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, 2020

OR

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

Commission File Number: 000-15006

CELLDEX THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ 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, 2020, 39,567,065 shares of common stock, $.001 par value per share, were outstanding.

CELLDEX THERAPEUTICS, INC.

FORM 10-Q

For the Quarterly Period Ended September 30, 2020

Table of Contents

PART I — FINANCIAL INFORMATION
Item 1. Unaudited Financial Statements

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

(In thousands, except share and per share amounts)

	September 30, 2020	December 31, 2019
ASSETS		
Current Assets:		
Cash and Cash Equivalents	$ 18,151	$ 11,232
Marketable Securities	181,443	53,151
Accounts and Other Receivables	838	1,015
Prepaid and Other Current Assets	2,493	1,300
Total Current Assets	202,925	66,698
Property and Equipment, Net	3,813	4,031
Operating Lease Right-of-Use Assets, Net	3,801	3,473
Intangible Assets, Net	45,190	48,690
Other Assets	41	41
Total Assets	$ 255,770	$ 122,933
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	$ 568	$ 1,174
Accrued Expenses	8,007	6,499
Current Portion of Operating Lease Liabilities	1,263	1,944
Current Portion of Other Long-Term Liabilities	2,362	2,026
Total Current Liabilities	12,200	11,643
Long-Term Portion of Operating Lease Liabilities	2,545	1,713
Other Long-Term Liabilities	11,050	15,551
Total Liabilities	25,795	28,907
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, 2020 and December 31, 2019	—	—
Common Stock, $.001 Par Value; 297,000,000 Shares Authorized; 39,562,472 and 16,972,077 Shares Issued and Outstanding at September 30, 2020 and December 31, 2019, Respectively	40	17
Additional Paid-In Capital	1,278,523	1,104,706
Accumulated Other Comprehensive Income	2,608	2,619
Accumulated Deficit	(1,051,196)	(1,013,316)
Total Stockholders' Equity	229,975	94,026
Total Liabilities and Stockholders' Equity	$ 255,770	$ 122,933

See accompanying notes to unaudited condensed consolidated financial statements

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

(In thousands, except per share amounts)

	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
REVENUES:				
Product Development and Licensing Agreements	$ 12	$ 55	$ 2,297	$ 379
Contracts and Grants	656	491	1,336	2,307
Total Revenues	668	546	3,633	2,686
OPERATING EXPENSES:				
Research and Development	10,708	11,101	32,109	32,333
General and Administrative	3,640	3,403	10,833	12,207
Intangible Asset Impairment	—	—	3,500	—
Other Asset Impairment	—	—	—	1,800
Loss (Gain) on Fair Value Remeasurement of Contingent Consideration	662	(2,114)	(4,236)	(1,612)
Total Operating Expenses	15,010	12,390	42,206	44,728
Operating Loss	(14,342)	(11,844)	(38,573)	(42,042)
Investment and Other Income, Net	118	431	465	1,611
Net Loss Before Income Tax Benefit	(14,224)	(11,413)	(38,108)	(40,431)
Income Tax Benefit	—	—	228	—
Net Loss	$ (14,224)	$ (11,413)	$ (37,880)	$ (40,431)
Basic and Diluted Net Loss Per Common Share	$ (0.36)	$ (0.75)	$ (1.44)	$ (2.92)
Shares Used in Calculating Basic and Diluted Net Loss Per Share	39,278	15,282	26,303	13,854
COMPREHENSIVE LOSS:				
Net Loss	$ (14,224)	$ (11,413)	$ (37,880)	$ (40,431)
Other Comprehensive Income (Loss):				
Unrealized Gain (Loss) on Marketable Securities	14	(3)	(11)	52
Comprehensive Loss	$ (14,210)	$ (11,416)	$ (37,891)	$ (40,379)

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, 2020	Nine Months Ended September 30, 2019
Cash Flows From Operating Activities:		
Net Loss	$ (37,880)	$ (40,431)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation and Amortization	3,174	3,713
Amortization and Premium of Marketable Securities, Net	(422)	(980)
(Gain) Loss on Sale or Disposal of Assets	(29)	7
Intangible Asset Impairment	3,500	—
Other Asset Impairment	—	1,800
Gain on Fair Value Remeasurement of Contingent Consideration	(4,236)	(1,612)
Non-Cash Income Tax Benefit	(228)	—
Stock-Based Compensation Expense	2,658	3,864
Changes in Operating Assets and Liabilities:		
Accounts and Other Receivables	177	2,435
Prepaid and Other Current Assets	(1,280)	208
Accounts Payable and Accrued Expenses	864	(884)
Other Liabilities	(1,491)	(3,535)
Net Cash Used in Operating Activities	(35,193)	(35,415)
Cash Flows From Investing Activities:		
Sales and Maturities of Marketable Securities	55,600	91,473
Purchases of Marketable Securities	(183,394)	(77,011)
Acquisition of Property and Equipment	(1,305)	(626)
Proceeds from Sale or Disposal of Assets	29	20
Net Cash (Used in) Provided by Investing Activities	(129,070)	13,856
Cash Flows From Financing Activities:		
Net Proceeds from Stock Issuances	170,964	13,826
Proceeds from Issuance of Stock from Employee Benefit Plans	218	9
Issuance of Term Loan	2,962	—
Payment of Term Loan	(2,962)	—
Net Cash Provided by Financing Activities	171,182	13,835
Net Increase (Decrease) in Cash and Cash Equivalents	6,919	(7,724)
Cash and Cash Equivalents at Beginning of Period	11,232	24,310
Cash and Cash Equivalents at End of Period	$ 18,151	$ 16,586
Non-cash Investing Activities		
Accrued construction in progress	$ 63	$ —

See accompanying notes to unaudited condensed consolidated financial statements

(1) Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared by Celldex Therapeutics, Inc. (the "Company" or "Celldex") in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and reflect the operations of the Company and its wholly-owned subsidiary. All intercompany 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, 2019, which are included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 26, 2020. 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, 2020.

At September 30, 2020, the Company had cash, cash equivalents and marketable securities of $199.6 million. The Company has had recurring losses and incurred a loss of $37.9 million for the nine months ended September 30, 2020. Net cash used in operations for the nine months ended September 30, 2020 was $35.2 million. The Company believes that the cash, cash equivalents and marketable securities at November 5, 2020 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 may take further steps to raise additional capital to meet its long-term liquidity needs including, but not 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. Although the Company has been successful in raising capital in the past, 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 beyond twelve months from the issuance date is also dependent on the timing and manner of payment of 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.

In December 2019, a novel strain of coronavirus, now referred to as COVID-19, surfaced in Wuhan, China. The virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to hundreds of countries, including the United States. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. In an effort to halt the outbreak of COVID-19, various states, including New Jersey, Massachusetts and Connecticut, where the Company has office, research and manufacturing facilities, have placed significant restrictions on travel and many businesses have announced extended closures which could adversely impact our operations. To date, the Company has not experienced significant delays or disruptions in planned and ongoing preclinical and clinical trials, manufacturing or shipping. Potential impacts to our business include delays in planned and ongoing preclinical and clinical trials including enrollment of patients, disruptions in time and resources provided by independent clinical investigators, contract research organizations, other third-party service providers, temporary closures of our facilities, disruptions or restrictions on our employees' ability to travel, and delays in manufacturing and/or shipments to and from third party suppliers and contract manufacturers for APIs and drug product. Any prolonged negative impacts to our business could materially impact our operating results and could lead to impairments of our Intangible (IPR&D) assets with a carrying value of $45.2 million at September 30, 2020.

