Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2024

or

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

Commission File Number 000-15006

CELLDEX THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**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)

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

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

Title of Each Class:	**Trading Symbol(s)**	**Name of Each Exchange Where Registered:**
Common Stock, par value $.001	CLDX	NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 and post 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the registrant's common stock held by non-affiliates as of June 30, 2024 was $2.4 billion. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the actions of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

The number of shares of common stock outstanding at February 14, 2025 was 66,383,811 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement for our 2025 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

Auditor Firm ID: 238 Auditor Name: PricewaterhouseCoopers LLP Auditor Location: Boston, Massachusetts

CELLDEX THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2024

TABLE OF CONTENTS

Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995: This Annual Report on Form 10-K 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 negotiate strategic partnerships, where appropriate, for our drug candidates;
- our ability to manage multiple clinical trials for a variety of drug candidates at different stages of development;
- the cost, timing, scope and results of ongoing preclinical and clinical testing;
- our expectations of the attributes of our product and development candidates, including pharmaceutical properties, efficacy, safety and dosing regimens;
- the cost, timing and uncertainty of obtaining regulatory approvals for our drug candidates;
- the availability, cost, delivery and quality of clinical management services provided by our clinical research organization partners;
- the availability, cost, delivery and quality of clinical and commercial-grade materials produced by our own manufacturing facility or supplied by contract manufacturers, suppliers and partners;
- our ability to commercialize our drug candidates and the growth of the markets for those drug candidates;
- our ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors;
- our ability to develop technological capabilities, including identification of novel and clinically important targets, exploiting our existing technology platforms to develop new drug candidates and expand our focus to broader markets for our existing targeted therapeutics;
- the cost of paying 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; and

- the factors listed under “Risk Factors” in this Annual Report on Form 10-K.

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.

PART I

Item 1. BUSINESS

Overview

Celldex Therapeutics, Inc., which we refer to as "Celldex," "we," "us," "our" or the "Company," is a biopharmaceutical company dedicated to exploring the science of mast cell biology and developing therapeutic antibodies which have the ability to engage the human immune system and/or directly affect critical pathways to improve the lives of patients with severe inflammatory, allergic, autoimmune and other devastating diseases. Our drug candidates include monoclonal and bispecific antibodies designed to address mast cell mediated diseases for which available treatments are inadequate.

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

- Barzolvolimab (also referred to as CDX-0159), a monoclonal antibody that specifically binds the KIT receptor and potently inhibits its activity, which is currently being studied across multiple mast cell driven diseases including
    - Chronic Urticarias: We initiated Phase 3 studies in chronic spontaneous urticaria (CSU) in July 2024. In November 2023, we announced that our Phase 2 study in CSU achieved the primary efficacy endpoint (statistically significant mean change from baseline to week 12 of urticaria activity score compared to placebo) and was well tolerated. Patients on study continued to receive barzolvolimab and, in September 2024, we reported data from 52 weeks of treatment—demonstrating sustained and deepening disease efficacy and a well tolerated long term safety profile. In July 2024, we announced that our Phase 2 study in chronic inducible urticaria (CIndU) 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 of 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 for 20 weeks of treatment;
    - Prurigo Nodularis (PN): In April 2024, we initiated a Phase 2 study in PN and enrollment is ongoing; positive data from a Phase 1b study in PN was reported in November 2023;
    - Eosinophilic Esophagitis (EoE): A Phase 2 study in EoE was initiated in June 2023 and is fully accrued; and
    - Atopic Dermatitis (AD): A Phase 2 study in AD was initiated in December 2024 and enrollment is ongoing.
- 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.
    - CDX-622 (TSLP & SCF): Our first bispecific candidate for inflammatory diseases is CDX-622 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 Phase 1a dose-escalation study in healthy volunteers was initiated and enrollment is ongoing.

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

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

Our future success depends upon many factors, including our ability, and that of any licensees and collaborators that we may have, to successfully develop, obtain regulatory approval for and commercialize our drug candidates. We have had no commercial revenues from sales of our drug candidates, and we have had a history of operating losses. It is possible that we may not be able to successfully develop, obtain regulatory approval for, or commercialize, our drug candidates, and we are subject to a number of risks that you should be aware of before investing in us. These risks are described more fully in "Item 1A. Risk Factors."

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 July 2024, we initiated two Phase 3 studies in CSU. Phase 1 studies in CSU and CIndU were successfully completed and Phase 2 studies are ongoing. In July 2023, we announced that enrollment was complete in the ongoing Phase 2 CSU study. In November 2023, we reported that barzolvolimab achieved the primary efficacy endpoint in this study, with a statistically significant mean change from baseline to week 12 of UAS7 (weekly urticaria activity score) compared to placebo and was well tolerated. In September 2024, we presented 52 week treatment data from the CSU study, demonstrating sustained and deepening disease efficacy and a well tolerated long term safety profile. We plan to present follow up data from this study through week 76 in 2025. In April 2024, we announced enrollment was complete in the ongoing Phase 2 CIndU study. In July 2024, we announced that our Phase 2 study in chronic inducible urticaria (CIndU) 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 of 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 for 20 weeks of treatment and were then followed for up to 24 additional weeks without treatment. We plan to present data from this study through week 44 in 2025. Patients with resumption of symptoms were eligible to enroll into an open label extension.

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 ongoing Phase 2 studies in eosinophilic esophagitis (EoE), prurigo nodularis (PN) and atopic dermatitis (AD). We continue to assess potential opportunities for barzolvolimab in other diseases where mast cells play an important role, such as dermatologic, respiratory, allergic, gastrointestinal and ophthalmic conditions.

Chronic Spontaneous Urticaria (CSU) Summary of Phase 1 and Phase 2 Data Presented to Date; 76 week Phase 2 follow up data to be presented in 2025.

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. Omalizumab, an IgE inhibitor, provides relief for roughly half of the remaining antihistamine refractory patients. Consequently, there is a need for additional therapies.

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. Secondary and exploratory objectives included pharmacokinetic and pharmacodynamic assessments, clinical activity outcomes and quality of life assessments. Barzolvolimab was administered intravenously as add on treatment to H1-antihistamines, either alone or in combination with H2-antihistamines and/or leukotriene receptor agonists. 45 patients with moderate to severe CSU refractory to antihistamines were enrolled and treated [35 barzolvolimab (n=9 in 0.5 mg/kg; n=8 in 1.5 mg/kg; n=9 in 3.0 mg/kg; n=9 in 4.5 mg/kg) and 10 placebo].

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

Phase 1 CSU: Summary of Clinical Activity Assessments at Week 12 & 24			
	4.5 mg/kg Q8	3.0 mg/kg Q8	1.5 mg/kg Q4
Mean Reduction Baseline UAS7; % at Week 12	82% (n=9)	67% (n=9)	67% (n=8)
Mean Reduction Baseline UAS7; % at Week 24	77% (n=7)	70% (n=6)	80% (n=7)
UAS7=0 (Complete Control); % at Week 12	67%	44%	57%
UAS7=0 (Complete Control); % at Week 24	43%	67%	57%
UAS7≤6 (Well-controlled); % at Week 12	67%	67%	57%
UAS7≤6 (Well-controlled); % at Week 24	57%	67%	57%
UCT ≥ 12 (Well-controlled); % at Week 12	89%	63%	75%
UCT ≥ 12 (Well-controlled); % at Week 24	67%	67%	75%

During post-treatment follow up, 71% (10 of 14) of patients who had been treated with doses greater than or equal to 1.5 mg/kg and had a complete response (UAS7=0) at week 12, remained urticaria free at week 24 (patients received last dose of barzolvolimab at week 8). Profound and durable improvement in angioedema symptoms as measured through the weekly angioedema activity score (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. The most common treatment emergent adverse events were hair color changes, COVID-19, headache, neutropenia and urinary tract infections (UTIs). UTIs and COVID-19 were reported as unrelated to treatment. Generally transient, asymptomatic and mild changes in hematologic parameters were observed, consistent with observations from prior studies. No pattern of further decrease was observed with multiple dose administration.

