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

FORM 10-Q

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

For the quarterly period ended September 30, 2017

OR

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

Commission File Number: 000-15006

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

Delaware	**No. 13-3191702**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

Perryville III Building, 53 Frontage Road, Suite 220, Hampton, New Jersey 08827
(Address of principal executive offices) (Zip Code)

(908) 200-7500
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth 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 ☐ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of October 31, 2017, 135,985,329 shares of common stock, $.001 par value per share, were outstanding.

CELLDEX THERAPEUTICS, INC.

FORM 10-Q

For the Quarterly Period Ended September 30, 2017

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PART I — FINANCIAL INFORMATION
Item 1. Unaudited Financial Statements

CELLDEX THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

(In thousands, except share and per share amounts)

	September 30, 2017	December 31, 2016
ASSETS		
Current Assets:		
Cash and Cash Equivalents	$ 54,735	$ 42,461
Marketable Securities	85,795	147,315
Accounts and Other Receivables	3,013	1,784
Prepaid and Other Current Assets	3,774	4,009
Total Current Assets	147,317	195,569
Property and Equipment, Net	11,308	13,192
Intangible Assets, Net	67,815	81,487
Other Assets	2,002	2,134
Goodwill	90,976	90,976
Total Assets	$ 319,418	$ 383,358
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	$ 1,278	$ 1,740
Accrued Expenses	17,845	28,657
Current Portion of Long-Term Liabilities	5,792	4,826
Total Current Liabilities	24,915	35,223
Other Long-Term Liabilities	75,351	82,704
Total Liabilities	100,266	117,927
Commitments and Contingent Liabilities		
Stockholders' Equity:		
Convertible Preferred Stock, $.01 Par Value; 3,000,000 Shares Authorized; No Shares Issued and Outstanding at September 30, 2017 and December 31, 2016	—	—
Common Stock, $.001 Par Value; 297,000,000 Shares Authorized; 132,108,478 and 120,516,654 Shares Issued and Outstanding at September 30, 2017 and December 31, 2016, respectively	132	121
Additional Paid-In Capital	1,025,108	982,255
Accumulated Other Comprehensive Income	2,588	2,541
Accumulated Deficit	(808,676)	(719,486)
Total Stockholders' Equity	219,152	265,431
Total Liabilities and Stockholders' Equity	$ 319,418	$ 383,358

See accompanying notes to unaudited condensed consolidated financial statements

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

(In thousands, except per share amounts)

	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
REVENUES:				
Product Development and Licensing Agreements	$ 1,238	$ 493	$ 2,488	$ 1,551
Contracts and Grants	2,686	1,727	6,799	3,362
Total Revenues	3,924	2,220	9,287	4,913
OPERATING EXPENSES:				
Research and Development	21,915	25,009	72,707	78,168
General and Administrative	5,346	6,950	19,109	24,049
In-Process Research and Development Impairment	13,000	—	13,000	—
Gain on Fair Value Remeasurement of Contingent Consideration	(4,600)	—	(200)	—
Amortization of Acquired Intangible Assets	224	254	672	760
Total Operating Expenses	35,885	32,213	105,288	102,977
Operating Loss	(31,961)	(29,993)	(96,001)	(98,064)
Investment and Other Income, Net	398	395	1,611	1,841
Net Loss Before Income Tax Benefit	(31,563)	(29,598)	(94,390)	(96,223)
Income Tax Benefit	5,200	—	5,200	—
Net Loss	$ (26,363)	$ (29,598)	$ (89,190)	$ (96,223)
Basic and Diluted Net Loss Per Common Share	$ (0.20)	$ (0.29)	$ (0.71)	$ (0.97)
Shares Used in Calculating Basic and Diluted Net Loss per Share	129,640	100,672	125,856	99,398
COMPREHENSIVE LOSS:				
Net Loss	$ (26,363)	$ (29,598)	$ (89,190)	$ (96,223)
Other Comprehensive Income:				
Unrealized Gain (Loss) on Marketable Securities	11	(113)	47	303
Comprehensive Loss	$ (26,352)	$ (29,711)	$ (89,143)	$ (95,920)

See accompanying notes to unaudited condensed consolidated financial statements

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

(In thousands)

	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
Cash Flows from Operating Activities:		
Net Loss	$ (89,190)	$ (96,223)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation and Amortization	3,392	2,135
Amortization of Intangible Assets	672	760
Amortization and Premium of Marketable Securities, Net	(171)	768
Loss on Sale or Disposal of Assets	6	74
In-Process Research and Development Impairment	13,000	—
Gain on Fair Value Remeasurement of Contingent Consideration	(200)	—
Income Tax Benefit	(5,200)	—
Stock-Based Compensation Expense	9,728	11,709
Non-Cash Expense	—	1,638
Changes in Operating Assets and Liabilities:		
Accounts and Other Receivables	(1,229)	(609)
Prepaid and Other Current Assets	525	(325)
Other Assets	132	—
Accounts Payable and Accrued Expenses	(10,888)	(11,560)
Other Liabilities	(987)	(1,054)
Net Cash Used in Operating Activities	(80,410)	(92,687)
Cash Flows from Investing Activities:		
Sales and Maturities of Marketable Securities	183,683	194,915
Purchases of Marketable Securities	(122,235)	(149,877)
Investment in Other	—	(1,801)
Acquisition of Property and Equipment	(1,598)	(2,113)
Net Cash Provided by Investing Activities	59,850	41,124
Cash Flows from Financing Activities:		
Net Proceeds from Stock Issuances	32,642	10,666
Proceeds from Issuance of Stock from Employee Benefit Plans	192	532
Net Cash Provided by Financing Activities	32,834	11,198
Net Increase (Decrease) in Cash and Cash Equivalents	12,274	(40,365)
Cash and Cash Equivalents at Beginning of Period	42,461	72,108
Cash and Cash Equivalents at End of Period	$ 54,735	$ 31,743
Non-cash Investing Activities		
Acquisition of Property and Equipment Included in Accounts Payable and Accrued Expenses	$ 75	$ 65
Non-cash Supplemental Disclosure		
Shares Issued to Former Kolltan Executive for Settlement of Severance	$ 302	$ —

See accompanying notes to unaudited condensed consolidated financial statements

CELLDEX THERAPEUTICS, INC.
Notes to Unaudited Condensed Consolidated Financial Statements
September 30, 2017

(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. In June 2017, the Company liquidated its wholly-owned subsidiary, Celldex Therapeutics Europe GmbH. All intercompany balances and 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, 2016, which are included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 14, 2017. 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, 2017.

At September 30, 2017, the Company had cash, cash equivalents and marketable securities of $140.5 million. The Company has had recurring losses and incurred a loss of $89.2 million for the nine months ended September 30, 2017. Net cash used in operations for the nine months ended September 30, 2017 was $80.4 million. The Company believes that the cash, cash equivalents and marketable securities at November 7, 2017 will be sufficient to meet estimated working capital requirements and fund planned operations for at least the next twelve months from the date of issuance of these financial statements.

During the next twelve months and beyond, the Company will take further steps to raise additional capital to meet its liquidity needs. These capital raising activities may include, but may not be limited to, one or more of the following: the licensing of drug candidates 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 financings 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. The Company's ability to continue funding its planned operations into and beyond twelve months from the issuance date is also dependent on the timing and manner of payment of future contingent milestones from the Kolltan acquisition, in the event that the Company achieves the drug candidate milestones related to those payments. The Company, at its option, may decide to pay those milestone payments in cash, shares of its common stock or a combination thereof. If the Company is unable to raise the funds necessary to meet its liquidity needs, it may have to delay or discontinue the development of one or more programs, discontinue or delay ongoing or anticipated clinical trials, license out programs earlier than expected, raise funds at a significant discount or on other unfavorable terms, if at all, or sell all or a part of the Company.

(2) Significant Accounting Policies

The significant accounting policies used in preparation of these condensed consolidated financial statements on Form 10-Q for the quarterly period ended September 30, 2017 are consistent with those discussed in Note 2 to the financial statements in our Annual Report on Form 10-K for the year ended December 31, 2016, except for the adoption of new accounting standards during the first nine months of 2017 as discussed below.

Newly-Adopted Accounting Pronouncements

On January 1, 2017, the Company adopted 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 Company elected to continue to estimate forfeitures expected to occur to determine stock-based compensation expense. Upon adoption, the Company's gross deferred tax assets and corresponding valuation allowance each increased by $17.7 million related to tax deductions from the exercise of stock options that previously would have been credited to additional paid-in-capital when realized.

On January 1, 2017, the Company adopted a new U.S. GAAP accounting standard which simplifies how an entity is required to test goodwill for impairment. A goodwill impairment will be measured by the amount by which a reporting unit's carrying value exceeds its fair value, with the amount of impairment not to exceed the carrying amount of goodwill.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board 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 consolidated financial statements upon adoption.

In May 2014, the FASB issued a new U.S GAAP accounting standard that updates guidance and disclosure requirements for recognizing revenue. The new revenue recognition standard provides a five-step model for recognizing revenue from contracts with customers. The core principle is that a company should recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. The new standard will be effective for the Company on January 1, 2018 and can be applied using one of two methods: retrospectively to each prior period presented or a modified retrospective application by recognizing a cumulative-effect adjustment as a component of equity as of the date of adoption. The Company expects to adopt the new revenue standard using the modified retrospective application method. During the fourth quarter of 2017, the Company plans to finalize its assessments over the impact that these standards may have on its consolidated financial statements and disclosures. As a result of adopting this standard, the Company plans to implement additional processes and controls, including additional disclosures, to comply with the new standard.

