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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 June 30, 2022

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 July 29, 2022, 46,772,351 shares of common stock, $.001 par value per share, were outstanding.

CELLDEX THERAPEUTICS, INC.

FORM 10-Q

For the Quarterly Period Ended June 30, 2022

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PART I — FINANCIAL INFORMATION
Item 1. Unaudited Financial Statements

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

(In thousands, except share and per share amounts)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 28,401	$ 39,143
Marketable securities	328,416	369,107
Accounts and other receivables	97	172
Prepaid and other current assets	11,065	2,417
Total current assets	367,979	410,839
Property and equipment, net	3,744	3,551
Operating lease right-of-use assets, net	3,944	2,970
Intangible assets, net	27,190	27,190
Other assets	104	104
Total assets	$ 402,961	$ 444,654
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 902	$ 1,228
Accrued expenses	11,229	12,000
Litigation settlement payable	15,000	—
Current portion of operating lease liabilities	1,425	1,746
Current portion of other long-term liabilities	1,393	1,554
Total current liabilities	29,949	16,528
Long-term portion of operating lease liabilities	2,586	1,296
Other long-term liabilities	5,333	7,354
Total liabilities	37,868	25,178
Commitments and contingent liabilities		
Stockholders' equity:		
Convertible preferred stock, $.01 par value; 3,000,000 shares authorized; no shares issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock, $.001 par value; 297,000,000 shares authorized; 46,764,703 and 46,730,198 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	47	47
Additional paid-in capital	1,568,124	1,561,142
Accumulated other comprehensive income	(417)	1,894
Accumulated deficit	(1,202,661)	(1,143,607)
Total stockholders' equity	365,093	419,476
Total liabilities and stockholders' equity	$ 402,961	$ 444,654

See accompanying notes to unaudited condensed consolidated financial statements

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

(In thousands, except per share amounts)

	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Revenues:				
Product development and licensing agreements	$ —	$ 26	$ 30	$ 29
Contracts and grants	163	3,454	307	4,136
Total revenues	163	3,480	337	4,165
Operating expenses:				
Research and development	20,731	12,356	37,786	25,076
General and administrative	7,154	4,306	14,066	8,426
(Gain) loss on fair value remeasurement of contingent consideration	(6,326)	258	(6,862)	741
Litigation settlement related loss	15,000	—	15,000	—
Total operating expenses	36,559	16,920	59,990	34,243
Operating loss	(36,396)	(13,440)	(59,653)	(30,078)
Investment and other income, net	392	67	599	167
Net loss	$ (36,004)	$ (13,373)	$ (59,054)	$ (29,911)
Basic and diluted net loss per common share	$ (0.77)	$ (0.34)	$ (1.26)	$ (0.76)
Shares used in calculating basic and diluted net loss per share	46,759	39,616	46,749	39,615
Comprehensive loss:				
Net loss	$ (36,004)	$ (13,373)	$ (59,054)	$ (29,911)
Other comprehensive income (loss):				
Unrealized (loss) gain on marketable securities	(529)	5	(2,311)	3
Comprehensive loss	$ (36,533)	$ (13,368)	$ (61,365)	$ (29,908)

See accompanying notes to unaudited condensed consolidated financial statements

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

(In thousands)

	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Cash flows from operating activities:		
Net loss	$ (59,054)	$ (29,911)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,552	1,539
Amortization and premium of marketable securities, net	1,308	(173)
Loss (gain) on sale or disposal of assets	57	(24)
(Gain) loss on fair value remeasurement of contingent consideration	(6,862)	741
Stock-based compensation expense	6,607	2,784
Changes in operating assets and liabilities:		
Accounts and other receivables	75	1,306
Prepaid and other current assets	(8,485)	(1,544)
Accounts payable and accrued expenses	(862)	(750)
Litigation settlement payable	15,000	—
Other liabilities	3,886	(3,982)
Net cash used in operating activities	(46,778)	(30,014)
Cash flows from investing activities:		
Sales and maturities of marketable securities	106,756	116,000
Purchases of marketable securities	(69,847)	(85,739)
Acquisition of property and equipment	(1,248)	(710)
Proceeds from sale or disposal of assets	—	24
Net cash provided by investing activities	35,661	29,575
Cash flows from financing activities:		
Proceeds from issuance of stock from employee benefit plans	375	49
Net cash provided by financing activities	375	49
Net decrease in cash and cash equivalents	(10,742)	(390)
Cash and cash equivalents at beginning of period	39,143	43,836
Cash and cash equivalents at end of period	$ 28,401	$ 43,446
Non-cash investing activities		
Accrued construction in progress	$ 54	$ —

See accompanying notes to unaudited condensed consolidated financial statements

CELLDEX THERAPEUTICS, INC.
Notes to Unaudited Condensed Consolidated Financial Statements
June 30, 2022

(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, 2021, which are included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2022. 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, 2022.

At June 30, 2022, the Company had cash, cash equivalents and marketable securities of $356.8 million. The Company has had recurring losses and incurred a loss of $59.1 million for the six months ended June 30, 2022. Net cash used in operations for the six months ended June 30, 2022 was $46.8 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 amounts due under the Settlement Agreement with Shareholder Representative Services LLC ("SRS") (refer to Note 13), in the event that the Company achieves the 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, which could adversely impact our operations. To date, we have 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 June 30, 2022.

(2) Significant Accounting Policies

The significant accounting policies used in preparation of these condensed consolidated financial statements on Form 10-Q for the three and six months ended June 30, 2022 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, 2021.

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. The adoption of this new guidance is not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

(3) Fair Value Measurements

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

	As of June 30, 2022	Level 1	Level 2	Level 3
		(In thousands)		
Assets:				
Money market funds and cash equivalents	$ 7,114	—	$ 7,114	—
Marketable securities	328,416	—	328,416	—
	$ 335,530	—	$ 335,530	—
Liabilities:				
Kolltan acquisition contingent consideration	$ —	—	—	$ —
	$ —	—	—	$ —

	As of December 31, 2021	Level 1	Level 2	Level 3
		(In thousands)		
Assets:				
Money market funds and cash equivalents	$ 26,220	—	$ 26,220	—
Marketable securities	369,107	—	369,107	—
	$ 395,327	—	$ 395,327	—
Liabilities:				
Kolltan acquisition contingent consideration	$ 6,862	—	—	$ 6,862
	$ 6,862	—	—	$ 6,862

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

The following table reflects the activity for the Company's contingent consideration liabilities measured at fair value using Level 3 inputs for the six months ended June 30, 2022 (in thousands):

	Other Liabilities: Contingent Consideration
Balance at December 31, 2021	$ 6,862
Fair value adjustments included in operating expenses	(6,862)
Balance at June 30, 2022	$ —

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 Pharmaceuticals, Inc. ("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.