(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, 2020 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, 2019, except as it relates to the adoption of new accounting standards during the first nine months of 2020 as discussed below.

Newly Adopted Accounting Pronouncements

On January 1, 2020, the Company adopted a new accounting standard that modifies certain disclosure requirements for fair value measurements. For instance, the Company is required to disclose weighted average information for significant unobservable inputs for all Level 3 fair value measurements. The adoption of this new guidance did not have a material impact on the Company's consolidated financial statements and related disclosures. Refer to Note 3 for the disclosures related to the Company's level 3 fair value measurements.

On January 1, 2020, the Company adopted a new accounting standard that clarifies the interaction between the accounting guidance for collaborative arrangements and revenue from contracts with customers. The amendments clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606, when the collaborative arrangement participant is a customer in the context of a unit of account. The adoption of this standard did not have a material impact on our consolidated financial statements, as we have no arrangements within the scope of ASC 808.

Recent Accounting Pronouncements

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

In June 2016, the FASB issued guidance on the Measurement of Credit Losses on Financial Instruments. The guidance requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, the standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. This standard will be effective for the Company on January 1, 2023. We are currently evaluating the potential impact that this standard may have 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, 2020	Level 1	Level 2	Level 3
		(In thousands)		
Assets:				
Money market funds and cash equivalents	$ 12,152	—	$ 12,152	—
Marketable securities	181,443	—	181,443	—
	$ 193,595	—	$ 193,595	—
Liabilities:				
Kolltan acquisition contingent consideration	$ 8,249	—	—	$ 8,249
	$ 8,249	—	—	$ 8,249

	As of December 31, 2019	Level 1	Level 2	Level 3
		(In thousands)		
Assets:				
Money market funds and cash equivalents	$ 4,024	—	$ 4,024	—
Marketable securities	53,151	—	53,151	—
	$ 57,175	—	$ 57,175	—
Liabilities:				
Kolltan acquisition contingent consideration	$ 12,485	—	—	$ 12,485
	$ 12,485	—	—	$ 12,485

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

The following table reflects the activity for the Company's contingent consideration liabilities measured at fair value using Level 3 inputs for the nine months ended September 30, 2020 (in thousands):

	Other Liabilities: Contingent Consideration
Balance at December 31, 2019	$ 12,485
Fair value adjustments included in operating expenses	(4,236)
Balance at September 30, 2020	$ 8,249

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 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. As of September 30, 2020, the weighted average discount rate used in calculating the fair value of contingent consideration was 9.4% (with a range of 9.3% to 10.1%) and the weighted average amount of time until the conditions of the milestone payments are met was 3 years.

During the three months ended September 30, 2020, the Company recorded a $0.7 million loss on fair value remeasurement of contingent consideration primarily due to changes in discount rates and the passage of time. During the nine months ended September 30, 2020, the Company recorded a $4.2 million gain on fair value remeasurement of contingent consideration primarily due to updated assumptions for CDX-3379 related milestones due to the discontinuation of the CDX-3379 program, changes in discount rates and the passage of time. During the three and nine months ended September 30, 2019, the Company recorded a $2.1 million and $1.6 million gain on fair value remeasurement of contingent consideration, respectively, primarily due to changes in discount rates, the passage of time and updated assumptions for the varlilumab program. The assumptions related to determining the fair value of contingent consideration include a significant amount of judgment, and any changes in the underlying estimates could have a material impact on the amount of contingent consideration adjustment recorded in any given period.

The Company did not have any transfers in or out of Level 3 assets or liabilities during the nine months ended September 30, 2020.

(4) Marketable Securities

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

		Gross Unrealized		
	Amortized Cost	Gains	Losses	Fair Value
	(In thousands)			
September 30, 2020				
U.S. government and municipal obligations (maturing in one year or less)	$ 79,969	$ 12	$ —	$ 79,981
Corporate debt securities (maturing in one year or less)	101,462	11	(11)	101,462
Total Marketable Securities	$ 181,431	$ 23	$ (11)	$ 181,443
December 31, 2019				
U.S. government and municipal obligations (maturing in one year or less)	$ 18,509	$ 13	$ —	$ 18,522
Corporate debt securities (maturing in one year or less)	34,619	13	(3)	34,629
Total Marketable Securities	$ 53,128	$ 26	$ (3)	$ 53,151

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, 2020 and December 31, 2019. 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 $0.3 million and $0.2 million in accrued interest at September 30, 2020 and December 31, 2019, respectively.

(5) Intangible Assets

At September 30, 2020 and December 31, 2019, the Company recorded indefinite-lived intangible assets of $45.2 million and $48.7 million, 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 (including CDX-0159) and the TAM program. The Company evaluated the CDX-3379 IPR&D asset for potential impairment as a result of the discontinuation of the CDX-3379 program in the second quarter of 2020. The Company concluded that the CDX-3379 IPR&D asset was fully impaired, and a non-cash impairment charge of $3.5 million was recorded during the second quarter of 2020. CDX-0159 is in Phase 1 development and the TAM program is in preclinical development. As of September 30, 2020, none of the Company’s IPR&D assets had reached technological feasibility nor did any have alternative future uses.

The Company performs an impairment test on IPR&D assets at least annually, or more frequently if events or changes in circumstances indicate that IPR&D assets may be impaired. Due to the nature of IPR&D projects, the Company may experience future delays or failures to obtain regulatory approvals to conduct clinical trials, failures of such clinical trials or other failures to achieve a commercially viable product, and as a result, may recognize further impairment losses in the future.

(6) Other Assets

In 2016, the Company entered into a research and collaboration agreement with an undisclosed private company to access novel technologies and paid $3.5 million to support research activities and make an investment in the private company. The Company recorded $1.8 million to other assets related to this investment and $1.7 million was recorded to research and development expense over the term of the research activities. The stock of the private company does not have a readily determinable fair value, and therefore it is measured at cost less impairment, if any. Based on information received in April 2019, it was determined that there was a deterioration of the private company's financial condition due to a working capital deficiency and an inability to secure additional funding as of March 31, 2019. Therefore, the Company concluded that the investment was impaired, and a non-cash impairment charge of $1.8 million was recorded during the first quarter of 2019. The Company assesses the private company's financial condition on a quarterly basis. There was no change in the value of the investment during the nine months ended September 30, 2020.

(7) Other Long-Term Liabilities

Other long-term liabilities include the following:

	September 30, 2020	December 31, 2019
	(In thousands)	
Net Deferred Tax Liabilities Related to IPR&D (Note 12)	$2,779	$3,007
Deferred Income From Sale of Tax Benefits	1,831	1,831
Contingent Milestones (Note 3)	8,249	12,485
Deferred Revenue (Note 11)	553	254
Total	13,412	17,577
Less Current Portion	(2,362)	(2,026)
Long-Term Portion	$ 11,050	$ 15,551

In November 2015, the Company received approval from the New Jersey Economic Development Authority and agreed to sell New Jersey tax benefits of $9.8 million to an independent third party for $9.2 million. 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 in other income related to the sale of these tax benefits during the three and nine months ended September 30, 2020 and $0.0 million and $0.2 million during the three and nine months ended September 30, 2019, respectively.