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 consolidated financial statements.

In August 2016, the FASB issued new U.S. GAAP guidance which clarifies the classification of certain cash receipts and payments in the statement of cash flows. This standard is effective for the company on January 1, 2018. The adoption of this new guidance is not expected to have a material impact on the Company's consolidated financial statements.

(3) Fair Value Measurements

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

	As of September 30, 2017	Level 1	Level 2	Level 3
		(In thousands)		
Assets:				
Money market funds and cash equivalents	$ 42,032	$ —	$ 42,032	$ —
Marketable securities	85,795	—	85,795	—
	$ 127,827	$ —	$ 127,827	$ —
Liabilities:				
Kolltan acquisition contingent consideration	$ 44,000	$ —	$ —	$ 44,000
	$ 44,000	$ —	$ —	$ 44,000

	As of December 31, 2016	Level 1	Level 2	Level 3
		(In thousands)		
Assets:				
Money market funds and cash equivalents	$ 20,445	$ —	$ 20,445	$ —
Marketable securities	147,315	—	147,315	—
	$ 167,760	$ —	$ 167,760	$ —
Liabilities:				
Kolltan acquisition contingent consideration	$ 44,200	$ —	$ —	$ 44,200
	$ 44,200	$ —	$ —	$ 44,200

The Company's financial assets consist mainly of cash and cash equivalents and marketable securities and are classified as Level 2 within the valuation hierarchy. 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.

The following table reflects the activity for the Company's contingent consideration liabilities measured at fair value using Level 3 inputs for the nine months ended September 30, 2017 (in thousands):

	Other Long-Term Liabilities: Contingent Consideration
Balance at December 31, 2016	$ 44,200
Fair value adjustments included in operating expenses	(200)
Balance at September 30, 2017	$ 44,000

The valuation technique used to measure fair value of the Company's Level 3 liabilities, which consist of contingent consideration related to the acquisition of Kolltan in 2016 (Note 11), was primarily an income approach. The Company may be required to pay future consideration of up to $172.5 million that is contingent upon the achievement of specified development, regulatory approvals or sales-based milestone events. The significant unobservable inputs used in the fair value measurement of the contingent consideration are estimates including probability of success, discount rates and amount of time until the conditions of the milestone payments are met.

During the three and nine months ended September 30, 2017, the Company recorded a $4.6 million and a $0.2 million gain on fair value remeasurement of contingent consideration, respectively, primarily due to a reduction in fair value attributed to the milestones related to the Company's anti-KIT program and partially offset by losses related to changes in discount rates and the passage of time affecting remaining milestones. The Company's anti-KIT program includes CDX-0158 and CDX-0159, a variant of CDX-0158. CDX-0159 is being fully developed in-house with the intention of replacing CDX-0158 in clinical development. The Company expects manufacturing and IND-enabling efforts for CDX-0159 will be completed in 2018.

The Company did not have any transfers of assets or liabilities between the fair value measurement classifications during the nine months ended September 30, 2017.

(4) Marketable Securities

The following is a summary of marketable securities, classified as available-for-sale:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(In thousands)		
September 30, 2017				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	$ 13,725	$ 5	$ (3)	$ 13,727
Maturing after one year through three years	—	—	—	—
Total U.S. government and municipal obligations	$ 13,725	$ 5	$ (3)	$ 13,727
Corporate debt securities				
Maturing in one year or less	$ 72,078	$ 3	$ (13)	$ 72,068
Maturing after one year through three years	—	—	—	—
Total corporate debt securities	$ 72,078	$ 3	$ (13)	$ 72,068
Total marketable securities	$ 85,803	$ 8	$ (16)	$ 85,795
December 31, 2016				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	$ 52,754	$ 5	$ (12)	$ 52,747
Maturing after one year through three years	296	8	—	304
Total U.S. government and municipal obligations	$ 53,050	$ 13	$ (12)	$ 53,051
Corporate debt securities				
Maturing in one year or less	$ 94,320	$ —	$ (56)	$ 94,264
Maturing after one year through three years	—	—	—	—
Total corporate debt securities	$ 94,320	$ —	$ (56)	$ 94,264
Total marketable securities	$ 147,370	$ 13	$ (68)	$ 147,315

The Company holds investment grade marketable securities and none were considered to be other-than-temporarily impaired as of September 30, 2017. Marketable securities include $0.3 million and $0.6 million in accrued interest at September 30, 2017 and December 31, 2016, respectively.

(5) Intangible Assets and Goodwill

Intangible Assets, Net

The table below presents information for the Company's finite-lived intangible assets that are subject to amortization and indefinite-lived intangible assets:

		September 30, 2017			December 31, 2016		
	Estimated Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
				(In thousands)			
Finite-lived Intangible Assets:							
License Rights	16 years	$ 14,500	$ (7,175)	$ 7,325	$ 14,500	$ (6,503)	$ 7,997
Indefinite-lived Intangible Assets:							
IPR&D	Indefinite	60,490	—	60,490	73,490	—	73,490
Total Intangible Assets, Net		$ 74,990	$ (7,175)	$ 67,815	$ 87,990	$ (6,503)	$ 81,487

Indefinite-lived intangible assets consist of acquired in-process research and development ("IPR&D") related to the development of glembatumumab vedotin acquired in connection with the CuraGen acquisition and the development of the anti-KIT program, CDX-3379 and the TAM programs acquired in connection with the Kolltan acquisition. As of September 30, 2017, no IPR&D asset had reached technological feasibility nor did any have alternative future uses.

The Company performs an impairment test on IPR&D assets at least annually, or more frequently if events or changes in circumstances indicate that IPR&D assets may be impaired. During the three and nine months ended September 30, 2017, the

Company recorded a non-cash partial impairment charge of $13.0 million on the anti-KIT program IPR&D assets acquired from Kolltan. The Company determined that changes in projected development and regulatory timelines related to the anti-KIT program taken together constituted a triggering event that required the Company to evaluate the intangible asset for impairment. As part of this evaluation, the present value of probability adjusted estimated net future cash flows was used to determine the fair value of the program and compared to the carrying value of the program. As a result of this impairment assessment, the Company concluded that a non-cash partial impairment charge of $13.0 million on the anti-KIT program IPR&D asset acquired from Kolltan be recorded for the three and nine months ended September 30, 2017 for the amount the fair value of the anti-KIT program exceeded its carrying amount.

Due to the nature of IPR&D projects, the Company may experience future delays or failures to obtain regulatory approvals to conduct clinical trials, failures of such clinical trials or other failures to achieve a commercially viable product, and as a result, may recognize further impairment losses in the future.

Goodwill

There have been no changes to the carrying amount of goodwill during the nine months ended September 30, 2017. The Company performs an annual impairment test of goodwill as of July 1 each year. The Company tested goodwill for impairment as of July 1, 2017 and concluded that goodwill was not impaired.

(6) Other Long-Term Liabilities

Other long-term liabilities include the following:

	September 30, 2017	December 31, 2016
	(In thousands)	
Deferred Rent	$ 669	$ 398
Net Deferred Tax Liabilities related to IPR&D	22,854	28,054
Deferred Income from Sale of Tax Benefits	8,940	9,436
Accrued Lease Restructuring	854	1,154
Long-Term Severance	100	539
Contingent Milestones	44,000	44,200
Deferred Revenue	3,726	3,749
Total	81,143	87,530
Less Current Portion	(5,792)	(4,826)
Long-Term Portion	$ 75,351	$ 82,704

In November 2015, December 2014, January 2014 and January 2013, 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 and $0.8 million to an independent third party for $9.2 million, $1.8 million, $1.0 million and $0.8 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. The Company recognized $0.0 million and $0.5 million in other income related to the sale of these tax benefits for the three and nine months ended September 30, 2017, respectively, and $0.0 million and $0.6 million during the three and nine months ended September 30, 2016, respectively.

In December 2016, the Company decided not to occupy the 11,500 square feet of expansion space ("Needham Expansion") at its Needham, Massachusetts facility. The Company agreed to lease the Needham Expansion in August 2015 and the term of the lease expires in July 2020. In October 2017, the Company entered into a sublease agreement for the Needham Expansion. In March 2017, the Company terminated its lease in Branford, CT and consolidated its Connecticut operations in its New Haven, CT facility. The Company recorded restructuring expense of $0.2 million to general and administrative expense related to the Branford, CT lease termination. The activity related to accrued lease restructuring for the nine months ended September 30, 2017 is presented below (in thousands):

	Accrued Lease Restructuring
Balance at December 31, 2016	$ 1,154
Expense	170
Payments	(470)
Balance at September 30, 2017	$ 854

(7) Stockholders' Equity

In May 2016, the Company and Cantor Fitzgerald & Co. ("Cantor") entered into a controlled equity offering sales agreement ("2016 Cantor Agreement") 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. During the nine months ended September 30, 2017, the Company issued 11,326,363 shares of its common stock under the 2016 Cantor Agreement resulting in net proceeds to the Company of $32.6 million, after deducting commission and offering expenses. At September 30, 2017, the Company had $11.7 million remaining in aggregate gross offering price available under the 2016 Cantor Agreement. In October 2017, the Company completed sales under the 2016 Cantor Agreement and issued 3,871,709 shares of its common stock resulting in net proceeds to the Company of $11.3 million.