During the three and six months ended June 30, 2022, the Company recorded a $6.3 million and $6.9 million gain on fair value remeasurement of contingent consideration, respectively, primarily due to the Company's decision to deprioritize the CDX-1140 program. During the three and six months ended June 30, 2021, the Company recorded a $0.3 million and $0.7 million loss on fair value remeasurement of contingent consideration, respectively, primarily due to 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 six months ended June 30, 2022.

(4) Marketable Securities

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(In thousands)		
June 30, 2022				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	$ 152,518	$ —	$ (1,494)	$ 151,024
Maturing after one year through three years	3,887	—	(17)	3,870
Total U.S. government and municipal obligations	$ 156,405	$ —	$ (1,511)	$ 154,894
Corporate debt securities				
Maturing in one year or less	$ 149,304	$ —	$ (829)	$ 148,475
Maturing after one year through three years	25,720	—	(673)	25,047
Total corporate debt securities	$ 175,024	$ —	$ (1,502)	$ 173,522
Total marketable securities	$ 331,429	$ —	$ (3,013)	$ 328,416

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(In thousands)		
December 31, 2021				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	$ 80,674	$ —	$ (133)	$ 80,541
Maturing after one year through three years	51,319	—	(184)	51,135
Total U.S. government and municipal obligations	$ 131,993	$ —	$ (317)	$ 131,676
Corporate debt securities				
Maturing in one year or less	$ 170,034	$ —	$ (28)	$ 170,006
Maturing after one year through three years	67,782	—	(357)	67,425
Total corporate debt securities	$ 237,816	$ —	$ (385)	$ 237,431
Total marketable securities	$ 369,809	$ —	$ (702)	$ 369,107

The Company holds investment-grade marketable securities, and none were in a continuous unrealized loss position for more than twelve months as of June 30, 2022 and December 31, 2021. 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 $1.1 million and $1.3 million in accrued interest at June 30, 2022 and December 31, 2021, respectively.

(5) Intangible Assets

At June 30, 2022 and December 31, 2021, the carrying value of the Company's indefinite-lived intangible assets was $27.2 million. Indefinite-lived intangible assets consist of acquired IPR&D related to the development of the anti-KIT program, including barzolvolimab (also referred to as CDX-0159), which was recorded in connection with the Kolltan acquisition. Barzolvolimab is in Phase 2 development. As of June 30, 2022, the IPR&D asset related to the anti-KIT program had not reached technological feasibility nor did the asset have alternative future uses.

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

(6) Other Long-Term Liabilities

Other long-term liabilities include the following:

	June 30, 2022	December 31, 2021
	(In thousands)	
Net deferred tax liabilities related to IPR&D (Note 11)	$ 1,613	$ 1,613
Deferred Income From Sale of Tax Benefits	4,650	—
Contingent milestones (Note 3 and Note 13)	—	6,862
Deferred revenue (Note 10)	463	433
Total	6,726	8,908
Less current portion	(1,393)	(1,554)
Long-term portion	$ 5,333	$ 7,354

In March 2022, the Company received approval from the New Jersey Economic Development Authority and agreed to sell New Jersey tax benefits of $5.0 million to an independent third party for $4.7 million. Under the agreement, the Company must maintain a base of operations in New Jersey for five years or the tax benefits must be paid back on a pro-rata basis based on the number of years completed.

(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 June 30, 2022, the Company had $50.0 million remaining in aggregate gross offering price available under the Company's November 2020 prospectus.

The changes in Stockholders' Equity during the three and six months ended June 30, 2022 and 2021 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, 2021	46,730,198	$ 47	$ 1,561,142	$ 1,894	$ (1,143,607)	$ 419,476
Shares issued under stock option and employee stock purchase plans	24,150	—	304	—	—	304
Stock-based compensation	—	—	3,153	—	—	3,153
Unrealized loss on marketable securities	—	—	—	(1,782)	—	(1,782)
Net loss	—	—	—	—	(23,050)	(23,050)
Consolidated balance at March 31, 2022	46,754,348	$ 47	$ 1,564,599	$ 112	$ (1,166,657)	$ 398,101
Shares issued under stock option and employee stock purchase plans	10,355	—	71	—	—	71
Stock-based compensation	—	—	3,454	—	—	3,454
Unrealized loss on marketable securities	—	—	—	(529)	—	(529)
Net loss	—	—	—	—	(36,004)	(36,004)
Consolidated balance at June 30, 2022	46,764,703	$ 47	$ 1,568,124	$ (417)	$ (1,202,661)	$ 365,093

	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

(8) Stock-Based Compensation

A summary of stock option activity for the six months ended June 30, 2022 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In Years)
Options outstanding at December 31, 2021	4,077,667	$ 30.02	8.0
Granted	1,570,900	$ 22.79	
Exercised	(29,910)	$ 8.05	
Canceled	(28,444)	$ 36.24	
Options outstanding at June 30, 2022	5,590,213	$ 28.07	8.20
Options vested and expected to vest at June 30, 2022	5,428,921	$ 28.25	8.17
Options exercisable at June 30, 2022	2,135,506	$ 39.84	6.76
Shares available for grant under the 2021 Plan	1,761,761		

The weighted average grant-date fair value of stock options granted during the three and six ended June 30, 2022 was $17.20 and $17.29, respectively.

The aggregate intrinsic value of stock options vested and expected to vest at June 30, 2022 was $48.6 million. The aggregate intrinsic value of stock options exercisable at June 30, 2022 was $26.2 million. As of June 30, 2022, total compensation cost related to non-vested employee, consultant and non-employee director stock options not yet recognized was approximately $51.2 million, net of estimated forfeitures, which is expected to be recognized as expense over a weighted average period of 3.0 years.

