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, 2026

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 28, 2026, 78,545,051 shares of common stock, $.001 par value per share, were outstanding.

CELLDEX THERAPEUTICS, INC.

FORM 10-Q

For the Quarterly Period Ended September 30, 2026

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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, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 26,952	$ 28,871
Marketable securities	623,367	489,702
Accounts and other receivables	355	2,015
Prepaid and other current assets	13,062	14,076
Total current assets	663,736	534,664
Property and equipment, net	10,997	5,334
Operating lease right-of-use assets, net	9,922	2,437
Intangible assets	27,190	27,190
Other assets	9,686	13,358
Total assets	$ 721,531	$ 582,983
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 11,240	$ 1,180
Accrued expenses	46,609	47,029
Current portion of operating lease liabilities	1,438	1,552
Current portion of other long-term liabilities	1,230	1,230
Total current liabilities	60,517	50,991
Long-term portion of operating lease liabilities	8,432	784
Other long-term liabilities	3,113	4,043
Total liabilities	72,062	55,818
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, 2026 and December 31, 2025	—	—
Common stock, $.001 par value; 297,000,000 shares authorized; 78,534,438 and 66,549,442 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	79	67
Additional paid-in capital	2,691,445	2,337,453
Accumulated other comprehensive income	(329)	3,626
Accumulated deficit	(2,041,726)	(1,813,981)
Total stockholders' equity	649,469	527,165
Total liabilities and stockholders' equity	$ 721,531	$ 582,983

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, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Revenues:				
Product development and licensing agreements	$ —	$ —	$ 7	$ 57
Contracts and grants	—	—	30	1,367
Total revenues	—	—	37	1,424
Operating expenses:				
Research and development	67,407	62,931	207,950	169,741
General and administrative	14,844	10,686	39,396	31,897
Total operating expenses	82,251	73,617	247,346	201,638
Operating loss	(82,251)	(73,617)	(247,309)	(200,214)
Investment and other income, net	6,694	6,573	19,564	22,774
Net loss	$ (75,557)	$ (67,044)	$ (227,745)	$ (177,440)
Basic and diluted net loss per common share	$ (0.96)	$ (1.01)	$ (3.06)	$ (2.67)
Shares used in calculating basic and diluted net loss per share	78,531	66,420	74,356	66,399
Comprehensive loss:				
Net loss	$ (75,557)	$ (67,044)	$ (227,745)	$ (177,440)
Other comprehensive (loss) income:				
Unrealized (loss) gain on marketable securities	(1,627)	426	(3,955)	451
Comprehensive loss	$ (77,184)	$ (66,618)	$ (231,700)	$ (176,989)

See accompanying notes to unaudited condensed consolidated financial statements

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

(In thousands)

	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Cash flows from operating activities:		
Net loss	$ (227,745)	$ (177,440)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,918	2,564
Amortization and premium of marketable securities, net	(3,117)	(4,973)
Loss on sale or disposal of assets	51	12
Stock-based compensation expense	27,905	27,308
Changes in operating assets and liabilities:		
Accounts and other receivables	1,660	610
Prepaid and other current assets	11	235
Other assets	3,672	383
Accounts payable and accrued expenses	9,027	6,430
Other liabilities	(2,415)	(2,134)
Net cash used in operating activities	(188,033)	(147,005)
Cash flows from investing activities:		
Sales and maturities of marketable securities	391,169	484,788
Purchases of marketable securities	(524,669)	(329,708)
Acquisition of property and equipment	(6,485)	(1,433)
Net cash (used in) provided by investing activities	(139,985)	153,647
Cash flows from financing activities:		
Net proceeds from stock issuances	323,832	—
Proceeds from issuance of stock from employee benefit plans	2,267	1,039
Net cash provided by financing activities	326,099	1,039
Net (decrease) increase in cash and cash equivalents	(1,919)	7,681
Cash and cash equivalents at beginning of period	28,871	28,356
Cash and cash equivalents at end of period	$ 26,952	$ 36,037
Non-cash investing activities		
Accrued construction in progress	$ 711	$ 472

See accompanying notes to unaudited condensed consolidated financial statements

CELLDEX THERAPEUTICS, INC.
Notes to Unaudited Condensed Consolidated Financial Statements
September 30, 2026

(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, 2025, which are included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on February 25, 2026. 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, 2026.

At September 30, 2026, the Company had cash, cash equivalents and marketable securities of $650.3 million. The Company has had recurring losses and incurred a loss of $227.7 million for the nine months ended September 30, 2026. Net cash used in operations for the nine months ended September 30, 2026 was $188.0 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 financings, 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 the future milestone under the Settlement Agreement (defined below) with Shareholder Representative Services LLC ("SRS") (refer to Note 16), in the event that the Company achieves the milestone related to that payment. The Company, at its option, may decide to pay that milestone 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, 2026 are consistent with those discussed in Note 2 to the financial statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2025.

Recent Accounting Pronouncements

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

In November 2024, the FASB issued ASU 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures*, which requires enhanced disclosures about specific types of expenses included in the expense captions presented on the face of the income statement. The standard is effective for annual reporting periods in fiscal years beginning after December 15, 2026, and interim reporting periods in fiscal years beginning after December 31, 2027, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2024-03 may have on its expense disclosures in the notes to the consolidated financial statements.

(3) Segment Information

The Company is managed as a single operating and reportable segment that operates in the business of development, manufacturing and commercialization of novel therapeutics for human health care. Our chief operating decision maker ("CODM"), the Chief Executive Officer, evaluates performance based on consolidated net loss. Other than general and administrative expenses as presented on the consolidated statement of operations, research and development expense disaggregated by program and by nature are considered to be the Company's significant segment expenses. These results are used, in part, by our CODM in evaluating the performance of the Company by comparing budget to actual results, and to allocate resources. All revenue is derived in and long-lived assets are located in the United States. The CODM does not receive asset information other than what is presented on the consolidated balance sheets.

The following table is a summary of the Company's research and development expenses disaggregated by program. The amounts disclosed reflect direct research and development costs and an allocation of indirect research and development costs to each program.

	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
	(In thousands)			
Barzolvolimab/Anti-KIT Program	$ 53,517	$ 51,619	$ 170,627	$ 133,967
CDX-622	3,794	5,617	11,590	14,906
Other Programs (a)	10,096	5,695	25,733	20,868
Total R&D Expense	$ 67,407	$ 62,931	$ 207,950	$ 169,741

(a) Other program expenses primarily include research and development expenses related to early-stage programs, revenue-generating programs and discontinued programs.

The following table is a summary of the Company's research and development expenses disaggregated by nature.

	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
	(In thousands)			
Personnel	$ 18,272	$ 14,455	$ 49,726	$ 42,184
Laboratory supplies	2,138	1,057	6,188	4,769
Facility	1,422	1,410	3,540	4,214
Product development (b)	38,401	42,371	130,304	108,073
Other expenses (c)	7,174	3,638	18,192	10,501
Total R&D expense	$ 67,407	$ 62,931	$ 207,950	$ 169,741

(b) Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing.

(c) Other expenses primarily include research and development consulting, insurance, licensing and software expenses.

(4) Fair Value Measurements

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

	As of September 30, 2026	Level 1	Level 2	Level 3
		(In thousands)		
Assets:				
Money market funds and cash equivalents	$ 15,106	—	$ 15,106	—
Marketable securities	623,367	—	623,367	—
	$ 638,473	—	$ 638,473	—

	As of December 31, 2025	Level 1	Level 2	Level 3
		(In thousands)		
Assets:				
Money market funds and cash equivalents	$ 19,115	—	$ 19,115	—
Marketable securities	489,702	—	489,702	—
	$ 508,817	—	$ 508,817	—

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

Contingent consideration liabilities measured at fair value using Level 3 inputs were $0.0 million as of September 30, 2026 and December 31, 2025. 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.

There was no gain or loss on fair value remeasurement of contingent consideration recorded during the three and nine months ended September 30, 2026 or September 30, 2025. The assumptions related to determining the fair value of contingent consideration include a significant amount of judgment, and any changes in the underlying estimates could have a material impact on the amount of contingent consideration adjustment recorded in any given period.

The Company did not have any transfers in or out of Level 3 assets or liabilities during the nine months ended September 30, 2026 or September 30, 2025.