Data from this study were reported across multiple medical meetings, including the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting in February 2023, the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress in June 2023 and the European Academy of Dermatology & Venereology (EADV) Congress in October 2023.

In June 2022, we initiated dosing in a Phase 2 study in patients with CSU who remained symptomatic despite antihistamine therapy; in July 2023, we announced that enrollment was complete. The study is being conducted at approximately 75 sites across 9 countries. The study is a randomized, double-blind, placebo-controlled, parallel group Phase 2 study evaluating the efficacy and safety profile of multiple dose regimens of barzolvolimab to determine the optimal dosing strategy. 208 patients have been randomly assigned on a 1:1:1:1 ratio to receive subcutaneous injections of barzolvolimab at 75 mg every 4 weeks, 150 mg every 4 weeks, 300 mg every 8 weeks or placebo during a 16-week placebo-controlled treatment phase. After 16 weeks, patients then enter a 36-week active treatment period, in which patients receiving placebo or the 75 mg dose are 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 remain on the same regimen as during the placebo-controlled treatment period. After 52 weeks, patients then enter a follow-up period for an additional 24 weeks. The primary endpoint of the study is mean change in baseline to week 12 in UAS7 (weekly urticaria activity score). Secondary endpoints include 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 of 2023 and 12 week treatment results were presented at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting in February 2024. Data from the 208 patients randomized in the study showed that barzolvolimab achieved the primary efficacy endpoint, with a statistically significant mean change from baseline to week 12 in UAS7 compared to placebo at all dose levels. Secondary and exploratory endpoints in the study were also achieved at week 12 and strongly support the primary endpoint results, including changes in ISS7 and HSS7 and responder analyses. Importantly, barzolvolimab demonstrated rapid, durable and clinically meaningful responses in patients with moderate to severe CSU refractory to antihistamines, including patients with prior omalizumab treatment. Demographics and baseline disease characteristics were well balanced across treatment groups. The majority of patients on study had severe disease (UAS7≥28).

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, 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 and these long term treatment data were presented in September at the European Academy of Dermatology & Venereology (EADV) Congress 2024. The data demonstrated a sustained and deepening disease efficacy and a well tolerated safety profile over a 52 week treatment period. Key highlighted 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.
- 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.

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. Both Phase 3 trials are randomized, double-blind, placebo-controlled, parallel group, global studies (approximately 40 countries; 250 sites per study) where approximately 915 patients per trial will be randomized evenly 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 will be re-randomized to active treatment across both dosing groups. The primary endpoint of the studies will evaluate 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. Enrollment is ongoing.

Chronic Inducible Urticaria (CIndU) Summary of Phase 1 and Phase 2 Data Presented to Date; 44 week Phase 2 follow up data to be presented in 2025.

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 are currently exploring cold-induced and dermographism (scratch-induced) urticarias in an ongoing Phase 2 study.

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.

In July 2022, we announced that the first patient had been dosed in a Phase 2 study in patients with CIndU who remain symptomatic despite antihistamine therapy; in April 2024, we announced that enrollment was complete. The study is being conducted at approximately 85 sites across approximately 12 countries. The randomized, double-blind, placebo-controlled, parallel group Phase 2 study is evaluating the efficacy and safety profile of multiple dose regimens of barzolvolimab in patients with CIndU to determine the optimal dosing strategy. 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 enter a follow-up phase for an additional 24 weeks. In addition, the study includes the option for patients who have symptoms following the treatment phase, including patients who were on placebo, to enroll in an open label extension where all patients receive 300 mg of barzolvolimab every 8 weeks. The primary endpoint of the study is the percentage of patients with a negative provocation test at week 12. Secondary endpoints include safety and other assessments of clinical activity including CTT (Critical Temperature Threshold), CFT (Critical Friction Threshold) and WI-NRS (Worst itch numeric rating scale).

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. 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 reflect 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.

We believe these results strongly support the further development of barzolvolimab in CIndU and plan to advance CIndU into Phase 3 registrational development.

Prurigo Nodularis (PN)

We have expanded clinical development of barzolvolimab into prurigo nodularis (PN). PN is a chronic skin disease characterized by the development of hard, intensely itchy (pruritic) nodules on the skin. Mast cells through their interactions with sensory neurons and other immune cells are believed to play an important role in amplifying chronic itch and neuroinflammation, both of which are a hallmark of PN. There is currently only one FDA approved therapy for PN, representing an area of significant unmet need. Industry sources estimate there are approximately 154,000 patients in the United States with PN who have undergone treatment within the last 12 months and, of these, approximately 75,000 would be biologic-eligible.

We have completed a Phase 1b multi-center, randomized, double-blind, placebo-controlled intravenous study in PN. Data from the study, including 24 weeks of follow-up, were presented at the 12th World Congress on Itch (WCI) held in November 2023. 24 adults (evaluable: n=23 safety; n=22 efficacy) with moderate to severe PN were randomized across three arms: (1) barzolvolimab 3.0 mg/kg (n=9), barzolvolimab 1.5 mg/kg (n=7) and placebo (n=8). The primary endpoint of the study was safety; key secondary

endpoints include changes from baseline in Worst Itch-Numerical Rating Scale (WI-NRS) & Investigator Global Assessment (IGA). The primary timepoint for evaluation of clinical activity was 8 weeks; patients were followed for safety and efficacy endpoints to 24 weeks. Patients on study generally had moderate to severe disease with mean baselines scores across all arms of 8.6 for WI-NRS and 3.3 for IGA.

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

- At week 8, the percentage of patients with ≥4-point decrease in WI-NRS was 57% and 43% for the single dose 3.0 or 1.5 mg/kg barzolvolimab arms, respectively, and 25% for the placebo arm; this level of response generally persisted out to week 16. In the 3.0 mg/kg arm, a ≥4-point decrease in WI-NRS reduction was seen as early as the first week and reached a high of 71% of patients at week six which was distinct from both the 1.5 mg/kg barzolvolimab and placebo arms.

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

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

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

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

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

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

Eosinophilic Esophagitis (EoE)

In July of 2023, we announced that the first patient had been dosed in a Phase 2 study of eosinophilic esophagitis (EoE). EoE, the most common type of eosinophilic gastrointestinal disease, is a chronic inflammatory disease of the esophagus characterized by the infiltration of eosinophils. This chronic inflammation can result in trouble swallowing, chest pain, vomiting and impaction of food in the esophagus, a medical emergency. Several studies have suggested that mast cells may be an important driver in the disease, demonstrating that the number and activation state of mast cells are greatly increased in EoE biopsies and that mast cell signatures correlate with markers of inflammation, fibrosis, pain and disease severity. Currently, there is only one FDA approved therapy for EoE, representing an area of significant unmet need. Industry sources estimate there are approximately 160,000 patients in the United States with EoE who have undergone treatment within the last 12 months and, of these, approximately 48,000 would be biologic-eligible. Given the lack of effective therapies for EoE and barzolvolimab's potential as a mast cell depleting agent, we believe EoE is an important indication for future study.

The randomized, double-blind, placebo-controlled, parallel group Phase 2 study is evaluating the efficacy and safety profile of subcutaneous barzolvolimab in patients with active EoE. To optimize potential efficacy signal in this difficult to treat indication, we have recently amended the protocol to dose 300 mg every 4 weeks rather than 8 weeks. Approximately 75 patients will be enrolled in total. In the revised protocol, patients will be randomly assigned on a 1:1 ratio to receive subcutaneous injections of barzolvolimab at 300 mg every 4 weeks or placebo during a 16-week placebo-controlled treatment phase. Patients then enter a 12-week active treatment phase, in which all patients will receive barzolvolimab 300 mg every 4 weeks. Patients then enter a follow-up phase for an additional 16 weeks. The primary endpoint of the study is reducing esophageal intraepithelial infiltration of mast cells as assessed by peak esophageal intraepithelial mast cell count. Secondary endpoints include the reduction of symptoms of dysphagia and esophageal intraepithelial infiltration of eosinophils and safety. The study includes approximately 60 clinical trial centers across 8 countries, including the United States. The study is fully accrued and we plan to present data from the study in the second half of 2025.