Stock-based compensation expense for the three and six months ended June 30, 2022 and 2021 was recorded as follows:

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
	(In thousands)		(In thousands)	
Research and development	$ 1,798	$ 762	$ 3,412	$ 1,423
General and administrative	1,656	747	3,195	1,361
Total stock-based compensation expense	$ 3,454	$ 1,509	$ 6,607	$ 2,784

The fair values of employee, consultant and non-employee director stock options granted during the three and six months ended June 30, 2022 and 2021 were valued using the Black-Scholes option pricing model with the following assumptions:

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Expected stock price volatility	90 – 91%	97 – 98%	90 – 97%	97 – 98%
Expected option term	6.0 Years	6.0 Years	6.0 Years	6.0 Years
Risk-free interest rate	2.7 – 3.6%	1.2 – 1.3%	1.7 – 3.6%	0.8 – 1.3%
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 six months ended June 30, 2022 are summarized below:

	Unrealized Loss on Marketable Securities	Foreign Currency Items	Total
		(In thousands)	
Balance at December 31, 2021	$ (702)	$ 2,596	$ 1,894
Other comprehensive loss	(2,311)	—	(2,311)
Balance at June 30, 2022	$ (3,013)	$ 2,596	$ (417)

No amounts were reclassified out of accumulated other comprehensive income during the six months ended June 30, 2022.

(10) Revenue

Contract and Grants Revenue

The Company has entered into agreements with Rockefeller University and 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 $0.2 million in revenue under these agreements during the three and six months ended June 30, 2022, respectively, and $3.2 million and $3.8 million during the three and six months ended June 30, 2021, respectively.

Contract Assets and Liabilities

At June 30, 2022 and December 31, 2021, the Company's right to consideration under all contracts was considered unconditional, and as such, there were no recorded contract assets. At June 30, 2022, the Company had $0.5 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, 2021, the Company had $0.4 million in contract liabilities recorded. Revenue recognized from contract liabilities as of December 31, 2021 during the three and six months ended June 30, 2022 was $0.1 million and $0.2 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 June 30, 2022 and December 31, 2021.

The net deferred tax liability of $1.6 million at June 30, 2022 and December 31, 2021 relates to the temporary differences associated with the IPR&D intangible assets acquired in previous business combinations and is not deductible for tax purposes.

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:

	Six Months Ended June 30,	
	2022	2021
Stock Options	5,590,213	4,344,622
Restricted Stock	—	—
	5,590,213	4,344,622

(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 payable in cash, in shares of Celldex's common stock or a combination of both, in the sole discretion of Celldex and subject to provisions of the Agreement and Plan of Merger, dated November 1, 2016 (the "Merger Agreement").

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.

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 (the "Litigation").

On June 20, 2022, the Company entered into a binding settlement term sheet (the "Term Sheet") with SRS, related to the Litigation, which, upon execution of a definitive settlement agreement and the payment of the Initial Payment (as defined below), would result in the joint dismissal, with prejudice, of all claims and counterclaims in the Litigation. The definitive settlement agreement between the Company and SRS was executed on July 15, 2022 (the "Settlement Agreement") and the Company and SRS jointly filed a Stipulation of Dismissal with prejudice relating to the Litigation on July 19, 2022.

Pursuant to the terms of the Term Sheet and the Settlement Agreement, all milestone payments provided for by the Merger Agreement are replaced in their entirety with the following payments, each of which is payable only once:

(i) The Company paid $15,000,000 upon execution of the Settlement Agreement (the "Initial Payment").

(ii) The Company shall pay $15,000,000 upon the Successful Completion (as defined in the Term Sheet) of a Phase 2 Clinical Trial (as defined in the Merger Agreement) of CDX-0159, subject to the $2,500,000 contractual credit as set forth in the Merger Agreement.

(iii) The Company shall pay $52,500,000 upon the first United States Food and Drug Administration or European Medicines Agency, or, in each case, any successor organization, regulatory approval of a Surviving Company Product (as defined the Term Sheet).

The above payment obligations replace, in their entirety, the contingent consideration in the form of development, regulatory approval and sales-based milestones of up to $172.5 million contained in the Merger Agreement.

Under the Settlement Agreement, each of the Company and SRS provided broad mutual releases of all claims relating to or arising out of the Merger Agreement, including without limitation, all claims brought in the Litigation or that could have been brought in the Litigation.

The Company elected to pay the Initial Payment in cash. A litigation settlement payable of $15.0 million has been recorded as of June 30, 2022 related to the Initial Payment. Any future milestone payments related to the CDX-0159 program, which was subject to the Litigation, will be recorded when and if payment becomes probable and reasonably estimable in accordance with the loss contingency model under ASC 450. Milestones related to the remaining Surviving Company Products are measured at fair value (refer to Note 3). When and if any of the remaining payments described above become due, they shall be payable, at the Company's sole election, in either cash or stock (as set forth in the Merger Agreement) or a combination thereof.

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 the future milestones, if any, under the Settlement Agreement with SRS;

- 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 our annual report on Form 10-K for the year ended December 31, 2021 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:

- Barzolvolimab (also referred to as CDX-0159), a monoclonal antibody that specifically binds the KIT receptor and potently inhibits its activity, is currently being studied across multiple mast cell driven diseases including:

    - Chronic Urticarias: In June and July 2022 respectively, we announced that enrollment had opened and the first patients had been dosed in Phase 2 studies in chronic spontaneous urticaria (CSU) and chronic inducible urticaria (CIndU). Positive interim data from the ongoing Phase 1b study in CSU were reported in July 2022. 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;

    - Prurigo Nodularis (PN): In December 2021 we announced that the first patient had been dosed in a Phase 1b study in PN; and

    - Eosinophilic Esophagitis (EoE): We plan to initiate a Phase 2 study in EoE by the end of 2022.

- 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 us.

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, 2021, we incurred an aggregate of $301.1 million in research and development expenses. The following table indicates the amount incurred for each of our significant research programs and for other identified research and development activities during the six months ended June 30, 2022 and 2021. The amounts disclosed in the following table reflect direct research and development costs, license fees associated with the underlying technology and an allocation of indirect research and development costs to each program.

	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
	(In thousands)	
Barzolvolimab/Anti-KIT Program	$ 21,918	$ 10,973
CDX-1140 and CDX-301	1,751	2,845
CDX-527	1,195	2,328
Other Programs	12,922	8,930
Total R&D Expense	$ 37,786	$ 25,076

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, which could adversely impact our operations. To date, we have 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.

