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

FORM 10-Q

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

For the quarterly period ended September 30, 2018

OR

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

Commission File Number: 000-15006

CELLEX THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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 No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

As of October 31, 2018, 172,465,567 shares of common stock, \$.001 par value per share, were outstanding.

CELLDEX THERAPEUTICS, INC.
FORM 10-Q
For the Quarterly Period Ended September 30, 2018
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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)

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
ASSETS		
Current Assets:		
Cash and Cash Equivalents	\$ 32,823	\$ 40,288
Marketable Securities	72,795	99,139
Accounts and Other Receivables	3,175	1,880
Prepaid and Other Current Assets	2,176	3,449
Total Current Assets	<u>110,969</u>	<u>144,756</u>
Property and Equipment, Net	6,699	10,372
Intangible Assets, Net	48,690	67,591
Other Assets	1,929	1,929
Goodwill	—	90,976
Total Assets	<u>\$ 168,287</u>	<u>\$ 315,624</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	\$ 2,311	\$ 1,715
Accrued Expenses	9,614	19,455
Current Portion of Long-Term Liabilities	4,926	6,566
Total Current Liabilities	<u>16,851</u>	<u>27,736</u>
Other Long-Term Liabilities	<u>23,302</u>	<u>51,519</u>
Total Liabilities	<u>40,153</u>	<u>79,255</u>
Commitments and Contingent Liabilities		
Stockholders' Equity:		
Convertible Preferred Stock, \$.01 Par Value; 3,000,000 Shares Authorized; No Shares Issued and Outstanding at September 30, 2018 and December 31, 2017	—	—
Common Stock, \$.001 Par Value; 297,000,000 Shares Authorized; 168,575,504 and 138,520,404 Shares Issued and Outstanding at September 30, 2018 and December 31, 2017, Respectively	169	139
Additional Paid-In Capital	1,078,419	1,046,183
Accumulated Other Comprehensive Income	2,582	2,564
Accumulated Deficit	<u>(953,036)</u>	<u>(812,517)</u>
Total Stockholders' Equity	<u>128,134</u>	<u>236,369</u>
Total Liabilities and Stockholders' Equity	<u>\$ 168,287</u>	<u>\$ 315,624</u>

See accompanying notes to unaudited condensed consolidated financial statements

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

(In thousands, except per share amounts)

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
REVENUES:				
Product Development and Licensing				
Agreements	\$ 131	\$ 1,238	\$ 2,792	\$ 2,488
Contracts and Grants	810	2,686	4,982	6,799
Total Revenues	<u>941</u>	<u>3,924</u>	<u>7,774</u>	<u>9,287</u>
OPERATING EXPENSES:				
Research and Development	11,918	21,915	55,242	72,707
General and Administrative	3,722	5,346	14,936	19,109
Goodwill Impairment	—	—	90,976	—
Intangible Asset Impairment	—	13,000	18,677	13,000
Gain on Fair Value Remeasurement of Contingent Consideration	(6,935)	(4,600)	(27,968)	(200)
Amortization of Acquired Intangible Assets	—	224	224	672
Total Operating Expenses	<u>8,705</u>	<u>35,885</u>	<u>152,087</u>	<u>105,288</u>
Operating Loss	(7,764)	(31,961)	(144,313)	(96,001)
Investment and Other Income, Net	521	398	1,767	1,611
Net Loss Before Income Tax Benefit	(7,243)	(31,563)	(142,546)	(94,390)
Income Tax Benefit	—	5,200	765	5,200
Net Loss	<u>\$ (7,243)</u>	<u>\$ (26,363)</u>	<u>\$ (141,781)</u>	<u>\$ (89,190)</u>
Basic and Diluted Net Loss Per Common Share	<u>\$ (0.04)</u>	<u>\$ (0.20)</u>	<u>\$ (0.94)</u>	<u>\$ (0.71)</u>
Shares Used in Calculating Basic and Diluted Net Loss Per Share	<u>163,679</u>	<u>129,640</u>	<u>150,636</u>	<u>125,856</u>
COMPREHENSIVE LOSS:				
Net Loss	\$ (7,243)	\$ (26,363)	\$ (141,781)	\$ (89,190)
Other Comprehensive Income (Loss):				
Unrealized Gain (Loss) on Marketable Securities	(8)	11	18	47
Comprehensive Loss	<u>\$ (7,251)</u>	<u>\$ (26,352)</u>	<u>\$ (141,763)</u>	<u>\$ (89,143)</u>

See accompanying notes to unaudited condensed consolidated financial statements

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

(In thousands)

	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Cash Flows From Operating Activities:		
Net Loss	\$ (141,781)	\$ (89,190)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation and Amortization	2,856	3,392
Amortization of Intangible Assets	224	672
Amortization and Premium of Marketable Securities, Net	(666)	(171)
Loss on Sale or Disposal of Assets	1,170	6
Goodwill Impairment	90,976	—
Intangible Asset Impairment	18,677	13,000
Gain on Fair Value Remeasurement of Contingent Consideration	(27,968)	(200)
Non-Cash Income Tax Benefit	(765)	(5,200)
Stock-Based Compensation Expense	6,329	9,728
Changes in Operating Assets and Liabilities:		
Accounts and Other Receivables	(790)	(1,229)
Prepaid and Other Current Assets	1,545	525
Other Assets	—	132
Accounts Payable and Accrued Expenses	(9,246)	(10,888)
Other Liabilities	(366)	(987)
Net Cash Used in Operating Activities	<u>(59,805)</u>	<u>(80,410)</u>
Cash Flows From Investing Activities:		
Sales and Maturities of Marketable Securities	178,335	183,683
Purchases of Marketable Securities	(151,558)	(122,235)
Acquisition of Property and Equipment	(651)	(1,598)
Proceeds from Sale or Disposal of Assets	342	—
Net Cash Provided by Investing Activities	<u>26,468</u>	<u>59,850</u>
Cash Flows From Financing Activities:		
Net Proceeds from Stock Issuances	25,453	32,642
Proceeds from Issuance of Stock from Employee Benefit Plans	419	192
Net Cash Provided by Financing Activities	<u>25,872</u>	<u>32,834</u>
Net (Decrease) Increase in Cash and Cash Equivalents	(7,465)	12,274
Cash and Cash Equivalents at Beginning of Period	40,288	42,461
Cash and Cash Equivalents at End of Period	<u>\$ 32,823</u>	<u>\$ 54,735</u>
<i>Non-cash Investing Activities</i>		
Accrued construction in progress	\$ 86	\$ 75
<i>Non-cash Supplemental Disclosure</i>		
Shares issued to former Kolltan executive for settlement of severance	\$ 65	\$ 302

See accompanying notes to unaudited condensed consolidated financial statements

CELLEX THERAPEUTICS, INC.
Notes to Unaudited Condensed Consolidated Financial Statements
September 30, 2018

(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 whollyowned 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, 2017, which are included in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 7, 2018. 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, 2018.