(8) Stockholders' Equity

In May 2016, the Company entered into a controlled equity offering sales agreement (the "Cantor Agreement") with Cantor Fitzgerald & Co. ("Cantor") to allow the Company to issue and sell shares of its common stock from time to time through Cantor, acting as agent. During the nine months ended September 30, 2020, the Company issued 7.1 million shares of common stock pursuant to the Cantor Agreement resulting in net proceeds of $29.6 million after deducting commission and offering expenses. At September 30, 2020, the Company had $13.8 million remaining in aggregate gross offering price available under a prospectus supplement filed pursuant to the agreement.

During the second quarter of 2020, the Company issued 15,384,614 shares of its common stock in an underwritten public offering resulting in net proceeds to the Company of $141.4 million, after deducting underwriting fees and offering expenses.

The changes in Stockholders' Equity during the three and nine months ended September 30, 2020 and 2019 are summarized below:

	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
			(In thousands, except share amounts)			
Consolidated Balance at December 31, 2019	16,972,077	$ 17	$ 1,104,706	$ 2,619	$ (1,013,316)	$ 94,026
Shares Issued under Stock Option and Employee Stock Purchase Plans	12,573	—	24	—	—	24
Shares Issued in Connection with Cantor Agreement	746,152	1	1,613	—	—	1,614
Share-Based Compensation	—	—	686	—	—	686
Unrealized Loss on Marketable Securities	—	—	—	(22)	—	(22)
Net Loss	—	—	—	—	(12,625)	(12,625)
Consolidated Balance at March 31, 2020	17,730,802	$ 18	$ 1,107,029	$ 2,597	$ (1,025,941)	$ 83,703
Shares Issued in Connection with Cantor Agreement	5,978,452	6	23,686	—	—	23,692
Shares Issued in Underwritten Offering	15,384,614	15	141,346	—	—	141,361
Share-Based Compensation	—	—	722	—	—	722
Unrealized Loss on Marketable Securities	—	—	—	(3)	—	(3)
Net Loss	—	—	—	—	(11,031)	(11,031)
Consolidated Balance at June 30, 2020	39,093,868	$ 39	$ 1,272,783	$ 2,594	$ (1,036,972)	$ 238,444
Shares Issued under Stock Option and Employee Stock Purchase Plans	68,204	—	194	—	—	194
Shares Issued in Connection with Cantor Agreement	400,400	1	4,296	—	—	4,297
Share-Based Compensation	—	—	1,250	—	—	1,250
Unrealized Gain on Marketable Securities	—	—	—	14	—	14
Net Loss	—	—	—	—	(14,224)	(14,224)
Consolidated Balance at September 30, 2020	39,562,472	$ 40	$ 1,278,523	$ 2,608	$ (1,051,196)	$ 229,975

	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
			(In thousands, except share amounts)			
Consolidated Balance at December 31, 2018	11,957,635	$ 12	$ 1,083,903	$ 2,583	$ (962,438)	$ 124,060
Shares Issued under Stock Option and Employee Stock Purchase Plans	3,507	—	9	—	—	9
Shares Issued in Connection with Cantor Agreement	883,569	1	4,150	—	—	4,151
Share-Based Compensation	—	—	1,693	—	—	1,693
Unrealized Gain on Marketable Securities	—	—	—	19	—	19
Net Loss	—	—	—	—	(17,239)	(17,239)
Consolidated Balance at March 31, 2019	12,844,711	$ 13	$ 1,089,755	$ 2,602	$ (979,677)	$ 112,693
Shares Cancelled under Stock Option and Employee Stock Purchase Plans	(222)	—	—	—	—	—
Shares Issued in Connection with Cantor Agreement	1,972,428	2	7,210	—	—	7,212
Share-Based Compensation	—	—	1,464	—	—	1,464
Unrealized Gain on Marketable Securities	—	—	—	36	—	36
Net Loss	—	—	—	—	(11,779)	(11,779)
Consolidated Balance at June 30, 2019	14,816,917	$ 15	$ 1,098,429	$ 2,638	$ (991,456)	$ 109,626
Shares Issued in Connection with Cantor Agreement	1,087,603	1	2,462	—	—	2,463
Share-Based Compensation	—	—	707	—	—	707
Unrealized Loss on Marketable Securities	—	—	—	(3)	—	(3)
Net Loss	—	—	—	—	(11,413)	(11,413)
Consolidated Balance at September 30, 2019	15,904,520	$ 16	$ 1,101,598	$ 2,635	$ (1,002,869)	$ 101,380

(9) Stock-Based Compensation

A summary of stock option activity for the nine months ended September 30, 2020 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In Years)
Options Outstanding at December 31, 2019	1,699,202	$ 44.87	8.0
Granted	1,490,925	$ 10.42	
Exercised	(36,960)	$ 3.85	
Canceled	(78,335)	$ 35.80	
Options Outstanding at September 30, 2020	3,074,832	$ 28.89	8.4
Options Vested and Expected to Vest at September 30, 2020	2,888,532	$ 30.19	8.4
Options Exercisable at September 30, 2020	871,007	$ 80.35	6.2
Shares Available for Grant Under the 2008 Plan	907,673		

The weighted average grant-date fair value of stock options granted during the three and nine month period ended September 30, 2020 was $9.25 and $7.99, respectively. Stock-based compensation expense for the three and nine months ended September 30, 2020 and 2019 was recorded as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
	(In thousands)		(In thousands)	
Research and development	$ 642	$ 330	$ 1,294	$ 1,740
General and administrative	608	377	1,364	2,124
Total stock-based compensation expense	$ 1,250	$ 707	$ 2,658	$ 3,864

The fair values of employee and director stock options granted during the three and nine months ended September 30, 2020 and 2019 were valued using the Black-Scholes option pricing model with the following assumptions:

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Expected stock price volatility	98%	91%	91 – 98%	91%
Expected option term	6.0 Years	6.0 Years	6.0 Years	6.0 Years
Risk-free interest rate	0.5%	1.6 – 1.9%	0.5 – 0.6%	1.6 – 2.5%
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, 2020 are summarized below:

	Unrealized Gain/(Loss) on Marketable Securities	Foreign Currency Items	Total
		(In thousands)	
Balance at December 31, 2019	$ 23	$ 2,596	$ 2,619
Other comprehensive loss	(11)	—	(11)
Balance at September 30, 2020	$ 12	$ 2,596	$ 2,608

No amounts were reclassified out of accumulated other comprehensive income during the nine months ended September 30, 2020.

(11) Revenue

Product Development and Licensing Revenue

The Company entered into an agreement with Rockefeller University in September 2013, as amended, (the "Rockefeller Agreement") pursuant to which the Company performs manufacturing and development services for Rockefeller University for their portfolio of antibodies against HIV. This portfolio was licensed to Gilead Sciences in January 2020 from Rockefeller University ("Rockefeller Transaction"). Pursuant to the Rockefeller Agreement, the Company received an upfront payment of $1.8 million as a result of the Rockefeller Transaction which was recorded to revenue during the first quarter of 2020. The Company is eligible to receive additional payments from Rockefeller University if this portfolio progresses through clinical and commercial development.

Contract and Grants Revenue

The Company has entered into the Rockefeller Agreement and an agreement with Duke University pursuant to which the Company performs manufacturing and research and development services on a time-and-materials basis or at a negotiated fixed-price. The Company recognized $0.2 million and $0.7 million in revenue under these agreements during the three and nine months ended September 30, 2020, respectively, and $0.4 million and $1.9 million during the three and nine months ended September 30, 2019, respectively.