(5) Marketable Securities

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(In thousands)		
September 30, 2026				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	$ 158,525	$ 4	$ (556)	$ 157,973
Maturing after one year through three years	95,494	—	(1,041)	94,453
Total U.S. government and municipal obligations	$ 254,019	$ 4	$ (1,597)	$ 252,426
Corporate debt securities				
Maturing in one year or less	$ 292,883	$ 3	$ (811)	$ 292,075
Maturing after one year through three years	79,390	—	(524)	78,866
Total corporate debt securities	$ 372,273	$ 3	$ (1,335)	$ 370,941
Total marketable securities	$ 626,292	$ 7	$ (2,932)	$ 623,367

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(In thousands)		
December 31, 2025				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	$ 151,270	$ 479	$ —	$ 151,749
Maturing after one year through three years	42,358	127	—	42,485
Total U.S. government and municipal obligations	$ 193,628	$ 606	$ —	$ 194,234
Corporate debt securities				
Maturing in one year or less	$ 257,064	$ 373	$ —	$ 257,437
Maturing after one year through three years	37,980	55	(4)	38,031
Total corporate debt securities	$ 295,044	$ 428	$ (4)	$ 295,468
Total marketable securities	$ 488,672	$ 1,034	$ (4)	$ 489,702

The Company holds investment-grade marketable securities. Unrealized losses are generally attributable to changes in interest rates. The aggregate fair value of marketable securities held by the Company in an unrealized loss position as of September 30, 2026 and December 31, 2025 was $576.5 million and $19.4 million, respectively. The Company has the intent and ability to hold its marketable securities until recovery and has determined that there has been no material change to the Company's credit risk. As a result, the Company determined it did not hold any investments with a credit loss at September 30, 2026 and December 31, 2025.

Marketable securities include $5.5 million and $4.4 million in accrued interest at September 30, 2026 and December 31, 2025, respectively.

(6) Leases

In 2025, the Company entered into a lease for office and laboratory space in New Haven, Connecticut, which commenced in July 2026. Upon commencement of the lease, the Company recognized an operating lease right-of-use asset of $3.5 million and a corresponding operating lease liability of $3.4 million during the quarter ended September 30, 2026. In addition, as a result of the lease, the Company's undiscounted future minimum lease payments under non-cancellable operating leases increased by approximately $4.5 million through 2031.

In June 2026, the Company entered into an amendment to its Hampton, New Jersey lease to expand its leased space from approximately 33,400 square feet to approximately 66,000 square feet and extend the lease term by an additional 36 months. As a result of the lease modification, the Company's operating lease right-of-use asset and operating lease liability increased by $3.5 million during the quarter ended June 30, 2026. The lease modification increased the Company's undiscounted future minimum lease payments under non-cancellable operating leases by approximately $4.4 million through 2030.

In July 2026, the Company entered into an amendment to its Fall River, Massachusetts lease to extend the lease term by an additional 36 months. As a result of the lease modification, the Company's operating lease right-of-use asset and operating lease liability increased by $2.0 million during the quarter ended September 30, 2026. The lease modification increased the Company's undiscounted future minimum lease payments under non-cancellable operating leases by approximately $2.5 million through 2030.

(7) Intangible Assets

At September 30, 2026 and December 31, 2025, 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), which was recorded in connection with the Kolltan acquisition. Barzolvolimab is in Phase 3 development. As of September 30, 2026, 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.

(8) Other Assets

The Company records advance payments for services that will not be performed within one year of the balance sheet date as other assets. Such amounts will be recognized as expense in the period in which the related services are performed. Advance payments reflected within other assets in our consolidated balance sheets were $9.1 million and $12.8 million at September 30, 2026 and December 31, 2025, respectively.

(9) Other Long-Term Liabilities

Other long-term liabilities include the following:

	September 30, 2026	December 31, 2025
	(In thousands)	
Net deferred tax liabilities related to IPR&D (Note 14)	$ 1,613	$ 1,613
Deferred income from sale of tax benefits	930	1,860
Deferred revenue (Note 13)	1,800	1,800
Total	4,343	5,273
Less current portion	(1,230)	(1,230)
Long-term portion	$ 3,113	$ 4,043

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 and $0.9 million in other income related to the sale of these tax benefits during the three and nine months ended September 30, 2026, respectively, and $0.0 million and $0.9 million during the three and nine months ended September 30, 2025, respectively.

(10) Stockholders' Equity

In 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.

On February 26, 2024, the Company entered into a controlled equity offering sales agreement ("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. At September 30, 2026, the Company had registered $300.0 million of its common stock to be sold pursuant to the Company's ATM Agreement, all of which remained unsold as of that date.

The Company's shelf registration statement expired on November 3, 2026, and no shares were sold under the ATM Agreement prior to such expiration.

In April 2026, the Company issued 11,896,750 shares of its common stock in an underwritten public offering resulting in net proceeds to the Company of $323.8 million, after deducting underwriting fees and offering expenses.

The changes in Stockholders' Equity during the three and nine months ended September 30, 2026 and 2025 are summarized below:

	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
			(In thousands, except share amounts)			
Consolidated balance at December 31, 2025	66,549,442	$ 67	$ 2,337,453	$ 3,626	$ (1,813,981)	$ 527,165
Shares issued under stock option and employee stock purchase plans	19,529	—	327	—	—	327
Stock-based compensation	—	—	8,523	—	—	8,523
Unrealized loss on marketable securities	—	—	—	(1,104)	—	(1,104)
Net loss	—	—	—	—	(78,685)	(78,685)
Consolidated balance at March 31, 2026	66,568,971	$ 67	$ 2,346,303	$ 2,522	$ (1,892,666)	$ 456,226
Shares issued under stock option and employee stock purchase plans	34,452	—	825	—	—	825
Shares issued in underwritten offering, net	11,896,750	12	323,820	—	—	323,832
Stock-based compensation	—	—	8,408	—	—	8,408
Unrealized loss on marketable securities	—	—	—	(1,224)	—	(1,224)
Net loss	—	—	—	—	(73,503)	(73,503)
Consolidated balance at June 30, 2026	78,500,173	$ 79	$ 2,679,356	$ 1,298	$ (1,966,169)	$ 714,564
Shares issued under stock option and employee stock purchase plans	34,265	—	1,115	—	—	1,115
Stock-based compensation	—	—	10,974	—	—	10,974
Unrealized loss on marketable securities	—	—	—	(1,627)	—	(1,627)
Net loss	—	—	—	—	(75,557)	(75,557)
Consolidated balance at September 30, 2026	78,534,438	$ 79	$ 2,691,445	$ (329)	$ (2,041,726)	$ 649,469

	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, 2024	66,374,549	$ 66	$ 2,298,849	$ 3,314	$ (1,555,224)	$ 747,005
Shares issued under stock option and employee stock purchase plans	9,642	—	202	—	—	202
Stock-based compensation	—	—	9,316	—	—	9,316
Unrealized gain on marketable securities	—	—	—	254	—	254
Net loss	—	—	—	—	(53,796)	(53,796)
Consolidated balance at March 31, 2025	66,384,191	$ 66	$ 2,308,367	$ 3,568	$ (1,609,020)	$ 702,981
Shares issued under stock option and employee stock purchase plans	10,050	—	63	—	—	63
Stock-based compensation	—	—	9,191	—	—	9,191
Unrealized loss on marketable securities	—	—	—	(229)	—	(229)
Net loss	—	—	—	—	(56,600)	(56,600)
Consolidated balance at June 30, 2025	66,394,241	$ 66	$ 2,317,621	$ 3,339	$ (1,665,620)	$ 655,406
Shares issued under stock option and employee stock purchase plans	52,605	—	774	—	—	774
Stock-based compensation	—	—	8,801	—	—	8,801
Unrealized gain on marketable securities	—	—	—	426	—	426
Net loss	—	—	—	—	(67,044)	(67,044)
Consolidated balance at September 30, 2025	66,446,846	$ 66	$ 2,327,196	$ 3,765	$ (1,732,664)	$ 598,363

(11) Stock-Based Compensation

A summary of stock option activity for the nine months ended September 30, 2026 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In Years)
Options outstanding at December 31, 2025	9,134,278	$ 26.49	7.1
Granted	2,799,370	$ 34.21	—
Exercised	(66,830)	$ 27.46	—
Canceled	(291,169)	$ 41.05	—
Options outstanding at September 30, 2026	11,575,649	$ 27.98	7.2
Options vested and expected to vest at September 30, 2026	11,364,937	$ 27.93	7.2
Options exercisable at September 30, 2026	6,458,473	$ 25.75	5.8
Shares available for grant under the Celldex Therapeutics, Inc. 2021 Omnibus Equity Incentive Plan (as amended, effective as of June 25, 2026) at September 30, 2026	3,516,635		

The weighted average grant-date fair value of stock options granted during the three and nine months ended September 30, 2026 was $23.84 and $21.12, respectively.

The aggregate intrinsic value of stock options vested and expected to vest at September 30, 2026 was $69.7 million. The aggregate intrinsic value of stock options exercisable at September 30, 2026 was $53.0 million. As of September 30, 2026, total compensation cost related to non-vested employee, consultant and non-employee director stock options not yet recognized was approximately $92.3 million, net of estimated forfeitures, which is expected to be recognized as expense over a weighted average period of 2.8 years.

