UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2019

OR

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

Commission File Number: 000-15006

CELLDEX THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $.001	CLDX	Nasdaq Capital Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 o	Accelerated filer x
Non-accelerated filer o	Smaller reporting company x Emerging growth company o

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. o

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

As of July 31, 2019, 15,018,604 shares of common stock, $.001 par value per share, were outstanding.

CELLDEX THERAPEUTICS, INC.

FORM 10-Q

For the Quarterly Period Ended June 30, 2019

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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)

	June 30, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash and Cash Equivalents	$ 19,744	$ 24,310
Marketable Securities	61,598	69,712
Accounts and Other Receivables	1,170	3,162
Prepaid and Other Current Assets	1,853	1,895
Total Current Assets	84,365	99,079
Property and Equipment, Net	5,086	6,111
Operating Lease Right-of-Use Assets, Net	3,974	—
Intangible Assets, Net	48,690	48,690
Other Assets	129	1,929
Total Assets	$ 142,244	$ 155,809
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	$ 1,016	$ 1,069
Accrued Expenses	5,410	7,007
Current Portion of Operating Lease Liabilities	2,538	—
Current Portion of Other Long-Term Liabilities	2,545	4,526
Total Current Liabilities	11,509	12,602
Long-Term Portion of Operating Lease Liabilities	1,867	—
Other Long-Term Liabilities	19,242	19,147
Total Liabilities	32,618	31,749
Commitments and Contingent Liabilities		
Stockholders' Equity:		
Convertible Preferred Stock, $.01 Par Value; 3,000,000 Shares Authorized; No Shares Issued and Outstanding at June 30, 2019 and December 31, 2018	—	—
Common Stock, $.001 Par Value; 297,000,000 Shares Authorized; 14,816,917 and 11,957,635 Shares Issued and Outstanding at June 30, 2019 and December 31, 2018, Respectively	15	12
Additional Paid-In Capital	1,098,429	1,083,903
Accumulated Other Comprehensive Income	2,638	2,583
Accumulated Deficit	(991,456)	(962,438)
Total Stockholders' Equity	109,626	124,060
Total Liabilities and Stockholders' Equity	$ 142,244	$ 155,809

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 June 30, 2019	Three Months Ended June 30, 2018	Six Months Ended June 30, 2019	Six Months Ended June 30, 2018
REVENUES:				
Product Development and Licensing Agreements	$ 195	$ 1,667	$ 325	$ 2,662
Contracts and Grants	520	1,096	1,815	4,172
Total Revenues	715	2,763	2,140	6,834
OPERATING EXPENSES:				
Research and Development	10,081	21,448	21,232	43,323
General and Administrative	3,908	5,621	8,804	11,215
Goodwill Impairment	—	—	—	90,976
Intangible Asset Impairment	—	—	—	18,677
Other Asset Impairment	—	—	1,800	—
(Gain)/Loss on Fair Value Remeasurement of Contingent Consideration	(1,017)	(7,433)	502	(21,033)
Amortization of Acquired Intangible Assets	—	—	—	224
Total Operating Expenses	12,972	19,636	32,338	143,382
Operating Loss	(12,257)	(16,873)	(30,198)	(136,548)
Investment and Other Income, Net	478	466	1,180	1,245
Net Loss Before Income Tax Benefit	(11,779)	(16,407)	(29,018)	(135,303)
Income Tax Benefit	—	—	—	765
Net Loss	$ (11,779)	$ (16,407)	$ (29,018)	$ (134,538)
Basic and Diluted Net Loss Per Common Share	$ (0.84)	$ (1.67)	$ (2.21)	$ (14.01)
Shares Used in Calculating Basic and Diluted Net Loss Per Share	13,952	9,829	13,129	9,600
COMPREHENSIVE LOSS:				
Net Loss	$ (11,779)	$ (16,407)	$ (29,018)	$ (134,538)
Other Comprehensive Income (Loss):				
Unrealized Gain on Marketable Securities	36	31	55	26
Comprehensive Loss	$ (11,743)	$ (16,376)	$ (28,963)	$ (134,512)

See accompanying notes to unaudited condensed consolidated financial statements

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

(In thousands)

	Six Months Ended June 30, 2019	Six Months Ended June 30, 2018
Cash Flows From Operating Activities:		
Net Loss	$ (29,018)	$ (134,538)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation and Amortization	2,505	2,021
Amortization of Intangible Assets	—	224
Amortization and Premium of Marketable Securities, Net	(652)	(380)
Loss on Sale or Disposal of Assets	7	1,069
Goodwill Impairment	—	90,976
Intangible Asset Impairment	—	18,677
Other Asset Impairment	1,800	—
Loss/(Gain) on Fair Value Remeasurement of Contingent Consideration	502	(21,033)
Non-Cash Income Tax Benefit	—	(765)
Stock-Based Compensation Expense	3,157	4,536
Changes in Operating Assets and Liabilities:		
Accounts and Other Receivables	1,992	(713)
Prepaid and Other Current Assets	(137)	801
Accounts Payable and Accrued Expenses	(1,598)	(5,895)
Other Liabilities	(2,833)	(397)
Net Cash Used in Operating Activities	(24,275)	(45,417)
Cash Flows From Investing Activities:		
Sales and Maturities of Marketable Securities	67,386	106,182
Purchases of Marketable Securities	(58,565)	(76,902)
Acquisition of Property and Equipment	(484)	(591)
Net Cash Provided by Investing Activities	8,337	28,689
Cash Flows From Financing Activities:		
Net Proceeds from Stock Issuances	11,363	19,960
Proceeds from Issuance of Stock from Employee Benefit Plans	9	374
Net Cash Provided by Financing Activities	11,372	20,334
Net Increase/(Decrease) in Cash and Cash Equivalents	(4,566)	3,606
Cash and Cash Equivalents at Beginning of Period	24,310	40,288
Cash and Cash Equivalents at End of Period	$ 19,744	$ 43,894
Non-cash Investing Activities		
Accrued construction in progress	$ 55	$ —
Non-cash Supplemental Disclosure		
Shares issued to former Kolltan executive for settlement of severance	$ —	$ 57

See accompanying notes to unaudited condensed consolidated financial statements

CELLDEX THERAPEUTICS, INC.
Notes to Unaudited Condensed Consolidated Financial Statements
June 30, 2019

(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 subsidiaries. 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, 2018, which are included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 7, 2019. 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, 2019.

At June 30, 2019, the Company had cash, cash equivalents and marketable securities of $81.3 million. The Company has had recurring losses and incurred a loss of $29.0 million for the six months ended June 30, 2019. Net cash used in operations for the six months ended June 30, 2019 was $24.3 million. The Company believes that the cash, cash equivalents and marketable securities at August 7, 2019 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.

The Board of Directors of the Company approved a one for fifteen reverse stock split of the Company's outstanding common stock, which was effected on February 8, 2019. All share and per share amounts in the financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split, including reclassifying an amount equal to the reduction in par value to additional paid-in capital.

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 three and six months ended June 30, 2019 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, 2018, except as it relates to the adoption of new accounting standards during the first six months of 2019 as discussed below.