Barzolvolimab (also referred to as CDX-0159)

Barzolvolimab 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. Barzolvolimab is designed to block KIT activation by disrupting both SCF binding and KIT dimerization. We believe that by targeting KIT, barzolvolimab may be able to inhibit mast cell activity and decrease mast cell numbers to provide potential clinical benefit in mast cell related diseases.

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. In June 2020, we completed a randomized, double-blind, placebo-controlled, single ascending dose escalation Phase 1a study of barzolvolimab in healthy subjects (n=32; 8 subjects per cohort, 6 barzolvolimab; 2 placebo). Subjects received a single intravenous infusion of barzolvolimab 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. Barzolvolimab 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 barzolvolimab program into mast cell driven diseases, including initially in CSU and 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. We are exploring cold-induced, dermographism (scratch-induced) and cholinergic (exercise-induced) urticarias. In June and July 2022 respectively, we announced the initiation of Phase 2 studies in both CSU and CIndU.

In October 2020, we announced that enrollment had opened and the first patient had been dosed in a Phase 1b multi-center study of barzolvolimab in CSU. This study is a randomized, double-blind, placebo-controlled clinical trial designed to assess the safety of multiple ascending doses of barzolvolimab 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. Barzolvolimab 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 June 2022, we reported positive interim data from the CSU study. As of the data cut-off on May 23, 2022, 34 patients with CSU were enrolled and treated [26 barzolvolimab (n=9 in 0.5 mg/kg; n=8 in 1.5 mg/kg; n=9 in 3.0 mg/kg) and 8 placebo]. The 0.5 mg/kg and 1.5 mg/kg cohorts had completed study participation through 24 weeks; 7 of 12 patients in the 3.0 mg/kg cohort had completed week 12; enrollment in the 4.5 mg/kg cohort was ongoing. Adverse events through data cutoff and hematology data through week 12 were included for all dose groups; clinical activity and tryptase data were included through week 12 for 0.5 mg/kg and 1.5 mg/kg, and through week 8 for 3 mg/kg (ongoing; reflecting the administration of only one dose). Data shows that barzolvolimab results in rapid, marked and durable responses in patients with moderate to severe CSU refractory to antihistamines, including patients with prior omalizumab treatment.

- Mean reduction from baseline in urticaria activity (Urticaria Activity Score over 7 days or UAS7) of 66.6% in all patients in the 1.5 mg/kg dose group (n=8) at week 12 and 75.1% in all patients in the 3.0 mg/kg dose group (n=9) at week 8 (reflects one dose; ongoing), demonstrating clinically meaningful symptom improvements for patients.

- Complete response (UAS7=0) of 57.1% in the 1.5 mg/kg dose group at week 12 and 44.4% at week 8 (reflects one dose; ongoing) in the 3 mg/kg dose group which is a key therapeutic goal.

- 75% well-controlled disease by Urticaria Control Test (UCT) in the 1.5 mg/kg dose group at week 12 and 83.3% in the 3 mg/kg dose group at week 8 (reflects one dose; ongoing).

- Patients with prior omalizumab therapy had similar symptom improvement as all patients.

- All three doses of barzolvolimab markedly improved urticaria symptoms and disease control, with rapid improvement in itch and hives. As predicted, the lowest dose of 0.5 mg/kg resulted in suboptimal clinical activity compared to the higher doses.

- Rapid onset of responses after initial dosing and sustained durability were observed; onset as early as 1 week after the first dose.

- Tryptase suppression, indicative of mast cell depletion, paralleled symptom improvement, demonstrating the impact of mast cell depletion on CSU disease activity.

- Barzolvolimab was well tolerated with a favorable safety profile; effects of multiple dose administration were consistent with observations in single dose studies. Most AEs were mild or moderate in severity and resolved while on study, with none leading to treatment discontinuation. The most common treatment emergent adverse events were urinary tract infections, headache, neutropenia and back pain. UTIs, headache and backpain were all reported as unrelated to treatment. Changes in hematologic parameters were consistent with observations in single dose studies, with no pattern of further decreases with multiple doses; hematologic values generally remained within the normal range.

In June 2022, we announced that the first patient has been dosed in a Phase 2 study in patients with CSU who remain symptomatic despite antihistamine therapy. The study will be conducted at more than 75 sites across 10 or more countries. The study is a randomized, double-blind, placebo-controlled, parallel group Phase 2 study evaluating the efficacy and safety profile of multiple dose regimens of barzolvolimab to determine the optimal dosing strategy. Approximately 168 patients will be randomly assigned on a 1:1:1:1 ratio to receive subcutaneous injections of barzolvolimab at 75 mg every 4 weeks, 150 mg every 4 weeks, 300 mg every 8 weeks or placebo during a 16-week placebo-controlled treatment phase. Patients will then enter a 36-week active treatment phase, in which patients not already randomized to barzolvolimab at 150 mg every 4 weeks or 300 mg every 8 weeks will be randomized 1:1 to receive one of these two dose regimens; patients already randomized to these treatment arms will remain on the same regimen as during the placebo-controlled treatment phase. Following the treatment period, patients will enter a 24-week follow up phase. The primary endpoint of the study is mean change in baseline to Week 12 in UAS7 (Urticaria Activity Score over 7 days). Secondary endpoints include safety and other assessments of clinical activity including ISS7 (Itch Severity Score over 7 days), HSS7 (Hive Severity Score over 7 days) and AAS7 (Angioedema Activity Score over 7 days).

In December 2020, we announced that enrollment had opened and the first patient had been dosed in a 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 barzolvolimab 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. Barzolvolimab is administered intravenously on Day 1 as add on treatment to H1-antihistamines.

In July 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 barzolvolimab 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 barzolvolimab. 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 barzolvolimab 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.

- Barzolvolimab 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 (PN). After a single dose of barzolvolimab, this patient experienced both a complete response of symptomatic dermographism and notable improvement of the PN.

In September 2021, we reported additional positive data from the study on measurements of symptom control and quality of life. A single dose of barzolvolimab (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).

