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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2021

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, 2021, 46,663,872 shares of common stock, $.001 par value per share, were outstanding.

CELLDEX THERAPEUTICS, INC.

FORM 10-Q

For the Quarterly Period Ended September 30, 2021

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PART I — FINANCIAL INFORMATION
Item 1. Unaudited Financial Statements

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

(In thousands, except share and per share amounts)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 72,184	$ 43,836
Marketable securities	350,905	150,586
Accounts and other receivables	197	1,802
Prepaid and other current assets	3,269	1,619
Total current assets	426,555	197,843
Property and equipment, net	3,342	3,815
Operating lease right-of-use assets, net	3,016	3,449
Intangible assets, net	27,190	30,690
Other assets	98	41
Total assets	$ 460,201	$ 235,838
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 836	$ 1,048
Accrued expenses	10,253	8,459
Current portion of operating lease liabilities	1,366	1,327
Current portion of other long-term liabilities	1,721	3,372
Total current liabilities	14,176	14,206
Long-term portion of operating lease liabilities	1,713	2,154
Other long-term liabilities	7,600	10,121
Total liabilities	23,489	26,481
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, 2021 and December 31, 2020	—	—
Common stock, $.001 par value; 297,000,000 shares authorized; 46,663,340 and 39,603,771 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	47	40
Additional paid-in capital	1,557,576	1,279,824
Accumulated other comprehensive income	2,548	2,589
Accumulated deficit	(1,123,459)	(1,073,096)
Total stockholders' equity	436,712	209,357
Total liabilities and stockholders' equity	$ 460,201	$ 235,838

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, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Revenues:				
Product development and licensing agreements	$ —	$ 12	$ 29	$ 2,297
Contracts and grants	153	656	4,288	1,336
Total revenues	153	668	4,317	3,633
Operating expenses:				
Research and development	13,557	10,708	38,633	32,109
General and administrative	5,821	3,640	14,247	10,833
Intangible asset impairment	3,500	—	3,500	3,500
(Gain) loss on fair value remeasurement of contingent consideration	(1,901)	662	(1,160)	(4,236)
Total operating expenses	20,977	15,010	55,220	42,206
Operating loss	(20,824)	(14,342)	(50,903)	(38,573)
Investment and other income, net	145	118	313	465
Net loss before income tax benefit	(20,679)	(14,224)	(50,590)	(38,108)
Income tax benefit	227	—	227	228
Net loss	$ (20,452)	$ (14,224)	$ (50,363)	$ (37,880)
Basic and diluted net loss per common share	$ (0.45)	$ (0.36)	$ (1.21)	$ (1.44)
Shares used in calculating basic and diluted net loss per share	45,453	39,278	41,582	26,303
Comprehensive loss:				
Net loss	$ (20,452)	$ (14,224)	$ (50,363)	$ (37,880)
Other comprehensive income (loss):				
Unrealized (loss) gain on marketable securities	(44)	14	(41)	(11)
Comprehensive loss	$ (20,496)	$ (14,210)	$ (50,404)	$ (37,891)

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, 2021	Nine Months Ended September 30, 2020
Cash flows from operating activities:		
Net loss	$ (50,363)	$ (37,880)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,291	3,174
Amortization and premium of marketable securities, net	(3,407)	(422)
Gain on sale or disposal of assets	(23)	(29)
Intangible Asset Impairment	3,500	3,500
Gain on fair value remeasurement of contingent consideration	(1,160)	(4,236)
Non-Cash Income Tax Benefit	(227)	(228)
Stock-based compensation expense	5,813	2,658
Changes in operating assets and liabilities:		
Accounts and other receivables	1,549	177
Prepaid and other current assets	(2,261)	(1,280)
Accounts payable and accrued expenses	1,757	864
Other liabilities	(3,855)	(1,491)
Net cash used in operating activities	(46,386)	(35,193)
Cash flows from investing activities:		
Sales and maturities of marketable securities	129,000	55,600
Purchases of marketable securities	(325,342)	(183,394)
Acquisition of property and equipment	(895)	(1,305)
Proceeds from sale or disposal of assets	25	29
Net cash used in investing activities	(197,212)	(129,070)
Cash flows from financing activities:		
Net proceeds from stock issuances	269,893	170,964
Proceeds from issuance of stock from employee benefit plans	2,053	218
Issuance of Term Loan	—	2,962
Payment of Term Loan	—	(2,962)
Net cash provided by financing activities	271,946	171,182
Net increase in cash and cash equivalents	28,348	6,919
Cash and cash equivalents at beginning of period	43,836	11,232
Cash and cash equivalents at end of period	$ 72,184	$ 18,151
Non-cash investing activities		
Accrued construction in progress	$ 46	$ 63

See accompanying notes to unaudited condensed consolidated financial statements

CELLDEX THERAPEUTICS, INC.
Notes to Unaudited Condensed Consolidated Financial Statements
September 30, 2021

(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, 2020, which are included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 29, 2021. 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, 2021.