Atopic Dermatitis (AD)

In December of 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 patienst 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. Approximately 120 patients will be 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 will be re-randomized at Week 16 into 1 of the 2 active treatment arms. Patients then enter 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. When all clinical trial sites are open, the study will include up to 50 clinical trial centers in the United States. Enrollment is ongoing.

Additional Barzolvolimab Development Activities

In 2023, we completed the transfer of our current barzolvolimab manufacturing process to a Contract Development & Manufacturing Organizations ("CDMO") and successfully scaled up the drug substance manufacturing process to produce larger cGMP batches in support of late-stage trials and to prepare for potential commercialization. Drug product manufacturing into 1 mL pre-filled syringes has been completed and are actively being used in the ongoing Phase 3 CSU trials.

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.

CDX-622

CDX-622 is a bispecific antibody that 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. TSLP has been directly implicated in several respiratory and dermatological disorders, such as asthma, chronic obstructive pulmonary disease (COPD), eosinophilic esophagitis, atopic dermatitis and chronic spontaneous urticaria, and in fibrotic diseases such as systemic sclerosis and idiopathic pulmonary fibrosis. In these disorders, TSLP is often upregulated and associated with disease severity. Similarly, mast cells drive or contribute to the pathophysiology of allergic, inflammatory, autoimmune and fibrotic disorders and CDX-622 contains a unique SCF neutralizing function that is expected to inhibit and deplete mast cells. 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. In preclinical studies, CDX-622 inhibits TSLP and SCF with similar potency to both its respective parental mAbs and comparator mAbs *in vitro*. CDX-622 was well tolerated in a multi-dose 8 week toxicology study in non-human primates. The No Adverse Event Level (NOAEL) was established to be 75 mg/kg, the highest dose level tested.

In November 2024, we initiated a Phase 1 study of CDX-622 in healthy volunteers. The Phase 1a clinical trial is a two-part, randomized, double-blind, placebo-controlled, dose escalation study designed to assess the safety, pharmacokinetics, and pharmacodynamics of single ascending doses (Part 1) and multiple ascending doses (Part 2) of CDX-622 in up to 56 healthy participants. A single dose of CDX-622 or placebo will be administered intravenously once during Part 1. In Part 2, CDX-622 or placebo will be administered every 3 weeks (Q3W) for up to 6 weeks following the first dose, for a total of 3 doses. Participants will be followed for 12 weeks in both Parts 1 and 2 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. A subcutaneous formulation is currently being manufactured and will be added to this study in 2025.

CDX-585 (development discontinued)

CDX-585 combined PD-1 blockade and anti-ILT4 blockade to overcome immunosuppressive signals in T cells and myeloid cells, respectively. We initiated a Phase 1 open-label, multi-center, multi-dose study in patients with advanced or metastatic solid tumors that had progressed during or after standard of care therapy. The dose-escalation phase of the study was completed and we announced in Q4 2024 that we would not advance CDX-585 given our expanding clinical development program in the inflammatory space.

Partnerships

We may enter into co-development and commercialization partnerships for any of our programs where appropriate. In the past, we have entered into collaborative partnership agreements with pharmaceutical and other companies and organizations that provided financial and other resources, including capabilities in research, development, manufacturing, and sales and marketing, to support our research and development programs and may enter into more of them in the future.

Partnership agreements may terminate without benefit to us if the underlying products are not fully developed. If we fail to meet our obligations under these agreements, they could terminate, and we might need to enter into relationships with other collaborators and to spend additional time, money and other valuable resources in the process. We cannot predict whether our collaborators will continue their development efforts or, if they do, whether their efforts will achieve success. Many of our collaborators face the same kinds of risks and uncertainties in their businesses that we face. A delay or setback to a partner will, at a minimum, delay the commercialization of any affected drug candidates, and may ultimately prevent it. Moreover, any partner could breach its agreement with us or otherwise not use best efforts to promote our products. A partner may choose to pursue alternative technologies or products that compete with our technologies or drug candidates. In either case, if a partner failed to successfully develop one of our drug candidates, we would need to find another partner. Our ability to do so would depend upon our legal right to do so at the time and whether the product remained commercially viable.

Research Collaboration and License Agreements

We have entered into license agreements whereby we have received licenses or options to license technology, specified patents and/or patent applications. These license and collaboration agreements generally provide for royalty payments equal to specified percentages of product sales, annual license maintenance fees, continuing patent prosecution costs and potential future milestone payments to third parties upon the achievement of certain development, regulatory and/or commercial milestones. Summarized below is our significant research collaboration and license agreement for our current clinical drug candidates.

Yale University (Yale)

Under a license agreement with Yale, we may be required to make a one-time payment to Yale of $3.0 million with respect to barzolvolimab upon achievement of a specified commercial milestone. In addition, we may be required to pay a low single-digit royalty on annual worldwide net sales of barzolvolimab. Unless earlier terminated by us or Yale, the Yale license agreement is due to expire no later than May 2038 but may expire earlier on a country-by-country basis under specified circumstances.

Competition

The biotechnology and pharmaceutical industry is intensely competitive and subject to rapid and significant technological change. Many of the products that we are attempting to develop and commercialize will be competing with existing therapies. Other companies are pursuing the development of new therapies that target the same diseases and conditions that we are targeting and may compete directly with our drug candidates. We face competition from companies, major universities and research institutions in the United States and abroad, including a number of large pharmaceutical companies, as well as firms specialized in the development and production of targeted therapies and immune modulators. Some of our competitors possess substantially greater financial, technical and human resources than we do.

The following table is a summary of the competitors of which we are aware that have initiated a Phase 3 study or have obtained marketing approval for a potentially competitive drug to barzolvolimab for treatment of CSU, CIndU, PN, EoE and AD.

Competitor	Competitor Product	Indication(s)
Abbvie	Rinvoq	AD
Amgen	Tezpire	EoE
Amgen/Kiowa Kirin	Rocatinlimab	AD and PN
Celltrion	CT-P39, omalizumab biosimilar	CSU
Eli Lilly	Olumiant and Ebglyss	AD
Galderma/Chugai	Nemluvio	PN and AD
Incyte	Povorcitinib	PN
Kashiv Biosciences	ADL-018 omalizumab biosimilar	CSU
Leo Pharma	Adbry	AD
Medimetriks	Difamilast	AD
Novartis	Remibrutinib	CSU and CIndU
Pfizer	Cibinqo	AD
Regeneron/Sanofi	Dupixent	CSU, PN, EoE and AD
Regeneron/Sanofi	Amlitelimab	AD
Teva	Tev-45779, omalizumab biosimilar	CSU
Vanda Pharmaceuticals	Tradipitant	AD

Our competitors may utilize discovery technologies and techniques or partner with collaborators in order to develop products more rapidly or successfully than us or our collaborators are able to. In addition, some competitors have significantly greater experience than we have in conducting preclinical and nonclinical testing and human clinical trials of drug candidates, scaling up manufacturing operations and obtaining regulatory approvals of drugs and manufacturing facilities. Accordingly, our competitors may succeed in obtaining regulatory approval for drugs more rapidly than we do. If we obtain regulatory approval and commence commercial sales of our drug candidates, we also will compete with respect to manufacturing efficiency and sales and marketing capabilities, areas in which we currently have limited experience.

In addition, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies and may establish exclusive collaborative or licensing relationships with our competitors. Moreover, technology controlled by third parties that may be advantageous to our business may be acquired or licensed by our competitors, thereby preventing us from obtaining technology on commercially reasonable terms, if at all. We will also compete for the services of third parties that may have already developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies to target the diseases on which we have focused both in the U.S. and outside of the U.S.

We also face competition in recruiting and retaining highly qualified scientific personnel and consultants and in the development and acquisition of technologies.

Our competitive position will depend upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the often lengthy period between technological conception and commercial sales. We will require substantial capital resources to complete development of some or all of our drug candidates, obtain the necessary regulatory approvals and successfully manufacture and market our drug candidates. In order to secure capital resources, we anticipate having to sell additional capital stock, which would dilute existing stockholders. We may also attempt to obtain funds through research grants and agreements with commercial collaborators. However, these types of funding are uncertain because they are at the discretion of the organizations and companies that control the funds. As a result, we may not receive any funds from grants or collaborations. Alternatively, we may borrow funds from commercial lenders, likely at high interest rates, which would increase the risk of any investment in us.