At September 30, 2018, the Company had cash, cash equivalents and marketable securities of \$105.6 million. The Company has had recurring losses and incurred a loss of \$141.8 million for the nine months ended September 30, 2018. Net cash used in operations for the nine months ended September 30, 2018 was \$59.8 million. The Company believes that the cash, cash equivalents and marketable securities at November 7, 2018 will be sufficient to meet estimated working capital requirements and fund planned operations for at least the next twelve months from the date of issuance of these financial statements.

During the next twelve months and beyond, the Company will take further steps to raise additional capital to meet its liquidity needs. These capital raising activities may include, but may not be limited to, one or more of the following: the licensing of drug candidates with existing or new collaborative partners, possible business combinations, issuance of debt, or the issuance of common stock or other securities via private placements or public offerings. While the Company may seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and the Company’s negotiating position in capital-raising efforts may worsen as existing resources are used. There is also no assurance that the Company will be able to enter into further collaborative relationships. Additional equity financings may be dilutive to the Company’s stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict the Company’s ability to operate as a business; and licensing or strategic collaborations may result in royalties or other terms which reduce the Company’s economic potential from products under development. The Company’s ability to continue funding its planned operations into and beyond twelve months from the issuance date is also dependent on the timing and manner of payment of future contingent milestones from the Kolltan acquisition, in the event that the Company achieves the drug candidate milestones related to those payments. The Company, at its option, may decide to pay those milestone payments in cash, shares of its common stock or a combination thereof. If the Company is unable to raise the funds necessary to meet its liquidity needs, it may have to delay or discontinue the development of one or more programs, discontinue or delay ongoing or anticipated clinical trials, license out programs earlier than expected, raise funds at a significant discount or on other unfavorable terms, if at all, or sell all or a part of the Company.

(2) Significant Accounting Policies

The significant accounting policies used in preparation of these condensed consolidated financial statements on Form 10-Q for the three and nine months ended September 30, 2018 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, 2017, except as it relates to the adoption of new accounting standards during the first nine months of 2018 as discussed below.

Newly Adopted Accounting Pronouncements

On January 1, 2018, the Company adopted the new U.S. GAAP standard “*Revenue from Contracts with Customers*” using a modified retrospective application method, recognizing an immaterial cumulative-effect adjustment to accumulated deficit. The Company applied the new guidance to (i) contracts not completed as of the date of adoption and (ii) all new revenue contracts entered into after January 1, 2018. Refer to Note 11 “*Revenue*” for additional details on this adoption and the Company’s updated revenue accounting policy and disclosures.

On January 1, 2018, the Company adopted a U.S. GAAP standard update “*Classification of Certain Cash Receipts and Cash Payments*” which clarifies the classification of certain cash receipts and payments in the statement of cash flows. The adoption of this new standard did not impact the Company’s consolidated financial statements.

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On July 1, 2018, the Company adopted a U.S. GAAP standard that aligns the accounting for share-based payment awards issued to employees and nonemployees. Under the new guidance, the existing employee guidance is applied to nonemployee share-based transactions. The adoption of this new standard did not have a material impact on the Company's consolidated financial statements.

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 February 2016, the FASB issued a new U.S. GAAP accounting standard which requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The Company will adopt the new guidance for its fiscal year beginning January 1, 2019 and expects to use 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 does not expect that this standard will have a material impact on its Consolidated Statement of Operations and Comprehensive Loss or Statement of Cash Flow, however the Company expects that adoption of this standard will result in the recognition of material right-of-use assets and lease liabilities on its Consolidated Balance Sheet.

In August 2018, the SEC issued a final rule amending certain disclosure requirements including expanding the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the consolidated balance sheet must be provided in a note or separate statement. This final rule will be effective for the quarter ended March 31, 2019. The Company is currently evaluating the impact of the final rule on its 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 for our fiscal year, 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.

(3) Fair Value Measurements

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

	As of September 30, 2018	Level 1	Level 2	Level 3
	(In thousands)			
Assets:				
Money market funds and cash equivalents	\$ 24,145	—	\$ 24,145	—
Marketable securities	72,795	—	72,795	—
	<u>\$ 96,940</u>	<u>—</u>	<u>\$ 96,940</u>	<u>—</u>
Liabilities:				
Kolltan acquisition contingent consideration	\$ 15,432	—	—	\$ 15,432
	<u>\$ 15,432</u>	<u>—</u>	<u>—</u>	<u>\$ 15,432</u>

	As of December 31, 2017	Level 1	Level 2	Level 3
	(In thousands)			
Assets:				
Money market funds and cash equivalents	\$ 24,061	—	\$ 24,061	—
Marketable securities	99,139	—	99,139	—
	<u>\$ 123,200</u>	<u>—</u>	<u>\$ 123,200</u>	<u>—</u>
Liabilities:				
Kolltan acquisition contingent consideration	\$ 43,400	—	—	\$ 43,400
	<u>\$ 43,400</u>	<u>—</u>	<u>—</u>	<u>\$ 43,400</u>

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The Company's financial assets consist mainly of money market funds and cash equivalents and marketable securities and are classified as Level 2 within the valuation hierarchy. The Company values its marketable securities utilizing independent pricing services which normally derive security prices from recently reported trades for identical or similar securities, making adjustments based on significant observable transactions. At each balance sheet date, observable market inputs may include trade information, broker or dealer quotes, bids, offers or a combination of these data sources.