Stock-based compensation expense for the three and nine months ended September 30, 2026 and 2025 was recorded as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(In thousands)		(In thousands)	
Research and development	$ 5,626	$ 4,743	$ 14,861	$ 14,210
General and administrative	5,348	4,058	13,044	13,098
Total stock-based compensation expense	$ 10,974	$ 8,801	$ 27,905	$ 27,308

The fair values of employee, consultant and non-employee director stock options granted during the three and nine months ended September 30, 2026 and 2025 were valued using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Expected stock price volatility	62 – 63%	76%	62 – 76%	76 – 81%
Expected option term	6.0 Years	6.0 Years	6.0 Years	6.0 Years
Risk-free interest rate	4.3 – 4.9%	4.0 – 4.2%	3.8 – 4.9%	4.0 – 4.7%
Expected dividend yield	None	None	None	None

(12) Accumulated Other Comprehensive Income

The changes in accumulated other comprehensive income, which is reported as a component of stockholders' equity, for the nine months ended September 30, 2026 are summarized below:

	Unrealized Gain (Loss) on Marketable Securities	Foreign Currency Items	Total
		(In thousands)	
Balance at December 31, 2025	$ 1,030	$ 2,596	$ 3,626
Other comprehensive loss	(3,955)	—	(3,955)
Balance at September 30, 2026	$ (2,925)	$ 2,596	$ (329)

No amounts were reclassified out of accumulated other comprehensive income during the nine months ended September 30, 2026.

(13) 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 no material revenue under the agreements with Rockefeller during the three and nine months ended September 30, 2026. The Company recognized $0.0 million and $1.4 million under the agreements with Rockefeller during the three and nine months ended September 30, 2025, respectively.

Contract Assets and Liabilities

At September 30, 2026 and December 31, 2025, the Company's right to consideration under all contracts were considered unconditional, and as such, no contract assets were recorded. Accordingly, amounts billed but not yet paid by customers were recorded as trade receivables at September 30, 2026 and December 31, 2025.

At September 30, 2026, the Company had $1.8 million in contract liabilities recorded, representing consideration billed in advance of performing manufacturing and research and development services. The Company expects to recognize this amount as revenue over the next 24 months as the related services are performed. At December 31, 2025, the Company had $1.8 million in contract liabilities recorded. No revenue was recognized from contract liabilities as of December 31, 2025 during the nine months ended September 30, 2026.

(14) Income Taxes

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted in the United States. The OBBBA includes significant corporate tax reforms, including (i) the permanent reinstatement of deducting domestic research and development expenditures as incurred (under prior law such expenditures were capitalized and amortized over five years) and (ii) the option to claim 100% accelerated depreciation deductions on qualified property. The corporate tax changes included in the OBBBA did not have a material impact on the Company's effective income tax rate during the three and nine months ended September 30, 2026, and the Company does not anticipate a material impact on its effective income tax rate in future periods.

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, 2026 and December 31, 2025.

The net deferred tax liability of $1.6 million at September 30, 2026 and December 31, 2025 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.

(15) 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,	
	2026	2025
Stock Options	11,575,649	9,178,172
Restricted Stock	—	—
	11,575,649	9,178,172

(16) 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 July 15, 2022, the Company entered into a definitive settlement agreement between the Company and SRS (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 Settlement Agreement, all milestone payments provided for by the Merger Agreement 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 paid $12.5 million upon the Successful Completion (as defined in the Settlement Agreement) of a Phase 2 Clinical Trial (as defined in the Merger Agreement) of barzolvolimab.

(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 Settlement Agreement).

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 in July 2022. The Company paid the second milestone for "successful completion" of a Phase 2 Clinical Trial of barzolvolimab in cash in November 2023.

A future milestone payment related to the 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. A future milestone payment related to the remaining Surviving Company Products is measured at fair value (refer to Note 4). When and if the remaining payment described above becomes due, 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.

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 development 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 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 negotiate strategic partnerships, where appropriate, for our drug candidates;
- our ability to manage multiple clinical trials for a variety of drug candidates at different stages of development;
- the cost, timing, scope and results of ongoing preclinical and clinical testing;
- our expectations of the attributes of our product and development candidates, including pharmaceutical properties, efficacy, safety and dosing regimens;
- the cost, timing and uncertainty of obtaining regulatory approvals for our drug candidates;
- the availability, cost, delivery and quality of clinical management services provided by our clinical research organization partners;
- the availability, cost, delivery and quality of clinical and commercial-grade materials produced by our own manufacturing facility or supplied by contract manufacturers, suppliers and partners;
- our ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors;
- our ability to develop technological capabilities, including identification of novel and clinically important targets, exploiting our existing technology platforms to develop new drug candidates and expand our focus to broader markets for our existing targeted therapeutics;

- the cost of paying the regulatory approval milestone under the merger agreement by which we acquired Kolltan Pharmaceuticals, Inc. ("Kolltan") and our related settlement agreement with Kolltan;

- our ability to raise sufficient capital to fund our preclinical and clinical studies and to meet our long-term liquidity needs, on terms acceptable to us, or at all. If we are unable to raise the funds necessary to meet our long-term liquidity needs, we may have to delay or discontinue the development of one or more programs, discontinue or delay ongoing or anticipated clinical trials, 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;

- our current expectations regarding the submission of a Biologics License Application ("BLA") to the FDA in 2027; 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, 2025 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 developing novel antibody-based treatments that engage the human immune system and directly affect critical pathways to improve the lives of patients with allergic, inflammatory and autoimmune disorders. Our drug candidates include monoclonal and bispecific antibodies designed to address mast cell mediated diseases 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 Spontaneous Urticaria (CSU): In September 2026, we announced positive topline results from our two Phase 3 studies in CSU, where best-in-disease results showed rapid, profound, sustained efficacy, supporting barzolvolimab's potential to be a transformational therapy in CSU. The trials met primary and all key secondary endpoints at Week 12 across both studies and both dose groups, and clinically meaningful and statistically significant benefit was demonstrated in omalizumab refractory CSU and patients with severe disease or severe angioedema. Efficacy was sustained or deepened from weeks 12 to 24, and barzolvolimab was well-tolerated with a favorable safety profile through 24 weeks. 1,939 patients were enrolled—the largest program conducted in antihistamine refractory CSU, including patients with advanced therapy experienced/refractory CSU. Treatment will continue in both trials to 52 weeks, and a Biologics License Application (BLA) submission to the FDA is anticipated in 2027. Data from the Phase 3 studies reported to date are consistent with results from our completed Phase 2 study in CSU. In Phase 2, the primary endpoint was met at Week 12 and patients on study continued to receive barzolvolimab for a total of 52 weeks of treatment. Sustained and deepening disease efficacy and a well tolerated

long term safety profile were demonstrated over the 52 week treatment period. In addition, at 76 weeks, 7 months after the completion of dosing with barzolvolimab, over 40% of patients (150mg Q4W) continued to experience profound, sustained complete response;

- Cold Urticaria (ColdU) and Symptomatic Dermographism (SD): We initiated a Phase 3 study in ColdU and SD in December 2025 and enrollment is ongoing. In July 2024, we announced that our Phase 2 study being conducted in two forms of chronic inducible urticaria (CIndU), ColdU and SD, achieved the primary efficacy endpoint (statistically significant difference between the percent of patients with a negative provocation test compared to placebo at Week 12) and was well tolerated. 12 week data from the CIndU study were presented in October 2024 and all secondary endpoints across the study were also met and were highly statistically significant and clinically meaningful. Patients on study continued to receive barzolvolimab and, in November 2025, we reported data from 20 weeks of treatment—demonstrating sustained efficacy and a well tolerated safety profile over the longer treatment period. In March 2026, we presented results that demonstrated that barzolvolimab re-treatment achieved similar profound efficacy to first exposure in patients with ColdU and SD; and

- Atopic Dermatitis (AD): A Phase 2 study in AD was initiated in December 2024 and enrollment was completed in January 2026. Topline data from the study is expected in late 2026.

- Our next generation bispecific antibody platform to support pipeline expansion with additional candidates for inflammatory diseases. 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.

  - In June 2026, we presented first-in-human data that demonstrated that neutralizing soluble SCF can selectively inhibit KIT signaling in mast cells. This approach provides a validated anchor mechanism that enables the development of diverse bispecific antibody candidates where a dual mechanism approach may overcome the heterogeneity inherent in the pathophysiology of many inflammatory disorders.

  - Our first bispecific candidate based on this science is CDX-622 (SCF & TSLP) which targets two complementary pathways that drive chronic inflammation, potently neutralizing the alarmin thymic stromal lymphopoietin (TSLP) and depleting mast cells via stem cell factor (SCF) starvation. In November 2024, a multi-part Phase 1a dose-escalation study in healthy volunteers was initiated and enrollment was completed across all parts in January 2026. Positive data from the single ascending dose portion of the study was presented in October 2025. Data from the multiple ascending dose portion of the study and from the subcutaneous administration portion of the study were presented in June 2026. CDX-622 was well tolerated at all dose levels and results showed rapid, profound, dose-dependent, and durable reductions in serum tryptase indicative of mast cell depletion, without measurably impacting other KIT functions. In January 2026, we initiated an open-label, single-dose Phase 1 proof of mechanism study in adults with mild to moderate asthma to assess the impact of dual neutralization of SCF and TSLP.

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

Our strategy 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.