Newly Adopted Accounting Pronouncements

On January 1, 2019, the Company adopted 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 was adopted using the modified retrospective transition method, which requires the Company to apply the standard as of the effective date and does not require restatement of prior periods. The Company elected to apply the package of practical expedients, which allowed the Company to not reassess: (i) whether expired or existing contracts contain leases; (ii) lease classification for any expired or existing leases; and (iii) initial direct costs for any existing leases. Adoption of this standard did not have a material impact on the Company's Consolidated Statement of Operations and Comprehensive Loss or Statement of Cash Flow, however, upon adoption, the Company recorded right-of-use assets of $3.8 million and lease liabilities of $4.7 million on its Consolidated Balance Sheet related to the Company's operating leases. The difference between the right-of-use assets and lease liabilities recorded upon adoption is due to certain adjustments required to the right-of-use assets for prepaid rent and accrued termination expenses. Refer to Note 5 "Leases" for the Company's updated lease accounting policy and disclosures.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the Company's consolidated financial statements upon adoption.

In June 2016, the FASB issued guidance on the Measurement of Credit Losses on Financial Instruments. The guidance requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, the standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. This standard will be effective for the Company on January 1, 2020. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

In August 2018, the FASB issued amendments that modify certain disclosure requirements for fair value measurements. The amendments become effective, including interim periods, beginning January 1, 2020. Early adoption, of all the amendments or only the provisions that eliminate or modify the requirements, is permitted. The adoption of this new guidance is not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

In November 2018, the FASB issued guidance to clarify the interaction between the accounting guidance for collaborative arrangements and revenue from contracts with customers. The amendments become effective, including interim periods, beginning January 1, 2020. Early adoption, including adoption in an interim period, is permitted. This guidance is required to be applied retrospectively as of the date of our adoption of the new revenue standard on January 1, 2018. We are currently evaluating the timing of our adoption and the expected impact this guidance could have on our consolidated financial statements and related disclosures.

(3) Fair Value Measurements

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

	As of June 30, 2019	Level 1	Level 2	Level 3
		(In thousands)		
Assets:				
Money market funds and cash equivalents	$ 13,867	—	$ 13,867	—
Marketable securities	61,598	—	61,598	—
	$ 75,465	—	$ 75,465	—
Liabilities:				
Kolltan acquisition contingent consideration	$ 14,281	—	—	$ 14,281
	$ 14,281	—	—	$ 14,281

	As of December 31, 2018	Level 1	Level 2	Level 3
		(In thousands)		
Assets:				
Money market funds and cash equivalents	$ 15,755	—	$ 15,755	—
Marketable securities	69,712	—	69,712	—
	$ 85,467	—	$ 85,467	—
Liabilities:				
Kolltan acquisition contingent consideration	$ 13,779	—	—	$ 13,779
	$ 13,779	—	—	$ 13,779

The Company's financial assets consist mainly of money market funds, 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 six months ended June 30, 2019 (in thousands):

	Other Liabilities: Contingent Consideration
Balance at December 31, 2018	$ 13,779
Fair value adjustments included in operating expenses	502
Balance at June 30, 2019	$ 14,281

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, was primarily an income approach. The Company may be required to pay future consideration of up to $127.5 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 six months ended June 30, 2019, the Company recorded a $1.0 million gain and $0.5 million loss on fair value remeasurement of contingent consideration, respectively, primarily due to changes in discount rates and the passage of time. During the three and six months ended June 30, 2018, the Company recorded a $7.4 million and $21.0 million gain on fair value remeasurement of contingent consideration, respectively, primarily due to discontinuation of the glembatumumab vedotin ("Glemba") and CDX-014 programs and updated assumptions for the varlilumab program.

The Company did not have any transfers of assets or liabilities between the fair value measurement classifications during the six months ended June 30, 2019.

(4) Marketable Securities

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(In thousands)			
June 30, 2019				
U.S. government and municipal obligations (maturing in one year or less)	$ 27,622	$ 25	$ —	$ 27,647
Corporate debt securities (maturing in one year or less)	33,934	17	—	33,951
Total Marketable Securities	$ 61,556	$ 42	$ —	$ 61,598
December 31, 2018				
U.S. government and municipal obligations (maturing in one year or less)	$ 27,355	$ —	$ (4)	$ 27,351
Corporate debt securities (maturing in one year or less)	42,370	—	(9)	42,361
Total Marketable Securities	$ 69,725	$ —	$ (13)	$ 69,712

The Company holds investment-grade marketable securities, and none were in a continuous unrealized loss position for more than twelve months as of June 30, 2019 and December 31, 2018. The unrealized losses are attributable to changes in interest rates and the Company does not believe any unrealized losses represent other-than-temporary impairments. Marketable securities include $0.1 million in accrued interest at June 30, 2019 and December 31, 2018, respectively.

(5) Leases

The Company has operating leases of office, manufacturing and laboratory space, which have remaining lease terms of one to six years and may include one or more options to renew or terminate early.

The Company determines if an arrangement contains a lease at inception. Operating lease right-of-use assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. Certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued lease payments, initial direct costs paid or incentives received. The Company's leases do not contain an implicit rate, and therefore the Company uses an estimated incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. Options to extend or terminate the lease are reflected in the calculation when it is reasonably certain that the option will be exercised. The Company has elected to account for lease and non-lease components as a single lease component, however non-lease components that are variable, such as common area maintenance and utilities, are generally paid separately from rent based on actual costs incurred and therefore are not included in the right-of-use asset and operating lease liability and are reflected as an expense in the period incurred. Leases with an initial term of 12 months or less are not recorded on the balance sheet.

During the first quarter of 2019, the Company amended its Hampton, New Jersey lease to eliminate 16,200 square feet of space and extend the remaining 33,400 square feet of space for an additional five-year term with an early termination option after three years. The Company recorded an additional right-of-use asset and lease liability of $1.4 million during the first quarter of 2019 for the initial 3 years related to the amendment.

Operating lease expense was $0.5 million and $1.2 million for the three and six months ended June 30, 2019, respectively. Variable lease expense was $0.3 million and $0.7 million for the three and six months ended June 30, 2019, respectively. Operating cash flows used for operating leases during the six months ended June 30, 2019 was $0.9 million. As of June 30, 2019, the weighted-average remaining lease term was 2 years and the weighted-average discount rate was 11.3%.

Future minimum lease payments under non-cancellable leases as of June 30, 2019 were as follows:

Remainder of 2019	$	1,313
2020		2,171
2021		508
2022		747
2023		311
Total lease payments		5,050
Less imputed interest		(645)
Present value of operating lease liabilities	$	4,405

Under the prior lease accounting guidance, operating lease obligations, including estimated variable lease obligations, as of December 31, 2018 were as follows:

2019	$	4,648
2020		3,140
Thereafter		—
Total lease payments	$	7,788

(6) Intangible Assets and Goodwill

Intangible Assets, Net

As a result of the discontinuation of the Glemba program, the Company concluded that the finite-lived intangible asset related to its Amgen Fremont license rights to develop and commercialize Glemba and the indefinite-lived Glemba IPR&D asset were fully impaired and a non-cash impairment charge of $18.7 million was recorded in the first quarter of 2018. Amortization expense related to the finite-lived intangible asset was $0.0 million for the three and six months ended June 30, 2019, and $0.0 million and $0.2 million for the three and six months ended June 30, 2018, respectively.