The following table reflects the activity for the Company's contingent consideration liabilities measured at fair value using Level 3 inputs for the nine months ended September 30, 2018 (in thousands):

	<u>Other Liabilities: Contingent Consideration</u>
Balance at December 31, 2017	\$ 43,400
Fair value adjustments included in operating expenses	(27,968)
Balance at September 30, 2018	<u>\$ 15,432</u>

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 \$162.5 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 months ended September 30, 2018, the Company recorded a \$6.9 million gain on fair value remeasurement of contingent consideration primarily due to lower probability that milestones related to our anti-KIT program would be triggered by the Company's current anti-KIT program development. During the nine months ended September 30, 2018, the Company recorded a \$28.0 million gain on fair value remeasurement of contingent consideration primarily due to discontinuation of the Glemba and CDX-014 programs, updated assumptions for the varlilumab program, and lower probability that milestones related to our anti-KIT program would be triggered by the Company's current anti-KIT program development. During the three and nine months ended September 30, 2017, the Company recorded a \$4.6 million and \$0.2 million gain on fair value remeasurement of contingent consideration, respectively, primarily due to a reduction in fair value attributed to the milestones related to the Company's anti-KIT program and partially offset by losses related to changes in discount rates and the passage of time affecting remaining milestones.

The Company did not have any transfers of assets or liabilities between the fair value measurement classifications during the nine months ended September 30, 2018.

(4) Marketable Securities

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

	Amortized Cost	Gross Unrealized		Fair Value
		Gains	Losses	
(In thousands)				
September 30, 2018				
U.S. government and municipal obligations (maturing in one year or less)	\$ 22,318	\$ —	\$ (7)	\$ 22,311
Corporate debt securities (maturing in one year or less)	50,491	—	(7)	50,484
Total Marketable Securities	<u>\$ 72,809</u>	<u>\$ —</u>	<u>\$ (14)</u>	<u>\$ 72,795</u>
December 31, 2017				
U.S. government and municipal obligations (maturing in one year or less)	\$ 26,164	\$ 3	\$ (9)	\$ 26,158
Corporate debt securities (maturing in one year or less)	73,007	1	(27)	72,981
Total Marketable Securities	<u>\$ 99,171</u>	<u>\$ 4</u>	<u>\$ (36)</u>	<u>\$ 99,139</u>

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The Company holds investment-grade marketable securities, and none were in a continuous unrealized loss position for more than twelve months as of September 30, 2018 and December 31, 2017. 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 and \$0.3 million in accrued interest at September 30, 2018 and December 31, 2017, respectively.

(5) Intangible Assets and Goodwill

Intangible Assets, Net

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

	Gross Carrying Amount	Accumulated Amortization	Accumulated Impairments	Net Carrying Amount
(In thousands)				
September 30, 2018				
Finite-lived Intangible Assets:				
License Rights	\$ 14,500	\$ (7,623)	\$ (6,877)	\$ —
Indefinite-lived Intangible Assets:				
IPR&D	60,490	—	(11,800)	48,690
Total Intangible Assets, Net	<u>\$ 74,990</u>	<u>\$ (7,623)</u>	<u>\$ (18,677)</u>	<u>\$ 48,690</u>
December 31, 2017				
Finite-lived Intangible Assets:				
License Rights	\$ 14,500	\$ (7,399)	\$ —	\$ 7,101
Indefinite-lived Intangible Assets:				
IPR&D	60,490	—	—	60,490
Total Intangible Assets, Net	<u>\$ 74,990</u>	<u>\$ (7,399)</u>	<u>\$ —</u>	<u>\$ 67,591</u>

Finite-lived intangible assets consist solely of license rights amended under a 2009 agreement with Amgen Fremont related to developing and commercializing Glemba. As a result of the discontinuation of the Glemba program, the Company recorded a non-cash impairment charge of \$6.9 million during the first quarter of 2018. Amortization expense related to this finite-lived intangible asset was \$0.0 million and \$0.2 million for the three and nine month periods ended September 30, 2018, respectively, and \$0.2 million and \$0.7 million for the three and nine month periods ended September 30, 2017, respectively.

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 and the TAM program. 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. As a result of the discontinuation of the Glemba program, the Company recorded a non-cash impairment charge of \$11.8 million during the first quarter of 2018. CDX-3379 is in Phase 2 development. The anti-KIT and TAM programs are in preclinical development. As of September 30, 2018, none of the remaining IPR&D assets had reached technological feasibility nor did any have alternative future uses. 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 changes in the carrying amount of goodwill for the nine months ended September 30, 2018 were as follows:

	Goodwill (In thousands)
Balance at December 31, 2017	\$ 90,976
Goodwill Impairment	(90,976)
Balance at September 30, 2018	<u>\$ —</u>

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The Company evaluated goodwill for potential impairment due to the METRIC failure. 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 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.

(6) Other Long-Term Liabilities

Other long-term liabilities include the following:

	September 30, 2018	December 31, 2017
	(In thousands)	
Net Deferred Tax Liabilities Related to IPR&D (Note 12)	\$ 3,007	\$ 3,772
Deferred Income From Sale of Tax Benefits	6,402	6,756
Other	1,305	1,344
Contingent Milestones (Note 4)	15,432	43,400
Deferred Revenue (Note 11)	2,082	2,813
Total	28,228	58,085
Less Current Portion	(4,926)	(6,566)
Long-Term Portion	<u>\$ 23,302</u>	<u>\$ 51,519</u>

In November 2015, December 2014 and January 2014, the Company received approval from the New Jersey Economic Development Authority and agreed to sell New Jersey tax benefits of \$9.8 million, \$1.9 million and \$1.1 million to an independent third party for \$9.2 million, \$1.8 million and \$1.0 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 \$0.4 million in other income related to the sale of these tax benefits during the three and nine months ended September 30, 2018, respectively, and \$0.0 million and \$0.5 million during the three and nine months ended September 30, 2017, respectively.

(7) 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 nine months ended September 30, 2018, the Company issued 29,760,486 shares of common stock under this controlled equity offering sales agreement with Cantor resulting in net proceeds of \$25.5 million after deducting commission and offering expenses. At September 30, 2018, the Company had \$41.3 million remaining in aggregate gross offering price available under the Cantor agreement. In October 2018, the Company issued 3,884,597 shares of its common stock resulting in net proceeds to the Company of \$1.6 million.

(8) Restructuring Expenses

As a result of the METRIC failure and discontinuation of the Glemba program, the Company approved a reduction in its workforce to reduce operating costs and recorded severance expense of \$1.2 million in the nine months ended September 30, 2018. At September 30, 2018, the Company recorded accrued severance of \$0.2 million related to this workforce reduction.

