016 compared to the three months ended June 30, 2015 was due to the timing of certain development and/or regulatory milestones achieved by our drug candidates. We expect license fee expense to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing. The \$2.7 million decrease in product development expenses for the three months ended June 30, 2016 compared to the three months ended June 30, 2015 was primarily the result of a decrease in clinical trial costs of \$3.2 million primarily related to decreases in Rintega clinical trial costs of \$5.0 million, partially offset by increases in glembatumumab vedotin and varlilumab clinical trial costs of \$2.0 million. An increase in contract manufacturing of \$0.8 million and in contract research of \$0.4 million were partially offset by a decrease in contract diagnostics of \$0.7 million. We expect product development expenses to decrease over the next twelve months due to the discontinuation of the Rintega program, which impact will be partially offset by increased expenses in our glembatumumab vedotin and varlilumab programs, although there may be fluctuations on a quarterly basis.

*General and Administrative Expense*

The \$0.4 million decrease in general and administrative expenses for the three months ended June 30, 2016 compared to the three months ended June 30, 2015 was primarily due to lower commercial planning costs of \$1.1 million partially offset by higher stock-based compensation of \$0.7 million. We expect general and administrative expense to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

*Amortization Expense*

Amortization expenses for the three months ended June 30, 2016 were relatively consistent compared to the three months ended June 30, 2015. We expect amortization expense of acquired intangible assets to decrease over the next twelve months as certain acquired intangible assets become fully amortized.

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*Investment and Other Income, Net*

Investment and other income, net for the three months ended June 30, 2016 were consistent with the three months ended June 30, 2015. We anticipate investment income to decrease over the next twelve months.

*Six Months Ended June 30, 2016 compared with Six Months Ended June 30, 2015*

	Six Months Ended June 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2016	2015	\$	%
(In thousands)				
<b>Revenue:</b>				
Product Development and Licensing Agreements	\$ 1,057	\$ 676	\$ 381	56%
Contracts and Grants	1,635	1,988	(353)	(18)%
<b>Total Revenue</b>	<b>\$ 2,692</b>	<b>\$ 2,664</b>	<b>\$ 28</b>	<b>1%</b>
<b>Operating Expense:</b>				
Research and Development	53,158	51,615	1,543	3%
General and Administrative	17,097	14,273	2,824	20%
Amortization of Acquired Intangible Assets	507	507	—	0%
<b>Total Operating Expense</b>	<b>70,762</b>	<b>66,395</b>	<b>4,367</b>	<b>7%</b>
Operating Loss	(68,070)	(63,731)	4,339	7%
Investment and Other Income, Net	1,445	1,198	247	21%
<b>Net Loss</b>	<b>\$ (66,625)</b>	<b>\$ (62,533)</b>	<b>\$ 4,092</b>	<b>7%</b>

#### Net Loss

The \$4.1 million increase in net loss for the six months ended June 30, 2016 compared to the six months ended June 30, 2015 was primarily the result of an increase in general and administrative and research and development expenses, partially offset by an increase in investment and other income, net.

#### Revenue

The \$0.4 million increase in product development and licensing agreements revenue for the six months ended June 30, 2016 compared to the six months ended June 30, 2015 was primarily related to our BMS agreement. The \$0.4 million decrease in contracts and grants revenue for the six months ended June 30, 2016 compared to the six months ended June 30, 2015 was primarily related to our Rockefeller University agreement.

#### Research and Development Expense

	Six Months Ended June 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2016	2015	\$	%
(In thousands)				
Personnel	\$ 17,611	\$ 13,773	\$ 3,838	28%
Laboratory Supplies	1,661	2,429	(768)	(32)%
Facility	2,884	2,768	116	4%
License Fees	439	209	230	110%
Product Development	26,253	29,457	(3,204)	(11)%

The \$3.8 million increase in personnel expenses for the six months ended June 30, 2016 compared to the six months ended June 30, 2015 was primarily due to higher stock-based compensation of \$1.3 million and increased headcount.