In July 2022 we announced that the first patient has been dosed in a Phase 2 study in patients with CIndU who remain symptomatic despite antihistamine therapy. The study will be conducted at more than 75 sites across 10 or more countries. The randomized, double-blind, placebo-controlled, parallel group Phase 2 study is evaluating the efficacy and safety profile of multiple dose regimens of barzolvolimab in patients with CIndU to determine the optimal dosing strategy. Approximately 180 patients in 2 cohorts (differentiated by CIndU subtype) including 90 patients with cold urticaria and 90 patients with symptomatic dermographism will be randomly assigned on a 1:1:1 ratio to receive subcutaneous injections of barzolvolimab at 150 mg every 4 weeks, 300 mg every 8 weeks or placebo during a 20-week treatment phase. Patients will then enter a follow-up phase for an additional 24 weeks. The primary endpoint of the study is the percentage of patients with a negative provocation test at Week 12 (using TempTest(R) and FricTest(R)). Secondary endpoints include safety and other assessments of clinical activity including CTT (Critical Temperature Threshold), CFT (Critical Friction Threshold) and WI-NRS (Worst itch numeric rating scale).

We have expanded clinical development of barzolvolimab into prurigo nodularis (PN). PN is 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. Industry sources estimate there are approximately 154,000 patients in the United States with PN who have undergone treatment within the last 12 months and, of these, approximately 75,000 would be biologic-eligible. In December 2021, the first patient was dosed 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 barzolvolimab in up to 30 patients with PN.

Manufacturing activities to support the introduction of the barzolvolimab subcutaneous formulation into the clinical program have been completed and, in September 2021, we initiated 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 barzolvolimab in healthy volunteers. In February 2022, we reported that subcutaneous administration of barzolvolimab was well tolerated and that multiple dose levels have been identified that possess promising pharmacokinetic and pharmacodynamic properties. Importantly, subcutaneous delivery of barzolvolimab resulted in dose-dependent, rapid and sustained decreases in serum tryptase compared with placebo and achieved sufficient exposure to produce tryptase suppression levels comparable with the levels that generated impressive clinical activity observed in the Phase 1 CIndU intravenous study. The Phase 2 multi-dose studies in urticaria are designed to evaluate 75mg and 150mg administered every 4 weeks and 300mg administered every 8 weeks. These doses support a 0.5 to 2 ml injection volume, allowing for a single injection as barzolvolimab advances towards potential commercialization. In 2022, we initiated transfer of our current barzolvolimab manufacturing process to a contract manufacturing organization to support late-stage trials and to prepare for potential commercialization.

In February 2022, we also reported interim data after completing the in-life dosing portion of our six-month chronic toxicology study in non-human primates; a subset of the animals will continue to be followed beyond clearance of the barzolvolimab antibody to study completion. As expected and consistent with other KIT-targeting agents, impact on spermatogenesis was observed which is anticipated to be fully reversible upon clearance of the antibody. There were no other clinically adverse findings reported in the study. We believe these data strongly support our Phase 2 studies in urticaria and in future indications.

In February 2022, we announced that we will be expanding clinical development of barzolvolimab into eosinophilic esophagitis (EoE), the most common type of eosinophilic gastrointestinal disease. EoE is a chronic inflammatory disease of the esophagus characterized by the infiltration of eosinophils. This chronic inflammation can result in trouble swallowing, chest pain, vomiting and impaction of food in the esophagus, a medical emergency. Several studies have suggested that mast cells may be an important driver in the disease, demonstrating that the number and activation state of mast cells are greatly increased in EoE biopsies and that mast cell signatures correlate with markers of inflammation, fibrosis, pain and disease severity. Currently, there are limited treatment options for EoE. Individuals often participate in an elimination diet to identify potential food allergens that may contribute to EoE, avoid difficult to swallow foods and undergo esophageal dilation. While not approved for EoE, proton pump inhibitors and the swallowing of topical corticosteroids are also used to address the disease. Industry sources estimate there are approximately 160,000 patients in the United States with EoE who have undergone treatment within the last 12 months and, of these, approximately 48,000 would be biologic-eligible. Given the lack of effective therapies for EoE and barzolvolimab's potential as a mast cell depleting agent, we believe EoE is an important indication for future study.

We continue to assess potential opportunities for barzolvolimab in other diseases where mast cells play an important role, such as dermatologic, respiratory, allergic, gastrointestinal and ophthalmic conditions.

CDX-527

CDX-527 is the first candidate from our bispecific antibody platform. Bispecifics provide opportunities to engage two independent pathways involved in controlling immune responses to tumors. CDX-527 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 to help prime and activate anti-tumor T cell responses through CD27 costimulation, while preventing PD-1 inhibitory signals that subvert the immune response.

Our 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 demonstrated good exposure starting at the 1 mg/kg dose and no evidence of significant anti-drug antibodies impact. Pharmacodynamic parameters demonstrated 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.

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 supported the design of the Phase 1 study to identify the dose for characterizing single-agent and combination activity.

The Phase 1 study was initiated in November 2017 in patients with recurrent, locally advanced or metastatic solid tumors and B cell lymphomas. The study was designed to determine the maximum tolerated dose, or MTD, during a dose-escalation phase 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.

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 reported using the same regimen, suggest that simultaneous treatment with chemotherapy and CD40 activation may not be optimal. The combination of CDX-1140 with pembrolizumab had completed the safety run-in phase and expansion cohorts in patients with checkpoint-refractory/resistant squamous cell head and neck cancer and non-small cell lung cancer were enrolled. When we reviewed updated data from this study in June of 2022, evidence of clinical benefit was most evident in patients with SCCHN, all of whom had progressive disease on prior anti-PD-1/L1 based therapies. Despite evidence of clinical benefit, questions remain to be answered about CDX-1140, and the broader CD40 agonist class, regarding the best clinical settings, regimens, and possible combinations before advancing into additional Celldex sponsored studies. Given our pipeline priorities and resource requirements, we will not progress further Company-sponsored studies at this time and are exploring alternative means of answering these questions, including through investigator sponsored studies.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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, 2021 for a discussion of our critical accounting policies and estimates. There have been no material changes to such critical accounting policies or estimates. 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 June 30, 2022 Compared with Three Months Ended June 30, 2021

	Three Months Ended June 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2022	2021	$	%
	(In thousands)			
Revenues:				
Product development and licensing agreements	$ —	$ 26	$ (26)	(100)%
Contracts and grants	163	3,454	(3,291)	(95)%
Total revenues	$ 163	$ 3,480	$ (3,317)	(95)%
Operating expenses:				
Research and development	20,731	12,356	8,375	68 %
General and administrative	7,154	4,306	2,848	66 %
(Gain) loss on fair value remeasurement of contingent consideration	(6,326)	258	(6,584)	(2,552)%
Litigation settlement related loss	15,000	—	15,000	n/a
Total operating expenses	36,559	16,920	19,639	116 %
Operating loss	(36,396)	(13,440)	22,956	171 %
Investment and other income, net	392	67	325	485 %
Net loss	$ (36,004)	$ (13,373)	$ 22,631	169 %