(8) Stock-Based Compensation

A summary of stock option activity for the nine months ended September 30, 2017 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In Years)
Options Outstanding at December 31, 2016	10,218,710	$ 11.14	6.5
Granted	2,309,900	$ 2.34	
Exercised	—	$ —	
Canceled	(945,792)	$ 9.21	
Options Outstanding at September 30, 2017	11,582,818	$ 9.54	5.9
Options Vested and Expected to Vest at September 30, 2017	11,460,583	$ 9.59	5.8
Options Exercisable at September 30, 2017	7,360,799	$ 11.05	4.1
Shares Available for Grant Under the 2008 Plan	7,780,663		

The weighted average grant-date fair value of stock options granted during the nine month period ended September 30, 2017 was $1.57. Stock-based compensation expense for the three and nine months ended September 30, 2017 and 2016 was recorded as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
	(In thousands)			
Research and development	$ 1,546	$ 2,042	$ 5,310	$ 5,866
General and administrative	1,193	1,754	4,418	5,843
Total stock-based compensation expense	$ 2,739	$ 3,796	$ 9,728	$ 11,709

The fair value of employee and director stock options granted during the three and nine month periods ended September 30, 2017 and 2016 were valued using the Black-Scholes option-pricing model with the following assumptions:

	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
Expected stock price volatility	76%	76%	76 — 77%	70 — 77%
Expected option term	6.0 years	6.0 years	6.0 years	6.0 years
Risk-free interest rate	2.0%	1.4%	2.0 — 2.3%	1.4 — 1.6%
Expected dividend yield	None	None	None	None

(9) Accumulated Other Comprehensive Income

The changes in accumulated other comprehensive income, which is reported as a component of stockholders' equity, for the nine months ended September 30, 2017 are summarized below:

	Unrealized (Loss) Gain on Marketable Securities	Foreign Currency Items	Total
	(In thousands)		
Balance at December 31, 2016	$ (55)	$ 2,596	$ 2,541
Other comprehensive gain	47	—	47
Balance at September 30, 2017	$ (8)	$ 2,596	$ 2,588

No amounts were reclassified out of accumulated other comprehensive income during the nine months ended September 30, 2017.

(10) Revenue

Rockefeller University (Rockefeller)

In 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 $0.3 million and $1.4 million in revenue related to the Rockefeller agreement during the three and nine months ended September 30, 2017, respectively, and $1.1 million and $1.8 million during the three and nine months ended September 30, 2016, respectively.

Bristol-Myers Squibb Company (BMS)

In 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, which was acquired by 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 share development costs and that the Company will be responsible for conducting the ongoing Phase 1/2 study.

The Company has determined that its performance obligations under the BMS agreement, which primarily include performing research and development, supplying varlilumab and participating in the joint development committee, should be accounted for as a single unit of accounting and estimated that its performance period under the BMS agreement would be 5 years. Accordingly, the $5.0 million up-front payment was initially recorded as deferred revenue and is being recognized as revenue on a straight-line basis over the estimated 5-year performance period using the Contingency Adjusted Performance Model ("CAPM"). The BMS agreement also provides for BMS to reimburse the Company for 50% of the external costs incurred by the Company in connection with the clinical trial. The BMS payments are recognized as revenue under the CAPM. The Company recorded $0.9 million and $2.1 million in revenue related to the BMS agreement during the three and nine months ended September 30, 2017, respectively, and $0.5 million and $1.5 million during the three and nine months ended September 30, 2016, respectively.

International AIDS Vaccine Initiative (IAVI)

In 2017, the Company entered into an agreement with IAVI pursuant to which the Company performs research and development and manufacturing services for IAVI outlined under subsequently negotiated task orders. Revenue is recognized as services are performed under the negotiated task orders. The Company recorded $1.7 million and $4.0 million in revenue related to the IAVI agreement during the three and nine months ended September 30, 2017, respectively.

Frontier Biotechnologies, Inc. (Frontier)

In 2017, the Company entered into an agreement with Frontier pursuant to which the Company performs research and development and manufacturing services for Frontier outlined under subsequently negotiated task orders. Revenue is recognized as services are performed under the negotiated task orders. The Company recorded $0.6 million in revenue related to the Frontier agreement during both the three and nine months ended September 30, 2017.

(11) Kolltan Acquisition

In connection with the Kolltan Acquisition, effective November 29, 2016, the Company issued 18,257,996 shares of common stock of the Company in exchange for all of the share and debt interests in Kolltan. The Company also agreed to issue an aggregate of 437,901 shares of its common stock, less tax withholdings, to certain former officers of Kolltan. During the nine months ended September 30, 2017, the Company issued 91,749 shares of its common stock and at September 30, 2017, the Company's remaining obligation is to issue 125,123 shares of its common stock, less tax withholdings, related to this severance obligation. In addition, in the event that certain specified preclinical and clinical development milestones related to Kolltan's development programs and/or Celldex's development programs and certain commercial milestones related to Kolltan's drug candidates are achieved, Celldex will be required to pay Kolltan's stockholders milestone payments of up to $172.5 million, which milestone payments may be made, at Celldex's sole election, in cash, in shares of Celldex's common stock or a combination of both, subject to provisions of the Merger Agreement.

The transaction was accounted for as a business combination with Celldex treated as the accounting acquirer. All of the assets acquired and liabilities assumed in the transaction are recognized at their acquisition-date fair values, while transaction costs associated with the transaction are expensed as incurred.

Purchase Price

The purchase price for Kolltan was based on the acquisition-date fair value of the consideration transferred, which was calculated based on the closing price of the Company's common stock of $4.02 per share on November 29, 2016. The acquisition-date fair value of the consideration transferred consisted of the following (in thousands):

Fair value of common stock issued for upfront payment	$	73,397
Fair value of contingent consideration		44,200
Kolltan transaction expenses paid in cash by the Company		3,768
Total consideration transferred	$	121,365

Allocations of Assets and Liabilities

The Company has allocated the consideration transferred for Kolltan to net tangible assets, intangible assets, and goodwill. The difference between the aggregate consideration transferred and the fair value of assets acquired and liabilities assumed was allocated to goodwill. This goodwill relates to the potential synergies from the Kolltan Acquisition and deferred tax liabilities related to acquired IPR&D intangible assets. None of the goodwill is expected to be deductible for income tax purposes. The following table summarizes the fair values of the assets acquired and liabilities assumed at the acquisition date (in thousands):

Cash and cash equivalents	$	8,160
Other current and long-term assets		799
Property and equipment, net		2,072
In-process research and development (IPR&D)		61,690
Goodwill		82,011
Deferred tax liabilities, net		(23,393)
Other assumed liabilities		(9,974)
Total	$	121,365

The purchase price allocation has been prepared on a preliminary basis and is subject to change as additional information becomes available concerning the fair value and tax basis of the acquired assets and liabilities. Any adjustments to the purchase price allocation will be made as soon as practicable but no later than one year from the acquisition date.

Pro Forma Financial Information

If the operations of the Company and Kolltan were combined as of January 1, 2016, the unaudited pro forma net loss for the three and nine months ended September 30, 2016 would have been $35.5 million and $120.4 million, respectively, or $(0.30) and $(1.02) per share, respectively. The unaudited pro forma combined results are not necessarily indicative of the actual results that would have occurred had the acquisition been consummated at that date or of the future operations of the combined entities.

(12) Income Taxes

Massachusetts, New Jersey and Connecticut are the three states in which the Company primarily operates or has operated and has income tax nexus. The Company's wholly-owned subsidiary, Celldex Australia Pty Ltd, operates in Brisbane, Australia. The Company is not currently under examination by any jurisdictions for any tax year.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its net deferred tax assets, which are comprised principally of net operating loss carryforwards, capitalized R&D expenditures and R&D tax credit carryforwards. The Company has determined that it is more likely than not that it will not recognize the benefits of federal and state deferred tax assets and, as a result, a full valuation allowance was maintained at September 30, 2017 and December 31, 2016 against the Company's net deferred tax assets.

As of September 30, 2017 and December 31, 2016, the Company had $22.9 million and $28.1 million of deferred tax liabilities, net recorded on the balance sheet primarily associated with temporary differences related to the Company's IPR&D assets. The $5.2 million decrease in deferred tax liabilities, net during the three and nine months ended September 30, 2017 was due to the partial impairment of the anti-KIT program IPR&D assets.

(13) Net Loss Per Share

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

	Nine months ended September 30,	
	2017	2016
Stock options	11,582,818	10,150,598
Restricted stock	96,668	60,000
	11,679,486	10,210,598

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 liquidity needs, on terms acceptable to us, or at all. If we are unable to raise the funds necessary to meet our liquidity needs, we may have to delay or discontinue the development of one or more programs, discontinue or delay ongoing 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;
- our ability to realize the anticipated benefits from the acquisition of Kolltan and to operate the combined business efficiently;
- 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 drug candidates and expand our focus to broader markets for our existing targeted immunotherapeutics;
- our ability to adapt our proprietary antibody-targeted technology, or APC Targeting Technology™, to develop new, safe and effective therapeutics for oncology and infectious disease indications;
- our ability to protect our intellectual property rights, including the ability to successfully defend patent oppositions filed against a European patent related to technology we use in varlilumab, and our ability to avoid intellectual property litigation, which can be costly and divert management time and attention; and
- the factors listed under the headings "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's annual report on Form 10-K for the year ended December 31, 2016 and other reports that we file with the Securities and Exchange Commission.