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, 2025, we incurred an aggregate of $662.2 million in research and development expenses. The following table indicates the amount incurred for each of our significant research programs and for other identified research and development activities during the nine months ended September 30, 2026 and 2025. The amounts disclosed in the following table reflect direct research and development costs and an allocation of indirect research and development costs to each program.

	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
	(In thousands)	
Barzolvolimab/Anti-KIT Program	$ 170,627	$ 133,967
CDX-622	11,590	14,906
Other Programs	25,733	20,868
Total R&D Expense	$ 207,950	$ 169,741

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

Barzolvolimab was initially studied in chronic spontaneous urticaria (CSU) and chronic inducible urticaria (CIndU), diseases where mast cell degranulation plays a central role in the onset and progression of the disease.

- In September 2026 we announced positive topline results from two Phase 3 studies of barzolvolimab in CSU. Best-in-disease results showed rapid, profound, sustained efficacy supporting barzolvolimab's potential to be a transformational therapy in CSU. EMBARQ-CSU1 and -CSU2 met primary and all key secondary endpoints at Week 12 across both studies and both dose groups, and clinically meaningful and statistically significant benefit was demonstrated in omalizumab refractory CSU and patients with severe disease or severe angioedema. Efficacy was sustained or deepened from weeks 12 to 24, and barzolvolimab was well-tolerated with a favorable safety profile through 24 weeks. We plan to present EMBARQ-CSU data at an upcoming medical meeting and submit a BLA to the FDA in 2027.

- A Phase 2 study in CSU has been completed. The primary endpoint of the study was achieved—a statistically significant mean change from baseline to Week 12 of UAS7 (weekly urticaria activity score) compared to placebo. All secondary endpoints were also met and barzolvolimab was well tolerated. Up to 51% of patients on study had a complete response and were symptom free (UAS7=0; no itch/no hives) at 12 weeks, which continued to deepen over 52 weeks of active therapy to up to 71% of patients. This profound clinical benefit continued even after patients were off therapy with up to 41% of patients reporting complete response seven months after receiving their last dose. Patients also reported clinically meaningful improvements in angioedema control and quality of life. At 12 weeks, up to 65% of barzolvolimab treated patients were angioedema free (AAS7=0), which increased to up to 77% at Week 52 and remained at up to 64% seven months after last dose. At 12 weeks, up to 67% of patients treated with barzolvolimab reported their CSU had no impact on their quality of life (DLQI 0/1), which increased to up to 82% at Week 52 and remained at up to 48% seven months after last dose.

- In December 2025, we initiated a Phase 3 study in two of the most common forms of CIndU—cold urticaria (ColdU) and symptomatic dermographism (SD).

- A Phase 2 study in ColdU and SD has been completed. The primary endpoint of the study was achieved—a statistically significant difference between the percent of patients with a negative provocation test compared to placebo at Week 12. All secondary endpoints were also met and barzolvolimab was well tolerated. Sustained efficacy and a favorable safety profile were observed over the continued (20 week) placebo controlled treatment period. Patients were then followed for

up to 24 additional weeks without treatment and patients with returning or continuing symptoms were eligible to enroll into an open label extension (OLE) where it was demonstrated that barzolvolimab re-treatment achieved similar profound efficacy to first exposure in patients with ColdU and SD.

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 atopic dermatitis (AD) and 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.

Chronic Spontaneous Urticaria (CSU) Summary of Phase 1, Phase 2, and Phase 3 Data

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. 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). Approximately 50% of patients with CSU achieve symptomatic control with antihistamines. Currently approved advanced therapies address downstream mediators/mechanisms in CSU and do not provide symptom free complete control (absence of itch and hives, UAS7=0) in a majority of patients. Consequently, there is a need for additional therapies.

Barzolvolimab uniquely targets the root cause of CSU—the mast cell. Based on results from completed Phase 1 and Phase 2 studies and the topline data from both ongoing Phase 3 trials in CSU (Q4W dosing), barzolvolimab has the potential to offer symptom free complete control (absence of itch and hives, UAS7=0) and clinically meaningful improvements in quality of life and angioedema in a majority of patients.

We have completed a Phase 1b randomized, double-blind, placebo-controlled multi-center study of barzolvolimab in CSU. The study was designed to assess the safety of multiple ascending doses of barzolvolimab in patients with CSU who remain symptomatic despite treatment with antihistamines. In the study and in post-treatment follow-up, barzolvolimab resulted in rapid, marked, and durable responses, and demonstrated prolonged disease control. Results were consistent in patients with prior omalizumab therapy experience. Profound and durable improvement in angioedema symptoms as measured through the weekly angioedema activity score (AAS7) was achieved across all dose levels evaluated with sustained activity observed with the 1.5 mg/kg and greater dose levels. 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. 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. Most adverse events were mild or moderate in severity and resolved while on study.

We have completed a Phase 2 study in patients with CSU who remained symptomatic despite antihistamine therapy. The study was conducted at approximately 75 clinical trial sites across 9 countries. The study was a randomized, double-blind, placebo-controlled, parallel group Phase 2 study that evaluated the efficacy and safety profile of multiple dose regimens of barzolvolimab to determine the optimal dosing strategy. 208 patients were 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. After 16 weeks, patients then entered a 36-week active treatment period, in which patients receiving placebo or the 75 mg dose were randomized to receive barzolvolimab 150 mg every 4 weeks or 300 mg every 8 weeks; patients already randomized to the 150 mg and 300 mg treatment arms remained on the same regimen as during the placebo-controlled treatment period. After 52 weeks, patients then entered a follow-up period for an additional 24 weeks. The primary endpoint of the study was mean change in baseline to Week 12 in UAS7 (weekly urticaria activity score). Secondary endpoints included safety and other assessments of clinical activity including ISS7 (weekly itch severity score), HSS7 (weekly hive severity score) and AAS7 (weekly angioedema activity score).

Topline data from this study were presented in November 2023 and 12 week treatment results were presented at the 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).

Phase 2 CSU: 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.

In June 2024, 12 week data on a secondary endpoint from the study, angioedema activity, and additional measures of angioedema control, were presented at the EAACI 2024 Congress. Approximately 72% of patients on study had angioedema at baseline. Barzolvolimab demonstrated significant improvements in AAS7 in patients with angioedema across all doses at Week 12. This improvement was rapid (within 2 weeks) and durable (continued through 12 weeks). Barzolvolimab demonstrated strong improvement in AAS7 independent of omalizumab status at Week 12. Patients on barzolvolimab experienced a > 8 point improvement in AAS7 (considered a clinically meaningful result) across all doses compared to placebo ($p<0.05$). Barzolvolimab increased angioedema free days compared to placebo through 12 weeks. Patients in the 300 mg cohort were angioedema free 77% of the time over the 12 week period.

Patients on study continued to receive barzolvolimab for up to 52 weeks. Long term treatment data were presented in September at the European Academy of Dermatology & Venereology (EADV) Congress 2024 and quality of life data were presented in March at the AAAAI Annual Meeting 2025. The data demonstrated a sustained and deepening disease efficacy, a well tolerated safety profile, greatly improved urticaria control and reduced disease impact on quality of life over a 52 week treatment period. Key highlights included:

- Improvements in UAS7 (weekly urticaria activity score), previously shown to be statistically significantly vs placebo at Week 12, were noted as early as Week 1 and were sustained or deepened at Week 52.
- At Week 16, patients receiving low dose barzolvolimab (75 mg) or placebo were transitioned to barzolvolimab 150 mg or 300 mg; after crossover, these patients experienced similar clinically meaningful disease response as the rest of the study population.
- 71% of patients treated with barzolvolimab 150 mg Q4W and 52% of patients treated with 300 mg Q8W had a complete response (no itch/hives; UAS7=0) at Week 52. These responses were observed early and sustained through 52 weeks.
- 74% of patients treated with barzolvolimab 150 mg Q4W and 68% of patients treated with 300 mg Q8W had well controlled (UAS7<6) disease at Week 52.
- These robust responses were observed regardless of prior omalizumab experience.
- Rapid and sustained improvement in urticaria control (UCT) and quality of life (DLQI) were observed in patients with CSU refractory to antihistamines.
  - Up to 82% of patients reported that CSU symptoms no longer had an impact on their quality of life at Week 52 and up to 95% of patients reported meaningful improvement in quality of life based on DLQI at Week 52.
  - Up to 82% of patients reported well-controlled urticaria based on UCT, and approximately half of patients reported complete control at Week 52.
- Barzolvolimab was well tolerated with a favorable safety profile through 52 weeks of treatment. Most adverse events were grade 1 (mild), mechanism related (KIT) and expected to be reversible. The most common treatment emergent adverse events occurring in greater than 10% of barzolvolimab treated patients were hair color changes, neutropenia, urticaria, skin hypopigmentation (areas of skin lightening) and nasopharyngitis (common cold). Neutrophil counts did not decline further with continued dosing and there was no association between infections and neutropenia. The hypopigmentation was observed with longer term exposure and did not lead to treatment discontinuation. Adverse events were not dose dependent.