At June 30, 2019 and 2018, the Company recorded indefinite-lived intangible assets of $48.7 million. Indefinite-lived intangible assets consist of acquired in-process research and development (“IPR&D”) related to the development of CDX-3379, the anti-KIT program (including CDX-0159) and the TAM program. CDX-3379 is in Phase 2 development. The anti-KIT and TAM programs are in preclinical development. As of June 30, 2019, none of the Company’s IPR&D assets 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. 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

The Company evaluated goodwill for potential impairment due to the discontinuation of the Glemba program in the first quarter of 2018. The carrying amount of the Company was compared to the Company’s fair value. The Company’s fair value assessment reflected a number of significant management assumptions and estimates including the Company’s probability forecasts for pipeline assets, income taxes, capital expenditures, market premium and changes in working capital requirements. Changes in these assumptions and/or discount rates could materially impact the Company’s conclusions. Through this assessment, it was determined that the carrying amount of the Company exceeded its fair value by over $91.0 million. As such, the full goodwill asset was considered impaired and a charge of $91.0 million was recorded during the first quarter of 2018.

(7) Other Assets

In 2016, the Company entered into a research and collaboration agreement with an undisclosed private company to access novel technologies and paid $3.5 million to support research activities and make an investment in the private company. The Company recorded $1.8 million to other assets related to this investment and $1.7 million was recorded to research and development expense over the term of the research activities. The stock of the private company does not have a readily determinable fair value, and therefore it is measured at cost less impairment, if any. Based on information received in April 2019, it was determined that there was a deterioration of the private company's financial condition due to a working capital deficiency and an inability to secure additional funding as of March 31, 2019. Therefore, the Company concluded that the investment was impaired, and a non-cash impairment charge of $1.8 million was recorded during the first quarter of 2019.

(8) Other Long-Term Liabilities

Other long-term liabilities include the following:

	June 30, 2019	December 31, 2018
	(In thousands)	
Net Deferred Tax Liabilities Related to IPR&D (Note 13)	$ 3,007	$ 3,007
Deferred Income From Sale of Tax Benefits	4,014	4,218
Other	—	1,083
Contingent Milestones (Note 3)	14,281	13,779
Deferred Revenue (Note 12)	485	1,586
Total	21,787	23,673
Less Current Portion	(2,545)	(4,526)
Long-Term Portion	$ 19,242	$ 19,147

In November 2015 and December 2014, the Company received approval from the New Jersey Economic Development Authority and agreed to sell New Jersey tax benefits of $9.8 million and $1.9 million to an independent third party for $9.2 million and $1.8 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 $0.2 million in other income related to the sale of these tax benefits during the three and six months ended June 30, 2019, respectively, and $0.0 million and $0.4 million during the three and six months ended June 30, 2018, respectively.

(9) Stockholders' Equity

In May 2016, the Company entered into an agreement with Cantor Fitzgerald & Co. ("Cantor") 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. In November 2017, the Company filed a prospectus supplement registering the offer and sale of shares of common stock of up to an additional $75.0 million under the agreement with Cantor. During the six months ended June 30, 2019, the Company issued 2,856,194 shares of common stock under this controlled equity offering sales agreement with Cantor resulting in net proceeds of $11.4 million after deducting commission and offering expenses. At June 30, 2019, the Company had $25.8 million remaining in aggregate gross offering price available under the Cantor agreement. In July 2019, the Company issued 201,687 shares of its common stock resulting in net proceeds to the Company of $0.5 million.

The changes in Stockholders' Equity during the three and six months ended June 30, 2019 and 2018 are summarized below:

	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	(In thousands, except share amounts)					
Consolidated Balance at December 31, 2018	11,957,635	12	1,083,903	2,583	(962,438)	124,060
Shares Issued under Stock Option and Employee Stock Purchase Plans	3,507	—	9	—	—	9
Shares Issued in Connection with Cantor Agreement	883,569	1	4,150	—	—	4,151
Share-Based Compensation	—	—	1,693	—	—	1,693
Unrealized Gain on Marketable Securities	—	—	—	19	—	19
Net Loss	—	—	—	—	(17,239)	(17,239)
Consolidated Balance at March 31, 2019	12,844,711	13	1,089,755	2,602	(979,677)	112,693
Shares Cancelled under Stock Option and Employee Stock Purchase Plans	(222)	—	—	—	—	—
Shares Issued in Connection with Cantor Agreement	1,972,428	2	7,210	—	—	7,212
Share-Based Compensation	—	—	1,464	—	—	1,464
Unrealized Gain on Marketable Securities	—	—	—	36	—	36
Net Loss	—	—	—	—	(11,779)	(11,779)
Consolidated Balance at June 30, 2019	14,816,917	15	1,098,429	2,638	(991,456)	109,626

	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
			(In thousands, except share amounts)			
Consolidated Balance at December 31, 2017	9,234,693	9	1,046,313	2,564	(812,517)	236,369
Shares Issued under Stock Option and Employee Stock Purchase Plans	9,453	—	374	—	—	374
Shares Issued in Connection with Cantor Agreement	312,802	—	11,689	—	—	11,689
Shares Issued in Connection with Kolltan Severance	971	—	38	—	—	38
Share-Based Compensation	—	—	2,488	—	—	2,488
Unrealized Loss on Marketable Securities	—	—	—	(5)	—	(5)
Adoption of ASC 606	—	—	—	—	1,263	1,263
Net Loss	—	—	—	—	(118,131)	(118,131)
Consolidated Balance at March 31, 2018	9,557,919	9	1,060,902	2,559	(929,385)	134,085
Shares Issued in Connection with Cantor Agreement	884,068	1	8,270	—	—	8,271
Shares Issued in Connection with Kolltan Severance	1,071	—	19	—	—	19
Share-Based Compensation	—	—	2,048	—	—	2,048
Unrealized Gain on Marketable Securities	—	—	—	31	—	31
Net Loss	—	—	—	—	(16,407)	(16,407)
Consolidated Balance at June 30, 2018	10,443,058	10	1,071,239	2,590	(945,792)	128,047

(10) Stock-Based Compensation

A summary of stock option activity for the six months ended June 30, 2019 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In Years)
Options Outstanding at December 31, 2018	866,132	$ 93.70	7.1
Granted	863,290	2.78	
Exercised	—	—	
Canceled	(39,348)	131.86	
Options Outstanding at June 30, 2019	1,690,074	46.37	8.4
Options Vested and Expected to Vest at June 30, 2019	1,538,046	50.45	8.3
Options Exercisable at June 30, 2019	529,136	132.85	5.7
Shares Available for Grant Under the 2008 Plan	433,391		

The weighted average grant-date fair value of stock options granted during the three and six month periods ended June 30, 2019 was $2.09. Stock-based compensation expense for the three and six month periods ended June 30, 2019 and 2018 was recorded as follows:

