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DELTA REPORT

10-Q

CLDX - CELLDEX THERAPEUTICS, INC

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	880
CHANGES	153
DELETIONS	398
ADDITIONS	329

REFINITIV

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2023 March 31, 2024

OR

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

Commission File Number: 000-15006

CELLDEX THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐

Emerging growth company ☐

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

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

As of October 27, 2023 April 30, 2024, 47,264,197 65,910,548 shares of common stock, $.001 par value per share, were outstanding.

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CELLDEX THERAPEUTICS, INC.

FORM 10-Q

For the Quarterly Period Ended September 30, 2023 March 31, 2024

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PART I — FINANCIAL INFORMATION

Item 1. Unaudited Financial Statements

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

(In thousands, except share and per share amounts)

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Assets				
Current assets:				
Cash and cash equivalents	$ 21,134	$ 29,429	$ 115,077	$ 34,814
Marketable securities	214,214	275,523	708,769	388,784
Accounts and other receivables	252	347	2,671	2,628
Prepaid and other current assets	10,333	12,394	8,807	5,467
Total current assets	245,933	317,693	835,324	431,693
Property and equipment, net	4,162	3,747	4,061	4,060
Operating lease right-of-use assets, net	2,864	4,001	2,165	2,577
Intangible assets	27,190	27,190	27,190	27,190
Other assets	107	104	107	107
Total assets	$ 280,256	$ 352,735	$ 868,847	$ 465,627
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	$ 3,586	$ 3,340	$ 3,234	$ 3,494
Accrued expenses	18,471	12,835	17,536	22,029
Current portion of operating lease liabilities	1,547	1,445	1,644	1,614
Current portion of other long-term liabilities	4,232	990	3,877	3,988
Total current liabilities	27,836	18,610	26,291	31,125
Long-term portion of operating lease liabilities	1,299	2,588	470	928
Other long-term liabilities	4,403	5,333	3,473	4,403
Total liabilities	33,538	26,531	30,234	36,456
Commitments and contingent liabilities				
Stockholders' equity:				
Convertible preferred stock, $.01 par value; 3,000,000 shares authorized; no shares issued and outstanding at September 30, 2023 and December 31, 2022	—	—		
Common stock, $.001 par value; 297,000,000 shares authorized; 47,264,197 and 47,200,695 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	47	47		
Convertible preferred stock, $.01 par value; 3,000,000 shares authorized; no shares issued and outstanding at March 31, 2024 and December 31, 2023			—	—
Common stock, $.001 par value; 297,000,000 shares authorized; 65,910,548 and 55,883,377 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively			66	56
Additional paid-in capital	1,598,591	1,580,829	2,266,472	1,823,168
Accumulated other comprehensive income	2,135	1,260	2,244	3,308
Accumulated deficit	(1,354,055)	(1,255,932)	(1,430,169)	(1,397,361)
Total stockholders' equity	246,718	326,204	838,613	429,171
Total liabilities and stockholders' equity	$ 280,256	$ 352,735	$ 868,847	$ 465,627

See accompanying notes to unaudited condensed consolidated financial statements

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

(In thousands, except per share amounts)

	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023
Revenues:						
Product development and licensing agreements	$ 2	$ —	$ 19	$ 30	$ 2	$ —
Contracts and grants	1,515	407	2,733	714	154	967
Total revenues	1,517	407	2,752	744	156	967
Operating expenses:						
Research and development	34,535	21,572	87,585	59,359	31,661	26,798
General and administrative	8,221	6,531	22,082	20,596	9,103	6,640
Gain on fair value remeasurement of contingent consideration	—	—	—	(6,862)		
Litigation settlement related loss	—	—	—	15,000		
Total operating expenses	42,756	28,103	109,667	88,093	40,764	33,438
Operating loss	(41,239)	(27,696)	(106,915)	(87,349)	(40,608)	(32,471)
Investment and other income, net	2,979	912	8,792	1,511	7,800	3,110
Net loss	$ (38,260)	$ (26,784)	$ (98,123)	$(85,838)	$(32,808)	$(29,361)
Basic and diluted net loss per common share	$ (0.81)	$ (0.57)	$ (2.08)	$ (1.83)	$ (0.56)	$ (0.62)
Shares used in calculating basic and diluted net loss per share	47,261	46,916	47,243	46,806	58,871	47,214
Comprehensive loss:						
Net loss	$ (38,260)	$ (26,784)	$ (98,123)	$(85,838)	$(32,808)	$(29,361)
Other comprehensive income (loss):						
Unrealized gain (loss) on marketable securities	63	305	875	(2,006)		
Unrealized (loss) gain on marketable securities					(1,064)	863
Comprehensive loss	$ (38,197)	$ (26,479)	$ (97,248)	$(87,844)	$(33,872)	$(28,498)

See accompanying notes to unaudited condensed consolidated financial statements

CELLDEX THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW

(Unaudited)

(In thousands)

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023
Cash flows from operating activities:				
Net loss	$ (98,123)	$ (85,838)	$ (32,808)	$ (29,361)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	2,249	2,223	775	726
Amortization and premium of marketable securities, net	(4,043)	1,366	(3,313)	(1,256)
Loss on sale or disposal of assets	—	1	8	—
Gain on fair value remeasurement of contingent consideration	—	(6,862)		
Stock-based compensation expense	16,678	11,103	7,202	4,340
Changes in operating assets and liabilities:				
Accounts and other receivables	95	(17)	(43)	(967)
Prepaid and other current assets	1,757	(7,928)	(6,209)	2,722
Other assets	(3)	—		
Accounts payable and accrued expenses	5,507	720	(4,781)	(3,448)
Other liabilities	1,125	3,262	(1,469)	(1,325)
Net cash used in operating activities	(74,758)	(81,970)	(40,638)	(28,569)
Cash flows from investing activities:				
Sales and maturities of marketable securities	249,703	192,866	77,311	127,000
Purchases of marketable securities	(183,172)	(132,613)	(392,178)	(73,846)
Acquisition of property and equipment	(1,152)	(1,593)	(344)	(585)
Proceeds from sale or disposal of assets	—	69		
Net cash provided by investing activities	65,379	58,729		
Net cash (used in) provided by investing activities			(315,211)	52,569
Cash flows from financing activities:				
Net proceeds from stock issuances			432,298	—
Proceeds from issuance of stock from employee benefit plans	1,084	2,681	3,814	694
Net cash provided by financing activities	1,084	2,681	436,112	694
Net decrease in cash and cash equivalents	(8,295)	(20,560)		
Net increase in cash and cash equivalents			80,263	24,694
Cash and cash equivalents at beginning of period	29,429	39,143	34,814	29,429
Cash and cash equivalents at end of period	$ 21,134	$ 18,583	$ 115,077	$ 54,123
Non-cash investing activities				
Accrued construction in progress	$ 488	$ 38	$ 105	$ 134

See accompanying notes to unaudited condensed consolidated financial statements

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CELLDEX THERAPEUTICS, INC.

Notes to Unaudited Condensed Consolidated Financial Statements

September 30, 2023 March 31, 2024

(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, 2022 December 31, 2023, which are included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on February 28, 2023 February 26, 2024. 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, 2023 December 31, 2024.

At September 30, 2023 March 31, 2024, the Company had cash, cash equivalents and marketable securities of $235.3 million $823.8 million. The Company has had recurring losses and incurred a loss of $98.1 million $32.8 million for the nine three months ended September 30, 2023 March 31, 2024. Net cash used in operations for the nine three months ended September 30, 2023 March 31, 2024 was $74.8 million $40.6 million. The Company believes that the cash, cash equivalents and marketable securities at the filing date of this Quarterly Report on 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 the future milestone under the Settlement Agreement (defined below) with Shareholder Representative Services LLC ("SRS") (refer to Note 13), in the event that the Company achieves the milestones milestone related to those payments. that payment. The Company, at its option, may decide to pay those that milestone payments payment 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.

(2) Significant Accounting Policies

The significant accounting policies used in preparation of these condensed consolidated financial statements on this Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2023 March 31, 2024 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, 2022, except as it relates to the adoption of new accounting standards during the first nine months of 2023 as discussed below. December 31, 2023.

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Newly Adopted Accounting Pronouncements

On January 1, 2023, the Company adopted ASU 2016-13: Financial Instruments - Credit Losses (Topic 326): 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 and establishes additional disclosure requirements related to credit risks. For available-for-sale debt securities with unrealized losses, the standard requires allowances to be recorded instead of reducing the amortized cost of the investment. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements and related disclosures.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB Financial Accounting Standards Board ("FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date. The Unless otherwise discussed, the Company has reviewed believes that the impact of recently issued accounting pronouncements and concluded they standards that are either not applicable to the business or yet effective will not expected to have a material impact on the Company's consolidated financial statements upon adoption.

In November 2023, the FASB issued ASU 2023-07 *Segment Reporting - Improvements to Reportable Segment Disclosures*, which improves reportable segment disclosure requirements, primarily through enhanced disclosure of significant segment expenses. The amendments in ASU 2023-07 apply to public entities, including those with a single reportable segment, and are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact that ASU 2023-07 will have on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures,* which requires public entities to disclose specific categories in the effective tax rate reconciliation, as well as additional information for reconciling items that exceed a quantitative threshold. ASU 2023-09 also requires all entities to disclose income taxes paid disaggregated by federal, state and foreign taxes, and further disaggregated for specific jurisdictions that exceed 5% of total income taxes paid, among other expanded disclosures. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-09 may have on its consolidated financial statements and related disclosures.

In March 2024, the SEC adopted final rules requiring public entities to provide certain climate-related information in their registration statements and annual reports. The rules require disclosure of, among other things: material climate-related risks; activities to mitigate or adapt to such risks; governance and management of such risks; and material greenhouse gas (GHG) emissions from operations owned or controlled (Scope 1) and/or indirect emissions from purchased energy consumed in operations (Scope 2). Additionally, the rules require disclosure in the notes to the financial statements of the effects of severe weather events and other natural conditions, subject to certain materiality thresholds. In April 2024, the SEC voluntarily stayed the new rules as a result of future adoption. pending legal challenges. Absent the result of pending legal challenges, and the removal of the stay, the rules were to become effective on a phased-in timeline, with the first requirements to be adopted for the Company's fiscal year beginning in 2025. The Company is assessing the effect of the new rules on its consolidated financial statements and related disclosures.