In June 2025, 52 week data on angioedema activity and additional measures of angioedema control were presented at the EAACI 2025 Congress. Barzolvolimab continued to demonstrate robust, durable and deepening improvements in angioedema symptoms over the treatment period.

- At Week 52, an 86% mean reduction from baseline was reported for 150 mg Q4W arm and an 82% reduction was reported for the 300 mg Q8W.
- Up to 77% of patients treated with barzolvolimab who had angioedema at baseline were angioedema free (AAS7=0) at Week 52, which we subsequently announced remained at up to 64% seven months after last dose.

- Patients treated with barzolvolimab were angioedema free up to 72% of the time over the 52 week treatment period. Up to 87% of patients reported clinically meaningful improvement (>8 point) in AAS7 at Week 52.

In June 2025, long term follow up data from the Phase 2 CSU study were presented at the EAACI 2025 Congress. At Week 76, seven months after receiving their final dose of barzolvolimab, patients continued to experience profound clinical benefit on study. Key highlights included:

- UAS7 mean change from baseline at Week 76 was -20.42 for patients treated with 150 mg Q4W and -21.10 for patients treated with 300 mg Q8W.

- 41% of patients treated with barzolvolimab 150 mg Q4W and 35% of patients treated with 300 mg Q8W had a complete response (no itch/hives; UAS7=0) at Week 76.

- 56% of patients treated with barzolvolimab 150 mg Q4W and 47% of patients treated with 300 mg Q8W had well controlled disease (UAS7≤6) at Week 76.

- 48% of patients treated with barzolvolimab 150 mg Q4W and 40% of patients treated with 300 mg Q8W reported that CSU had no impact on their quality of life at 76 weeks as measured by the Dermatology Life Quality Index (DLQI). Current clinical guidelines recommend complete response (UAS7=0) as the goal of treatment and achieving complete response is directly correlated to the greatest improvements in quality of life for patients.

- At 76 weeks, up to 64% of barzolvolimab treated patients remained angioedema free (AAS7=0) seven months after last dose of barzolvolimab (reported in company press release dated February 25, 2026).

- These robust responses and improvements in quality of life and angioedema were observed regardless of prior omalizumab experience.

- Barzolvolimab was well tolerated with a favorable safety profile through 76 weeks. No new safety signals were identified during the follow-up period. As expected, neutrophil counts returned to baseline following the completion of barzolvolimab treatment and the mild hair color changes and skin hypopigmentation observed on study were demonstrated to be reversible following discontinuation of treatment.

In September at EADV 2025, data were presented demonstrating rapid and strong efficacy regardless of baseline immunoglobulin E (IgE) levels. In November 2025, at the American College of Allergy, Asthma & Immunology's Annual Scientific (ACAAI) Meeting, data were presented demonstrating that barzolvolimab leads to rapid and profound improvements in UCT7 scores with sustained disease control off treatment.

We believe these results strongly support the further development of barzolvolimab in CSU.

In July 2024, we initiated two Phase 3 studies of barzolvolimab in CSU. The studies, EMBARQ-CSU1 and EMBARQ-CSU2, are designed to establish the efficacy and safety of barzolvolimab in adult patients with CSU who remain symptomatic despite H1 antihistamine treatment. 1,939 patients were enrolled—the largest program conducted in antihistamine refractory CSU, including patients with advanced therapy experienced/refractory CSU. The studies included 43 countries and over 500 sites. Both Phase 3 trials are randomized, double-blind, placebo-controlled, parallel group, global studies where patients have been randomized evenly per trial to barzolvolimab 150 mg every 4 weeks (following 300 mg loading dose), barzolvolimab 300 mg every 8 weeks (following 450 mg loading dose) or placebo for 52 weeks. At 24 weeks, patients on placebo are re-randomized to active treatment across both dosing groups. After completion of the 52 week treatment period, patients on study are followed for 16 weeks. The primary endpoint of the studies evaluates the clinical effect of barzolvolimab in reducing urticaria activity (weekly urticaria activity score; UAS7) at Week 12. The studies are designed to detect a clinically meaningful difference between each of the active arms versus placebo in the overall population as well as in the subpopulation of omalizumab refractory participants. The primary endpoint analysis was performed after all patients completed the placebo controlled portion of the study at 24 weeks.

In September 2026, we reported positive topline data from the Phase 3 EMBARQ-CSU1 and EMBARQ-CSU2 studies of barzolvolimab, which met primary and all key secondary endpoints. The studies demonstrated rapid, profound, sustained efficacy consistent with Phase 2 and unparallelled in CSU. Efficacy was sustained or deepened from weeks 12 to 24 across primary and all key secondary endpoints. Based on these results, we plan to submit a BLA to the FDA in 2027.

Primary Endpoint: Mean Change from Baseline in UAS7 at Week 12:				
	EMBARQ-CSU1		EMBARQ-CSU2	
	Baseline UAS7	LS Mean Change (SE) at Week 12	Baseline UAS7	LS Mean Change (SE) at Week 12
Placebo	30.9	-10.7 (0.65)	29.3	-11.4 (0.64)
150 mg Q4W	30.6	-20.2 (0.64) (p<.00001)	29.7	-20.2 (0.63) (p<.00001)
300 mg Q8W	30.3	-20.5 (0.65) (p<.00001)	29.6	-19.7 (0.64) (p<.00001)

P-values are for LS Mean treatment difference versus placebo.

- The primary endpoint showed clinically meaningful and highly statistically significant improvement.

All key secondary endpoints in both EMBARQ-CSU trials were met at Week 12 with high statistical significance and were clinically meaningful. Given the importance of Complete Response (complete absence of itch and hives) to patients and physicians, and barzolvolimab's unique ability to drive sustained Complete Response, we presented UAS7=0 data observed at both 12 and 24 weeks.

Proportion of Patients with Complete Response (UAS7=0) at Weeks 12 and 24		
	EMBARQ-CSU1	EMBARQ-CSU2
	12 Weeks	
Placebo	9.3%	12.6%
150 mg Q4W	42.4% (p<.00001)	45.7% (p<.00001)
300 mg Q8W	42.1% (p<.00001)	44.0% (p<.00001)
	24 Weeks	
Placebo	15.4%	17.6%
150 mg Q4W	49.0% (p<.00001)	54.0% (p<.00001)
300 mg Q8W	45.1% (p<.00001)	48.4% (p<.00001)

P-values are based on adjusted odds ratio of logistic regression models.

- Significantly more patients achieved Complete Response (UAS7=0) with both barzolvolimab doses vs. placebo at Weeks 12 and 24.

Proportion of Patients with Complete Response (UAS7=0) at Week 12 in Omalizumab-Refractory CSU		
	EMBARQ-CSU1	EMBARQ-CSU2
Placebo	9.3%	15.1%
150 mg Q4W	55.3% (p<.00001)	41.7% (p=.0089)
300 mg Q8W	44.3% (p=.00017)	46.4% (p=.0036)

P-values are based on adjusted odds ratio of logistic regression models.

- A higher proportion of patients achieved Complete Response (UAS7=0) vs. placebo at Week 12 in the sub-population of patients with CSU refractory to omalizumab.

Proportion of Patients with AAS7=0 at Week 12 in Patients with Baseline AAS7>0		
	EMBARQ-CSU1	EMBARQ-CSU2
Placebo	33.8%	33.7%
150 mg Q4W	62.7% (p<.00001)	74.3% (p<.00001)
300 mg Q8W	66.3% (p<.00001)	66.2% (p<.00001)

P-values are based on adjusted odds ratio of logistic regression models.

- A statistically higher proportion of patients achieved complete resolution of angioedema (AAS7=0) at Week 12 vs. placebo in patients with baseline AAS7>0.

Barzolvolimab was well-tolerated and demonstrated a favorable safety profile consistent with prior experience through the end of the placebo controlled period at Week 24. Patients continue to be treated through 52 weeks, and will be followed for 16 weeks after completion of treatment.

In addition, a global Phase 3b long term extension (LTE) study has been established for patient entry after completion of the EMBARQ - CSU Phase 3 trials. The study will consist of 2 Groups: Group 1 (Observation Group), containing patients whose disease remains well controlled (UAS7<16) and Group 2 (Barzolvolimab Retreatment Group) containing patients whose disease is currently moderate to severe (UAS7≥16). Patients in Group 2 will receive up to an additional year of treatment with barzolvolimab. Patients in the observation group (Group 1) whose CSU flares to a UAS7>/=16 in the first 6 months of the LTE will also be able to receive treatment.

Chronic Inducible Urticaria (CIndU) Summary of Phase 1 and Phase 2 Data

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 inducible urticarias other than antihistamines and patients attempt to manage symptoms associated with their disease through avoidance of triggers.

We completed a Phase 1b 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). The study was expanded to include a cohort (single dose, 3 mg/kg) in patients with cholinergic urticaria ("CholU") and a cohort at a lower dose (single dose, 1.5 mg/kg) in ColdU. Patient's symptoms were induced via provocation testing that resembles real life triggering situations. Secondary and exploratory objectives included pharmacokinetic and pharmacodynamic assessments, including changes from baseline provocation thresholds, measurement of tryptase and stem cell factor levels, clinical activity outcomes, quality of life assessments and measurement of tissue mast cells through skin biopsies.