Manufacturing

We are a research and development company and have limited experience in commercial manufacturing. To conduct late-stage clinical trials, as well as manufacture and commercialize our drug candidates, we engage CDMOs in the U.S and outside the U.S. to manufacture our drug candidates on a large scale at a competitive cost and in accordance with current Good Manufacturing Practices (cGMP) and U.S. and foreign regulatory requirements, as applicable. We also rely on CDMOs for filling, labeling and storage for studies inside and outside the U.S. Any manufacturing failures or compliance issues at our CDMOs could cause delays in our clinical studies or commercialization of our drug candidates.

We currently operate our own cGMP manufacturing facility in Fall River, Massachusetts, to produce drug substance for our current and planned early-stage clinical trials. Our Fall River manufacturing facility has 250L and 1000L bioreactor capacity and is able to manufacture in compliance with FDA and EU regulations, allowing us to distribute drug candidates to clinical sites in the U.S., EU and ROW for early-stage clinical trials. We have manufactured barzolvolimab and CDX-622 drug substance in our Fall River facility for our current and planned Phase 1 and Phase 2 clinical trials.

Our barzolvolimab drug product is currently administered subcutaneously. The subcutaneous formulation will allow for potential self-administration at home setting versus the need for intravenous dosing in a hospital or clinic setting. The subcutaneous form could improve the patient experience if the product becomes available commercially. In 2023, we completed the transfer of our current barzolvolimab manufacturing process to a CDMO and successfully scaled up the drug substance manufacturing process to produce larger cGMP batches in support of late-stage trials and to prepare for potential commercialization. Drug product manufacturing into 1 mL pre-filled syringes has been completed and are actively being used in the ongoing Phase 3 CSU trials. We are in the process of scaling up our drug product manufacturing. We believe that barzolvolimab can be scaled up to permit drug product manufacturing in commercial quantities.

Commercial Organization

We have limited commercial experience in marketing, sales, distribution and product reimbursement. We have the capability to provide current and future market insights to our research and development organization regarding our potential drug candidates. In the future, we may choose to expand our commercial team and build a full-scale commercial organization which we believe could provide us the opportunity to retain marketing rights to our drug candidates and commercialize such products ourselves where we deem appropriate or pursue strategic partnerships to develop, sell, market and distribute our drug candidates where we deem appropriate.

Patents, Licenses and Proprietary Rights

In general, our intellectual property strategy is to protect our technology by filing patent applications and obtaining patent rights covering our own technology, both in the United States and in foreign countries that we consider important to our business. In addition, we have acquired and will seek to acquire as needed or desired, exclusive rights of others through assignment or license to complement our portfolio of patent rights. We also rely on trade secrets, unpatented know-how and technological expertise and innovation to develop and maintain our competitive position.

Patents

The successful development and marketing of products by us will depend in part on our ability to create and maintain intellectual property, including patent rights. We are the owner or exclusive licensee to proprietary patent positions in the areas of immunotherapy technologies and antibody technologies. Although we continue to pursue patent protection for our products, no assurance can be given that any pending application will issue as a patent, that any issued patent will have a scope that will be of commercial benefit or that we will be able to successfully enforce our patent position against infringers. We routinely review our patent portfolio and adjust our strategies for prosecution and maintenance of individual cases according to a number of factors, including program priorities, stage of development and patent term.

The key patents and patent applications owned by us or licensed to us that we consider important to our current clinical programs include the following (except where stated otherwise, the indicated and estimated patent expiry dates are the estimated normal expirations if all maintenance fees and annuities are paid when due, and do not include any possible additional terms for Patent Term Adjustments (PTAs), Patent Term Extensions (PTEs), other term extensions or Supplementary Protection Certificates (SPCs), if these may be secured in due course):

- We own a portfolio of patents and patent applications directed to barzolvolimab and other anti-KIT receptor antibodies. These patents and patent applications include claims directed to particular anti-KIT antibody compositions of matter, including barzolvolimab compositions of matter, and methods of using such antibodies. A composition of matter patent has been issued in the U.S. which would have an estimated patent expiry date in 2034 (this includes additional term due to PTA, but does not include any PTE if this may be secured in due course) and further U.S. patent applications are pending. Patents have also been issued in Europe, Japan, Canada, China, Australia, New Zealand, Israel, India, the Republic of Korea, the Russian Federation, Singapore, Brazil, Mexico, South Africa and certain other countries. Where issued the foregoing would

have estimated normal patent expiry dates ranging from 2032 to 2033. Further (later filed) patent applications (relating to Fc sequences used in barzolvolimab and certain uses of barzolvolimab) are pending in the U.S., the European Patent Office, Japan, Canada, China, Australia, New Zealand, Israel, India, the Republic of Korea, the Eurasian Patent Office, Singapore, Brazil, Mexico and South Africa. If, when and where issued the latter would have estimated normal patent expiry dates in 2042.

- We own a pending international patent application directed to anti-SCF and anti-TSLP antibody sequences used in CDX-622 as compositions of matter. If, when and where issued any applications in the national and regional phases of this application would have estimated normal patent expiry dates in 2044.

There can be no assurance that patent applications owned by or licensed to us will result in granted patents or that, if granted, the resultant patents will afford protection against competitors with similar technology. It is also possible that third parties may obtain patents or other proprietary rights that may be necessary or useful to us. In cases where third parties are first to invent a particular product or technology, it is possible that those parties will obtain patents that will be sufficiently broad to prevent us from using important technology or from further developing or commercializing important drug candidates and immunotherapeutic systems. If licenses from third parties are necessary but cannot be obtained, commercialization of the covered products might be delayed or prevented. Even if these licenses can be obtained, they would probably require us to pay ongoing royalties and other costs, which could be substantial.

Although a patent has a statutory presumption of validity in the United States, the issuance of a patent is not conclusive as to validity or as to the enforceable scope of the patent claims. The validity or enforceability of a patent after its issuance by the Patent and Trademark Office can be challenged in litigation. As a business that uses a substantial amount of intellectual property, we face a heightened risk of intellectual property litigation. If the outcome of the litigation is adverse to the owner of the patent, third parties may then be able to use the invention covered by the patent without authorization or payment. There can be no assurance that our issued patents or any patents subsequently issued to or licensed by us will not be successfully challenged in the future. In addition, there can be no assurance that our patents will not be infringed or that the coverage of our patents will not be successfully avoided by competitors through design innovation.

We are aware that others, including universities and companies, have filed patent applications and have been granted patents in the United States and other countries which claim subject matter potentially useful or necessary to the commercialization of our products. The ultimate scope and validity of existing or future patents which have been or may be granted to third parties, and the availability and cost of acquiring rights in those patents necessary to the manufacture, use or sale of our products presently cannot be determined by us.

Third parties may have or may obtain valid and enforceable patents or proprietary rights that could block us from developing products using our technology, including:

- certain patents and pending patent applications in the United States and foreign countries relating to particular receptors, antigens and antigenic fragments targeted by our current drug candidates; and

- certain patents and pending patent applications in the United States and foreign countries relating to antibodies targeting certain receptors and other targets including anti- SCF antibodies, anti-TSLP antibodies and certain other antibodies and their sequences and uses.

In addition to the patents referred to in the previous paragraphs, there may be other patent applications and issued patents belonging to competitors that may require us to alter our drug candidates and immunotherapeutic delivery systems, pay licensing fees or cease some of our activities. If our drug candidates conflict with patents that have been or may be granted to competitors, universities or others, the patent owners could bring legal action against us claiming damages and seeking to enjoin manufacturing and marketing of the patented products. If any of these actions is successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to manufacture or market the affected products. There can be no assurance that we would prevail in any such action or that any license required under any such third-party patent would be made available on acceptable terms or at all. We believe that there may be significant litigation in the biotechnology industry regarding patent and other intellectual property rights. If we become involved in that litigation, we could consume substantial resources.