At September 30, 2021, the Company had cash, cash equivalents and marketable securities of $423.1 million. The Company has had recurring losses and incurred a loss of $50.4 million for the nine months ended September 30, 2021. Net cash used in operations for the nine months ended September 30, 2021 was $46.4 million. The Company believes that the cash, cash equivalents and marketable securities at the filing date of this Form 10-Q 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 acquisition of Kolltan Pharmaceuticals, Inc. ("Kolltan"), in the event that the Company achieves the drug candidate milestones related to those payments. The Company, at its option, may decide to pay those milestone payments in cash, shares of its common stock or a combination thereof. If the Company is unable to raise the funds necessary to meet its long-term liquidity needs, it may have to delay or discontinue the development of one or more programs, discontinue or delay ongoing or anticipated clinical trials, license out programs earlier than expected, raise funds at a significant discount or on other unfavorable terms, if at all, or sell all or a part of the Company.

The COVID-19 pandemic continues to have a major impact in the US and around the world. The availability of vaccines holds promise for the future, though new variants of the virus and potential waning immunity from vaccines may result in continued impact from this pandemic in the future, including supply chain and work force issues which could adversely impact our operations. To date, the Company has managed delays and disruptions without significant impact 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, and 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 in-process research and development ("IPR&D") assets with a carrying value of $27.2 million at September 30, 2021.

(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, 2021 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, 2020.

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, 2021	Level 1	Level 2	Level 3
		(In thousands)		
Assets:				
Money market funds and cash equivalents	$ 66,929	—	$ 66,929	—
Marketable securities	350,905	—	350,905	—
	$ 417,834	—	$ 417,834	—
Liabilities:				
Kolltan acquisition contingent consideration	$ 7,107	—	—	$ 7,107
	$ 7,107	—	—	$ 7,107

	As of December 31, 2020	Level 1	Level 2	Level 3
		(In thousands)		
Assets:				
Money market funds and cash equivalents	$ 35,066	—	$ 35,066	—
Marketable securities	150,586	—	150,586	—
	$ 185,652	—	$ 185,652	—
Liabilities:				
Kolltan acquisition contingent consideration	$ 8,267	—	—	$ 8,267
	$ 8,267	—	—	$ 8,267

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, 2021 (in thousands):

	Other Liabilities: Contingent Consideration
Balance at December 31, 2020	$ 8,267
Fair value adjustments included in operating expenses	(1,160)
Balance at September 30, 2021	$ 7,107

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, 2021, the weighted average probability of success used in calculating the fair value of contingent consideration was 48.0% (with a range of 5.1% to 68.6%), the weighted average discount rate was 5.6% (with a range of 5.1% to 6.7%) and the weighted average amount of time until the conditions of the milestone payments are met was 4 years. Weighted averages are calculated based on the relative fair value of our contingent consideration obligations.

During the three and nine months ended September 30, 2021, the Company recorded a $1.9 million and $1.2 million gain on fair value remeasurement of contingent consideration, respectively, primarily due to updated assumptions for the TAM program, changes in discount rates and the passage of time. 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. 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, 2021.

(4) Marketable Securities

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(In thousands)		
September 30, 2021				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	$ 24,291	$ 5	$ —	$ 24,296
Maturing after one year through three years	75,314	2	(17)	75,299
Total U.S. government and municipal obligations	$ 99,605	$ 7	$ (17)	$ 99,595
Corporate debt securities				
Maturing in one year or less	$ 183,504	$ —	$ (10)	$ 183,494
Maturing after one year through three years	67,844	8	(36)	67,816
Total corporate debt securities	$ 251,348	$ 8	$ (46)	$ 251,310
Total marketable securities	$ 350,953	$ 15	$ (63)	$ 350,905

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(In thousands)		
December 31, 2020				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	$ 40,328	$ 3	$ (2)	$ 40,329
Maturing after one year through three years	—	—	—	—
Total U.S. government and municipal obligations	$ 40,328	$ 3	$ (2)	$ 40,329
Corporate debt securities				
Maturing in one year or less	$ 110,265	$ 2	$ (10)	$ 110,257
Maturing after one year through three years	—	—	—	—
Total corporate debt securities	$ 110,265	$ 2	$ (10)	$ 110,257
Total marketable securities	$ 150,593	$ 5	$ (12)	$ 150,586

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, 2021 and December 31, 2020. 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 $0.8 million and $0.2 million in accrued interest at September 30, 2021 and December 31, 2020, respectively.

(5) Intangible Assets

At September 30, 2021 and December 31, 2020, the carrying value of the Company's indefinite-lived intangible assets was $27.2 million and $30.7 million, respectively. Indefinite-lived intangible assets consist of acquired IPR&D related to the development of the anti-KIT program (including CDX-0159) and the TAM program, a broad antibody discovery effort to generate antibodies that modulate the TAM family of RTKs, comprised of Tyro3, AxL and MerTK. CDX-0159 is in Phase 1 development and the TAM program is in preclinical development. As of September 30, 2021, 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. During the fourth quarter of 2020, the Company decided that although it had developed promising data for the AxL target within the TAM program, it would focus its efforts on out-licensing opportunities for its TAM program. As a result, the Company evaluated the TAM program IPR&D asset for potential impairment due to the change in projected development and regulatory timelines related to the program and recorded a non-cash partial impairment charge of $14.5 million for the fourth quarter of 2020. During the third quarter of 2021, the Company evaluated its out-licensing progress since December 31, 2020 and the status and expectation for the TAM program. Despite the Company's efforts to out-license, there was a lack of interest in the program from third parties. Therefore, the Company evaluated the TAM program IPR&D asset for potential impairment using a discounted cash flow fair value model and concluded that the TAM IPR&D asset was fully impaired. A non-cash impairment charge of $3.5 million was recorded for the three months ended September 30, 2021. 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 in the second quarter of 2020. 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 Long-Term Liabilities