Generally patients on 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, safety results were reported for 21 patients and activity results were reported for the 20 patients who received a full dose of barzolvolimab. At 1.5 mg/kg in the ColdU cohort, safety results were reported for 10 patients and activity results were reported for the 9 patients who received a full dose of 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 barzolvolimab.

Rapid (as early as 1 week) and durable responses were observed in 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. 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.

- A complete response was achieved in 100% (n=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 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 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. 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. 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 KIT inhibitor. Mild, transient, and asymptomatic decreases in hemoglobin and white blood cell parameters occurred for some patients.

- 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.

Data from this study were reported in Allergy (Nov 2022) and across multiple medical meetings, including the GA²LEN Global Urticaria Forum (GUF) in December and the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress in June 2022.

We completed a Phase 2 study in patients with CIndU who remain symptomatic despite antihistamine therapy. The study was conducted at approximately 85 sites across approximately 12 countries. The randomized, double-blind, placebo-controlled, parallel group Phase 2 study evaluated the efficacy and safety profile of multiple dose regimens of barzolvolimab in patients with CIndU to determine the optimal dosing strategy. 196 patients in 2 cohorts (differentiated by CIndU subtype) including 97 patients with cold

urticaria and 99 patients with symptomatic dermographism 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 then entered a follow-up phase for an additional 24 weeks. In addition, the study included the option for patients who had symptoms following the treatment phase, including patients who were on placebo, to enroll in an open label extension where all patients received 300 mg of barzolvolimab every 8 weeks. The primary endpoint of the study was the percentage of patients with a negative provocation test at Week 12. Secondary endpoints included safety and other assessments of clinical activity including CTT (Critical Temperature Threshold), CFT (Critical Friction Threshold) and WI-NRS (Worst itch numeric rating scale).

Topline primary endpoint data from this study were reported in July 2024 and 12 week treatment results were presented at the American College of Allergy, Asthma & Immunology's Annual Scientific Meeting. Data from the 193 patients randomized and treated in the study showed that barzolvolimab achieved the primary efficacy endpoint, a statistically significant difference between the percent of patients with a negative provocation test compared to placebo at Week 12 as assessed by the TempTest® in ColdU and the FricTest® in SD. Secondary and exploratory endpoints in the study were also achieved at Week 12 and strongly support the primary endpoint results, including responder analyses, improvements in Critical Temperature and Critical Friction Thresholds (CFT and CFT), changes in WI-NRSprovo (itch associated with provocation test) and Urticaria Control Test. Demographics and baseline disease characteristics were well balanced across treatment groups. Patients on study had poorly controlled disease on initial provocation testing. In cold urticaria, patients presented with a mean baseline critical temperature threshold of approximately 19°C or 66°F on the TempTest on initial provocation testing. In patients with symptomatic dermographism baseline FricTest thresholds were an average of 3.6 out of 4 pins. UCT scores at baseline also reflected poorly controlled disease.

Summary of Clinical Assessments at Week 12

	Cold Urticaria				Symptomatic Dermographism		
All measurements at Week 12	150 mg q4w (n=32)	300 mg q8w (n=32)	Placebo (n=32)		150 mg q4w (n=33)	300 mg q8w (n=33)	Placebo (n=31)
Primary endpoint: % of patients with negative provocation test (complete response)	46.9% **p=0.0023**	53.1% **p=0.0011**	12.5%		57.6% **p<0.0001**	42.4% **p=0.0003**	3.2%
% of patients with complete or partial response per provocation test	62.5% **p=0.0118**	75% **p=0.0006**	31.3%		66.6% **p<0.0001**	57.5% **p=0.0002**	12.9%
Improvement in Critical Temperature (CTT) and Critical Friction (CFT) Thresholds	-8.82°C **p<0.0001**	-9.61°C **p<0.0001**	-0.30°C		-2.46 pins **p<0.0001**	-2.27 pins **p=0.0002**	-0.82 pins
% of patients with Urticaria Control Test ≥12	58.6% **p=0.0048**	68.8% **p<0.0001**	31.0%		54.8% **p=0.0015**	65.5% **p<0.0001**	32.0%

Patients experienced rapid disease improvement as early as two weeks (the first assessment) after receiving the initial dose of barzolvolimab as demonstrated by reductions in critical temperature and friction thresholds resulting in hives and rapid reduction in itch at the time of provocation testing (WI-NRSprovo).

Barzolvolimab was well tolerated with a favorable safety profile consistent with prior studies. Most adverse events were grade 1 (mild). Through 12 weeks, the most common treatment emergent adverse events in barzolvolimab treated patients were hair color changes (13%; Grade 1, n=15 / Grade 2, n=2) and neutropenia (10%; Grade 1, n=7 / Grade 2, n=6), which are mechanism related (KIT) and expected to be reversible. The rate of infections was similar between barzolvolimab-treated patients and placebo with no association between neutropenia and infections.

In March 2025, quality of life data were presented at the AAAAI Annual Meeting 2025. A marked and rapid improvement in urticaria control (UCT) and quality of life (DLQI) was observed and sustained through the 12-week period in patients with ColdU and SD. Up to 60% of patients reported that CIndU symptoms no longer had an impact on their quality of life at Week 12 and up to 69% of patients reported well-controlled urticaria based on UCT at Week 12.

Patients on study continued to receive barzolvolimab for up to 20 weeks. Data from this longer term treatment period were presented in November 2025 at the ACAAI Annual Scientific Meeting. The data demonstrated sustained efficacy and a favorable safety profile over the 20 week placebo controlled treatment period. Key highlights at 20 weeks included:

- Up to 66% of patients with ColdU and 49% of patients with SD obtained a complete response compared to 16% and 10% of patients on placebo, respectively.

- Up to 78% of patients with ColdU and 58% of patients with SD obtained a partial or complete response compared to 25% and 16% of patients on placebo, respectively.

- Marked improvement in critical temperature threshold (from baseline values of 18.7°C and 20.7°C to Week 20 values of 10.7°C and 9.2°C for barzolvolimab 150 mg Q4W and 300 mg Q8W, respectively compared to baseline values of 18.6°C to Week 20 values of 18.2°C for placebo) and friction thresholds (from baseline values of 3.6 and 3.6 pins to 1.5 and 1.4 pins for barzolvolimab 150 mg Q4W and 300 mg Q8W, respectively compared to baseline values of 3.6 pins to 2.9 pins for placebo) were observed over the course of the 20 week treatment period. Sustained improvement in itch reduction at the time of provocation testing (WI-NRSprovo) was also observed at Week 20.

- After completing the treatment period, patients were eligible to enter a 24 week open label extension (OLE) upon resumption/continuation of symptoms. Consistent with the clinical endpoint results at Week 20, placebo-treated patients entered the OLE at a faster rate compared to barzolvolimab-treated patients.

- Barzolvolimab was well tolerated with a favorable safety profile over the 20 week treatment period consistent with previous studies. There was no difference between active treatment (2%) and placebo groups (3%) in rate of discontinuations due to adverse events. Most adverse events for patients on study drug were grade 1 (mild), mechanism related (KIT) and, as demonstrated in previous studies, expected to be reversible. The most common adverse events occurring in greater than 10% of patients in any treatment group through Week 20 were hair color changes (18%; Grade 1, n=22 / Grade 2, n=2) and neutropenia (12%; Grade 1, n=9 / Grade 2, n=6). Neutropenia was transient and there was no association with infections.

In March 2026, data from the Phase 2 ColdU and SD Open Label Extension (OLE) were presented at the AAAAI Annual Meeting 2026 demonstrating that retreatment with barzolvolimab leads to rapid improvement in urticaria control after symptom recurrence. Patients with disease recurrence during the main study follow-up period qualified for the OLE. 121 patients entered the OLE, 61 patients with ColdU and 60 patients with SD, and 116 patients completed treatment in the OLE. Patients treated with placebo in the main study entered the OLE faster than patients treated with barzolvolimab (median time of 56 days versus 105 days from last dose in main study). Barzolvolimab re-treatment achieved similar profound efficacy to first exposure in patients with ColdU and SD.

- With barzolvolimab re-treatment, 62% of patients with ColdU and 60% of patients with SD had a complete response at Week 20 in the OLE. These findings are consistent with the complete response rates in these patients to their initial treatment of 66% for ColdU and 49% for SD at Week 20 in the main study.

- Among patients with ColdU who achieved a complete response in the main study (n = 22), in the OLE, 82% of these patients achieved a complete response again and 95% achieved complete or partial response at Week 20.

- Among patients with SD who achieved a complete response in main study (n = 21), in the OLE, 86% of these patients achieved a complete response again and 100% achieved either a complete or partial response at Week 20.

- Marked, rapid reduction in critical temperature and friction thresholds were observed upon re-treatment.