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

OVERVIEW

We are a biopharmaceutical company focused on the development and commercialization of several immunotherapy technologies and other cancer-targeting biologics. Our drug candidates, including antibodies, antibody-drug conjugates and other protein-based therapeutics, are derived from a broad set of complementary technologies which have the ability to engage the human immune system and/or directly inhibit tumors 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 cancer. We established proof of principle in a Phase 1 study with varlilumab, which supported the initiation of combination studies in various indications. We also have a number of earlier stage drug candidates in clinical development, including CDX-3379, a human monoclonal antibody designed to block the activity of ErbB3 (HER3) in solid tumors; CDX-014, an antibody-drug conjugate targeting renal and ovarian cancers; CDX-1401, a targeted immunotherapeutic aimed at antigen presenting cells, or APCs, for cancer indications; and, CDX-301, an immune cell mobilizing agent and dendritic cell growth factor. Our drug candidates address market opportunities for which we believe current therapies are inadequate or non-existent.

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

The following table reflects Celldex-sponsored clinical studies that we are actively pursuing at this time. All programs are currently fully owned by Celldex.

Product (generic)	Indication/Field	Status	Sponsor
Glembatumumab vedotin	Triple negative breast cancer	Phase 2b	Celldex
Glembatumumab vedotin	Metastatic melanoma (with varlilumab or CPI[1])	Phase 2	Celldex
Varlilumab	Multiple solid tumors (with nivolumab)	Phase 2	Celldex[2]
CDX-3379	Head and neck squamous cell cancer (with cetuximab)	Phase 2[3]	Celldex
CDX-014	Renal cell carcinoma	Phase 1	Celldex
CDX-1140	Multiple solid tumors	Phase 1[3]	Celldex

[1]checkpoint inhibitor; [2]BMS collaboration; [3]expected to initiate by year-end 2017

We also routinely work with external parties, such as government agencies, to collaboratively advance our drug candidates. The following pipeline reflects clinical trials of our drug candidates being actively pursued by outside organizations. In addition to the studies listed below, we also have an Investigator Initiated Research (IIR) program with seven studies ongoing with our drug candidates and additional studies currently under consideration.

Product (generic)	Indication/Field	Status	Sponsor
Glembatumumab vedotin	Uveal melanoma	Phase 2	NCI (CRADA)
Glembatumumab vedotin	Squamous cell lung cancer	Phase 2	PrECOG, LLC
CDX-1401/CDX-301	Malignant melanoma	Phase 2	NCI (CRADA)
CDX-1401/atezolizumab/SGI-110	Ovarian cancer	Phase 1	NCI (CRADA)

The expenditures that will be necessary to execute our business plan are subject to numerous uncertainties. Completion of clinical trials may take several years or more, and the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product candidate. It is not unusual for the clinical development of these types of product candidates to

each take five years or more and for total development costs to exceed $100 million for each product candidate. We estimate that clinical trials of the type we generally conduct are typically completed over the following timelines:

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

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

- the number of patients that ultimately participate in the trial;
- the duration of patient follow-up that seems appropriate in view of results;
- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patient subjects; and
- the efficacy and safety profile of the product candidate.

We test potential product candidates in numerous preclinical studies for safety, toxicology and immunogenicity. We may then conduct multiple clinical trials for each product candidate. As we obtain results from trials, we may elect to discontinue or delay clinical trials for certain product candidates in order to focus our resources on more promising product candidates.

An element of our business strategy is to pursue the research and development of a broad portfolio of product candidates. This is intended to allow us to diversify the risks associated with our research and development expenditures. To the extent we are unable to maintain a broad range of product candidates, our dependence on the success of one or a few product candidates increases.

Regulatory approval is required before we can market our product candidates as therapeutic products. In order to proceed to subsequent clinical trial stages and to ultimately achieve regulatory approval, the regulatory agency must conclude that our clinical data are 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, 2016, we incurred an aggregate of $422.1 million in research and development expenses. The following table indicates the amount incurred for each of our significant research programs and for other identified research and development activities during the nine months ended September 30, 2017 and 2016. The amounts disclosed in the following table reflect direct research and development costs, license fees associated with the underlying technology and an allocation of indirect research and development costs to each program.

	Nine Months Ended September 30,	
	2017	2016
	(In thousands)	
Glembatumumab vedotin	$ 26,240	$ 20,577
Varlilumab	11,956	22,777
Anti-KIT Program	3,223	—
CDX-3379	3,611	—
CDX-014	1,925	3,059
CDX-1401	617	3,804
CDX-301	1,058	3,402
CDX-1140	5,788	1,642
TAM Program	3,914	—
Rintega	1,429	14,624
Other Programs	12,946	8,283
Total R&D Expense	$ 72,707	$ 78,168

Clinical Development Programs

Glembatumumab Vedotin

Glembatumumab vedotin is an antibody-drug conjugate, or ADC, that consists of a fully human monoclonal antibody, CR011, linked to a potent cell-killing drug, monomethyl auristatin E, or MMAE. The CR011 antibody specifically targets glycoprotein NMB, referred to as gpNMB, that is over-expressed in a variety of cancers including breast cancer, 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, glembatumumab vedotin targets and binds to gpNMB, and upon internalization into the targeted cell, glembatumumab vedotin is designed to release MMAE from CR011 to produce a cell-killing effect. Glembatumumab vedotin is being studied across multiple indications in company-sponsored trials and in collaborative studies with external parties. The U.S. Food and Drug Administration, or FDA, has granted Fast Track designation to glembatumumab 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 glembatumumab vedotin may be commercialized in those indications.

Treatment of Metastatic Breast Cancer: The Phase 1/2 study of glembatumumab vedotin administered intravenously once every three weeks evaluated patients with locally advanced or metastatic breast cancer (MBC) 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 supported an acceptable safety profile of glembatumumab vedotin at the pre-defined maximum dose level (1.88 mg/kg) in 6 patients. An additional 28 patients with MBC 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 exhibited an acceptable safety profile in this patient population with the most common adverse events being rash, neuropathy and fatigue. The primary anti-cancer 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 Phase 2 dose, median PFS was 9.1 weeks.

A subset of 10 patients had “triple negative disease,” a more aggressive metastatic breast cancer subtype that carries a high risk of relapse and reduced survival as well as limited therapeutic options. In these patients, the 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 subsequent EMERGE study was a randomized, multi-center Phase 2b study of glembatumumab 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 glembatumumab vedotin or single-agent Investigator's Choice chemotherapy. Patients randomized to receive Investigator's Choice were allowed to cross over to receive glembatumumab vedotin following disease progression. Activity endpoints included response rate, PFS and overall survival (OS). The final study results, as shown below, suggested that glembatumumab vedotin induced 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 glembatumumab vedotin were also observed to be greatest in patients with high gpNMB expression and, in particular, in patients with triple negative breast cancer who also had high gpNMB expression.

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

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

Tumor response assessed by RECIST 1.1, inclusive of response observed at a single time point.

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

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

In December 2013, we initiated METRIC, a randomized, controlled Phase 2b study of glembatumumab vedotin in patients with triple negative breast cancer that over-expresses gpNMB. Clinical trial study sites were opened 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 an opportunity existed to expand the study into the EU. The amendment expanded patient entry criteria to position it for the possibility of 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, defined as the time from randomization to the earlier of disease progression or death due to any cause. 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. Since implementation of these changes, both the FDA and central European regulatory authorities have reviewed the protocol design, and we believe the METRIC study could potentially support marketing approval in both the U.S. and Europe dependent upon data results and review.

Enrollment (n=327) in METRIC was completed in August 2017. The study calls for 203 progression events for evaluation of the primary endpoint, which will be assessed based on an independent, central reading of patient scans. The sum of the data, including the secondary endpoints of response rate, overall survival, duration of response and safety, will be important in assessing clinical benefit. Based on the current rate of progression events in the study, the Company projects that topline primary endpoint data should be available in the second quarter of 2018.

Efforts to ensure delivery of manufactured drug that is ready for commercialization and a companion diagnostic, including partnering with a diagnostic company, are underway. While we have made and continue to make progress on these fronts, we have made the decision to stage some of the more costly work in these areas to begin after we have received results from the study. While this step will extend the timeline to complete our regulatory filings, we believe this is the most prudent use of our funds as we seek to advance our pipeline overall.

Treatment of Metastatic Melanoma: The Phase 1/2 open-label, multi-center, dose escalation study evaluated the safety, tolerability and pharmacokinetics of glembatumumab vedotin in 117 patients with unresectable stage III or IV melanoma who had failed no more than one prior line of cytotoxic therapy. The MTD and resulting Phase 2 dose 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 dose. Glembatumumab vedotin was generally well tolerated, with the most frequent treatment-related adverse events being rash, fatigue, alopecia, pruritus, diarrhea and nausea. 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 glembatumumab vedotin in patients with unresectable stage III or IV melanoma, and enrollment has been completed. In May 2016, we amended the protocol to add a second cohort of patients to a glembatumumab 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, and enrollment has been completed. In November 2016, we amended the protocol to add a third cohort of patients evaluating glembatumumab vedotin in combination with an approved checkpoint inhibitor (i.e., nivolumab or pembrolizumab) following progression on the checkpoint inhibitor alone, and enrollment is ongoing. In September 2017, we amended the protocol again to add a fourth cohort of patients evaluating glembatumumab vedotin in combination with CDX-301 to assess the safety, tolerability and biologic activity of the combination. Following completion of this cohort and evaluation of available data, the protocol amendment also allows for the exploration of additional cohorts. The primary endpoint for each cohort is ORR, except the fourth cohort which is assessing safety and tolerability. Secondary endpoints include analyses of PFS, duration of response, OS, retrospective investigation of whether the anti-cancer activity of glembatumumab vedotin is dependent upon the degree of gpNMB expression in tumor tissue and safety of both the monotherapy and combination regimens.