Other long-term liabilities include the following:

	September 30, 2021	December 31, 2020
	(In thousands)	
Net deferred tax liabilities related to IPR&D (Note 11)	$ 1,613	$ 1,840
Contingent milestones (Note 3)	7,107	8,267
Deferred revenue (Note 10)	601	3,386
Total	9,321	13,493
Less current portion	(1,721)	(3,372)
Long-term portion	$ 7,600	$ 10,121

(7) 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. At September 30, 2021, the Company had $50.0 million remaining in aggregate gross offering price available under the Company's November 2020 prospectus.

In July 2021, the Company issued 6,845,238 shares of its common stock in an underwritten public offering resulting in net proceeds to the Company of $269.9 million, after deducting underwriting fees and offering expenses.

The changes in Stockholders' Equity during the three and nine months ended September 30, 2021 and 2020 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, 2020	39,603,771	$ 40	$ 1,279,824	$ 2,589	$ (1,073,096)	$ 209,357
Shares issued under stock option and employee stock purchase plans	10,867	—	74	—	—	74
Stock-based compensation	—	—	1,275	—	—	1,275
Unrealized loss on marketable securities	—	—	—	(2)	—	(2)
Net loss	—	—	—	—	(16,538)	(16,538)
Consolidated balance at March 31, 2021	39,614,638	$ 40	$ 1,281,173	$ 2,587	$ (1,089,634)	$ 194,166
Shares issued under stock option and employee stock purchase plans	2,058	—	(25)	—	—	(25)
Stock-based compensation	—	—	1,509	—	—	1,509
Unrealized gain on marketable securities	—	—	—	5	—	5
Net loss	—	—	—	—	(13,373)	(13,373)
Consolidated balance at June 30, 2021	39,616,696	$ 40	$ 1,282,657	$ 2,592	$ (1,103,007)	$ 182,282
Shares issued under stock option and employee stock purchase plans	201,406	—	2,004	—	—	2,004
Shares issued in underwritten offering, net	6,845,238	7	269,886	—	—	269,893
Stock-based compensation	—	—	3,029	—	—	3,029
Unrealized loss on marketable securities	—	—	—	(44)	—	(44)
Net loss	—	—	—	—	(20,452)	(20,452)
Consolidated balance at September 30, 2021	46,663,340	$ 47	$ 1,557,576	$ 2,548	$ (1,123,459)	$ 436,712

	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 at the market agreement	746,152	1	1,613	—	—	1,614
Stock-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 at the market agreement	5,978,452	6	23,686	—	—	23,692
Shares issued in underwritten offering, net	15,384,614	15	141,346	—	—	141,361
Stock-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 at the market agreement	400,400	1	4,296	—	—	4,297
Stock-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

(8) Stock-Based Compensation

A summary of stock option activity for the nine months ended September 30, 2021 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In Years)
Options outstanding at December 31, 2020	3,042,229	$ 28.93	8.2
Granted	1,350,210	$ 28.16	
Exercised	(192,464)	$ 9.53	
Canceled	(70,349)	$ 35.62	
Options outstanding at September 30, 2021	4,129,626	$ 29.46	8.2
Options vested and expected to vest at September 30, 2021	3,982,965	$ 29.81	8.2
Options exercisable at September 30, 2021	1,387,147	$ 51.75	6.7
Shares available for grant under the 2021 Plan	3,319,116		

The weighted average grant-date fair value of stock options granted during the three and nine months ended September 30, 2021 was $41.34 and $21.86, respectively.

The aggregate intrinsic value of stock options vested and expected to vest at September 30, 2021 was $140.6 million. The aggregate intrinsic value of stock options exercisable at September 30, 2021 was $47.3 million. As of September 30, 2021, total compensation cost related to non-vested employee, consultant and non-employee director stock options not yet recognized was approximately $33.7 million, net of estimated forfeitures, which is expected to be recognized as expense over a weighted average period of 2.9 years.

Stock-based compensation expense for the three and nine months ended September 30, 2021 and 2020 was recorded as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
	(In thousands)		(In thousands)	
Research and development	$ 1,504	$ 642	$ 2,927	$ 1,294
General and administrative	1,525	608	2,886	1,364
Total stock-based compensation expense	$ 3,029	$ 1,250	$ 5,813	$ 2,658

The fair values of employee, consultant and non-employee director stock options granted during the three and nine months ended September 30, 2021 and 2020 were valued using the Black-Scholes option pricing model with the following assumptions:

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Expected stock price volatility	98%	98%	97 – 98%	91 – 98%
Expected option term	6.0 Years	6.0 Years	6.0 Years	6.0 Years
Risk-free interest rate	1.1 – 1.2%	0.5%	0.8 – 1.3%	0.5 – 0.6%
Expected dividend yield	None	None	None	None

(9) Accumulated Other Comprehensive Income

The changes in accumulated other comprehensive income, which is reported as a component of stockholders' equity, for the nine months ended September 30, 2021 are summarized below:

	Unrealized Loss on Marketable Securities	Foreign Currency Items	Total
		(In thousands)	
Balance at December 31, 2020	$ (7)	$ 2,596	$ 2,589
Other comprehensive loss	(41)	—	(41)
Balance at September 30, 2021	$ (48)	$ 2,596	$ 2,548

No amounts were reclassified out of accumulated other comprehensive income during the nine months ended September 30, 2021.