Net Loss

The $22.6 million increase in net loss for the three months ended June 30, 2022, as compared to the three months ended June 30, 2021, was primarily due to the $15.0 million litigation settlement related loss recorded in the second quarter of 2022 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 June 30, 2022 was relatively consistent with the three months ended June 30, 2021. The $3.3 million decrease in contracts and grants revenue for the three months ended June 30, 2022, as compared to the three months ended June 30, 2021, was primarily due to a decrease in services performed under our manufacturing and research and development agreements with Rockefeller University and Gilead Sciences. We expect revenue to increase over the next twelve months as a result of an increase in services expected to be performed under our contract manufacturing and research and development agreement with Rockefeller University.

Research and Development Expense

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

	Three Months Ended June 30,		Increase/ (Decrease)	
	2022	2021	$	%
	(In thousands)			
Personnel	$ 7,979	$ 5,844	$ 2,135	37 %
Laboratory supplies	2,110	1,356	754	56 %
Facility	1,173	1,198	(25)	(2)%
Product development	7,945	2,972	4,973	167 %

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The $2.1 million increase in personnel expenses for the three months ended June 30, 2022, as compared to the three months ended June 30, 2021, was primarily due to higher stock-based compensation expense and an increase in employee headcount. We expect personnel expenses to increase over the next twelve months as a result of additional headcount to support the expanded development of barzolvolimab.

Laboratory supplies expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The $0.8 million increase in laboratory supply expenses for the three months ended June 30, 2022, as compared to the three months ended June 30, 2021, 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. Facility expenses for the three months ended June 30, 2022 was relatively consistent with the three months ended June 30, 2021. 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 $5.0 million increase in product development expenses for the three months ended June 30, 2022, as compared to the three months ended June 30, 2021, was primarily due to an increase in clinical trial and contract research expenses. We expect product development expenses to increase over the next twelve months as a result of further increases in barzolvolimab clinical trial, contract manufacturing and contract research expenses.

General and Administrative Expense

The $2.8 million increase in general and administrative expenses for the three months ended June 30, 2022, as compared to the three months ended June 30, 2021, was primarily due to higher legal, commercial planning, and stock-based compensation expenses. We expect general and administrative expenses to decrease over the next twelve months as a result of a decrease in legal expenses.

(Gain) Loss on Fair Value Remeasurement of Contingent Consideration

The $6.3 million gain on fair value remeasurement of contingent consideration for the three months ended June 30, 2022 was primarily due to our decision to deprioritize the CDX-1140 program. The $0.3 million loss on fair value remeasurement of contingent consideration for the three months ended June 30, 2021 was primarily due to the passage of time.

Litigation Settlement Related Loss

We recorded a loss of $15.0 million in the second quarter of 2022 related to the Initial Payment due under the binding settlement term sheet (the "Term Sheet") entered with SRS.

Investment and Other Income, Net

The $0.3 million increase in investment and other income, net for the three months ended June 30, 2022, as compared to the three months ended June 30, 2021, was primarily due to higher levels of cash and investment balances and higher interest rates on fixed income investments. We expect investment and other income to increase over the next twelve months due to higher other income related to our sale of New Jersey tax benefits.

Six Months Ended June 30, 2022 Compared with Six Months Ended June 30, 2021

	Six Months Ended June 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2022	2021	$	%
	(In thousands)			
Revenues:				
Product development and licensing agreements	$ 30	$ 29	$ 1	3 %
Contracts and grants	307	4,136	(3,829)	(93)%
Total revenues	$ 337	$ 4,165	$ (3,828)	(92)%
Operating expenses:				
Research and development	37,786	25,076	12,710	51 %
General and administrative	14,066	8,426	5,640	67 %
(Gain) loss on fair value remeasurement of contingent consideration	(6,862)	741	(7,603)	(1,026)%
Litigation settlement related loss	15,000	—	15,000	n/a
Total operating expenses	59,990	34,243	25,747	75 %
Operating loss	(59,653)	(30,078)	29,575	98 %
Investment and other income, net	599	167	432	259 %
Net loss	$ (59,054)	$ (29,911)	$ 29,143	97 %

Net Loss

The $29.1 million increase in net loss for the six months ended June 30, 2022, as compared to the six months ended June 30, 2021, was primarily due to the $15.0 million litigation settlement related loss recorded in the second quarter of 2022 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

Product development and licensing agreements revenue for the six months ended June 30, 2022, was relatively consistent with the six months ended June 30, 2021. The $3.8 million decrease in contracts and grants revenue for the six months ended June 30, 2022, as compared to the six months ended June 30, 2021, was primarily related to a decrease 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:

	Six Months Ended June 30,		Increase/ (Decrease)	
	2022	2021	$	%
	(In thousands)			
Personnel	$ 15,506	$ 11,882	$ 3,624	30 %
Laboratory supplies	3,747	3,115	632	20 %
Facility	2,479	2,452	27	1 %
Product development	13,103	5,734	7,369	129 %

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The $3.6 million increase in personnel expenses for the six months ended June 30, 2022, as compared to the six months ended June 30, 2021, 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 $0.6 million increase in laboratory supply expenses for the six months ended June 30, 2022, as compared to the six months ended June 30, 2021, 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. Facility expenses for the six months ended June 30, 2022 was relatively consistent with the six months ended June 30, 2021.

Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing. The $7.4 million increase in product development expenses for the six months ended June 30, 2022, as compared to the six months ended June 30, 2021, was primarily due to an increase in clinical trial and contract research expenses.

General and Administrative Expense

The $5.6 million increase in general and administrative expenses for the six months ended June 30, 2022, as compared to the six months ended June 30, 2021, was primarily due to higher legal, commercial planning, and stock-based compensation expenses.

(Gain) Loss on Fair Value Remeasurement of Contingent Consideration

The $6.9 million gain on fair value remeasurement of contingent consideration for the six months ended June 30, 2022 was primarily due to our decision to deprioritize the CDX-1140 program. The $0.7 million loss on fair value remeasurement of contingent consideration for the six months ended June 30, 2021 was primarily due to changes in discount rates and the passage of time.