(3) Fair Value Measurements

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

	As of September 30, 2023	Level 1	Level 2	Level 3	As of March 31, 2024	Level 1	Level 2	Level 3
		(In thousands)						

Assets:								
Money market funds and cash equivalents	$ 10,979	—	$ 10,979	—	$ 97,624	—	$ 97,624	—
Marketable securities	214,214	—	214,214	—	708,769	—	708,769	—
	$ 225,193	—	$ 225,193	—	$ 806,393	—	$806,393	—

	As of December 31, 2022	Level 1	Level 2	Level 3	As of December 31, 2023	Level 1	Level 2	Level 3
	(In thousands)				(In thousands)			
Assets:								
Money market funds and cash equivalents	$ 16,813	—	$ 16,813	—	$ 19,803	—	$ 19,803	—
Marketable securities	275,523	—	275,523	—	388,784	—	388,784	—
	$ 292,336	—	$ 292,336	—	$ 408,587	—	$408,587	—

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

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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.

Contingent consideration liabilities measured at fair value using Level 3 inputs were $0.0 million as of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023. 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, is 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 nine months ended September 30, 2023, there There was no gain or loss on fair value remeasurement of contingent consideration. During consideration recorded during the three and nine months ended September 30, 2022, the Company recorded a $0.0 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. March 31, 2024 or March 31, 2023. The assumptions related to determining the fair value of contingent consideration include a significant amount of judgment, and any changes in the underlying estimates could have a material impact on the amount of contingent consideration adjustment recorded in any given period.

The Company did not have any transfers in or out of Level 3 assets or liabilities during the nine three months ended September 30, 2023 March 31, 2024.

(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	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(In thousands)				(In thousands)			
September 30, 2023								
March 31, 2024								
Marketable securities								
U.S. government and municipal obligations								
Maturing in one year or less	$ 89,878	$ —	$ (186)	$ 89,692	$139,787	$ 14	$ (62)	$139,739
Maturing after one year through three years	7,880	—	(44)	7,836	93,179	—	(275)	92,904
Total U.S. government and municipal obligations	$ 97,758	$ —	$ (230)	$ 97,528	$232,966	$ 14	$ (337)	$232,643
Corporate debt securities								
Maturing in one year or less	$ 86,866	$ 2	$ (96)	$ 86,772	$371,025	$ 141	$ (142)	$371,024
Maturing after one year through three years	30,052	—	(138)	29,914	105,130	65	(93)	105,102
Total corporate debt securities	$ 116,918	$ 2	$ (234)	$ 116,686	$476,155	$ 206	$ (235)	$476,126
Total marketable securities	$ 214,676	$ 2	$ (464)	$ 214,214	$709,121	$ 220	$ (572)	$708,769

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(In thousands)							
December 31, 2022								

					(In thousands)			
December 31, 2023								
Marketable securities								
U.S. government and municipal obligations								
Maturing in one year or less	$ 97,246	$ 5	$ (369)	$ 96,882	$132,459	$ 143	$ (53)	$132,549
Maturing after one year through three years	—	—	—	—	26,009	77	—	26,086
Total U.S. government and municipal obligations	$ 97,246	$ 5	$ (369)	$ 96,882	$158,468	$ 220	$ (53)	$158,635
Corporate debt securities								
Maturing in one year or less	$ 179,613	$ —	$ (972)	$ 178,641	$183,625	$ 300	$ (10)	$183,915
Maturing after one year through three years	—	—	—	—	45,977	257	—	46,234
Total corporate debt securities	$ 179,613	$ —	$ (972)	$ 178,641	$229,602	$ 557	$ (10)	$230,149
Total marketable securities	$ 276,859	$ 5	$ (1,341)	$ 275,523	$388,070	$ 777	$ (63)	$388,784

The Company holds investment-grade marketable securities, and none were in a continuous unrealized loss position for more than twelve months as of September 30, 2023 and December 31, 2022. The unrealized securities. Unrealized losses are generally attributable to changes in interest rates and rates. The aggregate fair value of marketable securities held by the Company does not believe any in an unrealized losses represent other-than-temporary impairments. loss position as of March 31, 2024 and December 31, 2023 was $458.1 million and $80.4 million, respectively. The Company has the intent and ability to hold such its marketable securities until recovery and has determined that there has been no material change to their credit risk. As a result, the Company determined it did not hold any investments with a credit loss at September 30, 2023 March 31, 2024.

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Marketable securities include $1.2 million $4.7 million and $0.8 million $1.9 million in accrued interest at September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, respectively.

(5) Intangible Assets

At September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, the carrying value of the Company's indefinite-lived intangible assets was $27.2 million. Indefinite-lived intangible assets consist of acquired in-process research and development ("IPR&D") related to the development of the anti-KIT program including barzolvolimab (also referred to as CDX-0159) (including barzolvolimab), which was recorded in connection with the Kolltan acquisition. Barzolvolimab is in Phase 2 development. As of September 30, 2023 March 31, 2024, 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:

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
	(In thousands)			
			(In thousands)	
Net deferred tax liabilities related to IPR&D (Note 11)	$ 1,613	$ 1,613	$ 1,613	$ 1,613
Deferred Income From Sale of Tax Benefits	3,720	4,650		
Deferred income from sale of tax benefits			2,790	3,720
Deferred revenue (Note 10)	3,302	60	2,947	3,058
Total	8,635	6,323	7,350	8,391
Less current portion	(4,232)	(990)	(3,877)	(3,988)
Long-term portion	$ 4,403	$ 5,333	$ 3,473	$ 4,403

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. The Company recognized $0.0 million $0.9 million and $0.9 million in other income related to the sale of these tax benefits during the three and nine months ended September 30, 2023. March 31, 2024 and the three months ended March 31, 2023, respectively.

(7) Stockholders' Equity

In May 2016, November 2023, the Company filed an automatic shelf registration statement with the SEC to register for sale any combination of the types of securities described in the shelf registration statement, including shares of its common stock. Also in November 2023, the Company issued 8,538,750 shares of its common stock in an underwritten public offering resulting in net proceeds to the Company of $216.2 million, after deducting underwriting fees and offering expenses.

On February 26, 2024, the Company entered into a controlled equity offering sales agreement (the "Cantor ("ATM 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. Also on February 26, 2024, the Company terminated its pre-existing controlled equity offering sale agreement dated May 19, 2016 with Cantor. At September 30, 2023 March 31, 2024, the Company had $50.0 million remaining in aggregate gross offering price available under registered $300.0 million of its common stock to be sold pursuant to the Company's November 2020 prospectus. ATM Agreement, all of which remained unsold as of that date.

In March 2024, the Company issued 9,798,000 shares of its common stock in an underwritten public offering resulting in net proceeds to the Company of $432.3 million, after deducting underwriting fees and offering expenses.

The changes in Stockholders' Equity during the three months ended March 31, 2024 and 2023 are summarized below:

The changes in Stockholders' Equity during the three and nine months ended September 30, 2023 and 2022 are summarized below:

	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	S
	(In thousands, except share amounts)											
Consolidated balance at December 31, 2022	47,200,695	$ 47	$1,580,829	$ 1,260	$(1,255,932)	$ 326,204						
Consolidated balance at December 31, 2023							55,883,377	$ 56	$1,823,168	$ 3,308	$(1,397,361)	$
Shares issued under stock option and employee stock purchase plans	43,986	—	694	—	—	694	229,171	—	3,814	—	—	
Stock-based compensation	—	—	4,340	—	—	4,340						
Unrealized gain on marketable securities	—	—	—	863	—	863						
Net loss	—	—	—	—	(29,361)	(29,361)						
Consolidated balance at March 31, 2023	47,244,681	$ 47	$1,585,863	$ 2,123	$(1,285,293)	$ 302,740						

Shares issued under stock option and employee stock purchase plans	9,132	—	133	—	—	133						
Shares issued in underwritten offering, net							9,798,000	10	432,288	—	—	
Stock-based compensation	—	—	5,217	—	—	5,217	—	—	7,202	—	—	
Unrealized loss on marketable securities	—	—	—	(51)	—	(51)	—	—	—	(1,064)	—	
Net loss	—	—	—	—	(30,502)	(30,502)	—	—	—	—	(32,808)	
Consolidated balance at June 30, 2023	47,253,813	$ 47	$1,591,213	$ 2,072	$(1,315,795)	$ 277,537						
Shares issued under stock option and employee stock purchase plans	10,384	—	257	—	—	257						
Stock-based compensation	—	—	7,121	—	—	7,121						
Unrealized gain on marketable securities	—	—	—	63	—	63						
Net loss	—	—	—	—	(38,260)	(38,260)						
Consolidated balance at September 30, 2023	47,264,197	$ 47	$1,598,591	$ 2,135	$(1,354,055)	$ 246,718						
Consolidated balance at March 31, 2024							65,910,548	$ 66	$ 2,266,472	$ 2,244	$ (1,430,169)	$

	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

(In thousands, except share amounts)

Consolidated balance at December 31, 2022	47,200,695	$ 47	$1,580,829	$ 1,260	$(1,255,932)

Shares issued under stock option and employee stock purchase plans	331,360	—	2,306	—	—	2,306	43,986	—	694	—	—
Stock-based compensation	—	—	4,496	—	—	4,496	—	—	4,340	—	—
Unrealized gain on marketable securities	—	—	—	305	—	305	—	—	—	863	—
Net loss	—	—	—	—	(26,784)	(26,784)	—	—	—	—	(29,361)
Consolidated balance at September 30, 2022	47,096,063	$ 47	$1,574,926	$ (112)	$(1,229,445)	$ 345,416					
Consolidated balance at March 31, 2023							47,244,681	$ 47	$1,585,863	$ 2,123	$(1,285,293)

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(8) Stock-Based Compensation

A summary of stock option activity for the nine three months ended September 30, 2023 March 31, 2024 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In Years)	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In Years)
Options outstanding at December 31, 2022	5,085,662	$ 29.26	7.9			
Options outstanding at December 31, 2023				6,378,924	$ 29.69	7.5
Granted	1,553,275	$ 36.88		5,000	$ 37.08	
Exercised	(50,773)	$ 15.89		(222,619)	$ 16.27	
Canceled	(180,580)	$ 87.57		(2,568)	$ 83.21	
Options outstanding at September 30, 2023	6,407,584	$ 29.57	7.8			
Options vested and expected to vest at September 30, 2023	6,271,198	$ 29.54	7.7			
Options exercisable at September 30, 2023	3,088,826	$ 29.58	6.6			
Options outstanding at March 31, 2024				6,158,737	$ 30.16	7.4
Options vested and expected to vest at March 31, 2024				6,065,176	$ 30.14	7.3
Options exercisable at March 31, 2024				3,284,980	$ 29.45	6.3
Shares available for grant under the 2021 Plan	1,065,273			1,011,071		

The weighted average grant-date fair value of stock options granted during the three and nine months ended September 30, 2023 March 31, 2024 was $25.80 and $28.38, respectively. $28.64.