(10) Revenue

Product Development and Licensing Revenue

The Company's agreement with Rockefeller University, as amended (the "Rockefeller Agreement"), provides for the Company to perform 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 Gilead Sciences 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 $0.1 million and $4.0 million in revenue under these agreements during the three and nine months ended September 30, 2021, respectively, and $0.3 million and $0.9 million during the three and nine months ended September 30, 2020, respectively.

During the third quarter of 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 $0.0 million and $0.3 million in grant revenue under the award during the three and nine months ended September 30, 2021, respectively, and $0.3 million during the three and nine months ended September 30, 2020.

Contract Assets and Liabilities

At September 30, 2021 and December 31, 2020, the Company's right to consideration under all contracts was considered unconditional, and as such, there were no recorded contract assets. At September 30, 2021, the Company had $0.6 million in contract liabilities recorded, which is expected to be recognized during the next 12 months as manufacturing and research and development services are performed. At December 31, 2020, the Company had $3.4 million in contract liabilities recorded. Revenue recognized from contract liabilities as of December 31, 2020 during the three and nine months ended September 30, 2021 was $0.0 million and $3.4 million, respectively.

(11) 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, 2021 and December 31, 2020.

The net deferred tax liability of $1.6 million and $1.8 million at September 30, 2021 and December 31, 2020, 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. A $0.2 million non-cash income tax benefit was recorded during the third quarter of 2021 and a $0.9 million non-cash income tax benefit was recorded during the fourth quarter of 2020 related to impairments of the TAM program IPR&D asset. A $0.2 million non-cash income tax benefit was recorded during the second quarter of 2020 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.

(12) 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,	
	2021	2020
Stock Options	4,129,626	3,074,832
Restricted Stock	—	—
	4,129,626	3,074,832

(13) Kolltan Acquisition

On November 29, 2016, the Company acquired all of the share and debt interests of 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 payment of Kolltan Milestones , 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 Agreement and Plan of Merger, dated November 1, 2016 (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 and, because of this, as of September 30, 2021, 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 characterization of the development, regulatory approval and sales-based Kolltan Milestones relating to CDX-0158 as having been abandoned and contending instead that the related milestone payments are due from Celldex to the Kolltan stockholder. 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 relating to the discontinued CDX-0158 program. 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 regarding abandonment of the CDX-0158 milestones, based in part on SRS' assertion that the CDX-0159 program is in essence an extension of the CDX-0158 (formerly KTN0158) program. The parties entered into non-binding mediation in May 2021 following SRS's approach to Celldex about its interest in settlement or mediation discussions, but those discussions did not result in a resolution of the dispute. The case remains ongoing and we are currently unable to predict or estimate the outcome of this matter. The case is currently scheduled for trial in June 2022.

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, which was provided pursuant to the terms of the Merger Agreement.

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 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 COVID-19 pandemic on our business or on the economy generally;
- whether the COVID-19 pandemic 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 therapeutics;

- the cost of paying development, regulatory approval and sales-based milestones under the merger agreement by which we acquired Kolltan, and the cost, timing, and outcome of our declaratory judgment action against the Kolltan stockholder representative 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 preclinical and clinical studies and to meet our long-term liquidity needs, on terms acceptable to us, or at all. If we are unable to raise the funds necessary to meet our long-term liquidity needs, we may have to delay or discontinue the development of one or more programs, discontinue or delay 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, 2020 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, currently being studied in mast cell driven diseases.In October and December 2020 respectively, we announced that enrollment had opened and the first patients had been dosed in Phase 1b studies in chronic spontaneous urticaria (CSU) and chronic inducible urticaria (CIndU). Positive interim data from the Phase 1b study in CIndU were reported in July and September 2021 in patients with cold urticaria and symptomatic dermographism. The study has also been expanded to include patients with cholinergic urticaria and enrollment has opened in a Phase 1b study in prurigo nodularis.

- CDX-1140, an agonist monoclonal antibody targeted to CD40, a key activator of immune response, currently being studied in a Phase 1 study. Dose escalation was completed 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. We have initiated multiple expansion cohorts within the study, including a combination cohort with KEYTRUDA® (pembrolizumab) in patients refractory to PD1/PDL1 treatment.

- 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 agencies 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, 2020, we incurred an aggregate of $350.6 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, 2021 and 2020. 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, 2021	Nine Months Ended September 30, 2020
	(In thousands)	
CDX-0159/Anti-KIT Program	$ 18,264	$ 5,233
CDX-1140 and CDX-301	4,097	9,093
CDX-527	3,008	7,719
Other Programs	13,264	10,064
Total R&D Expense	$ 38,633	$ 32,109

Clinical Development Programs

The COVID-19 pandemic continues to have a major impact in the US and around the world. The availability of vaccines holds promise for the future, though new variants of the virus and potential waning immunity from vaccines may result in continued impact from this pandemic in the future, including supply chain and work force issues which could adversely impact our operations. To date, the Company has managed delays and disruptions without significant impact 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, and 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.

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.