The \$0.8 million decrease in laboratory supply expense for the six months ended June 30, 2016 compared to the six months ended June 30, 2015 was primarily due to lower manufacturing supply purchases.

The \$0.1 million increase in facility expenses for the six months ended June 30, 2016 compared to the six months ended June 30, 2015 was primarily due to leases for additional space we entered into during the past year.

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The \$0.2 million increase in license fee expenses for the six months ended June 30, 2016 compared to the six months ended June 30, 2015 was due to the timing of certain development and/or regulatory milestones achieved by our drug candidates.

The \$3.2 million decrease in product development expenses for the six months ended June 30, 2016 compared to the six months ended June 30, 2015 was primarily the result of a decrease in clinical trial costs of \$5.8 million primarily related to decreases in Rintega clinical trial costs of \$8.4 million, partially offset by increases in glembatumumab vedotin and varlilumab clinical trial costs of \$3.0 million. Contract manufacturing increased \$2.2 million and contract research and contract diagnostics also increased \$0.2 million and \$0.1 million, respectively.

#### General and Administrative Expense

The \$2.8 million increase in general and administrative expenses for the six months ended June 30, 2016 compared to the six months ended June 30, 2015 was primarily due to higher stock-based compensation of \$1.8 million, facility costs of \$0.3 million and legal costs of \$0.2 million.

#### Amortization Expense

Amortization expenses for the six months ended June 30, 2016 was relatively consistent as compared to the six months ended June 30, 2015.

#### Investment and Other Income, Net

The \$0.2 million increase in investment and other income, net for the six months ended June 30, 2016 compared to the six months ended June 30, 2015 was primarily due to higher levels of cash and investment balances compared to prior year.

## LIQUIDITY AND CAPITAL RESOURCES

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

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

At June 30, 2016, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of \$220.1 million. We incurred a net loss of \$66.6 million for the six months ended June 30, 2016. Net cash used in operations for the six months ended June 30, 2016 was \$68.7 million. We believe that the cash, cash equivalents and marketable securities at June 30, 2016 combined with the anticipated proceeds from future sales of our common stock under the Cantor agreement, are sufficient to meet estimated working capital requirements and fund planned operations through 2018.

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.

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*Operating Activities*

Net cash used in operating activities was \$68.7 million for the six months ended June 30, 2016 compared to \$57.4 million for the six months ended June 30, 2015. The increase in net cash used in operating activities was primarily due to an increase in net loss of \$4.1 million and changes in operating assets and liabilities. We expect that cash used in operating activities will decrease over the next twelve months primarily related to the discontinuation of the Rintega program, which impact will be partially offset by increased expenses in our glebatumumab vedotin and varlilumab programs, although there may be fluctuations on a quarterly basis.

Net cash used in operating activities was \$57.4 million for the six months ended June 30, 2015 compared to \$52.7 million for the six months ended June 30, 2014. The increase in net cash used in operating activities was primarily due to an increase in net loss of \$4.4 million and changes in working capital.

We have incurred and will continue to incur significant costs in the area of research and development, including preclinical studies 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 provided by investing activities was \$26.2 million for the six months ended June 30, 2016 compared to net cash used in investing activities of \$81.2 million for the six months ended June 30, 2015. The increase in net cash provided by investing activities was primarily due to net sales and maturities of marketable securities for the six months ended June 30, 2016 of \$29.3 million as compared to net purchases of marketable securities of \$78.1 million for the six months ended June 30, 2015.

Net cash used in investing activities was \$81.2 million for the six months ended June 30, 2015 compared to \$76.7 million for the six months ended June 30, 2014. The increase in net cash used in investing activities was primarily due to net purchases of marketable securities for the six months ended June 30, 2015 of \$78.1 million as compared to \$75.6 million for the six months ended June 30, 2014.

*Financing Activities*

Net cash provided by financing activities was \$2.9 million for the six months ended June 30, 2016 compared to \$192.1 million for the six months ended June 30, 2015. Net proceeds from stock issuances pursuant to employee benefit plans, were \$0.3 million during the six months ended June 30, 2016 compared to \$3.3 million for the six months ended June 30, 2015.