We presented mature data from the single-agent cohort in an oral presentation at the 2017 American Society of Clinical Oncology Annual Meeting in June. The cohort enrolled 62 evaluable patients with unresectable stage IV melanoma. All patients had been heavily pre-treated (median prior therapies = 3; range 1-8) and had progressed during or after checkpoint inhibitor therapy, and almost all patients had received both ipilimumab (n=58; 94%) and anti-PD-1/anti-PD-L1 (n=58; 94%) therapy. Twelve patients presented with BRAF mutation, and fifteen had prior treatment with BRAF or BRAF/MEK targeted agents. Median overall survival (OS) for all patients was 9.0 months (95% CI: 6.1, 13.0). As previously reported in October 2016, the primary endpoint of the cohort (threshold of 6 or more objective responses in 52 evaluable patients) was exceeded. 7 of 62 (11%) patients experienced a confirmed response, and an additional three patients also experienced single timepoint partial responses. Since data were reported in October 2016, one patient converted from a confirmed partial response to a confirmed complete response. The median duration of response was 6.0 months. A 52% disease control rate (patients without progression for greater than three months) was demonstrated, and median progression free survival (PFS) for all patients was 4.4 months. Consistent with previous studies in melanoma and breast cancer, rash was associated with greater clinical benefit. Patients who experienced rash in Cycle 1 experienced a 21% confirmed response rate, a more prolonged PFS with a median of 5.5 months (p=0.006; HR=0.39) and a more prolonged OS with a median of 15.8 months (p=0.026, HR=0.44). The safety profile was consistent with prior studies of glembatumumab vedotin with rash, neutropenia and neuropathy experienced as the most significant adverse events. Pre-treatment tumor tissue was available for 59 patients. All samples were gpNMB positive, and 78% of patients had tumors with 100% of their epithelial cells expressing gpNMB. Given both the high level of expression and the intensity of expression across this patient population, identifying a potential population for gpNMB enrichment is not feasible; therefore, all patients with metastatic melanoma could be evaluated as potential candidates for treatment with glembatumumab vedotin in future studies. We intend to conduct exploratory analyses of pre-entry skin biopsies in future patients to investigate potential predictors of response to glembatumumab vedotin, given the association of rash and outcome.

Data from the second cohort, combining glembatumumab vedotin and varlilumab, were accepted for presentation at the Society for Immunotherapy of Cancer's (SITC) 32nd Annual Meeting in November 2017. The cohort enrolled 34 patients with unresectable stage IV melanoma. All patients had been heavily pre-treated (median prior therapies = 3; range 1-8) and had progressed during or after checkpoint inhibitor (CPI) therapy (median prior CPI therapies = 2; range 1-4). Almost all patients had received ipilimumab (n=26; 76%) and/or anti-PD-1/anti-PD-L1 (n=34; 100%) therapy. Nine patients presented with BRAF mutation, and eleven had prior treatment with BRAF or BRAF/MEK targeted agents. Median PFS for all patients was 2.6 months (95% CI: 1.4, 2.8),

and median overall survival (OS) for all patients was 6.4 months (95% CI: 3.2, 8.3). One of 31 patients eligible for response evaluation experienced a confirmed partial response (3%) and an additional two patients also experienced single timepoint partial responses. 52% of patients experienced stable disease (minimum of six or more weeks). A 19% disease control rate (patients without progression for greater than three months) was demonstrated. The safety profile was consistent with prior studies of glembatumumab vedotin and there was no evidence of additive toxicity associated with the combination. Biological effects of varlilumab were consistent with prior observations and did not appear to be impacted by the addition of an antibody-drug conjugate (ADC). Modest clinical benefit in the combination could be due to multiple factors, including potential lack of sensitivity to immunotherapy in patients with checkpoint refractory disease, many of whom progressed so rapidly that they experienced a very short duration of varlilumab treatment (median 2 doses); a possible dearth of antigen presenting cells in tumors; and the potential for immune checkpoint molecules to remain unblocked without checkpoint inhibitor therapy. Planned future cohorts are designed to address some of these potential factors. No significant correlation between rash and outcome was observed, but will continue to be monitored in future cohorts.

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 and is ongoing. The study includes a dose-escalation phase followed by a two-stage Phase 2 portion (Simon two-stage design). The Phase 1, dose-escalation portion of the study is designed to assess the safety and tolerability of glembatumumab vedotin at varying dose levels. The first stage of the Phase 2 portion plans to 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 activity of glembatumumab 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 a Phase 2 study of glembatumumab vedotin in uveal melanoma. The study is a single-arm, open-label study in patients with locally recurrent or metastatic uveal melanoma. The study has a two stage design with a pre-specified activity threshold necessary in the first stage to progress enrollment to the second stage. The primary outcome measure is ORR. Secondary outcome measures include change in gpNMB expression on tumor tissue via immunohistochemistry, safety, OS and PFS. Data from this study were presented at 9th World Congress of Melanoma in October of 2017. Two (6%) objective responses were observed in 31 patients to date and 35% of patients experienced stable disease greater than 100 days (median 5.5 months). The disease control rate (response rate + stable disease) for all patients on study was noteworthy at 61%. Median PFS was 3.2 months and median OS was 11.8 months. For patients who experienced either a partial response or stable disease, median PFS was 5.5 months and median OS has not yet been reached. The NCI is conducting exploratory immune correlates to provide insight into target saturation, antigen release and potential combination strategies.

Varlilumab

Varlilumab is a fully human monoclonal agonist antibody that binds to and activates CD27, a critical co-stimulatory molecule in the immune activation cascade. We believe varlilumab works primarily by stimulating T cells, an important component of a person's immune system, to attack cancer cells. Restricted expression and regulation of CD27 enables varlilumab specifically to activate T cells, resulting in an enhanced immune response with the potential for a favorable safety profile. In preclinical studies, varlilumab has been shown to directly kill or inhibit the growth of CD27 expressing lymphomas and leukemias in *in vitro* and *in vivo* models. We have entered into license agreements with the University of Southampton, UK for intellectual property to use anti-CD27 antibodies and with Medarex (acquired by Bristol-Myers Squibb Company, or BMS) for access to the UltiMab technology to develop and commercialize human antibodies to CD27. Varlilumab was initially studied as a single-agent to establish a safety profile and assess immunologic and clinical activity in patients with cancer, but we believe the greatest opportunity for varlilumab is as an immune activator in combination with other agents. Currently, we are focusing our efforts on a Phase 1/2 clinical trial being conducted in collaboration with BMS and their PD-1 immune checkpoint inhibitor, Opdivo. Varlilumab is also being explored in combination studies, including with glembatumumab vedotin, and in ongoing and planned investigator-sponsored studies.

Single-Agent Phase 1 Study: Data from the completed, open-label Phase 1 study of varlilumab in patients with selected malignant solid tumors or hematologic cancers were presented at the Annual Meeting of the American Society of Clinical Oncology in June 2014. Varlilumab demonstrated an acceptable safety profile and induced immunologic activity in patients that is consistent with both its proposed mechanism of action and data in preclinical models. A total of 90 patients were dosed in the study at multiple clinical sites in the U.S. of which 55 patients were dosed in dose escalation cohorts (various solid and hematologic B- and T-cell tumors), and 35 patients were dosed in the expansion cohorts (melanoma, renal cell carcinoma and Hodgkin lymphoma) 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 to date. Two patients initially experienced significant objective responses including a complete response in Hodgkin lymphoma (patient remains in remission at 2.8+ years without further anticancer therapy as of September 2016; patient no longer on study) and a partial response in renal cell carcinoma (continued at 2.5+ years without further anticancer therapy as of June 2017). A patient with renal cell carcinoma that experienced significant stable disease (4+ years) has achieved a single-time point partial response at 4.2+ years without additional anticancer therapy. Twelve patients experienced stable disease up to 14 months. As of June 2017, there are two patients continuing in long term follow-up. Final results from the study in patients with solid tumors were published in the *Journal of Clinical Oncology* in April 2017.

Phase 1/2 Varlilumab/Opdivo® Combination Study: In 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 (acquired by 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 evaluate the activity of the combination in disease specific cohorts.

Data (n=36) from the Phase 1 dose escalation portion of the study were presented in an oral presentation at the American Society of Clinical Oncology Annual Meeting in June 2017. The majority of patients had PD-L1 negative tumor at baseline and presented with stage IV, heavily-pretreated disease. 80% of patients enrolled presented with refractory or recurrent colorectal (n=21) or ovarian cancer (n=8), a population expected to have minimal response to checkpoint blockade. The primary objective of the Phase 1 portion of the study was to evaluate the safety and tolerability of the combination. The combination was well tolerated at all varlilumab dose levels tested 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 evidence of immune activity, such as increase in inflammatory chemokines and decrease in T regulatory cells, was also noted. Notable disease control was also observed (stable disease or better for at least 3 months), considering the stage IV patient population contained mostly colorectal and ovarian cases (80%): 0.1 mg/kg varlilumab + 240 mg Opdivo: 1/5 (20%), 1 mg/kg varlilumab + 240 mg Opdivo: 5/15 (33%) and 10 mg/kg varlilumab + 240 mg Opdivo: 6/15 (40%).