- Barzolvolimab re-treatment resulted in clinically meaningful improvements in urticaria control, achieving a high rate of well controlled disease: up to 68% of patients with ColdU and 69% of patients with SD.
- Barzolvolimab was well tolerated with a safety profile consistent with prior studies.
- The ability to re-treat facilitates a real-world paradigm in which treatment for CIndU may be intermittent.

We believe these results strongly support the further development of barzolvolimab in ColdU and SD.

In December 2025, we initiated a Phase 3 study of barzolvolimab in adult patients with ColdU and SD who remain symptomatic despite H1 antihistamine treatment. The Phase 3 trial (EMBARQ-ColdU and SD) is a randomized, double-blind, placebo-controlled, parallel group, global Phase 3 study (approximately 75 clinical trial sites across 7 countries) where approximately 240 participants will be enrolled to 2 separate cohorts (differentiated by subtype) to include approximately 120 participants with ColdU and 120 participants with SD. Participants in each cohort will be randomized in a 1:1 ratio to one of two treatment arms: cohort 1: barzolvolimab 150 mg every 4 weeks (Q4W) following a loading dose of 450 mg on Day 1 or cohort 2: matching placebo for 24 weeks. At 24 weeks, all patients will receive open label barzolvolimab 300mg every 8 weeks (Q8W) for an additional 28 weeks for a total treatment duration of 52 weeks in the study. The primary endpoint of the study will evaluate the percentage of patients with complete response (negative provocation test) at Week 12 as assessed by the TempTest® in ColdU and the FricTest® in SD. After completing the 52 week treatment period, participants will continue to be followed for 16 weeks.

Prurigo Nodularis (PN)

In July 2026, we announced topline results from a Phase 2 study in prurigo nodularis (PN), a chronic skin disease characterized by the development of hard, intensely itchy (pruritic) nodules on the skin. Mast cells through their interactions with sensory neurons and other immune cells are believed to play an important role in amplifying chronic itch and neuroinflammation, both of which are a hallmark of PN. We designed the Phase 2 study to determine if barzolvolimab could deplete mast cells and, in turn, improve clinical outcomes in PN. Topline results demonstrated that the trial did not meet primary or key secondary endpoints at Week 12 at either dose level evaluated. Barzolvolimab was well-tolerated and demonstrated a favorable safety profile consistent with prior studies. Rapid and profound suppression of circulating tryptase, indicative of systemic mast cell depletion was observed. These data indicate that mast cells may not be the key pathogenic driver in PN. Based on these results, we are discontinuing the Phase 2 PN study.

Atopic Dermatitis (AD)

In December 2024, we announced the initiation of a Phase 2 study in atopic dermatitis (AD). AD is one of the most common chronic inflammatory skin diseases, with a lifetime prevalence of up to 20% of the US population and a substantial impact on quality of life (Kawakami, et al. 2009). Mast cells are strongly implicated in all facets of AD pathophysiology and the fundamental processes that characterize AD, including epithelial barrier dysfunction, immune cell recruitment, neuroinflammation (Keith, et al. 2023) and multiple other mast cell-associated factors that correlate with disease severity. Activated mast cells are also found in increased numbers in lesional biopsies. Two-thirds of patients treated with first line systemic therapy (1.7 million patients in the US) do not achieve complete control of their atopic dermatitis (Simpson, Bieber, Guttman-Yassky, et al. 2016) and new therapies that offer rapid, meaningful relief from the severe itching and breakdown of the skin associated with AD are needed. Given barzolvolimab's potential as a mast cell depleting agent, we believe AD 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 moderate to severe AD. 131 patients were randomly assigned on a 1:1:1 ratio to receive subcutaneous injections of barzolvolimab at either 150 or 300 mg or placebo every 4 weeks after an initial loading dose of 450 mg or placebo during a 16-week placebo-controlled treatment phase. Participants randomized into the placebo arm were re-randomized at Week 16 into 1 of the 2 active treatment arms. Patients then entered a 16-week active treatment phase, in which all patients will receive barzolvolimab every 4 weeks. The primary endpoint of the study is to evaluate the clinical efficacy of the two dose levels compared to placebo using the Peak Pruritus Numerical Rating Scale (PP-NRS) at Week 16, a well-defined, reliable, sensitive and valid scale for evaluating worst itch intensity in adults with moderate-to-severe AD. Secondary endpoints include the evaluation of the clinical efficacy of barzolvolimab, compared to placebo across multiple patient-reported outcomes, including assessing impressions of disease change and severity and improvements in quality of life. The study included approximately 40 clinical trial centers in the United States. Enrollment was completed in January 2026. Topline data from the study is expected in late 2026.

Additional Barzolvolimab Development Activities

The barzolvolimab manufacturing process has been successfully transferred and scaled up to produce larger cGMP batches at both Drug Substance (DS) and Drug Product (DP) commercial Contract Development and Manufacturing Organizations in support of late-stage trials and to prepare for potential commercialization. Drug product manufacturing into 1 mL pre-filled syringes has been completed and pre-filled syringes are actively being used in Phase 3 trials. In 2025, we initiated the Process Performance Qualification (PPQ) manufacturing runs for DS and anticipate the completion of those activities in 2026. DP PPQ activities were successfully completed.

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 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. 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. In June 2026 we presented first-in-human data that demonstrated neutralizing soluble SCF can selectively inhibit KIT signaling in mast cells. This approach provides a validated anchor mechanism that enables the development of diverse bispecific candidates where a dual mechanism approach may overcome the heterogeneity inherent in the pathophysiology of many inflammatory disorders.

CDX-622

CDX-622 is our first bispecific antibody based on this science and targets two complementary pathways that drive chronic inflammation, potently neutralizing the alarmin thymic stromal lymphopoietin (TSLP) and depleting mast cells via stem cell factor (SCF) starvation. We believe CDX-622 has significant potential across indications where both TSLP and mast cells play a pathogenic role. Combined neutralization of SCF and TSLP with CDX-622 is expected to simultaneously reduce tissue mast cells and inhibit Type 2 inflammatory responses to potentially offer enhanced therapeutic benefit in inflammatory and fibrotic disorders. CDX-622 has been engineered to disable effector function (AQQ) and reduce clearance (YTE). Prioritized indications include severe asthma, allergic rhinitis, and food allergy.

In November 2024, we initiated a multi-part Phase 1 study of CDX-622 in healthy volunteers and enrollment was completed across all parts in January 2026. The Phase 1a clinical trial is a three-part, randomized, double-blind, placebo-controlled, dose escalation study designed to assess the safety, pharmacokinetics, and pharmacodynamics of CDX-622 in up to 80 healthy participants.

A single dose of CDX-622 or placebo was administered intravenously (IV) once during Part 1. In Part 2, CDX-622 or placebo was administered IV every 2 weeks (Q2W) for up to 6 weeks following the first dose, for a total of 4 doses. In Part 3, a single dose of CDX-622 or placebo was administered subcutaneously once. Participants are followed for 12 weeks in all Parts following the last dose of study drug. The pharmacodynamic biomarkers from blood and skin will be highly informative on the ability of CDX-622 to engage and neutralize SCF and TSLP.

We presented positive data from the Phase 1 single ascending dose portion of the study (Part 1) at the CIA (Collegium Internationale Allergologicum) Biennial Symposium in October 2025. CDX-622 was well tolerated with no dose limiting toxicities and no emergent events related to systemic KIT inhibition. CDX-622 exhibited a good pharmacokinetic profile and induced rapid and sustained dose dependent reductions in serum tryptase, indicative of mast cell inhibition and depletion. Complete results from the Phase 1, first-in-human trial were presented at the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress in June 2026.

- Rapid, profound, dose-dependent, and durable reductions in serum tryptase were observed, indicative of tissue mast cell inhibition and depletion.
    - Tryptase decreases were comparable to KIT-targeting following multiple doses.
    - Biopsy data were consistent with greater impact on mucosal mast cells than skin mast cells.
- CDX-622 exhibited monoclonal antibody-like pharmacokinetics, with extended half-life and good exposure with subcutaneous administration, consistent with good bioavailability.
    - There was no evidence of immunogenicity at any dose.
- CDX-622 was well-tolerated in all study parts and at all dose levels. There were no dose-limiting toxicities or related serious adverse events.
    - The most commonly reported adverse event across the study was Grade 1 headache.
    - There were no meaningful changes in hair or skin pigmentation.
    - There was no meaningful impact on hematologic parameters.

Additionally, in June, Celldex presented new non-human primate data at the European Mast Cell and Basophil Research Network (EMBRN) that validates the approach of targeting soluble SCF to deplete mast cells. The preclinical study evaluated antibodies either targeting soluble SCF or both soluble and the membrane form of SCF. The data showed that targeting soluble SCF effectively depleted mast cells in a manner similar to targeting membrane SCF, but without measurable effect on spermatogenesis or melanogenesis in non-human primates.

Results to date support that combined TSLP neutralization and mast cell depletion with CDX-622 may result in broad efficacy in inflammatory diseases where both pathways play a pathogenic role.