Licenses

We have entered into significant license agreements relating to technologies that are being developed by us. Typically, institutions have granted us an exclusive worldwide license (with right to sublicense) to make, use and sell products embodying the licensed technology, subject to the reservation by the licensor of a non-exclusive right to use the technologies for non-commercial research purposes. Generally, the term of each license is through the expiration of the last of the patents issued with respect to the technologies covered by the license and/or a specified period from first commercial sale on a territory-by- territory basis. We have generally agreed to use reasonable efforts to develop and commercialize licensed products and to achieve specified milestones and pay license fees, milestone payments and royalties based on the net sales of the licensed products or to pay a percentage of sublicense income. If we breach our obligations, the licensor has the right to terminate the license, and, in some cases, convert the license to a non-exclusive license. Generally, we control and are responsible for the cost of defending the patent rights of the technologies that we license.

Proprietary Rights

We also rely on unpatented technology, trade secrets and confidential information, and no assurance can be given that others will not independently develop substantially equivalent information and techniques or otherwise gain access to our know-how and information, or that we can meaningfully protect our rights in such unpatented technology, trade secrets and information. We require each of our employees, consultants and advisors to execute a confidentiality agreement at the commencement of an employment or consulting relationship with us. The agreements generally provide that all inventions conceived by the individual in the course of employment or in providing services to us and all confidential information developed by, or made known to, the individual during the term of the relationship shall be the exclusive property of us and shall be kept confidential and not disclosed to third parties except in limited specified circumstances. There can be no assurance, however, that these agreements will provide meaningful protection for our information in the event of unauthorized use or disclosure of such confidential information.

Government Regulation

Our activities and products are significantly regulated by a number of governmental entities, including the U.S. Food and Drug Administration, or FDA, in the United States and by comparable authorities in other countries. These entities regulate, among other things, the manufacture, testing, safety, effectiveness, labeling, documentation, advertising and sale of our products. We must obtain regulatory approval from the FDA and comparable authorities in other countries, as applicable, for our drug candidates before we can commercialize such drugs in the U.S. and foreign jurisdictions. Product development within this regulatory framework takes a number of years and involves the expenditure of substantial resources. Many drug candidates that initially appear promising ultimately do not reach the market because they are found to be unsafe or ineffective when tested. Our inability to commercialize a product would impair our ability to earn future revenues.

FDA Approval Process

In the United States, the FDA regulates drugs and biological products under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, civil penalties and criminal prosecution.

The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of preclinical studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;

- submission to the FDA of an investigational new drug, or IND, application which must become effective before human clinical trials may begin;

- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug or biological product for each indication;
- submission to the FDA of a new drug application, or NDA, or a biologics license application, or BLA, as applicable;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA or BLA.

We expect that all of our clinical drug candidates will be subject to review as biological products under BLA standards.

Data obtained at any stage of testing is susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Moreover, during the regulatory process, new or changed drug approval policies may cause unanticipated delays or rejection of our product. We may not obtain necessary regulatory approvals within a reasonable period of time, if at all, or avoid delays or other problems in testing our products. Moreover, even if we received regulatory approval for a product, the approval may require limitations on use, which could restrict the size of the potential market for the product.

Clinical Trials

The FDA provides that human clinical trials may begin 30 days after receipt and review of an IND application, unless the FDA requests additional information or changes to the study protocol within that period. An IND must be sponsored and filed for each of our proposed drug candidates. Authorization to conduct clinical trials in no way assures that the FDA will ultimately approve the product. Clinical trials are generally conducted in three sequential phases. In a Phase 1 trial, the product is given to a small number of patients to test for safety (adverse effects), determine a recommended Phase 2 dose(s) and evaluate any signals of efficacy. Phase 2 trials are conducted on a limited group of the target patient population; safety, optimal dosage and efficacy are studied. A Phase 3 trial is performed in a large patient population, generally over a wide geographic area to provide evidence for the safety and efficacy of the product. The FDA maintains and exercises oversight authority throughout the clinical trial. Studies that are conducted in multiple countries are reviewed and authorized by additional regional or country specific health authorities in addition to the FDA. The additional international review often is slower than that of the FDA and may result in regulatory opinions that are different than the decisions provided by the FDA.

A product's safety and effectiveness in one clinical trial is not necessarily indicative of its safety and effectiveness in another clinical trial. Moreover, we may not discover all potential problems with a product even after completing clinical trials on it. Some of our products and technologies have undergone only preclinical testing. As a result, we do not know whether they are safe or effective for humans. Also, regulatory authorities may decide, contrary to our findings, that a product is unsafe or not as effective in actual use as its clinical trial results indicated. This could prevent the product's widespread use, require its withdrawal from the market or expose us to liability. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Any such action could materially harm us. Clinical trials are critical to the success of our products but are subject to unforeseen and uncontrollable delay, including delay in enrollment of patients. Any delay in clinical trials could delay our commercialization of a product.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information on the website www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be

delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's pharmacology, chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. FDA approval of the NDA or BLA is required before marketing of the product may begin in the United States. Under federal law, the submission of most NDAs and BLAs is additionally subject to a substantial application user fee and the sponsor of an approved NDA or BLA is also subject to annual prescription drug program fees.

The FDA conducts a preliminary review of all NDAs and BLAs within the first 60 days after receipt before accepting them for filing based on the agency's threshold determination that they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review of NDAs and BLAs. Most such applications for non-priority products are reviewed within ten to twelve months after filing, and most applications for priority review products, that is, drugs and biologics that the FDA determines represent a significant improvement over existing therapy, are reviewed in six to eight months after filing. The review process may be extended by the FDA for three additional months to consider certain late-submitted information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drugs or biological products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and integrity of the clinical data submitted.

The testing and approval processes require substantial time, effort and financial resources, and each may take many years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to develop our drug candidates and secure necessary governmental approvals, which could delay or preclude us from marketing our products.

After the FDA's evaluation of the NDA or BLA and inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug or biological product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will resume review and may subsequently issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

Even if the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post- approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as changes in indications, manufacturing changes and labeling, are subject to further testing requirements and FDA review and approval.

Special Regulatory Procedures

Fast track designation — The FDA is required to facilitate the development and expedite the review of drugs and biologics that are intended for the treatment of a serious or life-threatening disease or condition and that demonstrate the potential to address unmet medical needs. Under the fast track program, the sponsor of a new drug or biologic candidate may request the FDA to designate the product for a specific indication as a fast track product, concurrent with or after the filing of the IND for the drug candidate. A drug that receives fast track designation is eligible for some or all of the following: (i) more frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval; (ii) more frequent written communication from the FDA about such things as the design of the proposed clinical trials and use of biomarkers; (iii) eligibility for accelerated approval and priority review, if relevant criteria are met; and (iv) "Rolling Review," which means that a drug company can submit completed sections of its BLA or NDA for review by the FDA, rather than waiting until every section of the NDA or BLA is completed before the entire application can be reviewed. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the NDA or BLA is submitted. In addition, the fast track designation may be withdrawn by the FDA if it believes that the designation is no longer supported by data emerging in the clinical trial process.

Priority review — Under FDA policies, a drug candidate may be eligible for priority review. The priority review program provides for expedited review or an NDA or BLA, typically within a six to eight month time frame from the time a complete application is accepted for filing. Products regulated by the FDA's Center for Drug Evaluation and Research, or CDER, are eligible for priority review if they provide a significant improvement compared to marketed products in the treatment, diagnosis or prevention of a disease. Products regulated by the FDA's Center for Biologics Evaluation and Research, or CBER, are eligible for priority review if they provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious or life-threatening disease. A fast track designated drug candidate could be eligible for priority review if supported by clinical data at the time of the BLA or NDA submission.

Accelerated approval — Under the law and the FDA's accelerated approval regulations, the FDA may approve a drug or biologic for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based on a surrogate endpoint that is reasonably likely to predict clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Breakthrough therapy designation — The FDA is also required to expedite the development and review of the application for approval of drugs that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new drug candidate may request that the FDA designate the drug candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the drug candidate.

Orphan drug designation — Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is generally defined as a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA or BLA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug or biologic for the same orphan indication, except in limited circumstances. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application user fee.