During the quarter ended September 30, 2020, the Company was awarded a Small Business Innovation Research ("SBIR") grant from the National Institutes of Health (NIH) to support the Company's CDX-1140 and CDX-301 programs. The Company recognized $0.3 million in grant revenue under the award during the three months ended September 30, 2020.

Contract Assets and Liabilities

At December 31, 2019 and September 30, 2020, the Company's right to consideration under all contracts was considered unconditional, and as such, there were no recorded contract assets. At December 31, 2019 and September 30, 2020, the Company had $0.3 million and $0.6 million in contract liabilities recorded, respectively. Revenue recognized from contract liabilities as of December 31, 2019 during the three and nine months ended September 30, 2020 was $0.0 million and $0.2 million, respectively.

(12) Income Taxes

The Company has evaluated the positive and negative evidence bearing upon the realizability of its net deferred tax assets and considered its history of losses, ultimately concluding that it is "more likely than not" that the Company will not recognize the benefits of federal, state and foreign deferred tax assets and, as such, has maintained a full valuation allowance on its deferred tax assets as of September 30, 2020 and December 31, 2019.

The net deferred tax liability of $2.8 million and $3.0 million at September 30, 2020 and December 31, 2019, respectively, relates to the temporary differences associated with the IPR&D intangible assets acquired in previous business combinations and is not deductible for tax purposes. During the second quarter of 2020, a $0.2 million non-cash income tax benefit was recorded related to the impairment of the CDX-3379 IPR&D asset.

Massachusetts, New Jersey, New York and Connecticut 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. In periods in which the Company reports a net loss, there is no difference between basic and diluted net loss per share because dilutive shares of common stock are not assumed to have been issued as their effect is anti-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,	
	2020	2019
Stock Options	3,074,832	1,724,758
Restricted Stock	—	1,110
	3,074,832	1,725,868

(14) Kolltan Acquisition

On November 29, 2016, the Company acquired all of the share and debt interests of Kolltan Pharmaceuticals, Inc. ("Kolltan"), a clinical-stage biopharmaceutical company, in exchange for 1,217,200 shares of the Company's common stock plus contingent consideration in the form of development, regulatory approval and sales-based milestones ("Kolltan Milestones") of up to $172.5 million. The Kolltan Milestone payments, if any, may be made, at Celldex's sole election, in cash, in shares of Celldex's common stock or a combination of both, subject to provisions of the Merger Agreement. Certain Kolltan Milestones related to the METRIC clinical study, TAM partnership closing within two years of the acquisition, CDX-3379 and CDX-0158 have been abandoned consistent with the provisions of the Merger Agreement and, because of this, as of September 30, 2020, the Company believes that the adjusted amount we may be required to pay for future consideration is up to $107.5 million contingent upon the achievement of the Kolltan Milestones.

In October 2019, the Company received a letter from Shareholder Representative Services LLC ("SRS"), the hired representative of the former stockholders of Kolltan, notifying the Company that it objected to the Company's abandonment of certain Kolltan Milestones relating to development, regulatory approval and sales-based milestones. The Company disagrees with their objection and believes their objection to be without merit.

On August 18, 2020, Celldex filed a Verified Complaint in the Court of Chancery of the State of Delaware against SRS (acting in its capacity as the representative of the former stockholders of Kolltan pursuant to the Merger Agreement) seeking declaratory relief with respect to the rights and obligations of the parties relating to certain contingent milestone payments under the Merger Agreement. Specifically, Celldex sought the entry of an order declaring that:

(i) Celldex's determination to discontinue the development of CDX-0158 (formerly known as KTN0158) was proper and valid under the Merger Agreement;
(ii) the Milestone Abandonment Notice dated December 5, 2018 from Celldex was valid and effective under the Merger Agreement and that the "Successful Completion of Phase I Clinical Trial for KTN0158" Milestone has not been achieved and has properly been abandoned; and
(iii) under the Merger Agreement, the CDX-0159 program is not a program that results in milestone payments under the Merger Agreement.

In SRS' responsive Answer and Verified Counterclaim, SRS made claims of breach of contract with respect to the Merger Agreement, breach of implied covenant of good faith and fair dealing, declaratory relief, and unjust enrichment. The case remains ongoing and we are currently unable to predict or estimate the outcome of this matter.

Following the Company's discontinuation of the CDX-3379 program, the Company sent a milestone abandonment notice to SRS with respect to Kolltan Milestones related to the CDX-3379 program. In October 2020, the Company received notice that SRS has objected to that notice, seeking further information from the Company.

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

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

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

- our dependence on product candidates, which are still in an early development stage;
- our ability to successfully complete research and further development, including animal, preclinical and clinical studies, and, if we obtain regulatory approval, commercialization of our drug candidates and the growth of the markets for those drug candidates;
- our anticipated timing for preclinical development, regulatory submissions, commencement and completion of clinical trials and product approvals;
- The impact of the recent outbreak of a novel strain of coronavirus on our business or on the economy generally;
- Whether the recent coronavirus outbreak will affect the timing of the completion of our planned and/or currently ongoing preclinical/clinical trials;
- our ability to negotiate strategic partnerships, where appropriate, for our drug candidates;
- our ability to manage multiple clinical trials for a variety of drug candidates at different stages of development;
- the cost, timing, scope and results of ongoing preclinical and clinical testing;
- our expectations of the attributes of our product and development candidates, including pharmaceutical properties, efficacy, safety and dosing regimens;
- the cost, timing and uncertainty of obtaining regulatory approvals for our drug candidates;
- the availability, cost, delivery and quality of clinical management services provided by our clinical research organization partners;
- the availability, cost, delivery and quality of clinical and commercial-grade materials produced by our own manufacturing facility or supplied by contract manufacturers, suppliers and partners;
- our ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors;

- our ability to develop technological capabilities, including identification of novel and clinically important targets, exploiting our existing technology platforms to develop new drug candidates and expand our focus to broader markets for our existing targeted immunotherapeutics;

- the cost of paying development, regulatory approval and sales-based milestones under the merger agreement by which we acquired Kolltan, including under any future amendment to that agreement and the cost, timing, and outcome of our declaratory judgment action against SRS with respect to certain of those milestones;

- our ability to realize the anticipated benefits from the acquisition of Kolltan;

- our ability to raise sufficient capital to fund our animal, preclinical and clinical studies and to meet our liquidity needs, on terms acceptable to us, or at all. If we are unable to raise the funds necessary to meet our liquidity needs, we may have to delay or discontinue the development of one or more programs, discontinue or delay ongoing or anticipated clinical trials, license out programs earlier than expected, raise funds at significant discount or on other unfavorable terms, if at all, or sell all or part of our business;

- our ability to protect our intellectual property rights and our ability to avoid intellectual property litigation, which can be costly and divert management time and attention;

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

- the risk factors set forth elsewhere in this quarterly report on Form 10-Q and the factors listed under the headings “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in the Company’s annual report on Form 10-K for the year ended December 31, 2019 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 dedicated to developing therapeutic monoclonal and bispecific antibodies that address diseases for which available treatments are inadequate. Our drug candidates include antibody-based therapeutics which have the ability to engage the human immune system and/or directly affect critical pathways to improve the lives of patients with inflammatory diseases and many forms of cancer.