Litigation Settlement Related Loss

We recorded a loss of $15.0 million in the second quarter of 2022 related to the Initial Payment due under the Term Sheet entered with SRS.

Investment and Other Income, Net

The $0.4 million increase in investment and other income, net for the six months ended June 30, 2022, as compared to the six months ended June 30, 2021, was primarily due to higher levels of cash and investment balances and higher interest rates on fixed income investments.

LIQUIDITY AND CAPITAL RESOURCES

Our cash equivalents are highly liquid investments with a maturity of three months or less at the date of purchase and consist primarily of investments in money market mutual funds with commercial banks and financial institutions. We maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances. We invest our excess cash balances in marketable securities, including municipal bond securities, U.S. government agency securities and high-grade corporate bonds that meet high credit quality standards, as specified in our investment policy. Our investment policy seeks to manage these assets to achieve our goals of preserving principal and maintaining adequate liquidity.

The use of our cash flows for operations has primarily consisted of salaries and wages for our employees; facility and facility-related costs for our offices, laboratories and manufacturing facility; fees paid in connection with preclinical studies, clinical studies, contract manufacturing, laboratory supplies and services; and consulting, legal and other professional fees. We anticipate that our cash flows from operations will continue to be focused in these areas as we progress our current drug candidates through the clinical trial process and develop additional drug candidates. To date, the primary sources of cash flows from operations have been payments received from our collaborative partners and from government entities and payments received for contract manufacturing and research and development services provided by us. The timing of any new contract manufacturing and research and development agreements, collaboration agreements, government contracts or grants and any payments under these agreements, contracts or grants cannot be easily predicted and may vary significantly from quarter to quarter.

At June 30, 2022, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of $356.8 million. We have had recurring losses and incurred a loss of $59.1 million for the six months ended June 30, 2022. Net cash used in operations for the six months ended June 30, 2022 was $46.8 million. We believe that the cash, cash equivalents and marketable securities at June 30, 2022 are sufficient to meet estimated working capital requirements and fund planned operations through 2025. This could be impacted if we elect to pay the future milestones under the Settlement Agreement with SRS, 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 the future milestones under the Settlement Agreement with SRS, in the event that we achieve the 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 $46.8 million for the six months ended June 30, 2022 as compared to $30.0 million for the six months ended June 30, 2021. 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 the expanded development of barzolvolimab.

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, pursuant to our existing arrangements and arrangements we may enter in the future.

Investing Activities

Net cash provided by investing activities was $35.7 million for the six months ended June 30, 2022 as compared to $29.6 million for the six months ended June 30, 2021. The increase in net cash provided by investing activities was primarily due to net sales and maturities of marketable securities of $36.9 million for the six months ended June 30, 2022 as compared to $30.3 million for the six months ended June 30, 2021.

Financing Activities

Net cash provided by financing activities was $0.4 million for the six months ended June 30, 2022 as compared to $0.0 million for the six months ended June 30, 2021. The increase in net cash provided by financing activities was primarily due to an increase in proceeds from issuance of stock from employee benefit plans.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

We do not utilize derivative financial instruments. The carrying amounts reflected in the consolidated balance sheet of cash and cash equivalents, accounts receivables and accounts payable approximate fair value at June 30, 2022 due to the short-term maturities of these instruments.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

As of June 30, 2022, we evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2022. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within time periods specified by the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2022 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, we 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 (the "Litigation"). Specifically, we sought the entry of an order declaring that:

(i) Our 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 us 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 barzolvolimab 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 barzolvolimab program is in essence an extension of the CDX-0158 (formerly KTN0158) program.

On June 20, 2022, we entered into a binding settlement term sheet (the "Term Sheet") with SRS, related to the Litigation with SRS, which, upon execution of a definitive settlement agreement and the payment of the Initial Payment (as defined below), would result in the joint dismissal, with prejudice, of all claims and counterclaims in the Litigation. We executed the definitive settlement agreement with SRS on July 15, 2022 (the "Settlement Agreement") and we and SRS jointly filed a Stipulation of Dismissal with prejudice relating to the Litigation on July 19, 2022.

Pursuant to the terms of the Term Sheet and the Settlement Agreement, all milestone payments provided for by the Merger Agreement are replaced in their entirety with the following payments, each of which is payable only once:

(iv) We paid $15,000,000 upon execution of the Settlement Agreement (the "Initial Payment").

(v) We shall pay $15,000,000 upon the Successful Completion (as defined in the Term Sheet) of a Phase 2 Clinical Trial (as defined in the Merger Agreement) of CDX-0159, subject to the $2,500,000 contractual credit as set forth in the Merger Agreement.

(vi) We shall pay $52,500,000 upon the first United States Food and Drug Administration or European Medicines Agency, or, in each case, any successor organization, regulatory approval of a Surviving Company Product (as defined the Term Sheet).

The above payment obligations replace, in their entirety, the contingent consideration in the form of development, regulatory approval and sales-based milestones of up to $172.5 million contained in the Merger Agreement.

Under the Settlement Agreement, we and SRS provided broad mutual releases of all claims relating to or arising out of the Merger Agreement, including without limitation, all claims brought in the Litigation or that could have been brought in the Litigation.

We elected to pay the Initial Payment in cash. When and if any of the remaining payments described above become due, they shall be payable, at our sole election, in either cash or stock (as set forth in the Merger Agreement) or a combination thereof.

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, 2021, 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 us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our 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 February 28, 2022.

Item 6. Exhibits

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

EXHIBIT INDEX

Exhibit No.	Description
10.1	Binding Settlement Term Sheet, dated June 20, 2022 by and between Shareholder Representatives Services LLC, solely in its capacity as Stockholders Representative, and Celldex Therapeutics, Inc., incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K, filed on June 23, 2022 with the Securities and Exchange Commission
10.2	Confidential Settlement Agreement and Mutual Release, dated July 15, 2022 by and between Shareholder Representatives Services LLC, solely in its capacity as Stockholders Representative, and Celldex Therapeutics, Inc., incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K, filed on July 18, 2022 with the Securities and Exchange Commission
*10.3	Third Amendment to Lease Agreement between the Company and Perryville SPE LLC (successor-in-interest) to Crown Perryville, LLC dated as of May 23, 2022
*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.