These data supported 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, dermographism (scratch-induced) and cholinergic (exercise-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 is 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.

In December 2020, we announced that enrollment had opened and the first patient had been dosed in a second Phase 1b study in CIndU being conducted in Germany in patients who are refractory to antihistamines. This study is an open label clinical trial designed to evaluate the safety of a single dose (3 mg/kg) of CDX-0159 in patients with cold urticaria (n=10) or symptomatic dermographism (n=10). In March and June 2021, respectively, we added a third cohort (single dose, 3 mg/kg) in patients with cholinergic urticaria (n=10) and a fourth cohort at a lower dose (single dose, 1.5 mg/kg) in cold urticaria. Patient’s symptoms are 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 is administered intravenously on Day 1 as add on treatment to H1-antihistamines.

In July of 2021, we reported positive interim data from the cold urticaria and symptomatic dermographism cohorts. As of the data cut-off on June 11, 2021, 20 patients had received a single intravenous infusion of CDX-0159 at 3 mg/kg, including 11 patients with cold urticaria and 9 patients with symptomatic dermographism. Patients had high disease activity as assessed by provocation threshold testing. In patients with cold urticaria and symptomatic dermographism baseline critical temperature thresholds were 18.9°C/66°F (range: 5-27°C/41-80.6°F) and FricTest® thresholds were 3.8 (range: 3-4) of 4 pins. Safety results were reported for all 20 patients; activity results were reported for the 19 patients who received a full dose of CDX-0159. 14 of 19 patients completed the 12-week study observation period and five were ongoing (range of 2-8 weeks) as of June 11, 2021.

- All 19/19 (100%) patients experienced a clinical response as assessed by provocation threshold testing; 18/19 (95%) experienced a complete response and 1/19 (5%) experienced a partial response.10/10 (100%) patients with cold urticaria experienced a complete response. 8/9 (89%) patients with symptomatic dermographism experienced a complete response and 1/9 (11%) experienced a partial response. Compete responses were observed in all 3 patients (1 cold urticaria; 2 symptomatic dermographism) with prior Xolair® (omalizumab) experience, including two who were Xolair refractory.

- Rapid onset of responses after dosing and sustained durability were observed. Most patients with cold urticaria and symptomatic dermographism experienced a complete response by week 1 and by week 4, respectively. The median duration of response for patients was 77+ days for cold urticaria and 57+ days for symptomatic dermographism.

- Improvements in disease activity as reported by physician's and patient's global assessment of disease severity were consistent with the complete responses as measured by provocation testing.

- A single 3 mg/kg dose of CDX-0159 resulted in rapid, marked and durable suppression of serum tryptase and depletion of skin mast cells (87% depletion) as measured through biopsy. The kinetics of serum tryptase and skin mast cell depletion mirrored clinical activity. This confirmed that serum tryptase level is a robust pharmacodynamic biomarker for assessing mast cell burden and clinical activity in inducible urticaria and potentially in other diseases with mast cell driven involvement.

- CDX-0159 was generally well tolerated. The most common adverse events were hair color changes, mild infusion reactions, and transient changes in taste perception. Hair color changes (generally small areas of hair color lightening) and taste disorders (generally partial changes of ability to taste salt) are consistent with inhibiting KIT signaling in other cell types and are expected to be fully reversible. As previously reported in March 2021, a single severe infusion reaction of brief loss of consciousness was observed in a patient with a history of fainting. The patient rapidly recovered. Importantly, no evidence of mast cell activation as measured by serum tryptase monitoring was observed. There was no evidence of clinically significant decreases in hematology parameters—an important finding for a KIT inhibitor.

- One patient with symptomatic dermographism enrolled in the study also had a diagnosis of prurigo nodularis. After a single dose of CDX-0159, this patient experienced both a complete response of symptomatic dermographism and notable improvement of the prurigo nodularis.

In September of 2021, we reported additional positive data from the study on measurements of symptom control and quality of life. A single dose of CDX-0159 (3 mg/kg) resulted in a rapid and sustained improvement in urticaria control and greatly reduced disease impact on quality of life, as measured by the Urticaria Control Test (UCT) and Dermatology Life Quality Index (DLQI).

We continue to assess potential opportunities for CDX-0159 in other diseases where mast cells play an important role, such as dermatologic, respiratory, allergic, gastrointestinal and ophthalmic conditions. We have expanded clinical development of CDX-0159 into prurigo nodularis (PN), a chronic skin disease characterized by the development of hard, intensely itchy (pruritic) nodules on the skin. Mast cells through their interactions with sensory neurons and other immune cells are believed to play an important role in amplifying chronic itch and neuroinflammation, both of which are a hallmark of PN. There are currently no FDA approved therapies for PN, representing an area of significant unmet need. In September, enrollment opened in a Phase 1b multi-center, randomized, double-blind, placebo-controlled study designed to assess the safety and treatment effects across multiple dosing cohorts of CDX-0159 in up to 40 patients with PN.

Manufacturing activities to support the introduction of the CDX-0159 subcutaneous formulation into the clinical program have been completed and, in September of 2021, Celldex initiated and has since completed dosing in a randomized, double-blind, placebo-controlled, Phase 1 study designed to evaluate the safety of single ascending doses of the subcutaneous formulation of CDX-0159 in healthy volunteers.

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 concentrations to levels that may not be optimal for engaging CD40 expressing cells in the tumor microenvironment. 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.