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

- CDX-0159, a monoclonal antibody that specifically binds the KIT receptor and potently inhibits its activity, which recently completed a Phase 1a study in healthy subjects. We are studying CDX-0159 in mast cell driven diseases, including, initially, in urticarias. In October 2020, we announced that enrollment had opened and the first patient had been dosed in a Phase 1b study in chronic spontaneous urticaria (CSU). In addition, patients are currently being screened for enrollment to a second Phase 1b study in chronic inducible urticaria (CIndU);

- CDX-1140, an agonist monoclonal antibody targeted to CD40, a key activator of immune response, currently being studied as a single-agent and in combination with CDX-301, a dendritic cell growth factor. Dose escalation was completed in a Phase 1 study in solid tumors and lymphoma and the recommended dose for further study was determined to be 1.5 mg/kg for both CDX-1140 monotherapy and in combination with CDX-301. We have initiated multiple expansion cohorts within the study, including a combination cohort with KEYTRUDA® (pembrolizumab) in patients refractory to PD1/PDL1 treatment and a combination cohort with standard of care chemotherapy in patients with untreated metastatic pancreatic cancer. We are exploring additional combination cohorts with mechanisms that we believe could be complementary or synergistic with CDX-1140; and

- CDX-527, a bispecific antibody that uses our proprietary highly active anti-PD-L1 and CD27 human antibodies to couple CD27 co-stimulation with blockade of the PD-L1/PD-1 pathway, for which we initiated a Phase 1 study in advanced solid tumors in August 2020.

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

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

The expenditures that will be necessary to execute our business plan are subject to numerous uncertainties. Completion of clinical trials may take several years or more, and the length of time generally varies substantially according to the type, complexity, novelty and intended use of a drug candidate. It is not unusual for the clinical development of these types of drug candidates to each take five years or more, and for total development costs to exceed $100 million for each drug candidate. We estimate that clinical trials of the type we generally conduct are typically completed over the following timelines:

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

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

- the number of patients that ultimately participate in the trial;

- the duration of patient follow-up that seems appropriate in view of results;

- the number of clinical sites included in the trials;

- the length of time required to enroll suitable patient subjects; and

- the efficacy and safety profile of the drug candidate.

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

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

Regulatory approval is required before we can market our drug candidates as therapeutic products. In order to proceed to subsequent clinical trial stages and to ultimately achieve regulatory approval, the regulatory agency must conclude that our clinical data demonstrate that our product candidates are safe and effective. Historically, the results from preclinical testing and early clinical trials (through Phase 2) have often not been predictive of results obtained in later clinical trials. A number of new drugs and biologics have shown promising results in early clinical trials but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

Furthermore, our business strategy includes the option of entering into collaborative arrangements with third parties to complete the development and commercialization of our drug candidates. In the event that third parties take over the clinical trial process for one of our drug candidates, the estimated completion date would largely be under control of that third party rather than us. We cannot forecast with any degree of certainty which proprietary products, if any, will be subject to future collaborative arrangements, in whole or in part, and how such arrangements would affect our development plan or capital requirements. Our programs may also benefit from subsidies, grants, contracts or government or agency-sponsored studies that could reduce our development costs.

As a result of the uncertainties discussed above, among others, it is difficult to accurately estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete our research and development projects in a timely manner or our failure to enter into collaborative agreements, when appropriate, could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time to time in order to continue with our business strategy. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

During the past five years through December 31, 2019, we incurred an aggregate of $408.2 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, 2020 and 2019. 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, 2020	Nine Months Ended September 30, 2019
	(In thousands)	
CDX-0159/Anti-KIT Program	$ 5,233	$ 3,079
CDX-1140	6,816	5,514
CDX-527	7,719	6,823
TAM Program	1,715	3,670
Other Programs	10,626	13,247
Total R&D Expense	$ 32,109	$ 32,333

Clinical Development Programs

While our clinical development programs have not been significantly, negatively impacted by COVID-19 to date, we continue to carefully monitor the evolving situation closely across all our development programs and work to minimize potential impact/disruptions.

CDX-0159

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

CDX-0159 is designed to block KIT activation by disrupting both SCF binding and KIT dimerization. Celldex believes that by targeting KIT, CDX-0159 may be able to inhibit mast cell activity and decrease mast cell numbers to provide potential clinical benefit in mast cell related diseases.

In June 2020, we completed a randomized, double-blind, placebo-controlled, single ascending dose escalation Phase 1a study of CDX-0159 in healthy subjects (n=32; 8 subjects per cohort, 6 CDX-0159; 2 placebo). Subjects received a single intravenous infusion of CDX-0159 at 0.3, 1.0, 3.0, or 9.0 mg/kg or placebo. The objectives of the study included safety and tolerability, pharmacokinetics (PK) and pharmacodynamics (tryptase and stem cell factor) and immunogenicity. Tryptase is an enzyme synthesized and secreted almost exclusively by mast cells and decreases in plasma tryptase levels are believed to reflect a systemic reduction in mast cell burden in both healthy volunteers and in disease. Data from the study were featured in a late breaking presentation at the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress 2020 in June. CDX-0159 demonstrated a favorable safety profile as well as profound and durable reductions of plasma tryptase, consistent with systemic mast cell suppression.

- Most common adverse events were mild infusion-related reactions, all of which spontaneously resolved without intervention. Mild and asymptomatic decreases in neutrophil and white blood cell count were observed in laboratory testing.

- A single dose of CDX-0159 suppressed plasma tryptase levels in a dose-dependent manner, indicative of systemic mast cell suppression. Tryptase suppression below the level of detection was observed after a single 1.0 mg/kg dose and was maintained for more than 2 months at single doses of both 3.0 and 9.0 mg/kg of CDX-0159. A subset of subjects from the 3mg/kg and 9 mg/kg cohorts agreed to continued follow up for tryptase suppression which remained below the level of detection for over 3 months (14 weeks) in 50% of subjects and over 4 months (18 weeks) in all subjects, respectively.

- Dose dependent increases in plasma stem cell factor mirror decreases in tryptase, consistent with allosteric blockade of stem cell factor to KIT and demonstrate complete target engagement in vivo.

- Long serum half-life and non-immunogenic profile support a convenient dosing schedule.

- Enhanced PK profile and durable tryptase suppression at low doses support re-formulation for sub-cutaneous administration.

These data support expansion of the CDX-0159 program into mast cell driven diseases, including initially in chronic spontaneous urticaria (CSU) and chronic inducible urticaria (CIndU), diseases where mast cell degranulation plays a central role in the onset and progression of the disease. The prevalence of CSU and CIndU is approximately 0.5-1% of the total population or up to 1 to 3 million patients in the United States alone (Weller et al. 2010. Hautarzt. 61(8), Bartlett et al. 2018. DermNet. Org). CSU presents as itchy hives, angioedema or both for at least six weeks without a specific trigger; multiple episodes can play out over years or even decades. About 50% of patients with CSU achieve symptomatic control with antihistamines or leukotriene receptor antagonists. Omalizumab, an IgE inhibitor, provides relief for roughly half of the remaining antihistamine/leukotriene refractory patients. Consequently, there is a need for additional therapies. CIndUs are forms of urticaria that have an attributable cause or trigger associated with them, typically resulting in hives or wheals. Celldex is exploring cold-induced and dermographism (scratch-induced) urticarias.