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(9) Stock-Based Compensation

A summary of stock option activity for the nine months ended September 30, 2018 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In Years)
Options Outstanding at December 31, 2017	10,856,212	\$ 9.40	6.1
Granted	5,056,467	0.61	
Exercised	(104,500)	2.80	
Canceled	(2,568,090)	8.76	
Options Outstanding at September 30, 2018	<u>13,240,089</u>	6.22	7.4
Options Vested and Expected to Vest at September 30, 2018	12,884,023	6.36	7.3
Options Exercisable at September 30, 2018	6,190,301	10.97	5.2
Shares Available for Grant Under the 2008 Plan	5,096,110		

The weighted average grant-date fair value of stock options granted during the three and nine month periods ended September 30, 2018 was \$0.30 and \$0.44, respectively. Stock-based compensation expense for the three and nine month periods ended September 30, 2018 and 2017 was recorded as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
	(In thousands)		(In thousands)	
Research and development	\$ 799	\$ 1,546	\$ 3,088	\$ 5,310
General and administrative	994	1,193	3,241	4,418
Total stock-based compensation expense	<u>\$ 1,793</u>	<u>\$ 2,739</u>	<u>\$ 6,329</u>	<u>\$ 9,728</u>

The fair values of employee and director stock options granted during the three and nine month periods ended September 30, 2018 and 2017 were valued using the Black-Scholes option pricing model with the following assumptions:

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Expected stock price volatility	85%	76%	73 – 85%	76 – 77%
Expected option term	6.0 Years	6.0 Years	6.0 Years	6.0 Years
Risk-free interest rate	2.8%	2.0%	2.8 – 3.0%	2.0 – 2.3%
Expected dividend yield	None	None	None	None

(10) Accumulated Other Comprehensive Income

The changes in accumulated other comprehensive income, which is reported as a component of stockholders' equity, for the nine months ended September 30, 2018 are summarized below:

	Unrealized Gain/(Loss) on Marketable Securities	Foreign Currency Items	Total
	(In thousands)		
Balance at December 31, 2017	\$ (32)	\$ 2,596	\$ 2,564
Other comprehensive loss	18	—	18
Balance at September 30, 2018	<u>\$ (14)</u>	<u>\$ 2,596</u>	<u>\$ 2,582</u>

No amounts were reclassified out of accumulated other comprehensive income during the three or nine months ended September 30, 2018.

(11) Revenue

On January 1, 2018, the Company adopted a new revenue accounting standard, “*Revenue from Contracts with Customers*” (*ASC 606*). Upon adoption using the modified retrospective application, the Company recognized a \$1.3 million decrease to accumulated deficit, a \$0.8 million decrease in deferred revenue and \$0.5 million increase in accounts receivable due to the cumulative impact of adopting *ASC 606*. This impact was driven by the acceleration of revenue using a percentage-of-completion method of accounting under *ASC 606* for an open contract that had previously been accounted for using the Contingency Adjusted Performance Model (“CAPM”) under previous guidance.

Results for reporting periods beginning after January 1, 2018 are presented under *ASC 606* while prior period amounts were not adjusted and continue to be reported in accordance with historic accounting under previous guidance. There was not a material impact to revenues as a result of applying *ASC 606* for the three and nine month periods ended September 30, 2018, and there have not been significant changes to the Company’s business processes, systems or internal controls as a result of adopting the new standard. The Company expects revenue recognition to remain largely unchanged under the new standard.

Revenue Recognition

Revenues are recognized when performance obligations under agreements or contracts are satisfied, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those services.

The Company determines revenue recognition through the following steps:

- Identification of the contract, or contracts, with a customer;
- Identification of the performance obligations in the contract;
- Determination of the transaction price;
- Allocation of the transaction price to the performance obligations in the contract; and
- Recognition of revenue when, or as, the Company satisfies a performance obligation.

Revenue for the Company has historically been derived from biopharmaceutical product development agreements with collaborative partners for the research and development of therapeutic drug candidates. The terms of the agreements may include nonrefundable signing and licensing fees, funding for research, development and manufacturing, milestone payments and royalties on any product sales derived from collaborations. The Company assesses the multiple obligations typically within product development contracts to determine the distinct performance obligations and how to allocate the arrangement consideration to each distinct performance obligation.

Under product development agreements, revenue is generally recognized using a cost-to-cost measure of progress. Revenue is recognized based on the costs incurred to date as a percentage of the total estimated costs to fulfill the contract. Incurred cost represents work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer. Due to the nature of the work performed in these arrangements, the estimation of cost at completion is complex, subject to many variables, such as expected clinical trial costs, and requires significant judgements. Circumstances can arise that change original estimates of costs or progress toward completion. Any revisions to estimates are reflected in revenue on a cumulative catch-up basis in the period in which the change in circumstances became known.

Revenue for the Company is also derived from manufacturing and research and development arrangements. The Company owns and operates a cGMP manufacturing facility in Fall River, Massachusetts, to produce drug substance for its current and planned early-stage clinical trials. In order to utilize excess capacity, the Company has, from time to time, entered into contract manufacturing and research and development arrangements in which services are provided on a time-and-material basis or at a negotiated fixed-price. Revenue from time-and-material contracts is generally recognized on an output basis as labor hours and/or direct expenses are incurred. Under fixed-price contracts, revenue is generally recognized on an output basis as progress is made toward completion of the performance obligations using surveys of performance completed to date.

Contract Assets and Liabilities

The Company classifies the right to consideration in exchange for products or services transferred to a client as either a receivable or a contract asset. A receivable is a right to consideration that is unconditional as compared to a contract asset which is a right to consideration that is conditional upon factors other than the passage of time. At January 1, 2018 and September 30, 2018, the Company’s right to consideration under all contracts was considered unconditional, and as such, there were no recorded contract assets.

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The Company's contract liabilities result from arrangements where the Company has received payment in advance of performance under the contract. These amounts are included as deferred revenue within current portion of long-term liabilities on the condensed consolidated balance sheets. Revenue recognized from contract liabilities as of January 1, 2018 during the three and nine months ended September 30, 2018 was \$0.0 million and \$1.5 million, respectively. Revenue expected to be recognized in the future from contract liabilities as performance obligations are satisfied are not expected to be material.

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 varilumab 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 \$2.7 million in revenue related to this agreement during the three and nine months ended September 30, 2018, respectively.

Contract and Grants Revenue

In 2017, the Company entered into fixed-fee manufacturing and research and development arrangements with both the International AIDS Vaccine Initiative (IAVI) and Frontier Biotechnologies, Inc (Frontier). The Company recognized \$0.1 million and \$2.8 million in revenue under these agreements during the three and nine months ended September 30, 2018, respectively, and \$2.3 million and \$4.6 million during the three and nine months ended September 30, 2017.