Three partial responses (PR) were observed. A patient with PD-L1 negative, MMR proficient colorectal cancer, typically unlikely to respond to checkpoint blockade monotherapy, achieved a confirmed PR (95% decrease in target lesions) and, following completion of combination treatment, continues to receive treatment with Opdivo monotherapy at 22+ months. A patient with low PD-L1 (5% expression) squamous cell head and neck cancer achieved a confirmed PR (59% shrinkage) and experienced progression free survival of 6.7 months. A patient with PD-L1 negative ovarian cancer experienced a single timepoint PR (49% shrinkage) but discontinued treatment to a dose-limiting toxicity (immune hepatitis, an event known to be associated with checkpoint inhibition therapy). A subgroup analysis was conducted in patients with ovarian cancer based on an observed increase of PD-L1 and tumor-infiltrating lymphocytes in this patient population. In patients with paired baseline and on-treatment biopsies (n=13), only 15% were PD-L1 positive ($\geq$ 1% tumor cells) at baseline compared to 77% during treatment (p=0.015). Patients with increased tumor PD-L1 expression and tumor CD8 T cells correlated with better clinical outcome with treatment (stable disease or better).

The Phase 2 portion of the study opened to enrollment in April 2016 and includes cohorts in colorectal cancer (n=18), ovarian cancer (n=54), head and neck squamous cell carcinoma (n=54), renal cell carcinoma (n=25) and glioblastoma (n=20). Additional dosing schedules are being explored in ovarian cancer and in head and neck squamous cell carcinoma, increasing the overall size of the study compared to the original study design. The primary objective of the Phase 2 cohorts is ORR, except glioblastoma, where the primary objective is the rate of 12-month overall survival. Secondary objectives include pharmacokinetic assessments, determining the immunogenicity of varlilumab when given in combination with Opdivo and further assessing the anti-tumor activity of combination treatment. We plan to complete enrollment across all cohorts in the Phase 2 portion of the study in the first quarter of 2018 and expect to work with BMS to present data from the study at a future medical meeting.

Anti-Kit Program: CDX-0158 and CDX-0159

KIT activation is implicated in many disease processes including some cancers, neurofibromatosis and mast cell-related diseases, including autoimmune disease. CDX-0158, a humanized monoclonal antibody, is a potent inhibitor of wildtype KIT in mast cells and has demonstrated preclinical activity versus the most common oncogenic KIT mutations found in human gastrointestinal stromal tumors (GIST) in model cell lines and in spontaneous canine mast cell tumors (an established model for mastocytoma). A Phase 1 dose escalation study in patients with advanced refractory GIST and other KIT positive tumors opened to enrollment in December 2015 to determine the maximum tolerated dose, recommend a dose for further study and characterize the safety profile. A total of 28 patients have been treated with doses up to 15 mg/kg with one patient currently continuing on treatment. Importantly, no evidence of myelosuppression (an effect commonly associated with KIT inhibition) was observed in this study. Approximately two-thirds of the patients on study had infusion reactions that were manageable with pre-medication and longer infusion times. The biomarker data showed evidence of dose-related KIT engagement, and two patients experienced partial metabolic responses on fluorodeoxyglucose (FDG)-PET scan; however, these PET responses were not associated with tumor shrinkage.

The infusion reactions are believed to be the result of CDX-0158 acting as an agonist on mast cells *in vivo*, where the antibody can be cross-linked by Fc receptors and cause mast cell degranulation. Given the infusion reactions, modifications have been introduced into the Fc portion of the CDX-0158 antibody to prevent these interactions, which should eliminate the potential for Fc receptor mediated agonist activity. This second-generation version, called CDX-0159, also includes modifications to increase the half-life of the antibody, giving it additional benefits over CDX-0158. Preclinical data to date with CDX-0159 have demonstrated equivalent KIT inhibition to CDX-0158, but unlike CDX-0158, CDX-0159 does not induce KIT activation when Fc receptors are used to cross-link the antibodies. CDX-0159 is being fully developed in-house with the intention of replacing CDX-0158 in clinical development. We expect manufacturing and IND-enabling efforts for CDX-0159 will be completed in 2018.

CDX-3379

CDX-3379 is a human monoclonal antibody with half-life extension designed to block the activity of ErbB3 (HER3). We believe ErbB3 may be an important receptor regulating cancer cell growth and survival as well as resistance to targeted therapies and is expressed in many cancers, including head and neck, thyroid, breast, lung and gastric cancers, as well as melanoma. We believe the proposed mechanism of action for CDX-3379 sets it apart from other drugs in development in this class due to its ability to block both ligand-independent and ligand-dependent ErbB3 signaling by binding to a unique epitope. It has a favorable pharmacologic profile, including a longer half-life and slower clearance relative to other drug candidates in this class. CDX-3379 also has potential to enhance anti-tumor activity and/or overcome resistance in combination with other targeted and cytotoxic therapies to directly kill tumor cells. Tumor cell death and the ensuing release of new tumor antigens has the potential to serve as a focus for combination therapy with immuno-oncology approaches, even in refractory patients.

A Phase 1a/1b study was conducted, including a single-agent, dose-escalation portion and combination expansion cohorts. Data from the dose-escalation portion, which completed enrollment in September 2015, and initial data from the expansion cohorts (enrollment ongoing at the time) were presented at the American Society of Clinical Oncology Annual Meeting in June 2016. The single-agent, dose-escalation portion of the study did not identify an MTD, and there were no dose limiting toxicities. The most common adverse events included rash and diarrhea and were predominantly grade 1 or 2. Four combination arms across multiple tumor types were added to evaluate CDX-3379 with several drugs that target EGFR, HER2 or BRAF. They include combinations with Erbitux® (n=16), Tarceva® (n=8), Zelboraf® (n=4) and Herceptin® (n=10). Patients had advanced disease and were generally heavily pretreated. Across the combination arms, the most frequent adverse events were diarrhea, nausea, rash and fatigue. Objective responses were observed in the Erbitux and Zelboraf combination arms. In the Erbitux arm, there was one complete response in a patient with head and neck cancer, who had been previously treated with Erbitux and was refractory. In the Zelboraf arm, there were two partial responses in patients who had lung cancer, one of whom had been previously treated with Tafinlar® and was considered refractory. We have finalized plans for advancement into an open-label Phase 2 study in approximately 30 patients with recurrent/metastatic head and neck squamous cell cancer who are refractory to Erbitux (cetuximab). We anticipate initiating this study in the fourth quarter of 2017. The primary objective of the study is objective response rate. Second objectives include assessments of clinical benefit response (CBR), duration of response (DOR), PFS and OS, and safety and pharmacokinetics associated with the combination.

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 melanoma, lung, esophageal, liver, gastric, ovarian and bladder cancers, and up to 70% of synovial sarcomas, thus representing a broad opportunity. CDX-1401 is being developed for the treatment of malignant melanoma and a variety of solid tumors which express the cancer antigen NY-ESO-1. Preclinical studies have shown that CDX-1401 treatment results in 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 samples. Thirteen patients maintained stable disease for up to 13.4 months with a median of 6.7 months. Treatment indicates an acceptable safety profile to date, and there were no dose limiting toxicities. A variety of immune activation parameters were observed. 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 within 3 months of CDX-1401, 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. Together with Roche, we are supporting an investigator initiated study of CDX-1401 in combination with Tecentriq® (atezolizumab; anti-PD-L1) in patients with lung cancer.

CDX-1401's potential activity is being explored in investigator sponsored and collaborative studies. A Phase 2 study of CDX-1401 in combination with CDX-301 is being conducted in malignant melanoma by the Cancer Immunotherapy Trials Network (CITN) under a CRADA with the Cancer Therapy Evaluation Program of the NCI. This study was designed to determine the activity of CDX-1401 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 complete, and initial results were presented at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting. The data confirmed that CDX-1401 is capable of driving NY-ESO-1 immunity and further demonstrated the potential of CDX-301 as a combination agent for enhancing tumor specific immune responses. The NCI and CITN are planning to enroll additional cohorts to investigate alternative regimens of CDX-301.

In September 2017, a randomized, open-label Phase 1/2 study of CDX-1401 in combination with atezolizumab and SGI-110 opened to enrollment in recurrent ovarian, fallopian tube, or primary peritoneal cancer. This study is being conducted under a CRADA with the NCI Division of Cancer Treatment and Diagnosis and is designed to determine the activity of atezolizumab alone, atezolizumab plus SGI-110 and atezolizumab plus SGI-110 plus CDX-1401. The primary outcome of the Phase 1 dose escalation study is safety and only evaluates atezolizumab alone and in combination with SGI-110. The Phase 2 portion of the study is expected to add CDX-1401. The primary outcome of the Phase 2 portion of the study is a comparison of PFS between the three cohorts.

Other studies are being considered through investigator-sponsored and collaborative agreements.

CDX-301

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

A Phase 1 study of CDX-301 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 has an acceptable safety profile to date and can mobilize hematopoietic stem cell (HSC) populations in healthy volunteers.

At the 2016 ASCO Annual Meeting, initial results from a Phase 2 study of CDX-1401 in combination with CDX-301 in malignant melanoma were presented that further demonstrated the value of CDX-301 as a combination agent for enhancing tumor specific immune responses. The Phase 2 study was conducted by the Cancer Immunotherapy Trials Network, or CITN, under a CRADA with the Cancer Therapy Evaluation Program of the NCI. Based on these results the CITN is planning to enroll additional cohorts to investigate alternative regimens of CDX-301. Other studies are being considered through investigator-sponsored and collaborative agreements.