The aggregate intrinsic value of stock options vested and expected to vest at September 30, 2023 March 31, 2024 was $41.2 million $104.1 million. The aggregate intrinsic value of stock options exercisable at September 30, 2023 March 31, 2024 was $32.6 million $74.3 million. As of September 30, 2023 March 31, 2024, total compensation cost related to non-vested employee, consultant and non-employee director stock options not yet recognized was approximately $67.6 million $55.3 million, net of estimated forfeitures, which is expected to be recognized as expense over a weighted average period of 2.7 2.4 years.

Stock-based compensation expense for the three and nine months ended September 30, 2023 March 31, 2024 and 2022 2023 was recorded as follows:

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	Three Months Ended September 30,		Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2023	2022	2024	2023
	(In thousands)		(In thousands)			
					(In thousands)	
Research and development	$ 3,618	$ 2,342	$ 8,269	$ 5,754	$ 3,693	$ 2,162
General and administrative	3,503	2,154	8,409	5,349	3,509	2,178
Total stock-based compensation expense	$ 7,121	$ 4,496	$ 16,678	$ 11,103	$ 7,202	$ 4,340

The fair values of employee, consultant and non-employee director stock options granted during the three and nine months ended September 30, 2023 March 31, 2024 and 2022 2023 were valued using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2023	2022	2024	2023
Expected stock price volatility	92%	91%	92%	90 – 97%	92%	92%
Expected option term	6.0 Years	6.0 Years	6.0 Years	6.0 Years	6.0 Years	6.0 Years
Risk-free interest rate	4.1%	2.9 – 3.5%	3.5 – 4.1%	1.7 – 3.6%	4.0 – 4.3%	3.7 – 4.0%
Expected dividend yield	None	None	None	None	None	None

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(9) Accumulated Other Comprehensive Income

The changes in accumulated other comprehensive income, which is reported as a component of stockholders' equity, for the nine three months ended September 30, 2023 March 31, 2024 are summarized below:

	Unrealized Loss on Marketable Securities	Foreign Currency Items	Total	Unrealized Gain (Loss) on Marketable Securities	Foreign Currency Items	Total
		(In thousands)				
Balance at December 31, 2022	$ (1,336)	$ 2,596	$ 1,260			
Other comprehensive gain	875	—	875			
Balance at September 30, 2023	$ (461)	$ 2,596	$ 2,135			
				(In thousands)		
Balance at December 31, 2023				$ 712	$ 2,596	$ 3,308
Other comprehensive loss				(1,064)	—	(1,064)
Balance at March 31, 2024				$ (352)	$ 2,596	$ 2,244

No amounts were reclassified out of accumulated other comprehensive income during the nine three months ended September 30, 2023 March 31, 2024.

(10) Revenue

Contract and Grants Revenue

The Company has entered into agreements with Rockefeller University ("Rockefeller") 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 $1.5 million $0.2 million and $2.7 million $1.0 million in revenue under the agreements with Rockefeller during the three and nine months ended September 30, 2023, respectively, March 31, 2024 and $0.0 million and $0.2 million during the three and nine months ended September 30, 2022, 2023, respectively.

Contract Assets and Liabilities

At September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, the Company's right to consideration under all contracts was considered unconditional, and as such, there were no recorded contract assets. At September 30, 2023 March 31, 2024, the Company had $3.3 million $2.9 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, 2022 December 31, 2023, the Company had $0.1 million $3.1 million in contract liabilities recorded. Revenue recognized from contract liabilities as of December 31, 2022 December 31, 2023 during the three and nine months ended September 30, 2023 March 31, 2024 was less than $0.1 million $0.2 million.

(11) Income Taxes

The Company has evaluated the positive and negative evidence bearing upon the realizability of its net deferred tax assets and considered its history of losses, ultimately concluding that it is "more likely than not" that the Company will not recognize the

benefits of federal, state and foreign deferred tax assets and, as such, has maintained a full valuation allowance on its deferred tax assets as of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023.

The net deferred tax liability of $1.6 million at September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023 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.

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(12) Net Loss Per Share

Basic net loss per common share is based upon the weighted-average number of common shares outstanding during the period, excluding restricted stock that has been issued but is not yet vested. Diluted net loss per common share is based upon the weighted-average number of common shares outstanding during the period plus additional weighted-average potentially dilutive common shares outstanding during the period when the effect is dilutive. In periods in which the Company reports a net loss, there is no difference between basic and diluted net loss per share because dilutive shares of common stock are not assumed to have been issued as their effect is anti-dilutive. The potentially dilutive common shares that have not been included in the net loss per common share calculations because the effect would have been anti-dilutive are as follows:

	Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2024	2023
Stock Options	6,407,584	5,189,971	6,158,737	4,967,764
Restricted Stock	—	—	—	—
	6,407,584	5,189,971	6,158,737	4,967,764

(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 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 July 15, 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 were replaced in their entirety with the following payments, each of which is payable only once:

(i) The Company paid $15.0 million upon execution of the Settlement Agreement (the “Initial Payment”).

(ii) The Company shall pay $15.0 million paid $12.5 million upon the Successful Completion (as defined in the Term Sheet) Settlement Agreement) of a Phase 2 Clinical Trial (as defined in the Merger Agreement) of CDX-0159, subject to the $2.5 million contractual credit as set forth in the Merger Agreement. barzolvolimab.

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(iii) The Company shall pay $52.5 million 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 in the Term Sheet) Settlement Agreement).

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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 paid the Initial Payment in cash during in July 2022. The Company paid the three months ended September 30, 2022. Any second milestone for “successful completion” of a Phase 2 Clinical Trial of barzolvolimab in cash in November 2023.

A future milestone payments payment related to the CDX-0159 barzolvolimab 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 A future milestone payment related to the remaining Surviving Company Products are is measured at fair value (refer to Note 3). When and if any of the remaining payments payment described above become becomes due, they it 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.

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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 Quarterly 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 that are still in an early development stage; stages;
- our ability to successfully complete research and further development, including preclinical and clinical studies;
- our anticipated timing for preclinical development, regulatory submissions, commencement and completion of clinical trials and product approvals;
- our ability to negotiate strategic partnerships, where appropriate, for our drug candidates;
- our ability to manage multiple clinical trials for a variety of drug candidates at different stages of development;
- the cost, timing, scope and results of ongoing preclinical and clinical testing;
- our expectations of the attributes of our product and development candidates, including pharmaceutical properties, efficacy, safety and dosing regimens;
- the cost, timing and uncertainty of obtaining regulatory approvals for our drug candidates;
- the availability, cost, delivery and quality of clinical management services provided by our clinical research organization partners;
- the availability, cost, delivery and quality of clinical and commercial-grade materials produced by our own manufacturing facility or supplied by contract manufacturers, suppliers and partners;
- our ability to commercialize our drug candidates and the growth of the markets for those drug candidates;
- our ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors;
- our ability to develop technological capabilities, including identification of novel and clinically important targets, exploiting our existing technology platforms to develop new drug candidates and expand our focus to broader markets for our existing targeted therapeutics;
- the cost of paying development, the regulatory approval and sales-based milestones milestone under the merger agreement by which we acquired Kolltan Pharmaceuticals, Inc. ("Kolltan") and our related settlement agreement with Kolltan;

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- 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, discontinue or delay our commercial manufacturing efforts, discontinue or delay our efforts to expand into additional indications for our drug product candidates, 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;
- the impact of the COVID-19 pandemic on our business or on the economy generally; 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, 2022 December 31, 2023 and other reports that we file with the SEC.

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 exploring the science of mast cell biology and 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 severe inflammatory, allergic, autoimmune and other devastating diseases. Our drug candidates include monoclonal and bispecific antibodies designed to address mast cell mediated diseases and many forms of cancer. for which available treatments are inadequate.

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, which 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 We are currently planning for the first patients had been dosed in initiation of Phase 2 3 studies in chronic spontaneous urticaria (CSU) in summer 2024. In November 2023, we announced that our Phase 2 study in CSU achieved the primary efficacy endpoint (statistically significant mean change from baseline to week 12 of urticaria activity score compared to placebo) and was well tolerated. The study is ongoing and patients will continue to receive barzolvolimab for 52 weeks of treatment; we plan to report topline 52 week data in the second half of 2024. A Phase 2 study in chronic inducible urticaria (CIndU); completion of recently completed enrollment to the Phase 2 CSU study was announced in July 2023 and we anticipate reporting topline expect to report data from this study in late 2023. Data from the Phase 1b study in CSU were reported in February and June 2023. Positive interim data from the Phase 1b study in CIndU were reported in July and September 2021 and in December 2022 in patients with cold urticaria and symptomatic dermographism. Data from the cholinergic cohort included in the CIndU study were presented in June 2023; second half of 2024;
    - Prurigo Nodularis (PN): In December 2021 April 2024, we announced that the first patient had been dosed initiated a Phase 2 study in PN; positive data from a Phase 1b study in PN; enrollment PN was closed in February 2023 and we plan to present data from the study reported in November 2023;
    - Eosinophilic Esophagitis (EoE): A Phase 2 study in EoE was initiated in June 2023 and the first patient was dosed late that month. enrollment is ongoing.