In November 2017, we initiated a Phase 1 study of CDX-1140 in up to 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. 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. A combination cohort with CDX-301, a hematopoietic cytokine that uniquely expands dendritic cells and hematopoietic stem cells and a safety run-in combination cohort with gemcitabine/nab-paclitaxel in patients with previously untreated metastatic pancreatic adenocarcinoma have been completed. A combination of CDX-1140 with pembrolizumab has completed the safety run-in phase. Expansion cohorts in patients with checkpoint-refractory/resistant squamous cell head and neck cancer and non-small cell lung cancer are enrolling patients.

In November 2020, we reported interim Phase 1 data from patients treated at the maximum tolerated dose (MTD) and recommended dose of 1.5 mg/kg—one of the highest systemic dose levels in the CD40 agonist class. Interim data from the study were presented at the Society for Immunotherapy of Cancer’s (SITC) 35th Annual Meeting 2020 (n=41; 25 mono, 16 with CDX-301 and 29 with post-treatment scans). Preliminary safety data from the combination cohort with pembrolizumab (n=9; 4 at 0.72 mg/kg and 5 at 1.5 mg/kg CDX-1140) were also presented. CDX-1140 monotherapy and in combination with pembrolizumab was generally well tolerated with mostly grade 1 or 2 drug related adverse events. Activity at 1.5mg/kg dose of CDX-1140 included an ongoing complete response (CR; 18 months as of Oct 2021) in a patient with follicular lymphoma treated with CDX-1140 monotherapy. There was notable tumor shrinkage and/or necrosis in 6 patients with squamous cell head and neck cancer (SCCHN) treated with CDX-1140 alone or in combination with CDX-301 and stable disease (n=10) for 11 to 32 weeks. CDX-1140 provided good systemic exposure and resulted in marked changes in the tumor microenvironment.

In November 2021, we provided an update on the ongoing Phase 1 study. Emerging data from the safety run-in cohort of CDX-1140 with gemcitabine/nab-paclitaxel in patients with previously untreated metastatic pancreatic adenocarcinoma and external CD40 agonist data recently reported using the same regimen, suggest that simultaneous treatment with chemotherapy and CD40 activation may not be optimal. Alternative strategies for investigating CDX-1140 in pancreatic cancer in other regimens are being explored, including through investigator sponsored studies. The combination of CDX-1140 with pembrolizumab has completed the safety run-in phase. Expansion cohorts in patients with checkpoint-refractory/resistant squamous cell head and neck cancer and non-small cell lung cancer are enrolling patients. Of the six patients with squamous cell head and neck cancer treated with CDX-1140 at 1.5 mg/kg in combination with pembrolizumab, encouraging preliminary results have been observed including a confirmed partial response and durable stable disease. Of the six evaluable patients with non-small cell lung cancer, four have had stable disease as their best response. Adverse events, such as arthralgia, myalgia and fatigue, have occurred more frequently in combination with pembrolizumab relative to CDX-1140 monotherapy and the protocol has been amended to allow CDX-1140 dose reduction, if necessary, to help manage these toxicities. Enrollment to the study is ongoing.

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. The study includes up to approximately 40 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. Enrollment to the dose escalation portion of the study has been completed and an expansion cohort in ovarian cancer is enrolling patients.

Interim data were presented at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting in June that demonstrated a good safety profile along with promising pharmacodynamic and pharmacokinetic activity, which are important key hurdles for the development of bispecific antibodies. As of the data cut-off (April 16, 2021), 11 patients were enrolled in the first 5 dose escalation cohorts, 0.03 mg/kg through 3 mg/kg.CDX-527 was well tolerated, with no dose-limiting toxicities or treatment related serious adverse events observed. Pharmacokinetics and receptor occupancy demonstrate good exposure starting at the 1 mg/kg dose and no evidence of significant anti-drug antibodies impact. Pharmacodynamic parameters demonstrate biological activity consistent with immune activation including: transient increase in pro inflammatory cytokines/chemokines, upregulation of activation marker on T cells and particularly NK cells and a decrease in regulatory T cells.

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, 2020 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, 2021 Compared with Three Months Ended September 30, 2020

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2021	2020	$	%
	(In thousands)			
Revenues:				
Product development and licensing agreements	$ —	$ 12	$ (12)	(100)%
Contracts and grants	153	656	(503)	(77)%
Total revenues	$ 153	$ 668	$ (515)	(77)%
Operating expenses:				
Research and development	13,557	10,708	2,849	27 %
General and administrative	5,821	3,640	2,181	60 %
Intangible asset impairment	3,500	—	3,500	n/a
(Gain) loss on fair value remeasurement of contingent consideration	(1,901)	662	(2,563)	(387)%
Total operating expense	20,977	15,010	5,967	40 %
Operating loss	(20,824)	(14,342)	6,482	45 %
Investment and other income, net	145	118	27	23 %
Net loss before income tax benefit	(20,679)	(14,224)	6,455	45 %
Income tax benefit	227	—	227	n/a
Net loss	$ (20,452)	$ (14,224)	$ 6,228	44 %

Net Loss

The $6.2 million increase in net loss for the three months ended September 30, 2021, as compared to the three months ended September 30, 2020, was primarily the result of the non-cash intangible asset impairment expense related to the TAM program IPR&D asset and increases in research and development and general and administrative expenses, partially offset by an increase in the gain on fair value remeasurement of contingent consideration.