CDX-014

CDX-014 is a 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 restricted expression in healthy tissues, making it potentially amenable to an ADC approach. 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 anti-tumor activity in preclinical models of ovarian and renal cancers.

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 is evaluating cohorts of patients receiving increasing doses of CDX-014 to determine the maximum tolerated dose and a recommended dose for Phase 2 study. We anticipate expanding the Phase 1 study to encompass additional TIM-1 expressing tumor types and alternate dosing regimens. The Phase 2 portion of the study plans to 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.

CDX-1140

CDX-1140 is a fully human antibody targeted to CD40, a key activator of immune response which is found on dendritic cells, macrophages and B cells and is also expressed on many cancer cells. Potent CD40 agonist antibodies have shown encouraging results in early clinical studies; however, systemic toxicity associated with broad CD40 activation has limited their dosing. CDX-1140 has unique properties relative to other CD40 agonist antibodies: potent agonist activity is independent of Fc receptor interaction, contributing to more consistent, controlled immune activation; CD40L binding is not blocked, leading to potential synergistic effects of agonist activity near activated T cells in lymph nodes and tumors; and the antibody does not promote cytokine production in whole blood assays. CDX-1140 has shown direct anti-tumor activity in preclinical models of lymphoma.

Preclinical data, including the IND-enabling toxicology study of CDX-1140, were accepted for presentation at the Society for Immunotherapy of Cancer's (SITC) 32nd Annual Meeting in November 2017. This toxicology study of CDX-1140 clearly demonstrates strong immune activation effects and low systemic toxicity. The No Observable Adverse Effect Level (NOAEL) for CDX-1140 was determined to be 10 mg/kg in this study. The data support the design of the Phase 1 study of CDX-1140 to rapidly identify the dose for characterizing single-agent and combination activity. The Company believes that the potential for CDX-1140 will be best defined in combination studies with other immunotherapies or conventional cancer treatments.

We plan to initiate a Phase 1 study of CDX-1140 by year-end 2017. This study, which is expected to enroll up to approximately 105 patients with recurrent, locally advanced or metastatic solid tumors, is designed to determine the maximum tolerated dose during a dose-escalation phase (0.01 to 3.0 mg/kg once every four weeks until confirmed progression or intolerance) and to recommend a dose level for further study in a subsequent expansion phase. The expansion is designed to further evaluate the tolerability and biologic effects of selected dose(s) of CDX-1140 in specific tumor types. Secondary objectives include assessments of safety and tolerability, pharmacodynamics, pharmacokinetics, immunogenicity and additional measures of anti-tumor activity, including clinical benefit rate.

CRITICAL ACCOUNTING POLICIES

See Note 2 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for information regarding newly-adopted and recent accounting pronouncements. See also Note 2 to our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2016 for a discussion of our critical accounting policies. 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.

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RESULTS OF OPERATIONS

Three Months Ended September 30, 2017 Compared with Three Months Ended September 30, 2016

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2017	2016	$	%
	(In thousands)			
Revenue:				
Product Development and Licensing Agreements	$ 1,238	$ 493	$ 745	151%
Contracts and Grants	2,686	1,727	959	56%
Total Revenue	$ 3,924	$ 2,220	$ 1,704	77%
Operating Expense:				
Research and Development	21,915	25,009	(3,094)	(12)%
General and Administrative	5,346	6,950	(1,604)	(23)%
In-Process Research and Development Impairment	13,000	—	13,000	n/a
Gain on Fair Value Remeasurement of Contingent Consideration	(4,600)	—	4,600	n/a
Amortization of Acquired Intangible Assets	224	254	(30)	(12)%
Total Operating Expense	35,885	32,213	3,672	11%
Operating Loss	(31,961)	(29,993)	1,968	7%
Investment and Other Income, Net	398	395	3	1%
Net Loss Before Income Tax Benefit	(31,563)	(29,598)	1,965	7%
Income Tax Benefit	5,200	—	5,200	n/a
Net Loss	$ (26,363)	$ (29,598)	$ (3,235)	(11)%

Net Loss

The $3.2 million decrease in net loss for the three months ended September 30, 2017, as compared to the three months ended September 30, 2016, was primarily the result of a decrease in research and development and general and administrative expenses, the gain on fair value remeasurement of contingent consideration and the income tax benefit recognized offset by the in-process research and development impairment.

Revenue

The $0.7 million increase in product development and licensing agreements revenue for the three months ended September 30, 2017, as compared to the three months ended September 30, 2016, was primarily due to an increase in reimburseable clinical trial expenses from BMS associated with the Phase 1/2 study of varlilumab and Opdivo®, BMS's PD-1 immune checkpoint inhibitor. The $1.0 million increase in contracts and grants revenue for the three months ended September 30, 2017, compared to the three months ended September 30, 2016, was primarily related to our IAVI and Frontier agreements pursuant to which we perform manufacturing and R&D services for IAVI and Frontier.

Research and Development Expense

Research and development expenses consist primarily of (i) personnel expenses, (ii) laboratory supply expenses relating to the development of our technology, (iii) facility expenses, (iv) license fees and (v) product development expenses associated with our product candidates as follows:

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2017	2016	$	%
	(In thousands)			
Personnel	$ 8,933	$ 8,940	$ (7)	n/a
Laboratory Supplies	1,230	1,114	116	10%
Facility	2,056	1,537	519	34%
License Fees	162	942	(780)	(83)%
Product Development	7,316	10,697	(3,381)	(32)%

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes and were relatively consistent for the three months ended September 30, 2017, as compared to the three months ended September 30, 2016. Increases in salary expenses were offset by lower stock based compensation expense. We expect personnel expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Laboratory supplies expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The $0.1 million increase in laboratory supplies expense for the three months ended September 30, 2017, as compared to the three months ended September 30, 2016, was primarily due to higher laboratory services expenses. We expect laboratory supplies expense to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Facility expenses include depreciation, amortization, utilities, rent, maintenance, and other related expenses incurred at our facilities. The $0.5 million increase in facility expenses for the three months ended September 30, 2017, as compared to the three months ended September 30, 2016, was primarily due to the addition of the New Haven facility that we acquired with the Kolltan Acquisition and higher depreciation expense of $0.3 million. We expect facility expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

License fees expense includes annual license maintenance fees and milestone payments due upon the achievement of certain development, regulatory and/or commercial milestones. The $0.8 million decrease in license fee expenses for the three months ended September 30, 2017, as compared to the three months ended September 30, 2016, was due to the timing of certain development and/or regulatory milestones achieved by our drug candidates. We expect license fees 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 $3.4 million decrease in product development expenses for the three months ended September 30, 2017, as compared to the three months ended September 30, 2016, was primarily the result of decreases in varlilumab contract manufacturing and clinical trials expenses of $1.7 million and $1.0 million, respectively. We expect product development expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

General and Administrative Expense

The $1.6 million decrease in general and administrative expenses for the three months ended September 30, 2017, as compared to the three months ended September 30, 2016, was primarily due to lower commercial planning costs of $0.7 million and lower stock-based compensation of $0.6 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.

In-Process Research and Development Impairment

We recorded a non-cash impairment charge of $13.0 million on the anti-KIT program IPR&D assets acquired from Kolltan during the three months ended September 30, 2017. This impairment charge was related to changes in projected development and regulatory timelines regarding the anti-KIT program.

Gain on Fair Value Remeasurement of Contingent Consideration

The $4.6 million gain on fair value remeasurement of contingent consideration for the three months ended September 30, 2017 was primarily due to a reduction in fair value attributed to milestones related to our anti-KIT program. This gain was partially offset by losses related to changes in discount rates and the passage of time affecting remaining milestones. See Note 3 to the financial statements included herein for a discussion of the contingent consideration that may be payable related to the Kolltan Acquisition.

Amortization Expense

Amortization expenses for the three months ended September 30, 2017 were relatively consistent with the three months ended September 30, 2016. We expect amortization expense of acquired intangible assets to remain consistent over the next twelve months.

Investment and Other Income, Net

Investment and other income, net for the three months ended September 30, 2017 was consistent with the three months ended September 30, 2016. We anticipate investment income to decrease over the next twelve months primarily due to lower levels of cash and investment balances.

Income Tax Benefit

The income tax benefit relates to a $5.2 million decrease in deferred tax liabilities, net during the three months ended September 30, 2017. This decrease was due to the partial impairment of the anti-KIT program IPR&D assets.

Nine Months Ended September 30, 2017 Compared with Nine Months Ended September 30, 2016

	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2017	2016	$	%
	(In thousands)			
Revenue:				
Product Development and Licensing Agreements	$ 2,488	$ 1,551	$ 937	60%
Contracts and Grants	6,799	3,362	3,437	102%
Total Revenue	$ 9,287	$ 4,913	$ 4,374	89%
Operating Expense:				
Research and Development	72,707	78,168	(5,461)	(7)%
General and Administrative	19,109	24,049	(4,940)	(21)%
In-Process Research and Development Impairment	13,000	—	13,000	n/a
Gain on Fair Value Remeasurement of Contingent Consideration	(200)	—	200	n/a
Amortization of Acquired Intangible Assets	672	760	(88)	(12)%
Total Operating Expense	105,288	102,977	2,311	2%
Operating Loss	(96,001)	(98,064)	(2,063)	(2)%
Investment and Other Income, Net	1,611	1,841	(230)	(12)%
Net Loss Before Income Tax Benefit	(94,390)	(96,223)	(1,833)	(2)%
Income Tax Benefit	5,200	—	5,200	n/a
Net Loss	$ (89,190)	$ (96,223)	(7,033)	(7)%

Net Loss

The $7.0 million decrease in net loss for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016, was primarily the result of an increase in contracts and grants revenue, a decrease in general and administrative and research and development expenses and the income tax benefit recognized offset by the in-process research and development impairment.