Pediatric Information

Under the Pediatric Research Equity Act of 2003, an NDA, BLA or supplement to an NDA or BLA must contain data that are adequate to assess the safety and effectiveness of the drug or biological product for the claimed indications in all relevant pediatric

subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Under the Food and Drug Administration Safety and Innovation Act, or FDASIA, the FDA has additional authority to take action against manufacturers not adhering to pediatric study requirements. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan drug designation.

Post Approval

Any drug or biological products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA or BLA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the drug or biologic.

In addition, drug and biologic manufacturers and other entities involved in the manufacture and distribution of approved drugs and biological products are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. The FDA was also granted new inspection authorities under FDASIA. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution or other restrictions under a Risk Evaluation and Mitigation Strategy program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, untitled and warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- consent decrees, injunctions or the imposition of civil or criminal prosecution.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA, the Office of the Inspector General of Health and Human Services and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

Biosimilars and Exclusivity

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated approval pathway for biological products shown to be highly similar to, or interchangeable with, an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

The BPCIA includes, among other provisions, a 12-year exclusivity period from the date of first licensure, or BLA approval, of the reference product, during which approval of a 351(k) application referencing that product may not be made effective; a four-year exclusivity period from the date of first licensure of the reference product, during which a 351(k) application referencing that product may not be submitted; and an exclusivity period for certain biological products that have been approved through the 351(k) pathway as interchangeable biosimilars.

The BPCIA also establishes procedures for identifying and resolving patent disputes involving applications submitted under section 351(k) of the PHSA.

The BPCIA is complex and its interpretation and implementation by the FDA remains unpredictable. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate effect, implementation, and meaning of the BPCIA is subject to uncertainty.

Federal and State Fraud and Abuse, Data Privacy and Security and Transparency Laws

In addition to FDA restrictions on marketing and promotion of pharmaceutical products, several other types of federal and state laws have been applied to restrict certain marketing business practices in the biopharmaceutical and medical device industries in recent years. These laws include, without limitation, state and federal anti-kickback statutes and false claims statutes and false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to health care providers. Applicable state law may be broader in scope than federal law and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal and civil and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government health care programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to health care professionals.

In addition, the United States Foreign Corrupt Practices Act, or FCPA, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any official of another country, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in that capacity. In many countries, the health care professionals we may interact with may meet the FCPA's definition of a foreign government official.

Foreign Regulation

In order to market any therapeutic or diagnostic product outside of the United States, we need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Under the EU regulatory system, we will submit all of our marketing authorization applications under the centralized procedure. The centralized procedure is compulsory for medicines produced by biotechnology, or are for the treatment of cancer, or officially designated as 'orphan medicines.' The centralized procedure provides for the grant of a single marketing authorization that is valid for all EU member states. As in the United States, we may apply for designation of a drug candidate as an orphan drug for the treatment of a specific indication in the EU before the application for marketing authorization is made. The European Medicines Agency ("EMA") grants orphan medicinal product designation to promote the development of products that may offer therapeutic benefits for life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the EU. Orphan drugs in Europe enjoy economic and marketing benefits, including a 10-year market exclusivity period for the approved indication, but not for the same product, unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan-designated product.

Other Regulatory Processes

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA.

In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations will change or what the effect of such changes, if any, may be.

Third-Party Payor Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. Sales of any of our drug candidates, if approved, will depend, in part, on the extent to which the acquisition costs of the drugs will be covered by third-party payors, including government health programs such as Medicare and Medicaid, as well as commercial health insurers, such as managed care organizations. The process for determining reimbursement rates is separate from the payor coverage decision. Therefore, despite obtaining coverage, reimbursement rates may be lower than expected, which can result in significant out-of-pocket payments for the patient.

In order to secure coverage and reimbursement for any drug that might be approved for sale, we need to conduct analyses and pharmaco-economic studies in order to demonstrate the incremental value over and above the currently available treatment options. Our drug candidates may not be considered medically necessary, provide insufficient incremental value, or may not be deemed cost-effective per payor criteria. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved.

The containment of health care costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Given that the Inflation Reduction Act is now in place, potential implications for the biopharma industry are still being assessed. In the meantime, third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider our drugs to be cost-effective compared to other available therapies, they may not cover our drugs after approval as a benefit under their plans or, if they do, the level of reimbursement and/or restrictions in formulary placement may be such that they would significantly limit projected sales volumes. In addition to third-party payors, we will also need to negotiate formulary placement with hospitals, health systems and certain independent delivery networks. Such negotiations may be

more protracted than anticipated and may be compromised because of similar considerations, relating to insufficient incremental value and/or cost-effectiveness.

Pricing and reimbursement schemes vary widely from country to country. For example, certain EU member states may approve a specific price and volume for a drug product after which incremental revenues or profits need to be paid back by way of rebates. They may also institutionalize utilization restrictions, curb physicians' drug budgets, provide conditional reimbursement schemes that require additional evidence to be generated post-marketing authorization, etc. The downward pressure on health care costs in general, including prescription drugs, has been evident in EU markets for some time and is now a major focus of federal and state governments in the U.S. As a result, increasingly high barriers are being erected to the pricing and reimbursement of new drugs, despite regulatory efforts to bring drugs to market sooner. Cross- border trade has existed for some time in the EU, allowing pharmacies in one country to import, at a lower price, drug from another country, further exerting pricing pressures across the EU. There is U.S. legislation that establishes a process for states to import less expensive drugs from Canada to the U.S. In January 2024, the FDA authorized the state of Florida to establish such a program, although Florida must take several other steps before drugs begin to be imported. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our drugs.

The marketability of any drugs for which we receive regulatory approval for commercial sale may suffer if third-party payors and/or hospital administrators fail to provide adequate coverage, reimbursement or formulary placement. Coverage policies, third-party reimbursement rates and drug pricing regulations may change in the future. In addition, the States may continue to consider legislation of their own (e.g. Prescription Drug Afforability Boards) which could further restrict the ability to freely price drugs and/or curb utilization in the U.S. Even if favorable coverage and reimbursement status is attained for one or more drugs for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Employees

As a mission driven organization, we believe the engagement and dedication of our employees is central to our success and employ talented individuals who have the skills and expertise to help us achieve our goals.

As of December 31, 2024, we had 186 full-time employees, 29 of whom have Ph.D. and/or M.D. degrees. Of these employees, 157 were engaged in or directly support research and development activities. We consider our relationship with our employees to be good.

We believe that our success depends in large part on our ability to attract and retain experienced and skilled employees. We endeavor to provide competitive compensation and benefits packages designed to attract, retain and reward talented individuals who possess the skills necessary to support our business objectives, assist in the achievement of our strategic goals and increase stockholder value. We employ a pay for performance philosophy. Annual salary increases, incentive bonuses and stock option grants are available to all employees and are based on merit and include individual and corporate performance factors.

Much of our success is rooted in the diversity of our teams and our commitment to inclusion. We value diversity at all levels and continue to focus on extending our diversity and inclusion initiatives across our entire workforce. We believe that our business benefits from the different perspectives that a diverse workforce brings.

We are committed to the health, safety and well-being of our employees at all times. We follow federal, state and local rules and guidelines to ensure the safety of our workforce and provide resources to assist our employees in managing their overall physical and mental health.

Research and Development

We have dedicated a significant portion of our resources to our efforts to develop our drug candidates. We incurred research and development expenses of $163.6 million, $118.0 million and $82.3 million during the years ended December 31, 2024, 2023 and 2022, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development in 2025 as we continue to advance our drug candidates through clinical development.

Corporate and Available Information

We are incorporated in Delaware. Our website is located at *http://www.celldex.com.* On our website, investors can obtain, free of charge, a copy of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, our Code of Business Conduct and Ethics, including disclosure related to any amendments or waivers thereto, other reports and any amendments thereto filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act of 1934, as amended, as soon as reasonably practicable after we file such material electronically with, or furnish it to, the Securities and Exchange Commission, or the SEC. None of the information posted on our website is incorporated by reference into this Annual Report. The SEC also maintains a website at http://www.sec.gov that contains reports, proxy and information statements and other information regarding us and other companies that file materials with the SEC electronically.