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
	(In thousands)		(In thousands)	
Research and development	$ 654	$ 978	$ 1,410	$ 2,289
General and administrative	810	1,070	1,747	2,247
Total stock-based compensation expense	$ 1,464	$ 2,048	$ 3,157	$ 4,536

The fair values of employee and director stock options granted during the three and six month periods ended June 30, 2019 and 2018 were valued using the Black-Scholes option pricing model with the following assumptions:

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Expected stock price volatility	91%	85%	91%	73 - 85%
Expected option term	6.0 Years	6.0 Years	6.0 Years	6.0 Years
Risk-free interest rate	1.9 – 2.4%	2.9%	1.9 – 2.5%	2.8 – 3.0%
Expected dividend yield	None	None	None	None

(11) Accumulated Other Comprehensive Income

The changes in accumulated other comprehensive income, which is reported as a component of stockholders' equity, for the six months ended June 30, 2019 are summarized below:

	Unrealized Gain/(Loss) on Marketable Securities	Foreign Currency Items	Total
		(In thousands)	
Balance at December 31, 2018	$ (13)	$ 2,596	$ 2,583
Other comprehensive gain	55	—	55
Balance at June 30, 2019	$ 42	$ 2,596	$ 2,638

No amounts were reclassified out of accumulated other comprehensive income during the six months ended June 30, 2019.

(12) Revenue

Product Development and Licensing Revenue

The Company's primary product development and licensing revenue is associated with a clinical collaboration agreement with BMS entered into in 2014 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 this agreement, BMS made an upfront payment to Celldex of $5.0 million and provides funding for 50% of the external costs incurred by the Company in connection with the clinical trial. The Company recorded $0.1 million and $0.2 million in revenue related to this agreement during the three and six months ended June 30, 2019, respectively, and $1.7 million and $2.6 million during the three and six months ended June 30, 2018, respectively.

Contract and Grants Revenue

The Company has entered into agreements with Rockefeller University and Duke University pursuant to which the Company performs manufacturing and research and development services on a time-and-materials basis. The Company recognized $0.4 million and $1.5 million in revenue for labor hours and direct costs incurred under these agreements during the three and six months ended June 30, 2019, respectively, and $0.7 million and $1.4 million during the three and six months ended June 30, 2018, respectively.

The Company has entered into fixed-fee manufacturing and research and development arrangements with the International AIDS Vaccine Initiative and Frontier Biotechnologies, Inc. The Company recognized $0.1 million and $0.2 million in revenue under these agreements during the three and six months ended June 30, 2019, respectively, and $0.4 million and $2.7 million during the three and six months ended June 30, 2018, respectively.

Contract Assets and Liabilities

At December 31, 2018 and June 30, 2019, the Company's right to consideration under all contracts was considered unconditional, and as such, there were no recorded contract assets. At December 31, 2018 and June 30, 2019, the Company had $1.6 million and $0.5 million in contract liabilities recorded, respectively. Revenue recognized from contract liabilities as of December 31, 2018 during the three and six months ended June 30, 2019 was $0.4 million and $1.2 million, respectively.

(13) Income Taxes

The Company has evaluated the positive and negative evidence bearing upon the realizability of its net deferred tax assets and considered its history of losses, ultimately concluding that it is "more likely than not" that the Company will not recognize the benefits of federal, state and foreign deferred tax assets and, as such, has maintained a full valuation allowance on its deferred tax assets as of June 30, 2019 and December 31, 2018.

The net deferred tax liability of $3.0 million at June 30, 2019 and December 31, 2018 relates to the temporary differences associated with the IPR&D intangible assets acquired in previous business combinations and is not deductible for tax purposes. As a result of the discontinuation of the Glemba program, the Company recorded a $0.8 million non-cash income tax benefit during the first quarter of 2018.

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

(14) Net Loss Per Share

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

	Six Months Ended June 30,	
	2019	2018
Stock Options	1,690,074	931,080
Restricted Stock	1,110	4,000
	1,691,184	935,080

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 dependence on product candidates, which are still in an early development stage;
- our ability to successfully complete research and further development, including animal, preclinical and clinical studies, and, if we obtain regulatory approval, commercialization of our drug candidates and the growth of the markets for those drug candidates;
- our ability to raise sufficient capital to fund our animal, preclinical and 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 anticipated timing for preclinical development, regulatory submissions, commencement and completion of clinical trials and product approvals;
- our ability to negotiate strategic partnerships, where appropriate, for our drug candidates;
- 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 preclinical and clinical testing;
- our expectations of the attributes of our product and development candidates, including pharmaceutical properties, efficacy, safety and dosing regimens;
- 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;
- 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 realize the anticipated benefits from the acquisition of Kolltan;

- 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;

- our ability to develop and commercialize products without infringing the intellectual property rights of third parties; and

- the risk factors set forth elsewhere in this quarterly report on Form 10-Q 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, 2018 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 immunotherapies and other targeted biologics. Our drug candidates 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. They are aimed at addressing market opportunities for which we believe current therapies are inadequate or non-existent.

We are focusing our efforts and resources on the continued research and development of:

- CDX-1140, an agonist monoclonal antibody targeted to CD40, a key activator of immune response, currently being studied as a single-agent and in combination with CDX-301, a dendritic cell growth factor, in a Phase 1 dose-escalation study in multiple types of solid tumors and B cell lymphomas. In addition, we are evaluating the potential combination of CDX-1140 with varlilumab, an immune modulating antibody designed to target CD27 and enhance a patient’s immune response, especially in lymphomas which co-express CD40 and CD27 receptors;

- CDX-3379, a monoclonal antibody designed to block the activity of ErbB3 (HER3), currently in an early Phase 2 study in advanced head and neck squamous cell cancer in combination with Erbitux®; and,

- CDX-0159, a monoclonal antibody that specifically binds the KIT receptor, potently inhibits its activity and is expected to enter a Phase 1 study in healthy subjects by year end.

We routinely work with external parties to collaboratively advance our drug candidates. In addition to Celldex-led studies, we also have an Investigator Initiated Research (IIR) program with multiple studies ongoing with our drug candidates.

Our goal is to build a fully integrated, commercial-stage biopharmaceutical company that develops important therapies for patients with unmet medical needs. We believe 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. Currently, all programs are fully owned by Celldex.

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 drug candidate. It is not unusual for the clinical development of these types of drug candidates to each take five years or more, and for total development costs to exceed $100 million for each drug 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 drug candidate.

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

An element of our business strategy is to pursue the discovery, research and development of a broad portfolio of drug 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 drug candidates, our dependence on the success of one or a few drug candidates increases.

Regulatory approval is required before we can market our drug 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 demonstrate that our product candidates 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 drug candidates. In the event that third parties take over the clinical trial process for one of our drug 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, 2018, we incurred an aggregate of $469.9 million in research and development expenses. The following table indicates the amount incurred for each of our significant research programs and for other identified research and development activities during the six months ended June 30, 2019 and 2018. 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.