In 2013, the Company entered into an agreement, as amended, with Rockefeller University pursuant to which the Company performs manufacturing and research and development services for Rockefeller University. The Company recognized \$0.5 million and \$1.8 million in revenue for labor hours and direct costs incurred related to the Rockefeller University agreement during the three and nine months ended September 30, 2018, respectively, and \$0.3 million and \$1.4 million during the three and nine months ended September 30, 2017, respectively.

(12) Income Taxes

On December 22, 2017, the Tax Cuts and Jobs Act ("TCJA") was enacted and led to significant changes to U.S. tax law. Also on December 22, 2017, the SEC staff issued SAB 118, allowing companies to record the effects of the TCJA on a provisional basis during a measurement period not to extend beyond one year of the enactment date. SAB 118 was codified into *ASC 740* by ASU 2018-05.

The Company recognized an income tax benefit of \$19.1 million related to implementing applicable provisions of the TCJA during the year ended December 31, 2017. In accordance with SAB 118, the Company considered this adjustment to be a provisional amount based on the Company's best estimates at December 31, 2017. The Company's accounting for the tax effects of the TCJA is complete as of September 30, 2018.

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 September 30, 2018 and December 31, 2017.

A net deferred tax liability of \$3.0 million and \$3.8 million existed at September 30, 2018 and December 31, 2017, respectively, related to the temporary differences associated with the IPR&D intangible assets acquired in previous business combinations and 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.

(13) Net Loss Per Share

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

	Nine Months Ended September 30,	
	2018	2017
Stock Options	13,240,089	11,582,818
Restricted Stock	60,005	96,668
	<u>13,300,094</u>	<u>11,679,486</u>

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995: This report on Form 10-Q contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as “may,” “will,” “can,” “anticipate,” “assume,” “should,” “indicate,” “would,” “believe,” “contemplate,” “expect,” “seek,” “estimate,” “continue,” “plan,” “point to,” “project,” “predict,” “could,” “intend,” “target,” “potential” and other similar words and expressions of the future.

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

- our ability to successfully complete research and further development, including animal, preclinical and clinical studies, and, if we obtain regulatory approval, commercialization of our drug candidates and the growth of the markets for those drug candidates;
- our ability to raise sufficient capital to fund our clinical studies and to meet our liquidity needs, on terms acceptable to us, or at all. If we are unable to raise the funds necessary to meet our liquidity needs, we may have to delay or discontinue the development of one or more programs, discontinue or delay ongoing or anticipated clinical trials, license out programs earlier than expected, raise funds at significant discount or on other unfavorable terms, if at all, or sell all or part of our business;
- our ability to negotiate strategic partnerships, where appropriate, for our program assets;
- 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;
- the cost, timing and uncertainty of obtaining regulatory approvals for our drug candidates;
- the availability, cost, delivery and quality of clinical management services provided by our clinical research organization partners;
- the availability, cost, delivery and quality of clinical and commercial-grade materials produced by our own manufacturing facility or supplied by contract manufacturers, suppliers and partners, who may be the sole source of supply;
- our ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors;
- our ability to develop technological capabilities, including identification of novel and clinically important targets, exploiting our existing technology platforms to develop new drug candidates and expand our focus to broader markets for our existing targeted immunotherapeutics;
- our ability to regain compliance with applicable NASDAQ listing standards for continued listing of our common stock on the NASDAQ Global Market;
- our ability to realize the anticipated benefits and cost-savings from the restructuring we announced in April 2018;
- our ability to realize the anticipated benefits from the acquisition of Kolltan and to operate the combined business efficiently;
- our ability to protect our intellectual property rights, including the ability to successfully defend patent oppositions filed against a European patent related to technology we use in varlilumab, and our ability to avoid intellectual property litigation, which can be costly and divert management time and attention; and

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- 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, 2017 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 human monoclonal antibody targeted to CD40, a key activator of immune response, currently in a Phase 1 dose-escalation study in multiple types of solid tumors;
- CDX-3379, a human 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®;
- CDX-301, a dendritic cell growth factor, currently being evaluated in a combination study with CDX-1140; and
- Varlilumab, an immune modulating antibody targeting CD27 designed to enhance a patient’s immune response against cancer that is currently completing a Phase 1/2 study in combination with Opdivo® in collaboration with Bristol-Myers Squibb Company (BMS).

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 seven studies ongoing with our prioritized drug candidates and additional studies currently under consideration.

In April 2018, we announced that our Phase 2b METRIC Study of glembatumumab vedotin in metastatic triple-negative breast cancer did not meet its primary endpoint. Based on this result, in the second quarter of 2018, we prioritized our pipeline and evaluated our operational and workforce needs to extend our financial resources and direct them to continued pipeline advancement. As previously disclosed, in line with this initiative and to conserve resources, we discontinued development of glembatumumab vedotin, CDX-014 and CDX-1401.

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

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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 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.

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During the past five years through December 31, 2017, we incurred an aggregate of \$470.9 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 nine months ended September 30, 2018 and 2017. The amounts disclosed in the following table reflect direct research and development costs, license fees associated with the underlying technology and an allocation of indirect research and development costs to each program.

	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
	(In thousands)	
CDX-1140	\$ 3,756	\$ 5,788
CDX-3379	2,935	3,611
CDX-301	1,616	1,058
Varlilumab	7,222	11,956
Anti-KIT Program	6,436	3,223
TAM Program	4,245	3,914
Glembatumumab vedotin	16,355	26,240
CDX-014	1,412	1,925
CDX-1401	420	617
Other Programs	10,845	14,375
Total R&D Expense	<u>\$ 55,242</u>	<u>\$ 72,707</u>

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 rapidly 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 150 patients with recurrent, locally advanced or metastatic solid tumors and was recently amended to also include lymphoma. 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. To this end, in the second quarter of 2018, we amended the Phase 1 study protocol to also explore CDX-1140 in combination with CDX-301 and are considering additional combinations, including with varlilumab.

Interim data from the Phase 1 study has been accepted for presentation on Friday, November 9, 2018 at the Society for Immunotherapy of Cancer (SITC) Annual Meeting.

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 immunology 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.