Revenue

The $0.9 million increase in product development and licensing agreements revenue for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016, was primarily due to an increase in reimburseable clinical trial expenses related to our BMS agreement. The $3.4 million increase in contracts and grants revenue for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016, was primarily related to our IAVI and Frontier agreements executed in 2017.

Research and Development Expense

	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2017	2016	$	%
	(In thousands)			
Personnel	$ 28,079	$ 26,551	$ 1,528	6%
Laboratory Supplies	3,541	2,774	767	28%
Facility	6,649	4,421	2,228	50%
License Fees	479	1,381	(902)	(65)%
Product Development	26,965	36,950	(9,985)	(27)%

The $1.5 million increase in personnel expenses for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016, was primarily due to an increase in salaries expense and headcount related to the Kolltan acquisition.

The $0.8 million increase in laboratory supplies expense for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016, was primarily due to higher manufacturing supply purchases.

The $2.2 million increase in facility expenses for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016, was primarily due to the addition of our New Haven facility that we acquired with the Kolltan acquisition and higher depreciation expense of $1.3 million. In March 2017, the Company terminated its lease in Branford, CT and consolidated its Connecticut operations in its New Haven facility.

The $0.9 million decrease in license fees expense for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016, was due to the timing of certain development and/or regulatory milestones achieved by our drug candidates.

The $10.0 million decrease in product development expenses for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016, was primarily the result of (i) decreases in varlilumab and Rintega contract manufacturing expenses of $6.8 million and $2.5 million, respectively, partially offset by an increase in glembatumumab vedotin contract manufacturing expenses of $2.6 million and (ii) decreases in Rintega and varlilumab clinical trial costs of $5.1 million and $1.9 million, respectively, partially offset by increases in glembatumumab vedotin, anti-KIT and CDX-3379 clinical trial costs of $3.3 million.

General and Administrative Expense

The $4.9 million decrease in general and administrative expenses for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016, was primarily due to lower commercial planning costs of $3.1 million and lower stock-based compensation of $1.4 million.

In-Process Research and Development Impairment

We recorded a non-cash impairment charge of $13.0 million on the anti-KIT program IPR&D assets acquired from Kolltan during the nine months ended September 30, 2017. This impairment charge was related to changes in projected development and regulatory timelines regarding the anti-KIT program.

Gain on Fair Value Remeasurement of Contingent Consideration

The $0.2 million gain on fair value remeasurement of contingent consideration for the nine months ended September 30, 2017 was due to a reduction in fair value attributed to the milestones related to our anti-KIT program, partially offset by losses related to changes in discount rates and the passage of time affecting remaining milestones.

Amortization Expense

Amortization expenses for the nine months ended September 30, 2017 were relatively consistent as compared to the nine months ended September 30, 2016.

Investment and Other Income, Net

The $0.2 million decrease in investment and other income, net for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016, was primarily due to lower levels of cash and investment balances.

Income Tax Benefit

The deferred income tax benefit relates to a $5.2 million decrease in deferred tax liabilities, net during the nine months ended September 30, 2017. This decrease was due to the partial impairment of the anti-KIT program IPR&D assets.

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; and consulting, legal and other professional fees. To date, the primary sources of cash flows from operations have been payments received from our collaborative partners and from government entities. The timing of any new collaboration agreements, government contracts or grants and any payments under these agreements, contracts or grants cannot be easily predicted and may vary significantly from quarter to quarter.

At September 30, 2017, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of $140.5 million. We have had recurring losses and incurred a net loss of $89.2 million for the nine months ended September 30, 2017. Net cash used in operations for the nine months ended September 30, 2017 was $80.4 million. We believe that the cash, cash equivalents and marketable securities at September 30, 2017, combined with the $11.3 million in net proceeds from sales of common stock under the Cantor agreement during October 2017, are sufficient to meet estimated working capital requirements and fund planned operations through 2018; however, this could be impacted if we elected to pay contingent consideration related to the Kolltan acquisition, if any, in cash.

During the next twelve months, we will take further steps to raise additional capital to meet our liquidity needs. Our capital raising activities may include, but may not be limited to, one or more of the following: the licensing of drug candidates 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 financings 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. Our ability to continue funding our planned operations into and beyond twelve months from the issuance date is also dependent on the timing and manner of payment of future contingent milestones from the Kolltan acquisition, in the event that we achieve the drug candidate milestones related to those payments. We may decide to pay those milestone payments in cash, shares of our common stock or a combination thereof. If we are unable to raise the funds necessary to meet our liquidity needs, we may have to delay or discontinue the development of one or more programs, discontinue or delay ongoing or anticipated clinical trials, license out programs earlier than expected, raise funds at a significant discount or on other unfavorable terms, if at all, or sell all or a part of our business.

Operating Activities

Net cash used in operating activities was $80.4 million for the nine months ended September 30, 2017 as compared to $92.7 million for the nine months ended September 30, 2016. The decrease in net cash used in operating activities was primarily due to a decrease in net loss of $7.0 million and changes in operating assets and liabilities. We expect that cash used in operating activities will decrease over the next twelve months, although there may be fluctuations on a quarterly basis.

We have incurred and will continue to incur significant costs in the area of research and development, including preclinical 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 $59.9 million for the nine months ended September 30, 2017 as compared to $41.1 million for the nine months ended September 30, 2016. The increase in net cash provided by investing activities was primarily due to net sales and maturities of marketable securities for the nine months ended September 30, 2017 of $61.4 million as compared to $45.0 million for the nine months ended September 30, 2016.

Financing Activities

Net cash provided by financing activities was $32.8 million for the nine months ended September 30, 2017 as compared to $11.2 million for the nine months ended September 30, 2016. Net proceeds from stock issuances pursuant to employee benefit plans were $0.2 million during the nine months ended September 30, 2017 as compared to $0.5 million for the nine months ended September 30, 2016.

In May 2016, we entered into a controlled equity offering sales 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. During the nine months ended September 30, 2017 and 2016, we issued 11,326,363 and 2,395,949 shares, respectively, of our common stock under this agreement with Cantor resulting in net proceeds to us of $32.6 million and $10.7 million, respectively, after deducting commission and offering expenses.

AGGREGATE CONTRACTUAL OBLIGATIONS

The disclosures relating to our contractual obligations reported in our Annual Report on Form 10-K for the year ended December 31, 2016 which was filed with the SEC on March 14, 2017 have not materially changed since we filed that report.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

We do not utilize derivative financial instruments. The carrying amounts reflected in the consolidated balance sheet of cash and cash equivalents, accounts receivables and accounts payable approximates fair value at September 30, 2017 due to the short-term maturities of these instruments.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

As of September 30, 2017, we evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2017. 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 quarter ended September 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2016, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K may not be the only risks facing the Company. Additional risks and uncertainties not currently known to the Company or that the Company currently deems to be immaterial also may materially adversely affect the Company's business, financial condition and/or operating results.

There were no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 14, 2017.

Item 5. Other Information

On November 1, 2017, we determined that we should record a non-cash partial impairment charge of $13.0 million for the three months ended September 30, 2017 related to our anti-KIT program. The anti-KIT program was acquired as part of our acquisition of Kolltan Pharmaceuticals, Inc.in the fourth quarter of 2016. We determined that changes in projected development and regulatory timelines related to the anti-KIT program constituted a triggering event that required us to evaluate the intangible asset for impairment. The time periods to receive approvals from the FDA and other regulatory agencies are subject to uncertainty and therefore we will continue to evaluate the development progress for the anti-KIT program and monitor the remaining $27.0 million intangible asset for further impairment. See Note 5 to the consolidated financial statements included elsewhere in this quarterly report on Form 10-Q for further discussion of this impairment charge.

Item 6. Exhibits

The exhibits filed as part of this quarterly report on Form 10-Q are listed in the exhibit index immediately preceding the exhibits and are incorporated by reference herein.

EXHIBIT INDEX

Exhibit No.	Description
3.1	Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
3.2	Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
3.3	Second Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.2 of the Company's Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
3.4	Third Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q, filed May 10, 2002 with the Securities and Exchange Commission.
3.5	Fourth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K, filed on March 11, 2008 with the Securities and Exchange Commission.
3.6	Fifth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K, filed on March 11, 2008 with the Securities and Exchange Commission.
3.7	Sixth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.7 of the Company's Quarterly Report on Form 10-Q, filed November 10, 2008 with the Securities and Exchange Commission.
10.1	Employment Agreement, dated October 3, 2017, by and between Margo Heath-Chiozzi and Celldex Therapeutics., Inc., incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed on October 3, 2017 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.

CELLDEX THERAPEUTICS, INC.

BY:

/s/ ANTHONY S. MARUCCI

Dated: November 7, 2017

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

/s/ SAM MARTIN

Dated: November 7, 2017

Sam Martin
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION

I, Anthony S. Marucci, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 7, 2017

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

Exhibit 31.2

CERTIFICATION

I, Sam Martin, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 7, 2017

By: /s/ SAM MARTIN
Name: Sam Martin
Title: Senior Vice President and Chief Financial Officer

Exhibit 32.1

SECTION 1350 CERTIFICATIONS

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

Date: November 7, 2017

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

Date: November 7, 2017

By: /s/ SAM MARTIN
Name: Sam Martin
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.