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- Our next generation bispecific antibody platform to support pipeline expansion with additional candidates for inflammatory diseases and oncology. Targets are being selected based on new science as well as their compatibility to be used in bispecific antibody formats with our existing antibody programs. Development is focused on emerging, important pathways controlling inflammatory diseases or immunity to tumors.

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More detail on these programs is provided in the Clinical Development Programs section.

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.

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 total development costs could exceed hundreds of millions of dollars 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.

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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, 2022 December 31, 2023, we incurred an aggregate of $287.2 million $338.8 million in research and development expenses. The following table indicates the amount incurred for each of our significant research programs and for other identified research and development activities during the nine three months ended September 30, 2023 March 31, 2024 and 2022. 2023. The amounts disclosed in the following table reflect direct research and development costs, license fees associated with the underlying technology and an allocation of indirect research and development costs to each program.

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023
	(In thousands)			
				(In thousands)
Barzolvolimab/Anti-KIT Program	$ 59,009	$ 35,519	$ 23,778	$ 17,683
CDX-585	5,499	8,638	888	2,209
Other Programs	23,077	15,202	6,995	6,906
Total R&D Expense	$ 87,585	$ 59,359	$ 31,661	$ 26,798

Clinical Development Programs

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 By targeting KIT, barzolvolimab may be able has been shown to inhibit mast cell activity and decrease mast cell numbers, to which we believe could provide potential clinical benefit in mast cell related diseases.

In certain inflammatory diseases, such as Barzolvolimab was initially studied in 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. We are currently planning Phase 3 studies in CSU which are expected to initiate in summer 2024. Phase 1 studies in CSU and CIndU are complete were successfully completed and Phase 2 studies are ongoing. In July 2023, we announced that enrollment was complete in the ongoing Phase 2 CSU study. In November 2023, we reported that barzolvolimab achieved the primary efficacy endpoint in this study, with a statistically significant mean change from baseline to week 12 of UAS7 (weekly urticaria activity score) compared to placebo and was well tolerated. We plan to report 52 week data from this study in the second half of 2024. In April 2024, we announced that we had completed enrollment in the Phase 2 CIndU study and we expect to report data from this study in the second half of 2024.

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Based on the positive results reported in urticaria, we expanded development of barzolvolimab into additional indications where mast cells are believed to play an important role. We are conducting an ongoing Phase 2 study in eosinophilic esophagitis (EoE) and initiated a Phase 2 study in prurigo nodularis (PN) in April 2024 after reporting positive data from a Phase 1b study in PN in late 2023. We have selected atopic dermatitis as the next indication for the study of barzolvolimab and are currently planning the design of a Phase 2 study in this indication, including in patients who received prior biologics. 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. To this end, we are currently conducting an ongoing Phase 2 study in eosinophilic esophagitis and, after recently completing the Phase 1b study in PN, are planning for the initiation of a Phase 2 subcutaneous study in PN in early 2024. Phase 1 studies of barzolvolimab have been conducted with an intravenous formulation; a subcutaneous formulation has been successfully developed and is being used in Phase 2 studies.

Chronic Spontaneous Urticaria (CSU)

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. CSU It is one of the most frequent dermatologic diseases with a prevalence of 0.5-1.0% of the total population or up to approximately 1 to 3 million patients in the United States (Weller et al. 2010. Hautarzt. 61(8), Bartlett et al. 2018. DermNet. Org) DermNet.Org). Approximately 50% of patients with CSU achieve symptomatic control with antihistamines. Omalizumab, an IgE inhibitor, provides relief for roughly half of the remaining antihistamine refractory patients. Consequently, there is a need for additional therapies.

In October 2020, we announced that enrollment had opened and the first patient had been dosed in We have completed a Phase 1b randomized, double-blind, placebo-controlled multi-center study of barzolvolimab in CSU. This The study is a randomized, double-blind, placebo-controlled clinical trial was 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 included 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 and quality of life assessments. Barzolvolimab is was 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 February 2023 at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting and in June 2023 at the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress, we reported positive data from the CSU study at 12- and 24-weeks, respectively. The study is now complete with 45 patients with moderate to severe CSU refractory to antihistamines were enrolled and treated [35 barzolvolimab (n=9 in 0.5 mg/kg; n=8 in 1.5 mg/kg; n=9 in 3.0 mg/kg; n=9 in 4.5 mg/kg) and 10 placebo]. Activity data for the

At saturating doses (1.5 mg/kg and higher) are outlined below. Two, barzolvolimab resulted in rapid, marked and durable responses in patients did not receive with moderate to severe CSU refractory to antihistamines. The 1.5 mg/kg, 3.0 mg/kg and 4.5 mg/kg dose groups showed similar markedly improved urticaria symptoms, including rapid onset of responses (as early as 1 week after the first dose) and prolonged disease control with sustained durability up to 24 weeks. Patients with prior omalizumab therapy also had similar symptom improvement as all doses of study treatment [4.5 mg/kg (1), placebo (1)]. patients.

- Barzolvolimab resulted in rapid, marked and durable responses in patients with moderate to severe CSU refractory to antihistamines. Patients with prior omalizumab therapy also had similar symptom improvement as all patients. The 1.5 mg/kg, 3.0 mg/kg and 4.5 mg/kg dose groups showed similar markedly improved urticaria symptoms, including rapid onset of responses (as early as 1 week after the first dose) and prolonged disease control with sustained durability up to 24 weeks.

- Mean reduction from baseline in weekly urticaria activity score (UAS7) at week 12 was 67% in the 1.5 mg/kg dose group (n=8), 67% in the 3.0 mg/kg dose group (n=9) and 82% in the 4.5 mg/kg dose group (n=9). Mean reduction from baseline in urticaria activity (UAS7) UAS7 at week 24 was 80% in the 1.5 mg/kg dose group (n=7), 70% in the 3.0 mg/kg dose group (n=6) and 77% in the 4.5 mg/kg dose group (n=7).

- Complete response (UAS7=0) at week 12 was 57% in the 1.5 mg/kg dose group, 44% in the 3.0 mg/kg dose group and 67% in the 4.5 mg/kg dose group. Complete response (UAS7=0) at week 24 was 57% in the 1.5 mg/kg dose group, 67% in the 3.0 mg/kg dose group and 43% in the 4.5 mg/kg dose group.

- Well-controlled disease (UCT≥ 12) at week 12 was 75% in the 1.5 mg/kg dose group, 63% in the 3.0 mg/kg dose group and 89% in the 4.5 mg/kg dose group. Well-controlled disease (UCT≥ 12) at week 24 was 75% in the 1.5 mg/kg dose group, 67% in the 3.0 mg/kg dose group and 67% in the 4.5 mg/kg dose group.

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- During post-treatment follow up, 71% (10 of 14) of patients who had been treated with doses greater than or equal to 1.5 mg/kg and had a complete response (UAS7=0) at week 12, remained urticaria free at week 24 (patients received last dose of barzolvolimab at week 8).

- Profound and durable improvement in angioedema symptoms as measured through the weekly angioedema activity score over 7 days (AAS7) was achieved across all dose levels evaluated with sustained activity observed with the 1.5 mg/kg and greater dose levels.

o - 31 patients on study (n=26 barzolvolimab; 5=placebo) Patients also reported angioedema activity at baseline when enrolling improvements in quality of life outcomes as assessed by the study. 86% Dermatology Life Quality Index (DLQI) which surveys patients' perceptions of the barzolvolimab treated patients at 1.5 mg/kg or greater were angioedema free at week 12 symptoms and 83% were angioedema free at week 24. feelings, daily activities, leisure, work and school performance, personal relationships and treatment.

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- 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. tolerated. Most AEs were mild or moderate in severity and resolved while on study. The most common treatment emergent adverse events were hair color changes, COVID-19, headache, neutropenia and urinary tract infections (UTIs). UTIs and COVID-19 were reported as unrelated to treatment. There was one serious adverse event of salmonella gastroenteritis which was also not related to study therapy. Changes Generally transient, asymptomatic and mild changes in hematologic parameters were observed, consistent with observations in single dose studies, with no from prior studies. No pattern of further decreases decrease was observed with multiple doses; hematologic values generally remained within the normal range and returned to baseline levels during the follow up period. Five patients had decreases in neutrophil counts reported as AEs. The pattern observed in the neutrophil changes for these patients was similar to the pattern seen in patients across the barzolvolimab program to date— generally transient, asymptomatic, and mild and typically occurring in patients with screening and baseline neutrophil counts at the lower end of the normal range on study initiation. dose administration.

In October 2023, we presented data on quality of life outcomes Data from this study at were reported across multiple medical meetings, including the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting in February 2023, the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress in June 2023 and the European Academy of Dermatology & Venereology (EADV) Congress as assessed by the Dermatology Life Quality Index (DLQI). The DLQI survey assesses patients' perceptions of the impact of their disease across different aspects of their health-related quality of life and includes questions on symptoms and feelings, daily activities, leisure, work and school performance, personal relationships and treatment. A rapid improvement in the DLQI was noted within 4 weeks in all barzolvolimab treated patients. DLQI improvement was sustained at doses ≥1.5 mg/kg. Physician

Global Assessment (PhysGA) for the treated cohorts also improved by week 1 and was sustained through Week 24. DLQI and PhysGA trended closely with the dose-dependent improvement in UAS7 and UCT, tryptase suppression, and increases in SCF. October 2023.