Item 1A. RISK FACTORS

You should consider carefully these risk factors together with all of the information included or incorporated by reference in this Annual Report in addition to our financial statements and the notes to our financial statements. This section includes forward-looking statements.

The following is a discussion of the risk factors that we believe are material to us at this time. These risks and uncertainties are not the only ones facing us, and there may be additional matters that we are unaware of or that we currently consider immaterial. All of these could adversely affect our business, results of operations, financial condition and cash flows.

Summary of Risk Factors

Risks Related to Our Financial Condition and Capital Requirements

- Risks related to our need for additional capital to fund our operations.
- Risks related to the Merger Agreement and related Settlement Agreement with Kolltan.

Risks Related to Development and Regulatory Approval of Drug Candidates

- Risks related to our ability to fund and complete the research and development activities and obtain regulatory approval for our program assets.
- Risks related to the extensive and lengthy regulatory scrutiny to which we are subject.
- Risks related to our ability to commence, enroll, manage and complete our clinical trials.
- Risk of serious adverse or unacceptable side effects identified related to our drug candidates.
- Risk related to showing that our drug candidates are effective and competitive with other therapies and approved products.
- We may enter into collaboration agreements for our lead drug candidates that may not meet our expectations.

Risks Related to Commercialization of Our Drug Candidates

- Risks related to delays, difficulties or unanticipated costs in establishing sales, marketing and distribution capabilities.
- Risks related to the acceptance of our drug candidates by physicians, patients and third-party payors.
- Risks related to reimbursement decisions by third-party payors.
- Risks, including the terms of FDA approval, that could affect the demand for and sales and profitability of any of our drug candidates.

- Risks related to the failure to obtain regulatory approvals in foreign jurisdictions and risks related to international operations if we do obtain regulatory approval in foreign jurisdictions.

Risks Related to Reliance on Third Parties

- Risks related to our reliance on third parties.

Risks Related to Business Operations

- Risks related to strategic transactions.
- Risks related to managing our growth.
- Risks related to our ability to integrate and modify our technologies to create new drugs.
- Risks related to computer systems that we and third parties use and potential security breaches.
- Risks related to hazardous materials.
- Risks related to product liability claims.

Risks Related to Intellectual Property

- Risks related to intellectual property.

Regulatory Risks

- Risks related to the regulatory approval process for our drugs.
- Risks related to changes in product candidate manufacturing or formulation.
- Risks related to our compliance with laws and regulations.

Risks Related to Our Capital Stock

- Risks related to our history of losses and uncertainty of future profitability.
- Risks relates to the volatility of our common stock.
- Risks related to our use of our net operating loss carryforwards.

General Risk Factors

- Risks related to internal controls over financial reporting.
- Risks that our competitors may develop technologies that make ours obsolete.
- Risks related to health epidemics and outbreaks.
- Risks related to the global economy and supply chain disruptions.
- Risks related to the loss of our key executives and scientists.

- Risks that our employees may engage in misconduct or other improper activities.
- Risks related to our compliance with the Nasdaq Listing Rules.

Risks Related to Our Financial Condition and Capital Requirements

We currently have no product revenue and will need to raise capital to operate our business.

To date, we have generated no product revenue and cannot predict when and if we will generate product revenue. We had an accumulated deficit of $1.6 billion as of December 31, 2024. Until, and unless, we complete clinical trials and other development activity, and receive approval from the FDA and other regulatory authorities, for our drug candidates, we cannot sell our drugs and will not have product revenue. We expect to spend substantial funds to continue the research, development and testing of our products that are in the preclinical and clinical testing stages of development and to prepare to commercialize products in anticipation of FDA approval. Therefore, for the foreseeable future, we will have to fund all of our operations and development expenditures from cash on hand, equity or debt financings, licensing fees and grants. Additional financing will be required to meet our liquidity needs. If we do not succeed in raising additional funds on acceptable terms, we might not be able to complete planned preclinical and clinical trials or obtain approval of any drug candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts, forego attractive business opportunities or curtail operations. Any additional sources of financing could involve the issuance of our equity securities, which would have a dilutive effect on our stockholders. No assurance can be given that additional financing will be available to us when needed on acceptable terms, or at all.

We cannot be certain that we will achieve or sustain profitability in the future. Failure to achieve profitability could diminish our ability to sustain operations, pay dividends on our common stock, obtain additional required funds and make required payments on our present or future indebtedness.

We expect to incur future losses and we may never become profitable.

We have incurred operating losses of $195.1 million, $154.5 million and $115.2 million during 2024, 2023 and 2022, respectively, and expect to incur an operating loss in 2025 and beyond. We believe that operating losses will continue in 2025 and beyond because we are planning to incur significant costs associated with the development of our drug candidates. During the years ended December 31, 2024, 2023 and 2022, we incurred $73.0 million, $32.4 million and $23.8 million in clinical trial expense and $16.4 million, $24.1 million and $4.5 million in contract manufacturing expense. Our net losses have had and will continue to have an adverse effect on, among other things, our stockholders' equity, total assets and working capital. We expect that losses will fluctuate from quarter to quarter and year to year, and that such fluctuations may be substantial. We cannot predict when we will become profitable, if at all.

We will need additional capital to fund our operations, including the development, manufacture and potential commercialization of our drug candidates. If we do not have or cannot raise additional capital when needed, we may be unable to develop and ultimately commercialize our drug candidates successfully.

We expect to incur significant costs as we develop our drug candidates. The continuing development and commercialization of our drug candidates requires additional capital beyond our current resources. As of December 31, 2024, we had cash, cash equivalents and marketable securities of $725.3 million. During the next twelve months and beyond, we will take further steps to raise additional capital to fund our long-term liquidity needs. Our capital raising activities may include, but may not be limited to, one or more of the following:

- licensing of drug candidates with existing or new collaborative partners;
- possible business combinations;
- issuance of debt; or
- issuance of common stock or other securities via private placements or public offerings.

While we may seek capital through a number of means, 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 financing may be dilutive to our stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business; and licensing or strategic collaborations may result in royalties or other terms which reduce our economic potential from drug candidates under development. If we are unable to raise the funds necessary to meet our liquidity needs, we may have to delay or discontinue the development of one or more programs, discontinue or delay ongoing or anticipated clinical trials, 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 stockholders may be subject to substantial dilution if we elect to pay future milestone consideration to the former Kolltan stockholders in shares of common stock. If we elect to pay future milestone consideration in cash, we would likely need to raise additional capital.

In connection with the agreement pursuant to which we acquired Kolltan in 2016 (the "Merger Agreement") as modified by the definitive settlement agreement (the "Settlement Agreement") we entered on July 15, 2022 related to litigation arising from the Kolltan merger, in the event that regulatory approval by the United States Food and Drug Administration or European Medicines Agency of certain drug candidates are achieved, we will be required to pay to the former stockholders of Kolltan a milestone payment of $52,500,000, which milestone payment may be made, at our sole election, in cash, in shares of our common stock or a combination of both, subject to provisions of the Merger Agreement.

We may require additional capital to fund the milestone payment in cash, depending on the facts and circumstances at the time such payment becomes due. The number of shares of our common stock issuable in connection with a milestone payment, if any, will be determined based on the average closing price per share of our common stock for the five trading day period ending three calendar days prior to the achievement of such milestone. If we elect to pay the milestone payment in shares of our common stock, our stockholders would experience substantial dilution.

Risks Related to Development and Regulatory Approval of Drug Candidates

Our long-term success depends heavily on our ability to fund and complete the research and development activities and obtain regulatory approval for our program assets.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Clinical failure can occur at any stage of clinical development. Clinical and preclinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or preclinical trials. In addition, data obtained from trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a drug candidate. As part of development, we also must show that we can formulate and manufacture our product candidates in compliance with regulatory requirements.