In October 2020, we announced that enrollment had opened and the first patient had been dosed in a Phase 1b multi-center study of CDX-0159 in CSU. This study is a randomized, double-blind, placebo-controlled clinical trial designed to assess the safety of multiple ascending doses of CDX-0159 in up to 40 patients with CSU who remain symptomatic despite treatment with antihistamines. Secondary and exploratory objectives include pharmacokinetic and pharmacodynamic assessments, including measurement of tryptase and stem cell factor levels and clinical activity outcomes (impact on urticaria symptoms, disease control, clinical response) as well as quality of life assessments. CDX-0159 will be administered intravenously (0.5, 1.5, 3 and 4.5 mg/kg at varying dosing schedules) as add on treatment to H1-antihistamines, either alone or in combination with H2-antihistamines and/or leukotriene receptor agonists.

A second Phase 1b study in CIndU is being conducted in Germany and recently opened to enrollment. This study is an open label clinical trial designed to evaluate the safety of a single dose of CDX-0159 in up to 20 patients with cold contact urticaria (n=10) or symptomatic dermographism (n=10) who are refractory to antihistamines. Patient's symptoms will be induced via provocation testing that resembles real life triggering situations. Secondary and exploratory objectives include pharmacokinetic and pharmacodynamic assessments, including changes from baseline provocation thresholds, measurement of tryptase and stem cell factor levels, clinical activity outcomes (impact on urticaria symptoms, disease control, clinical response), quality of life assessments and measurement of tissue mast cells through skin biopsies. CDX-0159 will be administered intravenously (3.0 mg/kg) on Day 1 as add on treatment to H1-antihistamines.

We are also exploring additional mast cell driven diseases for future development.

CDX-1140

CDX-1140 is a fully human agonist monoclonal antibody targeted to CD40, a key activator of immune response, which is found on dendritic cells, macrophages and B cells and is also expressed on many cancer cells. Potent CD40 agonist antibodies have shown encouraging results in early clinical studies; however, systemic toxicity associated with broad CD40 activation has limited their dosing. CDX-1140 has unique properties relative to other CD40 agonist antibodies: potent agonist activity is independent of Fc receptor interaction, contributing to more consistent, controlled immune activation; CD40L binding is not blocked, leading to potential synergistic effects of agonist activity near activated T cells in lymph nodes and tumors; and the antibody does not promote cytokine production in whole blood assays. CDX-1140 has shown direct anti-tumor activity in preclinical models of lymphoma. Preclinical studies of CDX-1140 clearly demonstrate strong immune activation effects and low systemic toxicity and support the design of the Phase 1 study to identify the dose for characterizing single-agent and combination activity.

We initiated a Phase 1 study of CDX-1140 in November 2017. This study is expected to enroll up to approximately 260 patients with recurrent, locally advanced or metastatic solid tumors and B cell lymphomas. The study is designed to determine the maximum tolerated dose, or MTD, during a dose-escalation phase (0.01 to 3.0 mg/kg once every four weeks until confirmed progression or intolerance) and to recommend a dose level for further study in a subsequent expansion phase. The expansion is designed to further evaluate the tolerability and biologic effects of selected dose(s) of CDX-1140 in specific tumor types. Secondary objectives include assessments of safety and tolerability, pharmacodynamics, pharmacokinetics, immunogenicity and additional measures of anti-tumor activity, including clinical benefit rate. We believe that the potential for CDX-1140 will be best defined in combination studies with other immunotherapies or conventional cancer treatments.

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

Interim data from this ongoing study were presented at the Society for Immunotherapy of Cancer's (SITC) 34th Annual Meeting in November 2019. CDX-1140 monotherapy dose escalation in the study is complete and the maximum tolerated dose and recommended dose was defined as 1.5 mg/kg every four weeks. CDX-1140 monotherapy and combination with CDX-301 was generally well tolerated, with mostly grade 1 or grade 2 drug related adverse events reported. Two patients out of six experienced pneumonitis as dose limiting toxicities (DLTs) in the CDX-1140 3.0 mg/kg monotherapy cohort. There were no DLTs observed in the CDX-301 combination cohorts up to 0.72 mg/kg CDX-1140. A cohort of CDX-1140 at 1.5 mg/kg plus CDX-301, which was ongoing at the time of data release, has subsequently completed dose escalation with no DLTs observed; therefore, the recommended dose of CDX-1140 in combination with CDX-301 is 1.5mg/kg.

As of the cut-off date for data reporting for SITC, 62 patients with advanced refractory solid tumors or lymphoma were enrolled and 38 patients had pre- and post-treatment scans available. Patients were heavily pretreated (median of 4 prior therapies) and per protocol were required to have received all standard of care treatments prior to study entry. CDX-1140 demonstrated clinical and biological activity in the study.

- Two of five patients with head and neck squamous cell carcinoma (HNSCC) treated with CDX-1140 doses of 0.72 mg/kg or higher experienced clinical activity. The first patient experienced dramatic shrinkage of a large, protruding neck mass on physical exam after two doses of CDX-1140 at 1.5 mg/kg with documented evidence of tumor necrosis/cavitation on CT scan. This patient also reported decreased tumor pain. A second patient experienced cavitation of greater than 50% of lung metastases on CT scan after one dose of CDX-1140 3 mg/kg.

- A patient with gastroesophageal carcinoma experienced a RECIST response after two cycles of CDX-1140 0.36 mg/kg plus CDX-301 that included 41% shrinkage of liver and lymph node target lesions, with near complete resolution of the liver lesion. This response was durable for four months.

- Six patients experienced stable disease (n=4 CDX-1140 monotherapy; n=2 CDX-1140/CDX-301 combination) with a duration of 1.8 months to 5.4 months.

- One patient experienced immune unconfirmed progressive disease on their first scan and continued on treatment for 10+ months without confirmation of progressive disease at CDX-1140 0.09 mg/kg plus CDX-301.

Potent pharmacological effects associated with immune activation were also observed, including transient induction of inflammatory cytokines and chemokines associated with dendritic cell and T cell activation at higher dose levels. Similar activation was observed with each cycle of therapy. Peripheral blood immune cells had upregulated immune activation markers and CDX-301 markedly increased the number of dendritic cells and was associated with higher IL-12p40 induction, a key molecule for inducing anti-tumor T cell responses.

CDX-1140 monotherapy expansion cohorts in HNSCC, renal cell carcinoma and gastroesophageal adenocarcinoma have been added to the study, along with a combination cohort of CDX-1140 and CDX-301 in HNSCC. In addition, we have prioritized and are enrolling a cohort to evaluate CDX-1140 in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, under a clinical trial collaboration agreement with Merck (known as MSD outside of the U.S. and Canada). The cohort is designed to characterize the safety, pharmacodynamics and activity of CDX-1140 in combination with pembrolizumab in patients refractory to PD1/PDL1 treatment. We also recently initiated a cohort in combination with standard of care chemotherapy in patients with previously untreated metastatic pancreatic cancer. The Company is exploring additional combination cohorts with mechanisms that we believe could be complementary or synergistic with CDX-1140.

CDX-527

CDX-527 is the first candidate from Celldex's bispecific antibody platform. Bispecifics provide opportunities to engage two independent pathways involved in controlling immune responses to tumors. CDX-527 uses Celldex's proprietary highly active anti-PD-L1 and CD27 human antibodies to couple CD27 co-stimulation with blockade of the PD-L1/PD-1 pathway to help prime and activate anti-tumor T cell responses through CD27 costimulation, while preventing PD-1 inhibitory signals that subvert the immune response.

Celldex's prior clinical experience with combining CD27 activation and PD-1 blockade provide the rationale for linking these two pathways into one molecule. Preclinical data presented at the SITC 34th Annual Meeting in November 2019 demonstrated that CDX-527 is more potent at T cell activation and anti-tumor immunity than the combination of parental monoclonal antibodies.