	Six Months Ended June 30, 2019	Six Months Ended June 30, 2018
	(In thousands)	
CDX-1140	$ 3,195	$ 2,325
CDX-3379	2,180	1,672
Anti-KIT Program (including CDX-0159)	1,974	3,967
Varlilumab	1,947	5,660
CDX-301	635	1,164
CDX-527	3,412	208
TAM Program	2,571	3,056
Other Programs	5,318	25,271
Total R&D Expense	$ 21,232	$ 43,323

Clinical Development Programs

CDX-1140

CDX-1140 is a fully human agonist monoclonal 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 studies of CDX-1140 clearly demonstrate strong immune activation effects and low systemic toxicity and support the design of the Phase 1 study to identify the dose for characterizing single-agent and combination activity.

We initiated a Phase 1 study of CDX-1140 in November 2017. This study is expected to enroll up to approximately 180 patients with recurrent, locally advanced or metastatic solid tumors and B cell lymphomas. The study is designed to determine the maximum tolerated dose, or MTD, 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. We believe that the potential for CDX-1140 will be best defined in combination studies with other immunotherapies or conventional cancer treatments.

In support of this, the Phase 1 study protocol also allows for the exploration of CDX-1140 in combination with CDX-301 at a fixed dose of CDX-301 and escalating doses of CDX-1140. Dendritic cells, which express CD40, are often rare or missing from the tumor microenvironment and are critical for initiating anti-tumor immunity. CDX-301 is being utilized to increase the number of dendritic cells in blood and tissue available for CDX-1140 activation. CDX-1140 should, in turn, activate and mature the dendritic cells, an important step for enhancing anti-tumor immune responses.

Interim data from the Phase 1 study were presented in April 2019 at the American Association for Cancer Research (AACR) Annual Meeting. 30 patients were enrolled in the study at the time of data analysis (n=22 monotherapy; n=8 combination). Six monotherapy dosing cohorts in both solid tumors and non-Hodgkin lymphoma (NHL) (0.01, 0.03, 0.09, 0.18, 0.36 and 0.72 mg/kg) and two combination cohorts in solid tumors (0.09 and 0.18 mg/kg) with CDX-301 were completed. Enrollment to the seventh monotherapy cohort at 1.5 mg/kg and to the third CDX-301 combination cohort at 0.36 mg/kg were ongoing. In general, patients had advanced disease and were heavily pretreated (median number of prior therapies: 4 monotherapy arm; 3.5 combination arm). CDX-1140 was generally well tolerated. An MTD had not been reached. Three patients experienced serious treatment related adverse events (pneumonitis and hypoxia; possible cytokine release, fatigue and fever; and, fatigue and nausea). Across both arms of the study, there were no high grade (Grade 3 or above) drug-related changes observed in liver function tests or platelets, including at CDX-1140 dose levels which exceed the MTDs or recommended Phase 2 dose reported with other CD40 agonists. The addition of CDX-301 did not affect the tolerability of CDX-1140 at the dose levels tested. Dose dependent biological effects consistent with CD40-mediated immune activation were reported. Higher dose levels achieved circulating antibody concentrations in the range of 20 to 30 micrograms

CDX-1140 per milliliter. Transient dose-dependent pharmacodynamic effects were observed including activation of dendritic cells and B cells, along with increases in pro-inflammatory cytokines and chemokines in the blood, all of which are consistent with CD40-mediated immune activation and the hypothesis that CDX-1140 is achieving dose levels optimal for systemic exposure. The addition of CDX-301 further enhanced cytokine responses. While not anticipated at low CDX-1140 dose levels, stable disease was observed in this heavily pretreated population.

Continued enrollment is ongoing to define the MTD and select a dose for disease-specific expansion cohorts that will be monitored for clinical activity. Future combination opportunities are also being considered, including with PD-1 or PD-L1 inhibitors, chemotherapy, radiation therapy and Celldex's potent CD27 agonist monoclonal antibody varlilumab. Several B cell lymphomas, including diffuse large B-cell lymphoma and follicular lymphoma, also express both CD40 and CD27. Celldex's varlilumab is a potent CD27 agonist and has been shown to synergize with CDX-1140 in NHL models. We plan to present updated data from the Phase 1 study at a future medical meeting in 2019.

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. We believe 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. CDX-3379 has been evaluated in three Phase 1 studies for the treatment of multiple solid tumors that express ErbB3 and is currently being evaluated in a Phase 2 study in combination with Erbitux in Erbitux-resistant, advanced head and neck squamous cell carcinoma (HNSSC).

A Phase 1a/1b study of CDX-3379 was conducted in solid tumors. The study included a single-agent, dose-escalation portion and combination expansion cohorts. The single-agent, dose-escalation portion of the study did not identify an MTD, and there were no dose limiting toxicities. 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=9) 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 durable 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, as well as an unconfirmed partial response in a patient with thyroid cancer. Initial data were presented at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting.

In April 2018, results from a window-of-opportunity study evaluating the effect of CDX-3379 on potential biomarkers in patients with HNSCC were presented at the American Association for Cancer Research (AACR) Annual Meeting. The study enrolled 12 patients with newly diagnosed HNSCC who received two doses of CDX-3379, at a two-week interval prior to tumor resection. CDX-3379 reduced phosphorylated ErbB3 (pErbB3) levels in 83% (10/12) of patient samples, with greater than or equal to 50% decreases in 58% of patients (7/12), which met the primary study objective. Stable disease was observed in 92% (11/12) of patients prior to surgery, and a patient with HPV-negative disease experienced an exceptional response (greater than 92% tumor shrinkage). CDX-3379 was well-tolerated, and no treatment-related adverse events were observed.

Preclinical data from the combination of CDX-3379 and Erbitux in xenograft models of HNSCC were also presented at the AACR Annual Meeting in April 2018. Combining CDX-3379 and Erbitux inhibited tumor growth more potently than Erbitux alone. Mechanistic studies demonstrated a reduction of PD-L1 expression from the combination.

We initiated an open-label Phase 2 study in combination with Erbitux in patients with human papillomavirus (HPV) negative, Erbitux-resistant, advanced HNSCC who have previously been treated with an anti-PD1 checkpoint inhibitor, a population with limited options and a particularly poor prognosis. We opened the study to enrollment in November 2017. The study was initially designed as a Simon two-stage design with an interim futility analysis following enrollment of the first 13 patients. According to the study design, if at least one patient achieved an objective response in the first stage, enrollment could progress to the second stage. The primary endpoint of the study is objective response rate (ORR). Secondary endpoints include assessments of clinical benefit response (CBR), duration of response (DOR), progression-free survival (PFS), overall survival (OS), and safety and pharmacokinetics associated with the combination. Enrollment to the first stage of the Phase 2 study (n=15) is complete and interim data from the study were presented at the 2019 ASCO Annual Meeting in June that support the continued development of CDX-3379.

Patients had a median of 3 (range of 2-6) prior cancer therapy treatments. All patients had received prior checkpoint inhibitor treatment and 14 of 15 patients were cetuximab refractory. Notable clinical activity was observed in this refractory patient population. A durable confirmed complete response (11+ months) was observed; this response remains ongoing and the patient continues to receive treatment. An unconfirmed partial response (uPR) in a patient that had not received cetuximab was also observed. 7 patients experienced stable disease (47%; includes uPR). A clinical benefit rate of 29% was achieved (objective response or stable disease greater than or equal to 12 weeks). CDX-3379 in combination with cetuximab was generally associated with the expected target-mediated adverse events of diarrhea and rash.