SIGNATURES

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

CELLDEX THERAPEUTICS, INC.

BY:

/s/ ANTHONY S. MARUCCI

Dated: August 8, 2022

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

/s/ SAM MARTIN

Dated: August 8, 2022

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

THIRD AMENDMENT OF LEASE

THIS THIRD AMENDMENT OF LEASE, dated as of May 23, 2022, between **PERRYVILLE SPE LLC** ("Landlord"), and **CELLDEX THERAPEUTICS, INC.** ("Tenant").

W I T N E S S E T H:

WHEREAS, Landlord's predecessor-in-interest, Crown Perryville, LLC., and Tenant entered into that certain Lease dated as of May 1, 2013 (the "Original Lease") in the building known as Perryville Ill at Perryville Corporate Park located at 53 Frontage Road, Hampton, New Jersey 08827 (the "Building) , as amended by a First Amendment of Lease, dated as of June 17, 2015 (the "First Amendment"), and as further amended by a Second Amendment of Lease, dated as of March 8, 2019 (the "Second Amendment"), pursuant to which Tenant is currently leasing premises (the "Premises") consisting of approximately 3,539 rentable square feet located on a portion of the first (1st) floor and approximately 29,824 rentable square feet located on a portion of the second (2nd) floor (the Original Lease, as amended by the First Amendment and Second Amendment is hereinafter collectively referred to as the "Lease"); and

WHEREAS, Landlord and Tenant desire to amend the Lease on the express terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual premises and agreements herein contained, the parties hereby agree as follows:

1. **Incorporation of Recitals.** The recitals set forth above are incorporated herein by reference.

2. **Defined Terms.** All terms used herein not otherwise defined shall have the meanings ascribed to them in the Lease.

3. **Binding Effect.** This Third Amendment of Lease ("Amendment") shall be binding upon Landlord and Tenant upon the date of mutual execution and delivery hereof (the "Effective Date").

4. **Lease Amendments.** Effective as of the Effective Date, the Lease is hereby amended as follows:

    A. Landlord agrees that within a reasonable time period after the Effective Date, it shall at such time(s) as is mutually-acceptable to Landlord and Tenant and in a Building standard manner, utilizing Building standard materials and specifications (including without limitation Building standard colors): (i) professionally clean/shampoo the carpets in the Premises; and (ii) paint a specified wall in the Premises ("Landlord's

Work"). Tenant acknowledges and agrees that it shall be responsible at its sole cost and expense, to the extent necessary, to relocate and replace its equipment, furniture, furnishings and wiring in order for Landlord to perform Landlord's Work.

B. The terms set forth in Section 19.27. of the Original Lease as to a Renewal Option granted therein shall be reinstated for a potential Renewal Term commencing on August 1, 2025 through July 31, 2027, and for a potential second Renewal Term commencing on August 1, 2027 through July 31, 2030, upon all of the terms and conditions set forth in Section 19.27 of the Original Lease; provided, however, that the Renewal Term Rent for each Renewal Term shall be increased to 102.5% of the Base Rent/Renewal Term Rent for the last year of the subject term and the lease rate will increase 2.5% per year on a compounded, cumulative basis for each year of the subject Renewal Term.. Notwithstanding anything herein to the contrary, the terms set forth in said Section 19.27. as to: (i) two (2) additional periods of five (5) years, and (ii) as to a Base Rent of $15.00 with annual escalation of $0.50 per annum, are hereby deleted in connection with each Renewal Term provided for herein.

C. The Early Termination Option granted to Tenant in Section 11 of the Second Amendment is hereby deemed deleted in its entirety.

5. **No Broker.** Tenant covenants, warrants and represents to Landlord that there were no brokers or finders instrumental in consummating this Amendment and that no conversations or negotiations were had by Tenant with any brokers or finders concerning the transaction contemplated by this Amendment, other than The Garibaldi Group (the "Broker"). Tenant agrees to indemnify and hold Landlord harmless from and against any claims or suits for a brokerage commission arising out of any conversation or negotiations had by Tenant with any brokers or finders in connection with the transactions contemplated by this Amendment, other than the Broker, whom Landlord shall pay pursuant to a separate agreement.

6. **Miscellaneous.**

A. Except as expressly amended hereby, all of the terms, covenants, conditions and provisions of the Lease shall remain and continue unmodified, in full force and effect.

B. This Amendment sets forth the entire agreement between the parties regarding the subject matter hereof, superseding all prior agreements and understandings, written and oral, and may not be altered or modified except by a writing signed by both parties.

C. Landlord and Tenant each represent and warrant to the other that it has not relied upon any representation or warranty, express or implied, in entering into this Amendment, except those which are set forth herein.

D. The covenants and agreements herein contained shall bind and inure to the benefit of Landlord, its successors and assigns, and Tenant, its successors and assigns. If any of the provisions of this Amendment, or its application to any situation, shall be invalid or unenforceable to any extent, the remainder of this Amendment, or the application thereof to situations other than that as to which it is invalid or unenforceable, shall not be affected thereby, and every provision of this Amendment shall be valid and enforceable to the fullest extent permitted by law.

E. The captions of this Amendment are for convenience and reference only and in no way define, limit or describe the scope or intent of this Amendment.

F. Submission by Landlord of the within Amendment for execution by Tenant shall confer no rights nor impose any obligation on Landlord unless and until both Landlord and Tenant shall have executed this Amendment and duplicate originals thereof shall have been delivered by Landlord and Tenant to each other.

G. This Amendment may be signed in two identical counterparts, and both of such counterparts, when taken together, will be deemed to constitute the original of this Amendment. This Amendment may be executed and delivered via electronic facsimile transmission or as a ".pdf" attachment to an e-mail with the same force and effect as if it were executed and delivered by the parties simultaneously in the presence of one another.

IN WITNESS WHEREOF, the parties have executed this Third Amendment of Lease as of the date hereinabove set forth.

PERRYVILLE SPE LLC

By: /s/ BERNARD S. BERTRAM
Authorized Signatory

CELLDEX THERAPEUTICS, INC.

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

Exhibit 31.1

CERTIFICATION

I, Anthony S. Marucci, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 8, 2022

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

Exhibit 31.2

CERTIFICATION

I, Sam Martin, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 8, 2022

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

Exhibit 32.1

SECTION 1350 CERTIFICATIONS

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

Date: August 8, 2022

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

Date: August 8, 2022

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.