In August 2020, we announced the initiation of a Phase 1 dose-escalation study in up to ~90 patients with advanced or metastatic solid tumors that have progressed during or after standard of care therapy to be followed by tumor-specific expansion cohorts. The study is designed to determine the maximum tolerated dose, or MTD, during a dose-escalation phase and to recommend a dose level for further study in the subsequent expansion phase. The expansion is designed to further evaluate the tolerability, and biologic and anti-tumor effects of selected dose level(s) of CDX-527 in specific tumor types.

CRITICAL ACCOUNTING POLICIES

See Note 2 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for information regarding newly adopted and recent accounting pronouncements. See also Note 2 to our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2019 for a discussion of our critical accounting policies. There have been no material changes to such critical accounting policies. We believe our most critical accounting policies include accounting for contingent consideration, revenue recognition, intangible and long-lived assets, research and development expenses and stock-based compensation expense.

RESULTS OF OPERATIONS

Three Months Ended September 30, 2020 Compared with Three Months Ended September 30, 2019

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2020	2019	$	%
	(In thousands)			
Revenues:				
Product Development and Licensing Agreements	$ 12	$ 55	$ (43)	(78)%
Contracts and Grants	656	491	165	34%
Total Revenue	$ 668	$ 546	$ 122	22%
Operating Expenses:				
Research and Development	10,708	11,101	(393)	(4)%
General and Administrative	3,640	3,403	237	7%
Loss (Gain) on Fair Value Remeasurement of Contingent Consideration	662	(2,114)	2,776	131%
Total Operating Expense	15,010	12,390	2,620	21%
Operating Loss	(14,342)	(11,844)	2,498	21%
Investment and Other Income, Net	118	431	(313)	(73)%
Net Loss	$ (14,224)	$ (11,413)	$ 2,811	25%

Net Loss

The $2.8 million increase in net loss for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019, was primarily the result of an increase in the loss on fair value remeasurement of contingent consideration.

Revenue

Product development and licensing agreements revenue for the three months ended September 30, 2020 was consistent with the three months ended September 30, 2019. The $0.2 million increase in contracts and grants revenue for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019, was primarily due to an increase in revenue from the Company's SBIR grant, partially offset by a decrease in services performed under our contract manufacturing and research and development agreement with Rockefeller University. We expect revenue to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Research and Development Expense

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

	Three Months Ended September 30		Increase/ (Decrease)	
	2020	2019	$	%
	(In thousands)			
Personnel	$ 5,680	$ 5,493	$ 187	3%
Laboratory Supplies	763	1,380	(617)	(45)%
Facility	1,606	1,709	(103)	(6)%
Product Development	1,852	1,579	273	17%

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The $0.2 million increase in personnel expenses for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019, was primarily due to higher 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 $0.6 million decrease in laboratory supply expenses for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019, 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 $0.1 million decrease in facility expenses for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019, was primarily due to lower rent and depreciation expenses. We expect facility expenses to decrease over the next twelve months as a result of the consolidation our Massachusetts lab and manufacturing facilities in the second quarter of 2020. In July 2020, we extended the term of our Fall River lease through July 2023.

Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing. The $0.3 million increase in product development expenses for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019, was primarily due to an increase in contract manufacturing and clinical trial expenses of $0.6 million, partially offset by a decrease in contract research expenses of $0.3 million. We expect product development expenses to increase over the next twelve months, although there may be fluctuations on a quarterly basis.

General and Administrative Expense

The $0.2 million increase in general and administrative expenses for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019, was primarily due to higher stock-based compensation 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 $0.7 million loss on fair value remeasurement of contingent consideration for the three months ended September 30, 2020 was primarily due to changes in discount rates and the passage of time. The $2.1 million gain on fair value remeasurement of contingent consideration for the three months ended September 30, 2019 was primarily due to updated assumptions for the varlilumab program.

Investment and Other Income, Net

The $0.3 million decrease in investment and other income, net for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019, was primarily due to lower interest rates on fixed income investments. We anticipate investment and other income to increase over the next twelve months due to higher other income related to our sale of New Jersey tax benefits.

Nine Months Ended September 30, 2020 Compared with Nine Months Ended September 30, 2019

	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2020	2019	$	%
	(In thousands)			
Revenues:				
Product Development and Licensing Agreements	$ 2,297	$ 379	$ 1,918	506%
Contracts and Grants	1,336	2,307	(971)	(42)%
Total Revenue	$ 3,633	$ 2,686	$ 947	35%
Operating Expenses:				
Research and Development	32,109	32,333	(224)	(1)%
General and Administrative	10,833	12,207	(1,374)	(11)%
Intangible Asset Impairment	3,500	—	3,500	n/a
Other Asset Impairment	—	1,800	(1,800)	(100)%
Gain on Fair Value Remeasurement of Contingent Consideration	(4,236)	(1,612)	2,624	163%
Total Operating Expense	42,206	44,728	(2,522)	(6)%
Operating Loss	(38,573)	(42,042)	(3,469)	(8)%
Investment and Other Income, Net	465	1,611	(1,146)	(71)%
Net Loss Before Income Tax Benefit	(38,108)	(40,431)	(2,323)	(6)%
Income Tax Benefit	228	—	228	n/a
Net Loss	$ (37,880)	$ (40,431)	$ (2,551)	(6)%

Net Loss

The $2.6 million decrease in net loss for the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019, was primarily the result of an increase in the gain on fair value remeasurement of contingent consideration and a decrease in non-cash other asset impairment expense, partially offset by an increase in intangible asset impairment expense.

Revenue

The $1.9 million increase in product development and licensing agreements revenue for the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019, was primarily due to the $1.8 million received from the Rockefeller Transaction. The $0.9 million decrease in contracts and grants revenue for the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019, was primarily related to a decrease in services performed under our manufacturing and research and development agreement with Duke University.

Research and Development Expense

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

	Nine Months Ended September 30,		Increase/ (Decrease)	
	2020	2019	$	%
	(In thousands)			
Personnel	$ 16,513	$ 16,655	$ (142)	(1)%
Laboratory Supplies	2,998	3,433	(435)	(13)%
Facility	5,093	5,164	(71)	(1)%
Product Development	4,681	4,101	580	14%

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The $0.1 million decrease in personnel expenses for the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019, was primarily due to lower stock-based compensation expense.

Laboratory supplies expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The $0.4 million decrease in laboratory supply expenses for the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019, 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 $0.1 million decrease in facility expenses for the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019, was primarily due to lower rent and depreciation expenses.

Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing. The $0.6 million increase in product development expenses for the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019, was primarily due to an increase in clinical trial and contract manufacturing expenses of $1.4 million, partially offset by a decrease in contract research expenses of $0.8 million.

General and Administrative Expense

The $1.4 million decrease in general and administrative expenses for the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019, was primarily due to lower stock-based compensation expense and lower facility expenses as a result of the consolidation our Massachusetts lab and manufacturing facilities in the second quarter of 2020.

Intangible Asset Impairment

We evaluated the CDX-3379 IPR&D asset for potential impairment as a result of the discontinuation of the CDX-3379 program. We concluded that the CDX-3379 IPR&D asset was fully impaired, and a non-cash impairment charge of $3.5 million was recorded in the second quarter of 2020.