Revenue

Revenue from product development and licensing agreements for the three months ended September 30, 2021 was consistent with the three months ended September 30, 2020. The $0.5 million decrease in contracts and grants revenue for the three months ended September 30, 2021, as compared to the three months ended September 30, 2020, was primarily due to a decrease in revenue from the Company's SBIR grant and a decrease in services performed under our 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)	
	2021	2020	$	%
	(In thousands)			
Personnel	$ 7,155	$ 5,680	$ 1,475	26 %
Laboratory supplies	1,255	763	492	64 %
Facility	1,148	1,606	(458)	(29)%
Product development	3,101	1,852	1,249	67 %

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The $1.5 million increase in personnel expenses for the three months ended September 30, 2021, as compared to the three months ended September 30, 2020, was primarily due to higher stock-based compensation expense and an increase in employee headcount. We expect personnel expenses increase over the next twelve months as a result of expanded development of CDX-0159, 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 $0.5 million increase in laboratory supply expenses for the three months ended September 30, 2021, as compared to the three months ended September 30, 2020, was primarily due to higher 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 $0.5 million decrease in facility expenses for the three months ended September 30, 2021, as compared to the three months ended September 30, 2020, was primarily due to lower rent as a result of the consolidation of our Massachusetts lab and manufacturing facilities in the second quarter of 2020 and lower repairs expenses. We expect facility expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing. The $1.2 million increase in product development expenses for the three months ended September 30, 2021, as compared to the three months ended September 30, 2020, was primarily due to an increase in contract research and clinical trial expenses. We expect product development expenses to increase over the next twelve months as a result of expanded development of CDX-0159, although there may be fluctuations on a quarterly basis.

General and Administrative Expense

The $2.2 million increase in general and administrative expenses for the three months ended September 30, 2021, as compared to the three months ended September 30, 2020, was primarily due to higher personnel and legal expenses. We expect general and administrative expenses to increase over the next twelve months, although there may be fluctuations on a quarterly basis.

Intangible Asset Impairment

We evaluated the TAM program IPR&D asset for potential impairment as a result of a lack of interest in the program from third parties. We concluded that the TAM program IPR&D asset was fully impaired, and a non-cash impairment charge of $3.5 million was recorded in the third quarter of 2021.

(Gain) Loss on Fair Value Remeasurement of Contingent Consideration

The $1.9 million gain on fair value remeasurement of contingent consideration for the three months ended September 30, 2021 was primarily due to updated assumptions for the TAM program. 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.

Investment and Other Income, Net

Investment and other income, net for the three months ended September 30, 2021 was consistent with the three months ended September 30, 2020. We expect investment and other income to increase over the next twelve months due to higher levels of cash as a result of our July 2021 underwritten public offering, although there may be fluctuations on a quarterly basis.

Income Tax Benefit

A $0.2 million non-cash income tax benefit was recorded related to the impairment of the TAM program IPR&D asset in the third quarter of 2021.

Nine Months Ended September 30, 2021 Compared with Nine Months Ended September 30, 2020

	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2021	2020	$	%
	(In thousands)			
Revenues:				
Product development and licensing agreements	$ 29	$ 2,297	$ (2,268)	(99)%
Contracts and grants	4,288	1,336	2,952	221 %
Total revenues	$ 4,317	$ 3,633	$ 684	19 %
Operating expenses:				
Research and development	38,633	32,109	6,524	20 %
General and administrative	14,247	10,833	3,414	32 %
Intangible asset impairment	3,500	3,500	—	— %
Gain on fair value remeasurement of contingent consideration	(1,160)	(4,236)	(3,076)	(73)%
Total operating expense	55,220	42,206	13,014	31 %
Operating loss	(50,903)	(38,573)	12,330	32 %
Investment and other income, net	313	465	(152)	(33)%
Net loss before income tax benefit	(50,590)	(38,108)	12,482	33 %
Income tax benefit	227	228	(1)	— %
Net loss	$ (50,363)	$ (37,880)	$ 12,483	33 %

Net Loss

The $12.5 million increase in net loss for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, was primarily the result of an increase in research and development and general and administrative expenses and a decrease in the gain on fair value remeasurement of contingent consideration.

Revenue

The Company's agreement with Rockefeller University, as amended, (the "Rockefeller Agreement") provides for the Company to perform 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"). The $2.3 million decrease in product development and licensing agreements revenue for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, was primarily due to the $1.8 million received from the Rockefeller Transaction in the first quarter of 2020. The $3.0 million increase in contracts and grants revenue for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, was primarily related to an increase in services performed under our manufacturing and research and development agreements with Rockefeller University and Gilead Sciences.

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)	
	2021	2020	$	%
	(In thousands)			
Personnel	$ 19,037	$ 16,513	$ 2,524	15 %
Laboratory supplies	4,370	2,998	1,372	46 %
Facility	3,601	5,093	(1,492)	(29)%
Product development	8,835	4,681	4,154	89 %

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The $2.5 million increase in personnel expenses for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, was primarily due to higher stock-based compensation expense and an increase in employee headcount.

Laboratory supplies expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The $1.4 million increase in laboratory supply expenses for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, was primarily due to higher laboratory materials and supplies purchases.