In June 2022, we announced that the first patient had been dosed initiated dosing in a Phase 2 study in patients with CSU who remained symptomatic despite antihistamine therapy; in July 2023, we announced that enrollment had been completed to the study. was complete. The study is being conducted at approximately 75 sites across 9 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. 208 patients have been 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 After 16 weeks, patients then enter a 36-week active treatment phase, period, in which patients not already receiving placebo or the 75 mg dose are randomized to receive 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; weeks; patients already randomized to these the 150 mg and 300 mg treatment arms will remain on the same regimen as during the placebo-controlled treatment phase. Following the treatment period, period. After 52 weeks, patients will then enter a 24-week follow up phase. follow-up period for an additional 24 weeks. The primary endpoint of the study is mean change in baseline to week 12 in UAS7 (Urticaria Activity Score over 7 days) (weekly urticaria activity score). Secondary endpoints include safety and other assessments of clinical activity including ISS7 (Itch Severity Score over 7 days) (weekly itch severity score), HSS7 (Hive Severity Score over 7 days) (weekly hive severity score) and AAS7 (Angioedema Activity Score over 7 days) (weekly angioedema activity score). We plan to report topline

Topline data from this study late this year. were presented in November of 2023 and 12 week treatment results were presented at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting in February 2024. Data from the 208 patients randomized in the study showed that barzolvolimab achieved the primary efficacy endpoint, with a statistically significant mean change from baseline to week 12 in UAS7 compared to placebo at all dose levels. Secondary and exploratory endpoints in the study were also achieved at week 12 and strongly support the primary endpoint results, including changes in ISS7 and HSS7 and responder analyses. Importantly, barzolvolimab demonstrated rapid, durable and clinically meaningful responses in patients with moderate to severe CSU refractory to antihistamines, including patients with prior omalizumab treatment. Demographics and baseline disease characteristics were well balanced across treatment groups. The majority of patients on study had severe disease (UAS7≥28).

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Summary of Clinical Activity Assessments at Week 12				
	300 mg Q8W (n=51)	150 mg Q4W (n=52)	75 mg Q4W (n=53)	Placebo (n=51)
UAS7 Changes				
Baseline UAS7 (mean)	31.33	30.75	30.30	30.09
LS Mean change at Week 12	-23.87	-23.02	-17.06	-10.47
LS Mean difference from placebo (Confidence Interval, p value)	-13.41 (CI: -17.47, -9.34) **p<0.0001**	-12.55 (CI:-16.56, -8.55) **p<0.0001**	-6.60 (CI:-10.71, -2.49) p=0.0017	
HSS7 Changes				
Baseline HSS7 (mean)	14.92	15.05	14.86	14.47
LS Mean change at Week 12	-12.19	-11.19	-8.25	-4.95
LS Mean difference from placebo (Confidence Interval, p value)	-7.24 (CI:-9.36, -5.12) **p<0.0001**	-6.24 (CI:-8.33, -4.16), **p<0.0001**	-3.31 (CI:-5.40, -1.22), p=0.0020	
ISS7 Changes				
Baseline ISS7 (mean)	16.42	15.70	15.44	15.61
LS Mean change at Week 12	-11.79	-11.68	-8.62	-5.47
LS Mean difference from placebo (Confidence Interval, p value)	-6.32 (CI: -8.50, -4.13), **p<0.0001**	-6.21 (CI: -8.38, -4.04), **p<0.0001**	-3.16 (CI: -5.41, -0.91), p=0.0061	
Responder Analyses/Clinical Responses				
UAS7=0 (Complete Control)	37.5%	51.1%	22.9%	6.4%

UAS7≤6 (Well-controlled)	62.5%	59.6%	41.7%	12.8%

UAS7, HSS7 and ISS7 data were analyzed using ANCOVA model and multiple imputation.

Barzolvolimab demonstrated strong improvement in UAS7 independent of omalizumab status at Week 12. Approximately 20% (n=41) of enrolled patients received prior treatment with omalizumab and more than half of these patients had omalizumab-refractory disease. These patients experienced a similar clinical benefit as the overall treated population within their individual dosing groups consistent with the barzolvolimab mechanism of action.

Barzolvolimab was well tolerated with a favorable safety profile. Most adverse events were mild to moderate in severity; through 12 weeks, the most common treatment emergent adverse events in barzolvolimab treated patients were urticaria/CSU (10%), hair color changes (9%), and neutropenia/ANC decrease (8%). The rate of infections was similar between barzolvolimab treated patients and placebo with no association between neutropenia and infections.

Patients on study will continue to receive barzolvolimab for 52 weeks and we plan to report 52 week data in the second half of 2024. We believe these results strongly support the further development of barzolvolimab in CSU and are currently planning two Phase 3 studies of barzolvolimab which we plan to initiate in summer 2024.

Chronic Inducible Urticaria (CIndU)

CIndUs are forms of urticaria that have an attributable cause or trigger associated with them, typically resulting in hives or wheals. The prevalence of CIndU is estimated at 0.5% of the total population and is reported to overlap in up to 36% of CSU patients (Weller et al. 2010. Hautarzt. 61(8), Bartlett et al. 2018. DermNet.Org). There are currently no approved therapies for chronic

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inducible urticarias other than antihistamines and patients attempt to manage symptoms associated with their disease through avoidance of triggers. We are currently exploring cold-induced and dermographism (scratch-induced) and cholinergic (exercise-induced) urticarias. urticarias in an ongoing Phase 2 study.

In December 2020, we announced that enrollment had opened and the first patient had been dosed in 20

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We completed 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 in patients with CIndU refractory to antihistamines, conducted in Germany. This study was designed to evaluate the safety of a single intravenous dose (3 mg/kg) of barzolvolimab in patients with cold urticaria (ColdU) or symptomatic dermographism (SD). In March and June 2021, respectively, we added The study was expanded to include a third cohort (single dose, 3 mg/kg) in patients with cholinergic urticaria (“CholU”) and a fourth cohort at a lower dose (single dose, 1.5 mg/kg) in ColdU. Patient’s symptoms are were induced via provocation testing that resembles real life triggering situations. Secondary and exploratory objectives include included 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

Generally patients on Day 1 as add on treatment to H1-antihistamines.

In November 2022, data from study had high disease activity at baseline that was poorly controlled and marked impairment in quality of life. At 3 mg/kg in the ColdU and SD cohorts, treated with a single intravenous infusion of barzolvolimab at 3 mg/kg were published in *Allergy* (Terhorst-Molawi et al Allergy. 2022 Nov 16. doi: 10.1111/all.15585). Safety safety results were reported for 21 patients; patients and activity results were reported for the 20 patients who received a full dose of barzolvolimab. Patients had high disease activity. At baseline, patients’ mean scores (range) 1.5 mg/kg in the ColdU cohort, safety results were reported for Dermatology Life Quality Index (DLQI) [10.8 (2–21)] 10 patients and Urticaria Control Test (UCT) [6.0 (0–13)] indicated marked

impairment activity results were reported for the 9 patients who received a full dose of quality barzolvolimab. At 3 mg/kg in the cholinergic cohort, safety results were reported for 21 patients and activity results were reported for the 20 patients who received a full dose of life (QoL) barzolvolimab.

Rapid (as early as 1 week) and poorly controlled disease, respectively. Three durable responses were observed in patients (1 with ColdU and 2 with SD) were previously treated with omalizumab and chose to discontinue that treatment because they remained symptomatic. At baseline, as assessed by provocation thresholds, on average (range), were 18.9°C or 66°F (5–27°C or 41–80.6°F) for patients with ColdU and 3.5 (2–4) pins for patients with SD. testing.

- Rapid (as early as 1 week) and durable responses were observed in all patients as assessed by provocation testing. A complete response was achieved in 95% (n=19/20) of patients with ColdU and SD treated with a single dose at 3 mg/kg (n=10/10 ColdU; n=9/10 SD). , including 3 patients who experienced insufficient response to prior omalizumab treatment. The median duration (range) of complete response through the 12-week observation period was 77+ days (29–86; n=10) for patients with ColdU and 57+ days (16–70; n=9) for patients with SD. All three patients who experienced insufficient response to omalizumab treatment had a complete response after treatment with barzolvolimab.

- Following a single dose of barzolvolimab rapid improvements in urticaria control was observed. A UCT score of ≥12 (well controlled) was achieved by 80% (n=16/20) of the patients within week 4 post-treatment. By week 8, all patients (100%; n=20/20) achieved well-controlled urticaria, which was sustained to week 12 post-dose by 80% (n=16/20) of patients. Complete urticaria control (UCT=16) was achieved by 35% (n=7/20), 65% (n=13/20), and 40% (n=8/20) at weeks 4, 8, and 12, respectively.

- At baseline, patients in both treatment groups reported disease impact on their QoL. Disease impact significantly decreased after dosing; a score of 0–1 (minimal/none) A complete response was achieved by 80% in 100% (n=16/20) for 9 of 9) patients with ColdU treated with a single dose at 1.5 mg/kg, including 4 patients with disease refractory to omalizumab. The median duration of complete response through the 12-week observation period was 51+ days (7+ weeks). Following barzolvolimab administration, all patients who completed the DLQI during the study. Additionally, clinically meaningful improvements in QoL were attained and sustained to week 12. achieved well controlled disease (UCT>12) with 7 of 9 achieving complete control (UCT=16).

- A complete response was achieved in 56% (n=5 of 9) patients with cholinergic urticaria treated with a single dose at 3 mg/kg. Most responses remained durable through to week 12. 63% (5/8) patients reported well controlled disease (UCT ≥12) at week 8 and 50% (4/8) at week 12, respectively.

- Patients also reported improvements in quality of life outcomes as assessed by the Dermatology Life Quality Index (DLQI) which surveys patients' perceptions of symptoms and feelings, daily activities, leisure, work and school performance, personal relationships and treatment.