Other Asset Impairment

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

Gain on Fair Value Remeasurement of Contingent Consideration

The $4.2 million gain on fair value remeasurement of contingent consideration for the nine months ended September 30, 2020 was primarily due to updated assumptions for CDX-3379 related milestones due to the discontinuation of the CDX-3379 program, changes in discount rates and the passage of time. The $1.6 million gain on fair value remeasurement of contingent consideration for the nine months ended September 30, 2019 was primarily due to changes in discount rates, the passage of time and updated assumptions for the varlilumab program.

Investment and Other Income, Net

The $1.1 million decrease in investment and other income, net for the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019, was primarily due to lower interest rates on fixed income investments and lower other income related to our sale of New Jersey tax benefits.

Income Tax Benefit

A $0.2 million non-cash income tax benefit was recorded related to the impairment of the CDX-3379 IPR&D asset in the second quarter of 2020.

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, 2020, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of $199.6 million. We have had recurring losses and incurred a loss of $37.9 million for the nine months ended September 30, 2020. Net cash used in operations for the nine months ended September 30, 2020 was $35.2 million. We believe that the cash, cash equivalents and marketable securities at September 30, 2020 are sufficient to meet estimated working capital requirements and fund planned operations through 2023. This could be impacted if we elected to pay Kolltan contingent milestones, if any, in cash.

During the next twelve months, we may take further steps to raise additional capital to meet our long-term liquidity needs including, but not 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. Although we have been successful in raising capital in the past, 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 long-term liquidity needs, we may have to delay or discontinue the development of one or more programs, discontinue or delay ongoing or anticipated clinical trials, license out programs earlier than expected, raise funds at a significant discount or on other unfavorable terms, if at all, or sell all or a part of our business.

Operating Activities

Net cash used in operating activities was $35.2 million for the nine months ended September 30, 2020 as compared to $35.4 million for the nine months ended September 30, 2019. The decrease in net cash used in operating activities was primarily due to a decrease in general and administrative expenses and an increase in cash received related to product development and licensing agreements, partially offset by a decrease in investment income. 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 used in investing activities was $129.1 million for the nine months ended September 30, 2020 as compared to net cash provided by investing activities of $13.9 million for the nine months ended September 30, 2019. The increase in net cash used in investing activities was primarily due to net purchases of marketable securities for the nine months ended September 30, 2020 of $127.8 million as compared to net sales and maturities of marketable securities of $14.5 million for the nine months ended September 30, 2019.

Financing Activities

Net cash provided by financing activities was $171.2 million for the nine months ended September 30, 2020 as compared to $13.8 million for the nine months ended September 30, 2019.

During the nine months ended September 30, 2020, we issued 7.1 million shares of common stock under our Cantor Agreement resulting in net proceeds of $29.6 million after deducting commission and offering expenses. At September 30, 2020, we had $13.8 million remaining in aggregate gross offering price available under the agreement.

During the second quarter of 2020, the Company issued 15,384,614 shares of its common stock in an underwritten public offering resulting in net proceeds to the Company of $141.4 million, after deducting underwriting fees and offering expenses.

Aggregate Contractual Obligations

The disclosures relating to our contractual obligations reported in our Annual Report on Form 10-K for the year ended December 31, 2019 which was filed with the SEC on March 26, 2020 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 approximate fair value at September 30, 2020 due to the short-term maturities of these instruments.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

As of September 30, 2020, 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, 2020. 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, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

Shareholder Representative Services LLC (SRS) is the hired representative of the former stockholders of Kolltan Pharmaceuticals, Inc. (Kolltan) in connection with the Agreement and Plan of Merger, dated November 1, 2016, by and among Kolltan, Connemara Merger Sub 1, Inc., Connemara Merger Sub 2 LLC, and SRS (Merger Agreement). On August 18, 2020, Celldex filed a Verified Complaint in the Court of Chancery of the State of Delaware against SRS (acting in its capacity as the representative of the former stockholders of Kolltan pursuant to the Merger Agreement) seeking declaratory relief with respect to the rights and obligations of the parties relating to certain contingent milestone payments under the Merger Agreement. Specifically, Celldex sought the entry of an order declaring that:

(iv) Celldex's determination to discontinue the development of CDX-0158 (formerly known as KTN0158) was proper and valid under the Merger Agreement;
(v) the Milestone Abandonment Notice dated December 5, 2018 from Celldex was valid and effective under the Merger Agreement and that the "Successful Completion of Phase I Clinical Trial for KTN0158" Milestone has not been achieved and has properly been abandoned; and
(vi) under the Merger Agreement, the CDX-0159 program is not a program that results in milestone payments under the Merger Agreement.

In SRS' responsive Answer and Verified Counterclaim, SRS made claims of breach of contract with respect to the Merger Agreement, breach of implied covenant of good faith and fair dealing, declaratory relief, and unjust enrichment. The case remains ongoing and we are currently unable to predict or estimate the outcome of this matter.

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2019, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K may not be the only risks facing the Company. Additional risks and uncertainties not currently known to the Company or that the Company currently deems to be immaterial also may materially adversely affect the Company's business, financial condition and/or operating results.

Except as set forth below, there were no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 26, 2020.

Our stockholders may be subject to substantial dilution if we elect to pay future milestone consideration to the former Kolltan stockholders in shares of common stock. If we elect to pay future milestone consideration in cash we would likely need to raise additional capital.

The merger agreement between us and Kolltan ("Merger Agreement") provides that we will be required to pay Kolltan's former stockholders contingent consideration in the form of development, regulatory approval and sales-based milestones ("Kolltan Milestones") of up to $172.5 million. Certain Kolltan Milestones related to the METRIC clinical study, TAM partnership closing within two years of the acquisition, CDX-3379 and CDX-0158 have been abandoned consistent with the provisions of the Merger Agreement and, because of this, as of September 30, 2020, we believe that the adjusted amount we may be required to pay for future consideration is up to $107.5 million contingent upon the achievement of the Kolltan Milestones. We have previously sent abandonment notices to the representative of Kolltan's former stockholders with respect to certain of those Kolltan Milestones, to which the representative subsequently objected. We disagree with their objection and believe their objection to be without merit. We have filed a Verified Complaint in the Court of Chancery of the State of Delaware seeking declaratory relief with respect to the rights and obligations of the parties relating to certain contingent milestone payments under the Merger Agreement relating to the discontinued CDX-0158 program.

At this time, we are unable to reasonably assess the ultimate outcome of our litigation with the representative of Kolltan's former stockholders over its objection to our abandonment of certain Kolltan Milestones or determine an estimate of potential losses, if any. Further, there are disagreements between that representative and us with respect to our abandonment notice related to the discontinued CDX-3379 program.

Milestone payments under the Merger Agreement may be made, at our sole election, in cash, in shares of our common stock or a combination of both, although we are required to maintain a certain percentage of the overall consideration paid in Celldex common stock to satisfy certain tax requirements under the Merger Agreement. We may require additional capital to fund any milestone payments in cash, depending on the facts and circumstances at the time such payments become due. If we elect to pay the Kolltan Milestones in shares of our common stock, our stockholders would experience substantial dilution.

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.

CELLDEX THERAPEUTICS, INC.

BY:

/s/ ANTHONY S. MARUCCI

Dated: November 5, 2020

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

/s/ SAM MARTIN

Dated: November 5, 2020

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

Exhibit 31.1

CERTIFICATION

I, Anthony S. Marucci, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2020

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

Exhibit 31.2

CERTIFICATION

I, Sam Martin, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2020

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

Exhibit 32.1

SECTION 1350 CERTIFICATIONS

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

Date: November 5, 2020

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

Date: November 5, 2020

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.