Facility expenses include depreciation, amortization, utilities, rent, maintenance and other related expenses incurred at our facilities. The $1.5 million decrease in facility expenses for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, was primarily due to lower rent as a result of the consolidation of our Massachusetts lab and manufacturing facilities in the second quarter of 2020 and lower 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 $4.2 million increase in product development expenses for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, was primarily due to an increase in clinical trial and contract research expenses.

General and Administrative Expense

The $3.4 million increase in general and administrative expenses for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, was primarily due to higher personnel and legal expenses.

Intangible Asset Impairment

We evaluated the TAM program IPR&D asset for potential impairment as a result of a lack of interest in the program from third parties. We concluded that the TAM program IPR&D asset was fully impaired, and a non-cash impairment charge of $3.5 million was recorded in the third quarter of 2021.We 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. 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.

Gain on Fair Value Remeasurement of Contingent Consideration

The $1.2 million gain on fair value remeasurement of contingent consideration for the nine months ended September 30, 2021 was primarily due to updated assumptions for the TAM program, changes in discount rates and the passage of time. 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.

Investment and Other Income, Net

The $0.2 million decrease in investment and other income, net for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, was primarily due to lower interest rates on fixed income investments.

Income Tax Benefit

A $0.2 million non-cash income tax benefit was recorded related to the impairment of the TAM program IPR&D asset in the third quarter of 2021 and 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, 2021, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of $423.1 million. We have had recurring losses and incurred a loss of $50.4 million for the nine months ended September 30, 2021. Net cash used in operations for the nine months ended September 30, 2021 was $46.4 million. We believe that the cash, cash equivalents and marketable securities at September 30, 2021 are sufficient to meet estimated working capital requirements and fund planned operations through 2025. This could be impacted if we elect 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 $46.4 million for the nine months ended September 30, 2021 as compared to $35.2 million for the nine months ended September 30, 2020. The increase in net cash used in operating activities was primarily due to an increase in research and development and general and administrative expenses. We expect that cash used in operating activities will increase over the next twelve months as a result of expanded development of CDX-0159, 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 and clinical trials and clinical drug product manufacturing as our drug candidates are developed. We plan to spend significant amounts to progress our current drug candidates through the clinical trial 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 $197.2 million for the nine months ended September 30, 2021 as compared to $129.1 million for the nine months ended September 30, 2020. The increase in net cash used in investing activities was primarily due to net purchases of marketable securities of $196.3 million for the nine months ended September 30, 2021 as compared to $127.8 million for the nine months ended September 30, 2020.

Financing Activities

Net cash provided by financing activities was $271.9 million for the nine months ended September 30, 2021 as compared to $171.2 million for the nine months ended September 30, 2020. The increase in net cash provided by financing activities was primarily due to an increase in net proceeds from stock issuances.

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. No shares of common stock were sold under the Cantor Agreement during the nine months ended September 30, 2021.

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

During the third quarter of 2021, we issued 6,845,238 shares of common stock in an underwritten public offering resulting in net proceeds of $269.9 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, 2020 which was filed with the SEC on March 29, 2021 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, 2021 due to the short-term maturities of these instruments.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

As of September 30, 2021, 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, 2021. 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, 2021 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:

(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 regarding abandonment of the CDX-0158 milestones, based in part on SRS' assertion that the CDX-0159 program is in essence an extension of the CDX-0158 (formerly KTN0158) program. The parties entered into non-binding mediation in May 2021 following SRS's approach to Celldex about its interest in settlement or mediation discussions, but those discussions did not result in a resolution of the dispute. The case remains ongoing and we are currently unable to predict or estimate the outcome of this matter. The case is currently scheduled for trial in June 2022.

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, 2020, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K may not be the only risks facing the Company. Additional risks and uncertainties not currently known to the Company or that the Company currently deems to be immaterial also may materially adversely affect the Company's business, financial condition and/or operating results.

There were no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 29, 2021.

Item 5. Other Information

On November 3, 2021, we determined that a non-cash impairment charge of $3.5 million should be recorded for the three months ended September 30, 2021 related to our TAM program. The TAM program was acquired as part of our acquisition of Kolltan Pharmaceuticals, Inc. in the fourth quarter of 2016. During the fourth quarter of 2020, the Company decided that although it had developed promising data for the AxL target within the TAM program, it will focus its efforts on out-licensing opportunities for its TAM program. During the third quarter of 2021, the Company evaluated its out-licensing progress since December 31, 2020 and the status and expectation for the TAM program. We determined that the lack of interest in the program from third parties constituted a triggering event that required us to evaluate the intangible asset for impairment. See Note 5 to the unaudited condensed consolidated financial statements included in this quarterly report on Form 10-Q for further discussion of this impairment charge.

Item 6. Exhibits

The exhibits filed as part of this quarterly report on Form 10-Q are listed in the exhibit index 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.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
*101.SCH	Inline XBRL Taxonomy Extension Schema Document.
*101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
*101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
*101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
*101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibits 101).

* Filed herewith.
** Furnished herewith.
† Indicates a management contract or compensation plan, contract or arrangement.

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

Dated: November 9, 2021

/s/ SAM MARTIN
Sam Martin
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Dated: November 9, 2021

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 9, 2021

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 9, 2021

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 9, 2021

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

Date: November 9, 2021

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.