In January 2026, we initiated an open-label, single-dose Phase 1 proof of mechanism study to assess the safety, pharmacodynamics, and pharmacokinetics of CDX-622 in adults with mild to moderate asthma to assess the impact of dual neutralization of SCF and TSLP. Participants receive a single IV infusion of CDX-622 and are followed for 12 weeks. PD effects of CDX-622 on fractional exhaled nitric oxide (FeNO), absolute eosinophil count (AEC) and serum biomarkers, including TSLP- and SCF-related biomarkers, will be evaluated.

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, 2025 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, 2026 Compared with Three Months Ended September 30, 2025

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2026	2025	$	%
	(In thousands)			
Revenues:				
Product development and licensing agreements	$ —	$ —	$ —	n/a
Contracts and grants	—	—	—	n/a
Total revenues	$ —	$ —	$ —	n/a
Operating expenses:				
Research and development	67,407	62,931	4,476	7 %
General and administrative	14,844	10,686	4,158	39 %
Total operating expenses	82,251	73,617	8,634	12 %
Operating loss	(82,251)	(73,617)	8,634	12 %
Investment and other income, net	6,694	6,573	121	2 %
Net loss	$ (75,557)	$ (67,044)	$ 8,513	13 %

Net Loss

The $8.5 million increase in net loss for the three months ended September 30, 2026, as compared to the three months ended September 30, 2025, was primarily due to an increase in research and development expenses related to barzolvolimab and an increase in general and administrative expenses.

Revenue

No revenue was recorded for the three months ended September 30, 2026 and 2025. We expect revenue to increase over the next twelve months as a result of an increase in services expected to be performed under our contract manufacturing and research and development agreements with Rockefeller University, although there may be fluctuations on a quarterly basis.

Research and Development Expense

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

	Three Months Ended September 30,		Increase/ (Decrease)	
	2026	2025	$	%
	(In thousands)			
Personnel	$ 18,272	$ 14,455	$ 3,817	26 %
Laboratory supplies	2,138	1,057	1,081	102 %
Facility	1,422	1,410	12	1 %
Product development	38,401	42,371	(3,970)	(9)%

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The $3.8 million increase in personnel expenses for the three months ended September 30, 2026, as compared to the three months ended September 30, 2025, was primarily due to 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 development of barzolvolimab.

Laboratory supplies expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The $1.1 million increase in laboratory supply expenses for the three months ended September 30, 2026, as compared to the three months ended September 30, 2025, was primarily due to higher laboratory materials and supplies purchases. We expect laboratory supplies expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Facility expenses include depreciation, amortization, utilities, rent, maintenance and other related expenses incurred at our facilities. Facility expenses for the three months ended September 30, 2026 were relatively consistent with the three months ended September 30, 2025. We expect facility expenses to increase over the next twelve months as a result of our new lease in New Haven, Connecticut and the expansion of our space in Hampton, New Jersey, 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 $4.0 million decrease in product development expenses for the three months ended September 30, 2026, as compared to the three months ended September 30, 2025, was primarily due to a decrease in contract manufacturing expenses. We expect product development expenses to increase over the next twelve months primarily due to increased costs associated with the development of barzolvolimab, although there may be fluctuations on a quarterly basis.

General and Administrative Expense

The $4.2 million increase in general and administrative expenses for the three months ended September 30, 2026, as compared to the three months ended September 30, 2025, was primarily due to higher commercial planning expenses and an increase in employee headcount. We expect general and administrative expenses to increase over the next twelve months primarily due to increased costs to support commercial planning efforts and the continued growth of our organization in preparation for potential commercialization of barzolvolimab, although there may be fluctuations on a quarterly basis.

Investment and Other Income, Net

Investment and other income, net for the three months ended September 30, 2026 was relatively consistent with the three months ended September 30, 2025. 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 September 30, 2026 Compared with Nine Months Ended September 30, 2025

	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2026	2025	$	%
	(In thousands)			
Revenues:				
Product development and licensing agreements	$ 7	$ 57	$ (50)	(88)%
Contracts and grants	30	1,367	(1,337)	(98)%
Total revenues	$ 37	$ 1,424	$ (1,387)	(97)%
Operating expenses:				
Research and development	207,950	169,741	38,209	23 %
General and administrative	39,396	31,897	7,499	24 %
Total operating expenses	247,346	201,638	45,708	23 %
Operating loss	(247,309)	(200,214)	47,095	24 %
Investment and other income, net	19,564	22,774	(3,210)	(14)%
Net loss	$ (227,745)	$ (177,440)	$ 50,305	28 %

Net Loss

The $50.3 million increase in net loss for the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025, was primarily due to an increase in research and development expenses related to barzolvolimab and an increase in general and administrative expenses.

Revenue

The $1.3 million decrease in contracts and grants revenue for the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025, was primarily due to a decrease in revenue from 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:

	Nine Months Ended September 30,		Increase/ (Decrease)	
	2026	2025	$	%
	(In thousands)			
Personnel	$ 49,726	$ 42,184	$ 7,542	18 %
Laboratory supplies	6,188	4,769	1,419	30 %
Facility	3,540	4,214	(674)	(16)%
Product development	130,304	108,073	22,231	21 %

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The $7.5 million increase in personnel expenses for the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025, was primarily due to an increase in employee headcount.

Laboratory supplies expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The $1.4 million increase in laboratory supply expenses for the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025, was primarily due to higher laboratory materials and supplies purchases.

Facility expenses include depreciation, amortization, utilities, rent, maintenance and other related expenses incurred at our facilities. The $0.7 million decrease in facility expenses for the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025, was primarily due to lower expense related to our leased facilities.

Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing. The $22.2 million increase in product development expenses for the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025, was primarily due to an increase in barzolvolimab clinical trial and contract manufacturing expenses.

General and Administrative Expense

The $7.5 million increase in general and administrative expenses for the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025, was primarily due to higher commercial planning expenses and an increase in employee headcount.

Investment and Other Income, Net

The $3.2 million decrease in investment and other income, net for the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025, was primarily due to lower cash and investment balances prior to the April 2026 underwritten public offering and lower yields on fixed income investments.

LIQUIDITY AND CAPITAL RESOURCES

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

The use of our cash flows for operations has primarily consisted of salaries and wages for our employees; facility and facility-related costs for our offices, laboratories and manufacturing facility; fees paid in connection with preclinical studies, clinical studies, contract manufacturing, laboratory supplies and services; activities to support and prepare for potential commercialization; 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, 2026, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of $650.3 million. We have had recurring losses and incurred a loss of $227.7 million for the nine months ended September 30, 2026. Net cash used in operations for the nine months ended September 30, 2026 was $188.0 million. We believe that the cash, cash equivalents and marketable securities at September 30, 2026 are sufficient to meet estimated working capital requirements and fund current planned operations through 2028. This could be impacted if we elect to pay the future milestone under the Settlement Agreement with SRS in 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 financings, 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 milestone under the Settlement Agreement with SRS, in the event that we achieve the milestone related to that payment. We may decide to pay that milestone 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, delay commercialization activities, 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 $188.0 million for the nine months ended September 30, 2026 as compared to $147.0 million for the nine months ended September 30, 2025. The increase in net cash used in operating activities was primarily due to an increase in research and development expenses related to barzolvolimab and an increase in general and administrative expenses, partially offset by an increase in accounts payable during the nine months ended September 30, 2026. We expect that cash used in operating activities will increase over the next twelve months as a result of the increased costs associated with the 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 $140.0 million for the nine months ended September 30, 2026 compared to net cash provided by investing activities of $153.6 million for the nine months ended September 30, 2025. The increase in net cash used in investing activities was primarily due to net purchases of marketable securities of $133.5 million for the nine months ended September 30, 2026 as compared to net sales and maturities of marketable securities of $155.1 million for the nine months ended September 30, 2025.

Financing Activities

Net cash provided by financing activities was $326.1 million for the nine months ended September 30, 2026 as compared to $1.0 million for the nine months ended September 30, 2025. The increase in net cash provided by financing activities was primarily due to an increase in proceeds from stock issuances.

In April 2026, we issued 11,896,750 shares of common stock in an underwritten public offering resulting in net proceeds of $323.8 million, after deducting underwriting fees and offering expenses.

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, 2026 due to the short-term maturities of these instruments.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

As of September 30, 2026, 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, 2026. 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, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1A. Risk Factors

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, 2025, 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 25, 2026.

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.

SIGNATURES

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

CELLDEX THERAPEUTICS, INC.

BY:

/s/ ANTHONY S. MARUCCI

Dated: November 5, 2026

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

/s/ SAM MARTIN

Dated: November 5, 2026

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

Exhibit 31.1

CERTIFICATION

I, Anthony S. Marucci, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2026

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

Exhibit 31.2

CERTIFICATION

I, Sam Martin, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2026

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

Exhibit 32.1

SECTION 1350 CERTIFICATIONS

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

Date: November 5, 2026

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

Date: November 5, 2026

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.