- A single dose of barzolvolimab led to marked decreases in tryptase and in skin mast cells. The kinetics correlated with improvements in provocation testing and clinical activity, consistent with a central role for mast cells in the pathogenesis of ColdU and SD. 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 well tolerated. Most tolerated across all cohorts. In the 3 mg/kg ColdU and SD cohorts, most adverse events were mild, and the most common (≥3 patients) were hair color changes (76%; n=16/21), infusion reactions (43%; n=9/21), taste changes (38%; n=8/21), nasopharyngitis (24%; n=5/21), malaise (24%; n=5/21), and headache (19%; n=4/21). Hair color changes (generally small areas of hair color lightening) and taste disorders (generally partial changes of ability to taste salt or umami) are consistent with inhibiting KIT signaling in other cell types and completely resolved over time during follow-up. Infusion reactions, which manifested as localized hives and itching as well as erythema and feeling hot, resolved spontaneously. One patient with a history of fainting experienced loss of consciousness during infusion. The patient rapidly recovered. Importantly, no evidence of mast cell activation as measured by serum tryptase monitoring was observed in this patient. Overall, Barzolvolimab was also generally well tolerated by patients in the 1.5 mg/kg ColdU cohort and the 3.0 mg/kg cholinergic cohort with a similar safety profile to that reported previously. Across the Phase 1b inducible urticaria study, mean hematology parameters generally remained within the normal ranges—an important finding for a

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KIT inhibitor. Mild, transient, and asymptomatic decreases in hemoglobin and white blood cell parameters occurred for some patients.

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In December 2022, we presented long term follow up data from the 3.0 mg/kg cohorts in cold urticaria and symptomatic dermographism at the GA²LEN Global Urticaria Forum (GUF) 2022. 14 patients consented to the optional long term follow up evaluation (6 cold, 8 symptomatic dermographism); 10 of the 14 still had complete control of their disease as assessed by provocation testing at week 12. Data were collected at one or more timepoints beyond week 12 through week 36.

- Long term follow up data was collected from the 3.0 mg/kg cohorts in cold urticaria and symptomatic dermographism. 14 patients consented to the optional evaluation (6 cold, 8 symptomatic dermographism); 10 of the 14 still had complete control of their disease as assessed by provocation testing at week 12. Data were collected at one or more timepoints beyond week 12 through week 36. Most patients had return of symptoms and/or loss of urticaria control between 12 and 36 weeks. Remarkably, two patients remained provocation negative at 36 weeks, and four had well controlled disease (UCT ≥12) 36 weeks post dosing.
- Serum tryptase exhibits a similar rate of recovery as clinical symptoms, while skin mast cells return at a slower rate. Tissue KIT signaling, as approximated by SCF levels, was rapidly inhibited after dose administration and fully reactivated approximately 18 weeks after dosing.
- Tryptase levels return to pretreatment levels during follow up, while mast cells continue to recover. Drug related adverse events noted during the study all resolved.

In December 2022, we also presented 12 week treatment results for the 1.5 mg/kg cohort Data from this study were reported in cold urticaria at Allergy (Nov 2022) and across multiple medical meetings, including the GA²LEN Global Urticaria Forum (GUF) 2022. 10 patients received a single intravenous infusion in December and the European Academy of barzolvolimab at 1.5 mg/kg. Patients had high disease activity as assessed by provocation threshold testing with a mean baseline critical temperature threshold of 18.4°C or 65°F with a range from 6 to 27°C or 43 to 81°F. All patients had disease refractory to antihistamines Allergy and five patients had disease refractory to omalizumab. Safety results were reported for all 10 patients; activity results were reported for the 9 patients who received a full dose of barzolvolimab, including four patients with omalizumab refractory disease.

- All 9 of 9 (100%) patients evaluable for activity treated at 1.5 mg/kg experienced a complete response as assessed by provocation threshold testing, including 4 patients with disease refractory to omalizumab. Rapid onset of responses after dosing and sustained durability were observed in the 1.5 mg/kg cohort. 6 of 9 patients treated achieved a complete response within a week of dosing. The median duration of response was 51+ days (7+ weeks).
- Improvements in disease activity as reported by Urticaria Control Test (UCT) were consistent with the complete responses as measured by provocation testing. All patients entered the study with poorly controlled disease (mean UCT score at baseline of 5.9 and a range of 1-11). Following barzolvolimab administration, all patients achieved well controlled disease (UCT>12) with 7 of 9 achieving complete control (UCT=16).
- A single 1.5 mg/kg dose of barzolvolimab resulted in rapid, marked and durable suppression of serum tryptase; the kinetics of tryptase depletion mirrored changes in provocation threshold and UCT. Barzolvolimab was generally well tolerated and the safety profile at 1.5mg/kg was similar to the profile observed with 3.0 mg/kg.
- No new treatment emergent AEs of concern were noted. While mild, transient and asymptomatic decreases in hemoglobin and white blood cell (WBC) parameters were noted, consistent with prior studies, the hematology parameters generally remained within the normal range.

To date, 19 of 19 (100%) patients with cold urticaria treated with either a single dose of barzolvolimab at 1.5 or 3.0 mg/kg in this Phase 1b study have experienced a complete response by provocation testing, including 5 patients with omalizumab refractory disease.

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Data from the cholinergic cohort in the Phase 1b CIndU study were presented Clinical Immunology (EAACI) Annual Congress in June at the EAACI Hybrid Congress 2023. In this open-label, Phase 1 trial, a cohort of patients with antihistamine refractory cholinergic urticaria (n=9) received a single intravenous 3.0 mg/kg barzolvolimab dose with a 12-week follow-up. Assessments included provocation testing using pulse-controlled ergometry (PCE; complete response, CR=no whealing within 40 minutes of test initiation), urticaria control test (UCT), quality of life assessments, and measurement of circulating tryptase and stem cell factor and skin mast cell numbers. Safety assessments included adverse events and clinical laboratory monitoring. Data reported at EAACI included treatment and safety data through 12 weeks.

- 56% (5/9) patients achieved a complete response (negative test) with PCE provocation testing with just one dose of barzolvolimab and most responses remained durable through to week 12. PCE testing included controlled exercise on a stationary bicycle with monitoring for development of itch and wheals.

- 63% (5/8) patients reported well controlled disease (UCT ≥12) at week 8 and 50% (4/8) at week 12, respectively.

- 100% (6/6) patients who reported on quality of life (QoL) measurements at week 8 had clinically significant improvements in QoL. These improvements in QoL were sustained through week 12 for the majority (5/7, 71%) of patients.

- The kinetics of tryptase and mast cell reduction mirrored clinical activity.

- Barzolvolimab was generally well tolerated in patients with CholU, with a similar safety profile to that reported previously. The most common AEs were mainly mild; hair color changes (78%), nasopharyngitis (67%), taste disorders (44%), and infusion related reactions (33%). Hematology parameters were consistent with previous observation and generally remained within the normal ranges. Mild, transient, and asymptomatic decreases in hemoglobin and white blood cell parameters were noted.

2022.

In July 2022, we announced that the first patient has had been dosed in a Phase 2 study in patients with CIndU who remain symptomatic despite antihistamine therapy. therapy; in April 2024, we announced that enrollment was complete. The study is being conducted at approximately 85 sites across approximately 12 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 180 196 patients in 2 cohorts (differentiated by CIndU subtype) including 90 97 patients with cold urticaria and 90 99 patients with symptomatic dermographism will be were 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. In addition, the study includes the option for patients who have symptoms following the treatment phase, including patients who were on placebo, to enroll in an open label extension where all patients receive 300 mg of barzolvolimab every 8 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).

Data from this study are expected in the second half of 2024.

Prurigo Nodularis (PN)

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 is currently only one FDA approved therapy 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

We have completed a Phase 1b multi-center, randomized, double-blind, placebo-controlled intravenous study designed to assess the safety and treatment effects across multiple dosing cohorts of barzolvolimab in up to 30 patients with PN. Enrolling an intravenous, early stage study in the dermatology setting was challenging and the study took longer than expected to complete. In February 2023, we closed enrollment at 24 patients, which we believed would provide sufficient data for analysis to inform future development decisions in PN. Data from the study, including 24 weeks of follow-up, have been accepted for presentation were presented at the 12th World Congress on Itch (WCI) being held in early November 2023. We are currently planning 24 adults (evaluable: n=23 safety; n=22 efficacy) with moderate to severe PN were randomized across three arms: (1) barzolvolimab 3.0 mg/kg (n=9), barzolvolimab 1.5 mg/kg (n=7) and placebo (n=8). The primary endpoint of the study was safety; key secondary endpoints include changes from baseline in Worst Itch-Numerical Rating Scale (WI-NRS) & Investigator Global Assessment (IGA). The primary timepoint for the initiation evaluation of a Phase 2 subcutaneous clinical activity was 8 weeks; patients were followed for safety and efficacy endpoints to 24 weeks. Patients on study generally had moderate to severe disease with mean baselines scores across all arms of 8.6 for WI-NRS and 3.3 for IGA.

A single IV dose of 3.0 mg/kg barzolvolimab resulted in rapid and durable reductions in itch and healing of skin lesions in patients with moderate to severe PN in early 2024. and that barzolvolimab was generally well tolerated.

- At week 8, the percentage of patients with ≥4-point decrease in WI-NRS was 57% and 43% for the single dose 3.0 or 1.5 mg/kg barzolvolimab arms, respectively, and 25% for the placebo arm; this level of response generally persisted out to

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week 16. In the 3.0 mg/kg arm, a ≥4-point decrease in WI-NRS reduction was seen as early as the first week and reached a high of 71% of patients at week six which was distinct from both the 1.5 mg/kg barzolvolimab and placebo arms.

% of Subjects with ≥4-point decrease in WI-NRS							
Dose	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
1.5 mg/kg	0	14	29	14	29	29	29	43
3.0 mg/kg	**14**	**29**	**29**	**29**	**57**	**71**	**57**	**57**
placebo	0	0	13	13	25	38	38	25

- At week 8, 29% of patients achieved clear or almost clear skin according to IGA following a single dose of barzolvolimab 3.0 mg/kg. This effect was noted as early as week 2 (the first clinic visit) and was maintained out to week 12/16. No patients treated at 1.5 mg/kg barzolvolimab or placebo achieved clear or almost clear skin according to IGA through week 8. 2 additional patients in the 1.5 mg/kg arm, 2 additional patients in the 3.0 mg/kg arm and 1 patient on placebo had IGA 0/1 at timepoints between weeks 8 and 24.