Emerging data from the Phase 2 study and earlier studies of CDX-3379 suggest that antitumor activity may be associated with somatic mutations in certain genes. Based on these observations, next-generation sequencing was performed on tumor samples from 18 patients with HNSCC treated with CDX-3379 across three clinical studies of CDX-3379 that have enrolled patients with HNSCC. This data set included four patients with clinical responses, eight patients with stable disease and/or tumor shrinkage, and six patients with progressive disease. Key findings are outlined below.

- All four clinical responses occurred in patients with mutations in the FAT1 gene.
- All four clinical responses occurred in patients with a primary tumor site of oral cavity.
- Three of the four clinical responses occurred in patients who also had mutations in NOTCH1, NOTCH2 or NOTCH3 genes.
- Also, of note, all patients (n=7 of 18) who experienced clinical benefit (objective response or stable disease greater than or equal to 12 weeks) had FAT1 and/or NOTCH1-3 mutations.
- FAT1 and NOTCH genes are associated with tumor suppression. Inactivating mutations in the FAT1 and NOTCH genes occur in sizeable subsets of HPV negative HNSCC tumors, having been identified in 32% (FAT1) and 26% (NOTCH) of these tumors, respectively. Preclinical studies investigating the association of CDX-3379 sensitivity and inactivating mutations of FAT1 and other genes are ongoing.

Based on these biomarker observations and the notable clinical activity observed in this refractory patient population, the study has been expanded (n= ~45 patients, including at least 15 patients with FAT1 mutations) to allow for an evaluation of the utility of biomarkers for future patient selection. Enrollment is ongoing.

CDX-0159

CDX-0159 is a humanized monoclonal antibody that specifically binds the KIT receptor and potently inhibits its activity. The KIT receptor tyrosine kinase is expressed in a variety of cells, including mast cells, and its activation by its ligand SCF regulates mast cell growth, differentiation, survival, chemotaxis and degranulation. In certain inflammatory diseases, such as chronic idiopathic urticaria (CIU), mast cell degranulation plays a central role in the onset and progression of the disease.

CDX-0159 is a re-engineered variant of CDX-0158, which was specifically designed to block KIT activation by disrupting both SCF binding and KIT dimerization. Preclinical and clinical data with CDX-0158 demonstrated robust inhibition of mast cell activity and decreased mast cell numbers, supporting the concept that targeting KIT can modulate mast cell activity and potentially provide clinical benefit in mast cell related diseases. CDX-0159 was re-designed to ablate Fc receptor interactions and effector function and improve its safety profile, while preserving full KIT inhibitory activity. In addition, CDX-0159 was modified to provide extended half-life following administration.

We plan to submit an Investigational New Drug (IND) Application and initiate a Phase 1a study of CDX-0159 by year end 2019. The study is designed to evaluate the safety profile, pharmacokinetics and pharmacodynamics of single ascending doses of CDX-0159 in healthy subjects. Following completion of this study, we plan to further study CDX-0159 in CIU, a mast cell-related disease. CIU presents as itchy hives, angioedema or both for at least six weeks without a specific trigger; multiple episodes can play out over years or even decades. About 50% of patients with CIU achieve symptomatic control with antihistamines or leukotriene receptor antagonists. Omalizumab, an IgE inhibitor, provides relief for roughly half of the remaining antihistamine/leukotriene refractory patients. Consequently, there is a need for more effective later line therapies.

Varlilumab

Varlilumab is a fully human agonist monoclonal 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. 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.

Single-Agent Phase 1 Study: In an open-label Phase 1 study of varlilumab in patients with selected malignant solid tumors or hematologic cancers, 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 received varlilumab in the study at multiple clinical sites in the U.S. In both the solid tumor and hematologic dose escalations, the pre-specified maximum dose level (10 mg/kg) was reached without identification of an MTD. The majority of adverse events, or AEs, related to treatment were mild to moderate (Grade 1/2) in severity, and no significant immune-mediated adverse events typically associated with checkpoint blockade were observed. Durable, multi-year clinical benefit was demonstrated in select patients without additional anti-cancer therapy. 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, or BMS, to evaluate the safety, tolerability and preliminary efficacy of varlilumab and Opdivo, BMS's PD-1 immune checkpoint inhibitor, in a Phase 1/2 study. The Phase 1 portion of the study was initiated in January 2015 and conducted in adult patients with multiple solid tumors to assess the safety and tolerability of varlilumab at varying doses when administered with Opdivo. It was followed by a Phase 2 expansion to evaluate the activity of the combination in disease specific cohorts. Enrollment to the Phase 2 portion of the study was completed in January 2018 with cohorts in colorectal cancer (n=21), ovarian cancer (n=58), head and neck squamous cell carcinoma (HNSCC) (n=24), renal cell carcinoma (RCC) (n=14) and glioblastoma (GBM) (n=22). The primary objective of the Phase 2 cohorts was objective response rate, or ORR, except glioblastoma, where the primary objective was the rate of 12-month OS.

The combination of varlilumab and nivolumab was generally well tolerated across indications at all varlilumab dose levels/schedules tested. Clinical data from patients with "cold" tumors with low expectation of response to checkpoint inhibition monotherapy suggested potential benefit from the combination. Uniquely in the ovarian cancer cohort, increased PD-L1 and CD8 TIL were observed in ~ 60% of patients with paired biopsy samples. Patients with increase in PD-L1 and CD8 TIL had good clinical outcome and higher doses of varlilumab trended towards better activity then lower/less frequent dosing. In recurrent GBM, results in the subgroup (n=16) with unmethylated MGMT appeared promising with 2 (14%) partial responses noted and a median overall survival of 12.5 months. Among colorectal cancer patients, durable clinical responses were observed in a patient with MSI-high tumor and one with a high mutational burden. In HNSCC, in the subgroup (n=9) with PD-L1 negative disease, one partial response was observed (13%) and a median OS of 11 months was reported. Given the changing treatment paradigm in RCC, only fourteen patients were treated in the study; 39% of these patients experienced stable disease.

Future development of varlilumab is focused on inclusion in internal combination studies, including potentially in the ongoing Phase 1 trial of CDX-1140, and several external investigator-initiated studies.

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, and in combination with other agents may potentiate anti-tumor responses. Depending on the setting, cells expanded by CDX-301 promote either enhanced or permissive immunity. We believe CDX-301 may hold significant opportunity for synergistic development in combination with other proprietary molecules in our portfolio, as well as with approved or investigational therapies for the treatment of cancer.

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 dendritic cell and hematopoietic stem cell populations in healthy volunteers. The study was published in the journal Bone Marrow Transplantation in 2015.

CDX-301 is being used as a priming agent to potentially increase the number of cells available to respond to CDX-1140 in the ongoing Phase 1 trial of CDX-1140. CDX-301 is also in clinical development for multiple cancers in ongoing investigator-sponsored and collaborative studies, including in combination with treatments that release tumor antigens, such as radiation therapy.