In May 2016, we entered into an agreement with Cantor Fitzgerald & Co. to allow us to issue and sell shares of our common stock having an aggregate offering price of up to \$60.0 million from time to time through Cantor, acting as agent. In June and July 2016, we issued 593,111 and 1,109,536 shares under the agreement and raised \$2.7 million and \$5.0 million in net proceeds, respectively. At July 31, 2016, we had \$52.0 million remaining in aggregate offering price available under the agreement.

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

**AGGREGATE CONTRACTUAL OBLIGATIONS**

The disclosures relating to our contractual obligations reported in our Annual Report on Form 10-K/A for the year ended December 31, 2015 which was filed with the SEC on February 25, 2016 have not materially changed since we filed that report.

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

We own financial instruments that are sensitive to market risk as part of our investment portfolio. Our investment portfolio is used to preserve our capital until it is used to fund operations, including our research and development activities. None of these market-risk sensitive instruments are held for trading purposes. We invest our cash primarily in money market mutual funds. These investments are evaluated quarterly to determine the fair value of the portfolio. From time to time, we invest our excess cash balances in marketable securities including municipal bond securities, U.S. government agency securities, and high-grade corporate bonds that meet high credit quality standards, as specified in our investment policy. Our investment policy seeks to manage these assets to

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achieve our goals of preserving principal and maintaining adequate liquidity. Because of the short-term nature of these investments, we do not believe we have material exposure due to market risk. The impact to our financial position and results of operations from likely changes in interest rates is not material.

We do not utilize derivative financial instruments. The carrying amounts reflected in the balance sheet of cash and cash equivalents, accounts receivables and accounts payable approximates fair value at June 30, 2016 due to the short-term maturities of these instruments.

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

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

As of June 30, 2016, we evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2016. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within time periods specified by the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

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

There were no changes in our internal control over financial reporting during the three months ended June 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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## **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/A for the year ended December 31, 2015, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K/A 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/A filed with the Securities and Exchange Commission on February 25, 2016.

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<b>Item 6.</b>	<b>Exhibits</b>
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| 3.1 | Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company’s Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.                                    |
| 3.2 | Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company’s Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.        |
| 3.3 | Second Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.2 of the Company’s Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission. |
| 3.4 | Third Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company’s Quarterly Report on Form 10-Q, filed May 10, 2002 with the Securities and Exchange Commission.                             |
| 3.5 | Fourth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company’s Current Report on Form 8-K, filed on March 11, 2008 with the Securities and Exchange Commission.                          |
| 3.6 | Fifth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.2 of the Company’s Current Report on Form 8-K, filed on March 11, 2008 with the Securities and Exchange Commission.                           |
| 3.7 | Sixth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.7 of the Company’s Quarterly Report on Form 10-Q, filed November 10, 2008 with the Securities and Exchange Commission.                        |

10.1	Controlled Equity Offering Sales Agreement, dated May 19, 2016, by and between Celldex Therapeutics, Inc. and Cantor Fitzgerald & Co., incorporated by reference to Exhibit 1.1 to the Company's current report on Form 8-K, filed on May 19, 2016 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.

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## SIGNATURES

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

### CELLEX THERAPEUTICS, INC.

BY:

/s/ ANTHONY S. MARUCCI

Dated: August 8, 2016

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

/s/ AVERY W. CATLIN

Dated: August 8, 2016

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

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## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
3.1	Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
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*101	XBRL Taxonomy Extension Definition Linkbase Document.

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\* Filed herewith.  
\*\* Furnished herewith.

CERTIFICATION

I, Anthony S. Marucci, certify that:

1. I have reviewed this report on Form 10-Q of Celldex Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2016

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

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CERTIFICATION

I, Avery W. Catlin, certify that:

1. I have reviewed this report on Form 10-Q of Celldex Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2016

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

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SECTION 1350 CERTIFICATIONS

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

Date: August 8, 2016

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

Date: August 8, 2016

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.

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