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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 head and neck squamous cell carcinoma (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 significant tumor shrinkage (92% in primary tumor; 26% in metastatic lesion). 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 head and neck squamous cell carcinoma 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 have initiated an open-label Phase 2 study in combination with Erbitux in approximately 30 patients with human papillomavirus (HPV) negative, Erbitux-resistant, advanced head and neck squamous cell carcinoma 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 employs a two-stage design with an interim futility analysis following enrollment of the first 13 patients. Enrollment to the first stage of the Phase 2 study (n=13) is nearing completion with a number of patients still undergoing treatment and not yet eligible for response evaluation. The primary objective of the study is objective response rate. Secondary objectives include assessments of clinical benefit response (CBR), duration of response (DOR), PFS and overall survival (OS), and safety and pharmacokinetics associated with the combination. CDX-3379 is also being studied in an investigator-sponsored study.

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. We have entered into license agreements with the University of Southampton, UK for intellectual property to use anti-CD27 antibodies and with Medarex (acquired by Bristol-Myers Squibb Company, or BMS) for access to the UltiMab technology to develop and commercialize human antibodies to CD27. Varlilumab was initially studied as a single-agent to establish a safety profile and assess immunologic and clinical activity in patients with cancer, but we believe the greatest opportunity for varlilumab is as an immune activator in combination with other agents.

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 BMS to evaluate the safety, tolerability and preliminary efficacy of varlilumab and Opdivo, BMS' 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 (n=24), renal cell carcinoma (n=14) and glioblastoma (n=22). The primary objective of the Phase 2 cohorts is objective response rate, or ORR, except glioblastoma, where the primary objective is the rate of 12-month OS.

Data from the ovarian and colorectal cancer cohorts were presented in an oral presentation at the 2018 ASCO Annual Meeting. Sixty-six patients with ovarian cancer were treated in the study (8 patients in Phase 1; 58 patients in Phase 2). Patients had a median of three prior lines of therapy, 91% had Stage IV disease and 66% had PD-L1 negative tumors. The overall response rate was 14% (n=9; 7 confirmed, 2 unconfirmed) across 64 response-evaluable patients. For patients with paired tumor samples (n=24) from before and during treatment, increases in tumor expression of PD-L1 and CD8+ TIL levels were observed. These increases were associated with improved clinical outcome, including improved progression-free survival (PFS) and response rate.

Forty-two patients with colorectal cancer were treated in the study (21 patients in Phase 1; 21 patients in Phase 2). Patients had a median of four prior lines of therapy, 100% had Stage IV disease and 87% had PD-L1 negative tumors. One patient had disease that was MSI-high and 21 patients had disease that was MSI-low/mismatch repair (MMR) proficient; MSI status for the remaining 20 patients was unknown. One patient with PD-L1 negative, MSI-high disease experienced a confirmed partial response in the Phase 2 study portion. Of note, a patient with PD-L1 negative disease, initially considered MMR proficient as determined by standard screening laboratory analysis, achieved a near complete response in the Phase 1 portion of the study, which continued at last follow-up at 35 months. This patient's tumor had a high mutational burden and mutations in genes regulating DNA repair, which together likely contributed to the response. Disease control rate for the response-evaluable population was 20% (8/41).

In the second quarter of 2018, we reported preliminary data from the head and neck squamous cell carcinoma (HNSCC) and renal cell carcinoma (RCC) cohorts. Twenty-seven patients with HNSCC were treated in the study (3 patients in Phase 1; 24 patients in Phase 2). Patients had a median of two prior lines of therapy, 96% had Stage IV disease, 63% had PD-L1 negative tumors and 52% had HPV positive tumors. The overall response rate was 15% (n=4 confirmed) across 27 response-evaluable patients. In this small sample size, no correlation between PDL-1 status and clinical outcome was observed. Given the changing treatment paradigm in renal cell carcinoma, only fourteen patients with RCC were treated in the study, all in Phase 2. All patients had experienced prior angiogenic therapy, with a range of 1 to 4 prior treatments, 100% had Stage IV disease and 50% had PD-L1 negative tumors. 39% of patients experienced stable disease.

Data from the GBM cohort has been accepted for presentation on Saturday, November 17, 2018 at the Society for Neuro-oncology (SNO) Annual Meeting.

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 licensed CDX-301 from Amgen Inc. and 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 and planned investigator-sponsored and collaborative studies, including in combination with treatments that release tumor antigens, such as radiation therapy.

CRITICAL ACCOUNTING POLICIES

See Note 3 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, 2017 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 revenue recognition standard on January 1, 2018. 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 September 30, 2018 Compared with Three Months Ended September 30, 2017

	Three Months Ended September 30,		Increase/ (Decrease) \$	Increase/ (Decrease) %
	2018	2017		
	(In thousands)			
Revenues:				
Product Development and Licensing Agreements	\$ 131	\$ 1,238	\$ (1,107)	(89)%
Contracts and Grants	810	2,686	(1,876)	(70)%
Total Revenue	\$ 941	\$ 3,924	\$ (2,983)	(76)%
Operating Expenses:				
Research and Development	11,918	21,915	(9,997)	(46)%
General and Administrative	3,722	5,346	(1,624)	(30)%
Intangible Asset Impairment	—	13,000	(13,000)	(100)%
Gain on Fair Value Remeasurement of Contingent Consideration	(6,935)	(4,600)	2,335	51%
Amortization of Acquired Intangible Assets	—	224	(224)	(100)%
Total Operating Expense	8,705	35,885	(27,180)	(76)%
Operating Loss	(7,764)	(31,961)	(24,197)	(76)%
Investment and Other Income, Net	521	398	123	31%
Net Loss Before Income Tax Benefit	\$ (7,243)	\$ (31,563)	\$ (24,320)	(77)%
Income Tax Benefit	—	5,200	(5,200)	(100)%
Net Loss	(7,243)	(26,363)	(19,120)	(73)%

Net Loss

The \$19.1 million decrease in net loss for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017, was primarily the result of a decrease in intangible asset impairment expense and a decrease in research and development expenses.

Revenue

The \$1.1 million decrease in product development and licensing agreements revenue for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017, was primarily due to a decrease in revenue related to our BMS agreement. The \$1.9 million decrease in contracts and grants revenue for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017, was primarily related to a decrease in services performed under our contract manufacturing and research and development agreement with the International AIDS Vaccine Initiative.