% of Subjects with IGA 0/1				
Dose	Baseline	Week 2	Week 4	Week 8
1.5 mg/kg	0	0	0	0
3.0 mg/kg	**0**	**14**	**14**	**29**
Placebo	0	0	0	0

- Clinical activity was associated with profound serum tryptase reduction. At the 3.0 mg/kg dose, tryptase was profoundly reduced to, or below, the level of quantification and this level of reduction was maintained at least through 8 weeks. Tryptase reduction was observed in the 1.5 mg/kg arm but to a lesser extent.

- Adverse Events were generally mild to moderate in intensity and considered unrelated to treatment. During the initial 8 week observation period in the 3.0 mg/kg dosing arm, an anaphylactic reaction occurred in a complicated patient with multiple comorbidities; the event fully resolved without sequelae. Generally, AEs seen during the 24-week follow-up period were consistent with comorbidities commonly observed in the PN population.

In April 2024 we initiated a Phase 2 subcutaneous study in PN. This randomized, double-blind, placebo-controlled, parallel group study is evaluating the efficacy and safety profile of 2 dose levels of barzolvolimab compared to placebo in approximately 120 patients with moderate to severe PN who had inadequate response to prescription topical medications, or for whom topical medications are medically inadvisable (such as concerns for safety). Patients are randomly assigned on a 1:1:1 ratio to receive barzolvolimab injections of 150 mg Q4W after an initial loading dose of 450 mg, 300 mg Q4W after an initial loading dose of 450 mg, or placebo during a 24-week Treatment Phase. Participants then enter a follow-up phase with no study treatment for an additional 16 weeks through week 40. The primary objective of this study is to evaluate the clinical effect of barzolvolimab, compared to placebo, on itch response as measured by the proportion of participants with ≥ 4-point improvement in the worst intensity itch per a numeric rating scale (WI-NRS). Secondary objectives include but are not limited to additional measures of itch response from baseline compared to different timepoints, the assessment of skin lesions as measured by the Investigator Global Assessment (IGA), QoL outcomes and safety. The study will include approximately 50 clinical trial centers worldwide, including the United States.

Eosinophilic Esophagitis (EoE)

In July of 2023, we announced that the first patient had been dosed in a Phase 2 study of eosinophilic esophagitis (EoE). EoE, the most common type of eosinophilic gastrointestinal disease, 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 is only one FDA approved therapy for EoE, representing an area of significant unmet need. 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.

The randomized, double-blind, placebo-controlled, parallel group Phase 2 study is evaluating the efficacy and safety profile of subcutaneous barzolvolimab in patients with active EoE. To optimize potential efficacy signal in this difficult to treat indication, we have recently amended the protocol to dose 300 mg every 4 weeks rather than 8 weeks. Approximately 60 75 patients will be enrolled in total. In the revised protocol, patients will be randomly assigned on a 1:1 ratio to receive subcutaneous injections of barzolvolimab at 300 mg every 8 4 weeks or placebo during a 16-week placebo-controlled treatment phase. Patients then enter a 12-week active treatment phase, in which all patients will receive barzolvolimab 300 mg every 8 4 weeks. Patients then enter a follow-up phase for an additional 16 weeks. The primary endpoint of the study is reducing esophageal intraepithelial infiltration of mast cells as assessed by peak esophageal intraepithelial mast cell count. Secondary endpoints include the reduction of symptoms of dysphagia and esophageal intraepithelial infiltration of eosinophils and safety. When all clinical trial sites are open, the The study will include includes approximately 60 clinical trial centers across 8 countries, including the United States. Enrollment is ongoing.

Additional Barzolvolimab Development Activities

Manufacturing activities to support In 2023, we completed the introduction transfer of the barzolvolimab subcutaneous formulation into the clinical program have been completed and, in February 2022, we reported that subcutaneous administration of barzolvolimab administered to healthy volunteers 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 and CSU intravenous studies. The Phase 2 multi-dose studies in urticaria are designed to evaluate 75 mg and 150 mg administered every 4 weeks and 300 mg 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 transferred our current barzolvolimab manufacturing process to a contract CMO and successfully scaled up the drug substance manufacturing organization process to produce larger cGMP batches in support of late-stage trials and to prepare for potential commercialization. Drug product manufacturing into 1 mL pre-filled syringes has been completed in support of Phase 3 trials. We are in the process of scaling up our drug product manufacturing. We believe that barzolvolimab can be scaled up to permit drug product manufacturing in commercial quantities.

In February 2022, we reported interim data after completing the in-life dosing portion of our six-month chronic toxicology study in non-human primates. The only clinically adverse finding at the completion of dosing was a profound impact on spermatogenesis, an expected and well understood effect of KIT inhibition. As a standard part of toxicology studies, some animals from each group continued to be observed through a recovery period to understand the reversibility of any adverse findings. Due to the very high concentrations of barzolvolimab at the end of dosing, the recovery period was approximately one year. As we expected, and consistent with previous findings with KIT blocking antibodies, we were pleased to report in December 2022, that during this recovery period spermatogenesis fully recovered in all male animals as measured by both sperm count and motility. The final histologic analysis and study report were completed in early 2023 and were consistent with previously reported results. We are encouraged with these findings and believe these data strongly support our Phase 2 studies in urticaria and in future indications. continued development of barzolvolimab.

Bispecific Platform

Our next generation bispecific antibody platform is supporting the expansion of our pipeline with additional candidates for inflammatory diseases and oncology. Targets are being selected based on new science as well as their compatibility to be used in bispecific antibody formats with our existing antibody programs. Development is focused on emerging, important pathways controlling inflammatory diseases or immunity to tumors.

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CDX-585

CDX-585 combines our proprietary highly active PD-1 blockade and anti-ILT4 blockade to overcome immunosuppressive signals in T cells and myeloid cells, respectively. ILT4 is emerging as an important immune checkpoint on myeloid cells and is thought to contribute to resistance to PD-1 blockade. Interactions of PD-1 and ILT4 with their ligands are known to deliver immune suppressive signals that can attenuate anti-tumor immune responses. The concept behind CDX-585 is to simultaneously inhibit both T cell and myeloid suppressive signals to potentiate the anti-tumor activity of both cell types, and potentially overcome PD-1 resistance. In preclinical studies, CDX-585 was demonstrated to be a potent inhibitor of PD-1 signaling in comparison to the approved PD-1 antibody, nivolumab. In addition, CDX-585 activated and promoted a strong inflammatory phenotype in human macrophage and dendritic cell cultures. Together these activities of CDX-585 enhanced the response in a mixed lymphocyte reaction assay above that observed for either parental mAb or

the combination of the PD-1 and ILT4 mAbs. The *in vivo* efficacy of CDX-585 was also demonstrated in a melanoma humanized mouse model. CDX-585 has successfully completed GMP manufacturing and IND-enabling studies to support clinical development. CDX-585 will initially be developed for the treatment of solid tumors either as monotherapy or in combination with other oncologic treatments.

In late May 2023, we announced that the first patient had been dosed in the Phase 1 study of CDX-585. This open-label, multi-center, intravenous study of CDX-585 is being evaluated in patients with advanced or metastatic solid tumors that have progressed during or after standard of care therapy. The dose-escalation phase of the study (n=~30 patients) is designed to determine a maximum tolerated dose (MTD) and to select CDX-585 dose(s) for future evaluation in tumor specific expansion cohorts. In the first

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phase, increasing doses of CDX-585 will be administered intravenously (0.03 mg/kg up to 10.0 mg/kg) every 2 weeks until confirmed disease progression, intolerance, or for a maximum of 2 years. In the second phase, potential expansion cohorts will evaluate the safety, tolerability and biologic effects, including anti-tumor activity, of selected dose level(s) of CDX-585 in specific tumor types. Enrollment is ongoing.

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, 2022 December 31, 2023 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 September 30, 2023 March 31, 2024 Compared with Three Months Ended September 30, 2022 March 31, 2023

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)	Three Months Ended March 31,		Increase/ (Decrease)	Increase/ (Decrease)
	2023	2022	$	%	2024	2023	$	%
	(In thousands)				(In thousands)			
Revenues:								
Product development and licensing agreements	$ 2	$ —	$ 2	n/a	$ 2	$ —	$ 2	n/a
Contracts and grants	1,515	407	1,108	272 %	154	967	(813)	(84)%
Total revenues	$ 1,517	$ 407	$ 1,110	273 %	$ 156	$ 967	$ (811)	(84)%
Operating expenses:								
Research and development	34,535	21,572	12,963	60 %	31,661	26,798	4,863	18 %

General and administrative	8,221	6,531	1,690	26 %	9,103	6,640	2,463	37 %
Total operating expenses	42,756	28,103	14,653	52 %	40,764	33,438	7,326	22 %
Operating loss	(41,239)	(27,696)	13,543	49 %	(40,608)	(32,471)	8,137	25 %
Investment and other income, net	2,979	912	2,067	227 %	7,800	3,110	4,690	151 %
Net loss	$ (38,260)	$ (26,784)	$ 11,476	43 %	$(32,808)	$(29,361)	$ 3,447	12 %

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Net Loss

The $11.5 million $3.4 million increase in net loss for the three months ended September 30, 2023 March 31, 2024, as compared to the three months ended September 30, 2022 March 31, 2023, was primarily due to an increase increases in research and development expense, and general and administrative expenses, partially offset by an increase in investment and other income, net.