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, 2018 for a discussion of our critical accounting policies. There have been no material changes to such critical accounting policies except for the adoption of the updated lease accounting standard on January 1, 2019. We believe our most critical accounting policies include accounting for business combinations, revenue recognition, intangible and long-lived assets, research and development expenses and stock-based compensation expense.

RESULTS OF OPERATIONS

Three Months Ended June 30, 2019 Compared with Three Months Ended June 30, 2018

	Three Months Ended June 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2019	2018	$	%
	(In thousands)			
Revenues:				
Product Development and Licensing Agreements	$ 195	$ 1,667	$ (1,472)	(88)%
Contracts and Grants	520	1,096	(576)	(53)%
Total Revenue	$ 715	$ 2,763	$ (2,048)	(74)%
Operating Expenses:				
Research and Development	10,081	21,448	(11,367)	(53)%
General and Administrative	3,908	5,621	(1,713)	(30)%
Gain on Fair Value Remeasurement of Contingent Consideration	(1,017)	(7,433)	(6,416)	(86)%
Total Operating Expense	12,972	19,636	(6,664)	(34)%
Operating Loss	(12,257)	(16,873)	(4,616)	(27)%
Investment and Other Income, Net	478	466	12	3%
Net Loss	$ (11,779)	$ (16,407)	$ (4,628)	(28)%

Net Loss

The $4.6 million decrease in net loss for the three months ended June 30, 2019, as compared to the three months ended June 30, 2018, was primarily the result of a decrease in research and development expenses, partially offset by the decrease in gain on fair value remeasurement of contingent consideration.

Revenue

The $1.5 million decrease in product development and licensing agreements revenue for the three months ended June 30, 2019, as compared to the three months ended June 30, 2018, was primarily due to a decrease in revenue related to our BMS agreement as a result of the completion of our combination clinical study. The $0.6 million decrease in contracts and grants revenue for the three months ended June 30, 2019, as compared to the three months ended June 30, 2018, was primarily related to a decrease in services performed under our contract manufacturing and research and development agreements with Rockefeller University and the International AIDS Vaccine Initiative. We expect revenue to decrease over the next twelve months, although there may be fluctuations on a quarterly basis.

Research and Development Expense

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

	Three Months Ended June 30		Increase/ (Decrease)	
	2019	2018	$	%
	(In thousands)			
Personnel	$ 5,408	$ 7,719	$ (2,311)	(30)%
Laboratory Supplies	1,257	1,212	45	4%
Facility	1,558	2,019	(461)	(23)%
Product Development	827	7,576	(6,749)	(89)%

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The $2.3 million decrease in personnel expenses for the three months ended June 30, 2019, as compared to the three months ended June 30, 2018, was primarily due to a decrease in headcount and lower severance expense related to the workforce reduction that occurred in the second quarter of 2018 as a result of the discontinuation of the Glemba program. 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. Laboratory supply expenses for the three months ended June 30, 2019 were consistent with the three months ended June 30, 2018. We expect laboratory supplies expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Facility expenses include depreciation, amortization, utilities, rent, maintenance and other related expenses incurred at our facilities. The $0.5 million decrease in facility expenses for the three months ended June 30, 2019, as compared to the three months ended June 30, 2018, was primarily due to lower depreciation expense. We expect facility expenses to decrease over the next twelve months as a result of the reduction in leased space in our Hampton, New Jersey facility. In addition, in June 2019, we decided to consolidate our Massachusetts lab and manufacturing facilities to further preserve our financial resources and direct them towards reaching meaningful development milestones across our pipeline. The lease in Needham, MA will not be renewed and most functions and employees will be integrated into our Fall River, MA facility in 2020. We estimate that this consolidation along with the reduction in square footage at our Hampton, NJ facility earlier this year will decrease our facility footprint by over 35% and will save the Company over $3.5 million annually starting in the second half of 2020.

Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing. The $6.7 million decrease in product development expenses for the three months ended June 30, 2019, as compared to the three months ended June 30, 2018, was primarily due to a decrease in clinical trial expenses of $3.9 million and a decrease in contract manufacturing expenses of $2.2 million. We expect product development expenses to increase over the next twelve months as a result of increased clinical trial expenses.

General and Administrative Expense

The $1.7 million decrease in general and administrative expenses for the three months ended June 30, 2019, as compared to the three months ended June 30, 2018, was primarily due to a decrease in headcount, lower commercial planning costs and lower lease restructuring expense. We expect general and administrative expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Gain on Fair Value Remeasurement of Contingent Consideration

The $1.0 million gain on fair value remeasurement of contingent consideration for the three months ended June 30, 2019 was primarily due to changes in discount rates and the passage of time. The $7.4 million gain on fair value remeasurement of contingent consideration for the three months ended June 30, 2018 was due to a reduction in fair value as a result of discontinuation of the CDX-014 program and updated assumptions for the varlilumab program.

Investment and Other Income, Net

Investment and other income, net for the three months ended June 30, 2019 was consistent with the three months ended June 30, 2018. We anticipate investment income to decrease over the next twelve months due to lower levels of cash and investment balances.

Six Months Ended June 30, 2019 Compared with Six Months Ended June 30, 2018

	Six Months Ended June 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2019	2018	$	%
	(In thousands)			
Revenues:				
Product Development and Licensing Agreements	$ 325	$ 2,662	$ (2,337)	(88)%
Contracts and Grants	1,815	4,172	(2,357)	(56)%
Total Revenue	$ 2,140	$ 6,834	$ (4,694)	(69)%
Operating Expenses:				
Research and Development	21,232	43,323	(22,091)	(51)%
General and Administrative	8,804	11,215	(2,411)	(21)%
Goodwill Impairment	—	90,976	(90,976)	(100)%
Intangible Asset Impairment	—	18,677	(18,677)	(100)%
Other Asset Impairment	1,800	—	1,800	n/a
Loss/(Gain) on Fair Value Remeasurement of Contingent Consideration	502	(21,033)	21,535	102%
Amortization of Acquired Intangible Assets	—	224	(224)	(100)%
Total Operating Expense	32,338	143,382	(111,044)	(77)%
Operating Loss	(30,198)	(136,548)	(106,350)	(78)%
Investment and Other Income, Net	1,180	1,245	(65)	(5)%
Net Loss Before Income Tax Benefit	(29,018)	(135,303)	(106,285)	(79)%
Income Tax Benefit	—	765	(765)	(100)%
Net Loss	$ (29,018)	$ (134,538)	$ (105,520)	(78)%

Net Loss

The $105.5 million decrease in net loss for the six months ended June 30, 2019, as compared to the six months ended June 30, 2018, was primarily the result of a decrease in non-cash goodwill and intangible asset impairment expense and a decrease in research and development expenses, partially offset by the increase in loss on fair value remeasurement of contingent consideration.

Revenue

The $2.3 million decrease in product development and licensing agreements revenue for the six months ended June 30, 2019, as compared to the six months ended June 30, 2018, was primarily due to a decrease in revenue related to our BMS agreement as a result of the completion of our combination clinical study. The $2.4 million decrease in contracts and grants revenue for the six months ended June 30, 2019, as compared to the six months ended June 30, 2018, was primarily related to a decrease in services performed under our contract manufacturing and research and development agreements with Rockefeller University and the International AIDS Vaccine Initiative, partially offset by an increase in services performed under our manufacturing and research and development agreement with Duke University.