[Table of Contents](#)*Research and Development Expense*

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

	Three Months Ended September 30,		Increase/ (Decrease)	
	2018	2017	\$	%
	(In thousands)			
Personnel	\$ 5,810	\$ 8,933	\$ (3,123)	(35)%
Laboratory Supplies	886	1,230	(344)	(28)%
Facility	1,819	2,056	(237)	(12)%
License Fees	56	162	(106)	(65)%
Product Development	1,764	7,316	(5,552)	(76)%

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The \$3.1 million decrease in personnel expenses for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017, was primarily due to a decrease in headcount and lower stock-based compensation expense. We expect personnel expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Laboratory supplies expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The \$0.3 million decrease in laboratory supply expenses for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017, was primarily due to lower laboratory materials and supplies purchases. 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 \$0.2 million decrease in facility expenses for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017, was primarily due to lower depreciation expense. We expect facility expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

License fee expenses include annual license maintenance fees and milestone payments due upon the achievement of certain development, regulatory and/or commercial milestones. The \$0.1 million decrease in license fee expenses for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017, was due to the timing of certain development and/or regulatory milestones achieved by our drug candidates. We expect license fee expense to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing. The \$5.6 million decrease in product development expenses for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017, was primarily due to a decrease in clinical trial expenses of \$3.2 million and a decrease in contract manufacturing expenses of \$1.9 million. We expect product development expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

General and Administrative Expense

The \$1.6 million decrease in general and administrative expenses for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017, was primarily due to a decrease in headcount and lower legal expense and marketing 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 \$6.9 million gain on fair value remeasurement of contingent consideration for the three months ended September 30, 2018 was primarily due to lower probability that milestones related to our anti-KIT program would be triggered by the Company's current anti-KIT program development.

[Table of Contents](#)*Amortization Expense*

The decrease in amortization expense for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017, 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 increase in investment and other income, net for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017, was primarily due to higher interest rates on fixed income investments. We anticipate investment income to decrease over the next twelve months due to lower levels of cash and investment balances.

Nine Months Ended September 30, 2018 Compared with Nine Months Ended September 30, 2017

	Nine Months Ended September 30,		Increase/ (Decrease) \$	Increase/ (Decrease) %
	2018	2017		
(In thousands)				
Revenues:				
Product Development and Licensing Agreements	\$ 2,792	\$ 2,488	\$ 304	12%
Contracts and Grants	4,982	6,799	(1,817)	(27)%
Total Revenue	\$ 7,774	\$ 9,287	\$ (1,513)	(16)%
Operating Expenses:				
Research and Development	55,242	72,707	(17,465)	(24)%
General and Administrative	14,936	19,109	(4,173)	(22)%
Goodwill Impairment	90,976	—	90,976	n/a
Intangible Asset Impairment	18,677	13,000	5,677	44%
Gain on Fair Value Remeasurement of Contingent Consideration	(27,968)	(200)	27,768	139%
Amortization of Acquired Intangible Assets	224	672	(448)	(67)%
Total Operating Expense	152,087	105,288	46,799	44%
Operating Loss	(144,313)	(96,001)	48,312	50%
Investment and Other Income, Net	1,767	1,611	156	10%
Net Loss Before Income Tax Benefit	(142,546)	(94,390)	48,156	51%
Income Tax Benefit	765	5,200	(4,435)	(85)%
Net Loss	\$ (141,781)	\$ (89,190)	\$ 52,591	59%

Net Loss

The \$52.6 million increase in net loss for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, was primarily the result of the non-cash charges related to fully impairing our goodwill asset and Glemba-related intangible assets. This increase was partially offset by the gain on fair value remeasurement of contingent consideration and a decrease in research and development expenses.

Revenue

The \$0.3 million increase in product development and licensing agreements revenue for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, was primarily due to an increase in revenue related to our BMS agreement. The \$1.8 million decrease in contracts and grants revenue for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, was primarily related to a decrease in services performed under our contract manufacturing and research and development agreement with International AIDS Vaccine Initiative.

[Table of Contents](#)*Research and Development Expense*

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

	Nine Months Ended September 30,		Increase/ (Decrease)	
	2018	2017	\$	%
	(In thousands)			
Personnel	\$ 22,586	\$ 28,079	\$ (5,493)	(20)%
Laboratory Supplies	3,354	3,541	(187)	(5)%
Facility	5,901	6,649	(748)	(11)%
License Fees	214	479	(265)	(55)%
Product Development	16,689	26,965	(10,276)	(38)%

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The \$5.5 million decrease in personnel expenses for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, was primarily due to a decrease in headcount and lower stock-based compensation expense partially offset by severance expense of \$1.0 million.

Laboratory supplies expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The \$0.2 million decrease in laboratory supply expenses for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, 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 \$0.7 million decrease in facility expenses for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, was primarily due to lower depreciation expense.

License fee expenses include annual license maintenance fees and milestone payments due upon the achievement of certain development, regulatory and/or commercial milestones. The \$0.3 million decrease in license fee expenses for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, was due to the timing of certain development and/or regulatory milestones achieved by our drug candidates.

Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing. The \$10.3 million decrease in product development expenses for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, was primarily due to a decrease in clinical trial expenses of \$5.8 million and a decrease in contract manufacturing expenses of \$3.2 million.

General and Administrative Expense

The \$4.2 million decrease in general and administrative expenses for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, was primarily due to a decrease in headcount and lower stock-based compensation expense and marketing expense.

Gain on Fair Value Remeasurement of Contingent Consideration

The \$28.0 million gain on fair value remeasurement of contingent consideration for the nine months ended September 30, 2018 was due to discontinuation of the Glemba and CDX-014 programs, updated assumptions for the varlilumab program, and lower probability that milestones related to our anti-KIT program would be triggered by the Company's current anti-KIT program development.

Amortization Expense

The decrease in amortization expense for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, 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 \$0.2 million increase in investment and other income, net for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, was primarily due to higher interest rates on fixed income investments.

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 September 30, 2018, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of \$105.6 million. We have had recurring losses and incurred a loss of \$141.8 million for the nine months ended September 30, 2018. Net cash used in operations for the nine months ended September 30, 2018 was \$59.8 million. We believe that the cash, cash equivalents and marketable securities at September 30, 2018, 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. 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.