Revenue

Revenue from product development and licensing agreements for the three months ended September 30, 2023 March 31, 2024 was relatively consistent with the three months ended September 30, 2022 March 31, 2023. The $1.1 million increase $0.8 million decrease in contracts and grants revenue for the three months ended September 30, 2023 March 31, 2024, as compared to the three months ended September 30, 2022 March 31, 2023, was primarily due to an increase a decrease in revenue from our contract manufacturing and research and development agreements with Rockefeller University. We expect revenue to increase over the next twelve months primarily due to an increase in services expected to be performed under our contract manufacturing and research and development agreements 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:

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	Three Months Ended September 30,		Increase/ (Decrease)		Three Months Ended March 31,		Increase/ (Decrease)	
	2023	2022	$	%	2024	2023	$	%
	(In thousands)							

					(In thousands)			
Personnel	$ 10,532	$ 8,610	$ 1,922	22 %	$11,440	$ 9,024	$2,416	27 %
Laboratory supplies	1,249	1,075	174	16 %	1,308	1,408	(100)	(7)%
Facility	1,282	1,088	194	18 %	1,286	1,209	77	6 %
Product development	19,457	9,271	10,186	110 %	15,525	13,295	2,230	17 %

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The $1.9 million $2.4 million increase in personnel expenses for the three months ended September 30, 2023 March 31, 2024, as compared to the three months ended September 30, 2022 March 31, 2023, 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 $0.2 million increase in laboratory Laboratory supply expenses for the three months ended September 30, 2023, as compared to March 31, 2024 were relatively consistent with the three months ended September 30, 2022, was primarily due to higher laboratory materials and supplies purchases. March 31, 2023. We expect laboratory supplies expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Facility expenses include depreciation, amortization, utilities, rent, maintenance and other related expenses incurred at our facilities. The $0.2 million increase in facility Facility expenses for the three months ended September 30, 2023, as compared to March 31, 2024 were relatively consistent with the three months ended September 30, 2022, was primarily due to higher repairs and depreciation expense. March 31, 2023. 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 $10.2 million $2.2 million increase in product development expenses for the three months ended September 30, 2023 March 31, 2024, as compared to the three months ended September 30, 2022 March 31, 2023, was primarily due to an increase in barzolvolimab clinical trial and expenses, partially offset by a decrease in barzolvolimab contract manufacturing expenses. We expect product development expenses to increase over the next twelve months as a result of the expanded development of barzolvolimab, although there may be fluctuations on a quarterly basis.

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General and Administrative Expense

The $1.7 million $2.5 million increase in general and administrative expenses for the three months ended September 30, 2023 March 31, 2024, as compared to the three months ended September 30, 2022 March 31, 2023, was primarily due to higher stock-based compensation and recruiting barzolvolimab commercial planning expenses. We expect general and administrative expenses to remain relatively consistent increase over the next twelve months as a result of the expanded development of barzolvolimab and an increase in commercial planning efforts, although there may be fluctuations on a quarterly basis.

Investment and Other Income, Net

The $2.1 million $4.7 million increase in investment and other income, net for the three months ended September 30, 2023 March 31, 2024, as compared to the three months ended September 30, 2022 March 31, 2023, was primarily due to higher interest rates on fixed income investments. levels of cash as a result of our November 2023 and March 2024 underwritten public offerings. We expect investment and other income to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

	Nine Months Ended	Increase/	Increase/

	September 30,		(Decrease)	(Decrease)
	2023	2022	$	%
	(In thousands)			
Revenues:				
Product development and licensing agreements	$ 19	$ 30	$ (11)	(37)%
Contracts and grants	2,733	714	2,019	283 %
Total revenues	$ 2,752	$ 744	$ 2,008	270 %
Operating expenses:				
Research and development	87,585	59,359	28,226	48 %
General and administrative	22,082	20,596	1,486	7 %
Gain on fair value remeasurement of contingent consideration	—	(6,862)	(6,862)	(100)%
Litigation settlement related loss	—	15,000	(15,000)	(100)%
Total operating expenses	109,667	88,093	21,574	24 %
Operating loss	(106,915)	(87,349)	19,566	22 %
Investment and other income, net	8,792	1,511	7,281	482 %
Net loss	$ (98,123)	$ (85,838)	$ 12,285	14 %

Net Loss

The $12.3 million increase in net loss for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, was primarily due to an increase in research and development expenses and a decrease in the gain on fair value remeasurement of contingent consideration, partially offset by the $15.0 million litigation settlement related loss recorded in the second quarter of 2022 and an increase in investment and other income.

Revenue

Revenue from product development and licensing agreements for the nine months ended September 30, 2023, was relatively consistent with the nine months ended September 30, 2022. The $2.0 million increase in contracts and grants revenue for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, was primarily related to an increase in services performed under our manufacturing and research and development agreements with Rockefeller University.

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Research and Development Expense

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

	Nine Months Ended September 30,		Increase/ (Decrease)	
	2023	2022	$	%
	(In thousands)			
Personnel	$ 28,559	$ 24,116	$ 4,443	18 %
Laboratory supplies	4,167	4,821	(654)	(14)%
Facility	3,699	3,566	133	4 %
Product development	45,348	22,374	22,974	103 %

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The $4.4 million increase in personnel expenses for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, 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 $0.7 million decrease in laboratory supply expenses for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, was primarily due to lower laboratory materials and supplies purchases.

Facility expenses include depreciation, amortization, utilities, rent, maintenance and other related expenses incurred at our facilities. The $0.1 million increase in facility expenses for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, was primarily due to higher repairs expense.

Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing. The $23.0 million increase in product development expenses for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, was primarily due to an increase in barzolvolimab clinical trial and contract manufacturing expenses.

General and Administrative Expense

The $1.5 million increase in general and administrative expenses for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, was primarily due to an increase in stock-based compensation and recruiting expenses, partially offset by a decrease in legal expenses.

Gain on Fair Value Remeasurement of Contingent Consideration

The $6.9 million gain on fair value remeasurement of contingent consideration for the nine months ended September 30, 2022 was primarily due to our decision to deprioritize the CDX-1140 program.

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 $7.3 million increase in investment and other income, net for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, was primarily due to higher interest rates on fixed income investments and higher other income related to our sale of New Jersey tax benefits.

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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 September 30, 2023 March 31, 2024, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of $235.3 million $823.8 million. We have had recurring losses and incurred a loss of $98.1 million $32.8 million for the nine three months ended September 30, 2023 March 31, 2024. Net cash used in operations for the nine three months ended September 30, 2023 March 31, 2024 was $74.8 million $40.6 million. We believe that the cash, cash equivalents and marketable securities at September 30, 2023 March 31, 2024 are sufficient to meet estimated working capital requirements and fund current planned operations through 2025, which include our ongoing and planned Phase 2 studies in CSU, CIndU, EoE, and PN. 2027. This could be impacted if we elect to pay the future milestones milestone under the Settlement Agreement with SRS if any, in cash.

cash, in the event that we achieve the milestone related to that payment.

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 milestone under the Settlement Agreement with SRS, in the event that we achieve the milestones milestone related to those payments. that payment. We may decide to pay those that milestone payments payment 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 $74.8 million $40.6 million for the nine three months ended September 30, 2023 March 31, 2024 as compared to $82.0 million $28.6 million for the nine three months ended September 30, 2022 March 31, 2023. The decrease increase in net cash used in operating activities was primarily due to the $15.0 million Initial Payment made to SRS under the Settlement Agreement increases in the third quarter of 2022, research and development and general and administrative expenses, partially offset by an increase in investment income as a result of higher interest rates on fixed income investments and a decrease in prepayments, partially offset by an increase in research and development expenses. levels of cash. We expect that cash used in operating activities will remain relatively consistent increase over the next twelve months although there may be fluctuations on as a quarterly basis.

Table result of Contentsthe 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 used in investing activities was $315.2 million for the three months ended March 31, 2024 compared to net cash provided by investing activities was $65.4 million of $52.6 million for the nine three months ended September 30, 2023 as compared to $58.7 million for the nine months ended September 30, 2022 March 31, 2023. The increase in net cash provided by used in investing activities was primarily due to net purchases of marketable securities of $314.9 million for the three months ended March 31, 2024 as compared to net sales and maturities of marketable securities of $66.5 million $53.2 million for the nine three months ended September 30, 2023 as compared to $60.3 million for the nine months ended September 30, 2022 March 31, 2023.

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Financing Activities

Net cash provided by financing activities was $1.1 million $436.1 million for the nine three months ended September 30, 2023 March 31, 2024 as compared to $2.7 million $0.7 million for the nine three months ended September 30, 2022 March 31, 2023. The decrease increase in net cash provided by financing activities was primarily due to a decrease an increase in net proceeds from stock issuances under employee benefit plans. issuances.

In March 2024, we issued 9,798,000 shares of common stock in an underwritten public offering, resulting in net proceeds of $ 432.3 million, after deducting underwriting fees and offering expenses.

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Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

We do not utilize derivative financial instruments. The carrying amounts reflected in the consolidated balance sheet of cash and cash equivalents, accounts receivables and accounts payable approximate fair value at September 30, 2023 March 31, 2024 due to the short-term maturities of these instruments.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

As of September 30, 2023 March 31, 2024, we evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2023 March 31, 2024. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within time periods specified by the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2023 March 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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Item 5. Other Information

During the period covered by this Quarterly Report on Form 10-Q, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

PART II — OTHER INFORMATION

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023, 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 SEC on February 28, 2023 February 26, 2024.

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Item 5. Other Information

During the period covered by this Quarterly Report on Form 10-Q, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

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

EXHIBIT INDEX

Exhibit No.	Description
*31.1	Certification of President and Chief Executive Officer
*31.2	Certification of Senior Vice President and Chief Financial Officer
**32.1	Section 1350 Certifications
*101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
*101.SCH	Inline XBRL Taxonomy Extension Schema Document.
*101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
*101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
*101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
*101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101).

* Filed herewith.

** Furnished herewith.

† Indicates a management contract or compensation plan, contract or arrangement.

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SIGNATURES

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

CELLDEX THERAPEUTICS, INC.

BY:

/s/ ANTHONY S. MARUCCI

Dated: November 2, 2023 May 6, 2024

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

/s/ SAM MARTIN

Dated: November 2, 2023 May 6, 2024

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

Exhibit 31.1

CERTIFICATION

I, Anthony S. Marucci, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 2, 2023 May 6, 2024

By: /s/ ANTHONY S. MARUCCI

Name: Anthony S. Marucci

Title: President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Sam Martin, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 2, 2023 May 6, 2024

By: /s/ SAM MARTIN

Name: Sam Martin

Title: Senior Vice President and Chief Financial Officer

Exhibit 32.1

SECTION 1350 CERTIFICATIONS

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

Date: November 2, 2023 May 6, 2024

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

Date: November 2, 2023 May 6, 2024

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.

DISCLAIMER

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