Research and Development Expense

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

	Six Months Ended June 30,		Increase/ (Decrease)	
	2019	2018	$	%
	(In thousands)			
Personnel	$ 11,162	$ 16,776	$ (5,614)	(33)%
Laboratory Supplies	2,053	2,469	(416)	(17)%
Facility	3,454	4,082	(628)	(15)%
Product Development	2,522	14,925	(12,403)	(83)%

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The $5.6 million decrease in personnel expenses for the six months ended June 30, 2019, as compared to the six months ended June 30, 2018, was primarily due to a decrease in headcount, lower stock-based compensation expense and lower severance expense related to the workforce reduction that occurred in the second quarter of 2018 as a result of the discontinuation of the Glemba program.

Laboratory supplies expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The $0.4 million decrease in laboratory supply expenses for the six months ended June 30, 2019, as compared to the six months ended June 30, 2018, was primarily due to lower laboratory materials and supplies purchases.

Facility expenses include depreciation, amortization, utilities, rent, maintenance and other related expenses incurred at our facilities. The $0.6 million decrease in facility expenses for the six months ended June 30, 2019, as compared to the six months ended June 30, 2018, was primarily due to lower depreciation expense.

Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing. The $12.4 million decrease in product development expenses for the six months ended June 30, 2019, as compared to the six months ended June 30, 2018, was primarily due to a decrease in clinical trial expenses of $7.2 million and a decrease in contract manufacturing expenses of $4.2 million.

General and Administrative Expense

The $2.4 million decrease in general and administrative expenses for the six months ended June 30, 2019, as compared to the six months ended June 30, 2018, was primarily due to a decrease in headcount, lower commercial planning costs and lower lease restructuring expense.

Other Asset Impairment

We concluded that the Company’s investment in an undisclosed private company was impaired as a result of a deterioration in the private company’s financial condition and recorded a non-cash impairment charge of $1.8 million during the first quarter of 2019.

Loss on Fair Value Remeasurement of Contingent Consideration

The $0.5 million loss on fair value remeasurement of contingent consideration for the six months ended June 30, 2019 was primarily due to changes in discount rates and the passage of time. The $21.0 million gain on fair value remeasurement of contingent consideration for the six months ended June 30, 2018 was due to discontinuation of the Glemba and CDX-014 programs and updated assumptions for the varlilumab program.

Amortization Expense

The decrease in amortization expense for the six months ended June 30, 2019, as compared to the six months ended June 30, 2018, was the result of impairing the remaining balance of our intangible assets subject to amortization during the first quarter of 2018 due to the discontinuation of the Glemba program.

Investment and Other Income, Net

The $0.1 million decrease in investment and other income, net for the six months ended June 30, 2019, as compared to the six months ended June 30, 2018, was primarily due to lower other income related to our sale of New Jersey tax benefits.

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 and payments received for contract manufacturing and research and development services provided by us. The timing of any new contract manufacturing and research and development agreements, collaboration agreements, government contracts or grants and any payments under these agreements, contracts or grants cannot be easily predicted and may vary significantly from quarter to quarter.

At June 30, 2019, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of $81.3 million. We have had recurring losses and incurred a loss of $29.0 million for the six months ended June 30, 2019. Net cash used in operations for the six months ended June 30, 2019 was $24.3 million. We believe that the cash, cash equivalents and marketable securities at June 30, 2019, combined with the anticipated proceeds from future sales of our common stock under the Cantor agreement, are sufficient to meet estimated working capital requirements and fund planned operations through 2020, although there is no assurance that future sales under the Cantor agreement will occur. This could be impacted if we elected to pay Kolltan contingent milestones, 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 $24.3 million for the six months ended June 30, 2019 as compared to $45.4 million for the six months ended June 30, 2018. The decrease in net cash used in operating activities was primarily due to decreases in both general and administrative and research and development expenses. We expect that cash used in operating activities will remain relatively consistent 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 $8.3 million for the six months ended June 30, 2019 as compared to $28.7 million for the six months ended June 30, 2018. The decrease in net cash provided by investing activities was primarily due to net sales and maturities of marketable securities for the six months ended June 30, 2019 of $8.8 million as compared to $29.3 million for the six months ended June 30, 2018.

Financing Activities

Net cash provided by financing activities was $11.4 million for the six months ended June 30, 2019 as compared to $20.3 million for the six months ended June 30, 2018. Net proceeds from stock issuances pursuant to employee benefit plans were $0.0 million during the six months ended June 30, 2019 as compared to $0.4 million for the six months ended June 30, 2018.

In May 2016, we entered into an agreement with Cantor Fitzgerald & Co. (“Cantor”) to allow us to issue and sell shares of our common stock having an aggregate offering price of up to $60.0 million from time to time through Cantor, acting as agent. In November 2017, we filed a prospectus supplement registering the offer and sale of shares of common stock of up to an additional $75.0 million under the agreement with Cantor. During the six months ended June 30, 2019, we issued 2,856,194 shares of common stock under this controlled equity offering sales agreement with Cantor resulting in net proceeds of $11.4 million after deducting commission and offering expenses. At June 30, 2019, we had $25.8 million remaining in aggregate gross offering price available under the Cantor agreement. In July 2019, we issued 201,687 shares of its common stock resulting in net proceeds to us of $0.5 million.

Aggregate Contractual Obligations

Except as set forth below, the disclosures relating to our contractual obligations reported in our Annual Report on Form 10-K for the year ended December 31, 2018 which was filed with the SEC on March 7, 2019 have not materially changed since we filed that report.

In March 2019, the Company amended its Hampton, New Jersey lease to eliminate 16,200 square feet of space and extend the remaining 33,400 square feet of space for an additional five-year term with an early termination option after three years.

OFF-BALANCE SHEET ARRANGEMENTS

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

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 approximate fair value at June 30, 2019 due to the short-term maturities of these instruments.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

As of June 30, 2019, we evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2019. 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 June 30, 2019 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, 2018, 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 7, 2019.

Item 6. Exhibits

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

EXHIBIT INDEX

Exhibit No.	Description
10.1	Celldex Therapeutics, Inc. Amended and Restated 2008 Stock Option and Incentive Plan (as amended, effective as of June 19, 2019), incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K, filed on June 20, 2019 with the Securities and Exchange Commission.
10.2	Celldex Therapeutics, Inc. Amended and Restated 2004 Employee Stock Purchase Plan (effective as of June 19, 2019), incorporated by reference to Exhibit 10.2 to the Company's current report on Form 8-K, filed on June 20, 2019 with the Securities and Exchange Commission.
10.3	Employment Agreement, dated July 8, 2019, by and between Diane Young and Celldex Therapeutics., Inc., incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed on June 24, 2019 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.

SIGNATURES

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

CELLDEX THERAPEUTICS, INC.

BY:

/s/ ANTHONY S. MARUCCI

Dated: August 7, 2019

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

/s/ SAM MARTIN

Dated: August 7, 2019

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: August 7, 2019

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: August 7, 2019

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: August 7, 2019

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

Date: August 7, 2019

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.