On May 29, 2018, we received a written notice from the Listing Qualifications department of The NASDAQ Stock Market (the "Notice") indicating that we are not in compliance with the \$1.00 Minimum Bid Price requirement set forth in NASDAQ Listing Rule 5450(a)(1) for continued listing on the NASDAQ Global Market. If we do not regain compliance with Listing Rule 5450(a)(1) by November 26, 2018, we intend to apply to transfer to the NASDAQ Capital Market where we should be afforded an additional 180-day period in which to regain compliance, provided that (i) we meet the applicable market value of publicly held shares requirement for continued listing and all other applicable requirements for initial listing on the NASDAQ Capital Market (except for the bid price requirement) based on our most recent public filings and market information and (ii) we notify NASDAQ of our intent to cure the bid price requirement deficiency prior to the completion of the second 180-day compliance period by effecting a reverse stock split, if necessary. At our 2018 Annual Meeting of Stockholders, our stockholders approved a proposal to grant discretionary authority to our board of directors to amend our certificate of incorporation to effect a reverse split of our outstanding shares of common stock within a range of one share of common stock for every ten shares of common stock to one share of common stock for every fifteen shares of common stock, with the exact reverse split ratio to be decided and publicly announced by the board of directors prior to the effective time of the amendment to the Company's certificate of incorporation.

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Operating Activities

Net cash used in operating activities was \$59.8 million for the nine months ended September 30, 2018 as compared to \$80.4 million for the nine months ended September 30, 2017. 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 \$26.5 million for the nine months ended September 30, 2018 as compared to \$59.9 million for the nine months ended September 30, 2017. The decrease in net cash provided by investing activities was primarily due to net sales and maturities of marketable securities for the nine months ended September 30, 2018 of \$26.8 million as compared to \$61.4 million for the nine months ended September 30, 2017.

Financing Activities

Net cash provided by financing activities was \$25.9 million for the nine months ended September 30, 2018 as compared to \$32.8 million for the nine months ended September 30, 2017. Net proceeds from stock issuances pursuant to employee benefit plans were \$0.4 million during the nine months ended September 30, 2018 as compared to \$0.2 million for the nine months ended September 30, 2017.

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 nine months ended September 30, 2018, we issued 29,760,486 shares of common stock under this controlled equity offering sales agreement with Cantor resulting in net proceeds of \$25.5 million after deducting commission and offering expenses. At September 30, 2018, we had \$41.3 million remaining in aggregate gross offering price available under the Cantor agreement. In October 2018, we issued 3,884,597 shares of its common stock resulting in net proceeds to us of \$1.6 million.

Aggregate Contractual Obligations

The disclosures relating to our contractual obligations reported in our Annual Report on Form 10-K for the year ended December 31, 2017 which was filed with the SEC on March 7, 2018 have not materially changed since we filed that report.

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 approximates fair value at September 30, 2018 due to the short-term maturities of these instruments.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

As of September 30, 2018, we evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2018. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within time periods specified by the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2018 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

Any investment in our business involves a high degree of risk. Before making an investment decision, you should carefully consider the information we include in this Quarterly Report on Form 10-Q, including the risks described below and our condensed financial statements and accompanying notes, and the additional information in the other reports we file with the Securities and Exchange Commission along with the risks described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

The risks described below and 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.

Except as set forth below, there have been no material changes to the risk factors previously disclosed and included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and as updated in our quarterly report on Form 10-Q for the quarter ended June 30, 2018.

We are not currently in compliance with the continued listing requirements for NASDAQ. If the price of our common stock continues to trade below \$1.00 per share for a sustained period or we do not meet other continued listing requirements, our common stock may be delisted from the NASDAQ Global Market, which could affect the market price and liquidity for our common stock and reduce our ability to raise additional capital.

Our common stock is listed on the NASDAQ Global Market. In order to maintain that listing, we must satisfy minimum financial and other requirements including, without limitation, a requirement that our closing bid price be at least \$1.00 per share. On May 29, 2018, we received a written notice from NASDAQ indicating that we are not in compliance with the minimum bid price requirement for continued listing on the NASDAQ Global Market. We have until November 26, 2018 to regain compliance. We can regain compliance if at any time prior to November 26, 2018 the bid price of our common stock closes at or above \$1.00 per share for a minimum of ten consecutive business days.

If we fail to regain compliance with the minimum bid price requirement by November 26, 2018, we may apply to transfer to The NASDAQ Capital Market where we should be afforded an additional 180-day period to regain compliance provided that (i) we meet the applicable market value of publicly held shares requirement for continued listing and all other applicable requirements for initial listing on the NASDAQ Capital Market (except for the bid price requirement) based on our most recent public filings and market information and (ii) we notify NASDAQ of our intent to cure the bid price requirement deficiency prior to the completion of the second 180-day compliance period by effecting a reverse stock split, if necessary. At our annual meeting of stockholders in June 2018, our stockholders approved a proposal to grant discretionary authority to our board of directors to amend our certificate of incorporation to effect a reverse split of our outstanding shares of common stock within a range of one share of common stock for every ten shares of common stock to one share of common stock for every fifteen shares of common stock, with the exact reverse split ratio to be decided and publicly announced by the board of directors prior to the effective time of the amendment to our certificate of incorporation. We intend to monitor the closing bid price of our common stock and consider our available options to resolve our noncompliance with the minimum bid price requirement. No determination regarding our response has been made at this time. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or we will otherwise be in compliance with other NASDAQ listing criteria. If we fail to regain compliance with the minimum bid requirement or to meet the other applicable continued listing requirements for the NASDAQ Global Market in the future and NASDAQ determines to delist our common stock, the delisting could adversely affect the market price and liquidity of our common stock and reduce our ability to raise additional capital. In addition, if our common stock is delisted from NASDAQ and the trading price remains below \$5.00 per share, trading in our common stock might also become subject to the requirements of certain rules promulgated under the Exchange Act, which require additional disclosure by broker-dealers in connection with any trade involving a stock defined as a "penny stock" (generally, any equity security not listed on a national securities exchange or quoted on NASDAQ that has a market price of less than \$5.00 per share, subject to certain exceptions).

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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
*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.

CELLEX THERAPEUTICS, INC.

BY:

/s/ ANTHONY S. MARUCCI

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

Dated: November 7, 2018

/s/ SAM MARTIN

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

Dated: November 7, 2018

CERTIFICATION

I, Anthony S. Marucci, certify that:

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

Date: November 7, 2018

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

CERTIFICATION

I, Sam Martin, certify that:

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

Date: November 7, 2018

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

SECTION 1350 CERTIFICATIONS

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

Date: November 7, 2018

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

Date: November 7, 2018

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.