We will need substantial additional financing to complete the development of our drug candidates and comply with the regulatory requirements governing this process. Further, even if we complete the development of our drug candidates and gain marketing approvals from the FDA and comparable foreign regulatory authorities in a timely manner, we cannot be sure that such drug candidates will be commercially successful in the pharmaceutical market. If the results of clinical trials, the anticipated or actual timing of marketing approvals, or the market acceptance of any of our drug candidates, if approved, do not meet the expectations of investors or public market analysts, the market price of our common stock would likely decline.

Our drug candidates are subject to extensive regulatory scrutiny.

All of our drug candidates are at various stages of development, and our activities and drug candidates are significantly regulated by a number of governmental entities, including the FDA in the United States and by comparable authorities in other countries. These entities regulate, among other things, the manufacture, testing, safety, effectiveness, labeling, documentation, advertising and sale of drugs and drug candidates. We or our partners must obtain regulatory approval for a drug candidate in all of these areas before we can

commercialize any of our drug candidates. Product development within this regulatory framework takes a number of years and involves the expenditure of substantial resources. This process typically requires extensive preclinical and clinical testing, which may take longer or cost more than we anticipate, and may prove unsuccessful due to numerous factors. Many drug candidates that initially appear promising ultimately do not reach the market because they are found to be unsafe or ineffective when tested. Companies in the pharmaceutical, biotechnology and immunotherapeutic drug industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. Our inability to commercialize a drug candidate would impair our ability to earn future revenues.

Premarket review of our product candidates by the FDA and/or other regulatory authorities is a lengthy and uncertain process and approval may be delayed, limited or denied, any of which would adversely affect our ability to generate operating revenues.

We are not permitted to market our drug product candidates in the United States until we receive approval of an application by the FDA. The time required to obtain approval by the FDA is unpredictable, but typically takes multiple years following the commencement of clinical trials, and depends upon numerous factors, including the substantial discretion of the FDA and the type, complexity and novelty of the product candidates involved. Similar processes are used in countries outside of the U.S. We have not submitted a marketing application such as BLA or NDA to the FDA or any similar application to any other regulatory authority in any jurisdiction.

The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA:

- could determine that the information provided by us as part of an IND or BLA/NDA is inadequate, contains clinical deficiencies or otherwise fails to demonstrate safety and effectiveness of any of our product candidates for any indication;
- may not find the data from pre-clinical and clinical trials sufficient to support the submission of a marketing application or to obtain marketing approval, including any findings that the safety risks outweigh clinical and other benefits of our product candidates;
- may require us to perform additional studies to demonstrate the safety, efficacy, pharmacokinetics, or other properties of our product candidates prior to approval, or require such studies as a condition of approval;
- may disagree with our clinical trial designs or our interpretation of data from product development manufacturing data, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the supply of the API used in our product candidates;
- may identify deficiencies in our own manufacturing processes or our proposed scale-up of the manufacturing processes or facilities for the production of our product candidates;
- may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;
- may change its approval policies or adopt new regulations; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

The time and expense of the approval process, as well as the unpredictability of future clinical trial results and other contributing factors, may result in our failure to obtain regulatory approval to market, in the United States or other jurisdictions, barzolvolimab and other drug candidates that we are developing or may seek to develop in the future, which would significantly harm our business, results of operations and prospects. In such case, we may also not have the resources to conduct new clinical trials and/or we may determine that further clinical development of any such drug candidate is not justified and may discontinue any such programs.

If our drug candidates do not pass required tests for safety and effectiveness, we will not be able to obtain regulatory approval and derive commercial revenue from them.

In order to succeed, we will need to obtain regulatory approval for our drug candidates. The FDA has not approved any of our drug candidates for sale to date. Our drug candidates are in various stages of preclinical and clinical testing. Preclinical tests are performed at an early stage of a product's development and provide information about a drug candidate's safety and effectiveness before initiating human clinical trials. Preclinical tests can last years. If a product passes its preclinical tests satisfactorily and we determine that further development is warranted, we would file an IND application for the product with the FDA, and, if the FDA gives its approval, we would begin Phase 1 clinical tests. Phase 1 testing generally lasts between 6 and 24 months. If Phase 1 test results are satisfactory and the FDA gives its approval, we can begin Phase 2 clinical tests. Phase 2 testing generally lasts between 6 and 36 months. If Phase 2 test results are satisfactory and the FDA gives its approval, we can begin Phase 3 pivotal studies. Phase 3 studies generally last between 12 and 48 months. Once clinical testing is completed and a BLA or NDA is filed with the FDA, it may take more than a year to receive FDA approval.

In all cases we must show that a drug candidate is both safe and effective before the FDA, or drug approval agencies of other countries where we intend to sell the product, will approve it for sale. Our research and testing programs must comply with drug approval requirements both in the United States and in other countries, since we are developing our drug candidates with the intention to, or could later decide to, commercialize them both in the U.S. and abroad. A product may fail for safety or effectiveness at any stage of the testing process. A major risk we face is the possibility that none of our products under development will come through the testing process to final approval for sale, with the result that we cannot derive any commercial revenue from them after investing significant amounts of capital in multiple stages of preclinical and clinical testing.

Success in early clinical trials does not ensure that later clinical trials will be successful, and we cannot assure you that any of the clinical trials that we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval.

The results of preclinical studies and early clinical trials may not be predictive of the results of later- stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. Preclinical and clinical data are susceptible to various interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in preclinical studies and early-stage clinical trials have nonetheless failed to replicate such results in later-stage clinical trials and subsequently failed to obtain marketing approval. Drug candidates in later-stage clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical and initial clinical trials, even if certain analyses of primary or secondary endpoints in those early trials showed trends towards efficacy. Later-stage clinical trials with larger numbers of patients or longer durations of therapy may also reveal safety concerns that were not identified in earlier smaller or shorter trials. Our failure to demonstrate efficacy and safety data sufficient to support marketing approval for any of our other drug candidates would substantially harm our business, prospectus, financial condition and results of operations.

Product testing is critical to the success of our drug candidates but subject to delay or cancellation if we have difficulty enrolling patients.

As our portfolio of drug candidates moves from preclinical testing to clinical testing, and then through progressively larger and more complex clinical trials, we will need to enroll an increasing number of patients with the appropriate characteristics. At times we have experienced difficulty enrolling patients, and we may experience more difficulty as the scale of our clinical testing program increases. The factors that affect our ability to enroll patients are largely uncontrollable and include principally the following:

- the nature of the clinical test;
- the size of the patient population;
- patients' willingness to receive a placebo or less effective treatment on the control arm of a clinical study;
- the distance between patients and clinical test sites; and
- the eligibility criteria for the trial.

If we cannot enroll patients as needed, our costs may increase, or we may be forced to delay or terminate testing for a product.

We may have delays in commencing, enrolling and completing our clinical trials, and we may not complete them at all.

We have not completed the clinical trials necessary to obtain FDA approval to market any of our drug candidates in development. Clinical trials for our products in development may be delayed or terminated as a result of many factors, including the following:

- inability to reach agreements on acceptable terms with prospective contract research organizations (CROs) and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- difficulty in enrolling patients in our clinical trials;
- inability to maintain necessary supplies of study drug and comparator to maintain predicted enrollment rates at clinical trial sites;
- patients failing to complete clinical trials due to dissatisfaction with the treatment, side effects or other reasons;
- failure by regulators to authorize us to commence a clinical trial;
- suspension or termination by regulators of clinical research for many reasons, including concerns about patient safety, bias or failure of our contract manufacturers to comply with cGMP requirements;
- delays or failure to obtain clinical supply for our products necessary to conduct clinical trials from contract manufacturers, including commercial grade-clinical supply for our Phase 3 clinical trials;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our product candidates;
- drug candidates demonstrating a lack of efficacy during clinical trials;
- inability to continue to fund clinical trials or to find a partner to fund the clinical trials;
- competition with ongoing clinical trials and scheduling conflicts with participating clinicians; and
- delays in completing data collection and analysis for clinical trials.

Any delay or failure to commence, enroll or complete clinical trials, fulfill regulatory requirements and obtain FDA approval for our drug candidates could have a material adverse effect on our cost to develop and commercialize, and our ability to generate revenue from, a particular drug candidate.

If serious adverse or unacceptable side effects are identified during the development of our drug candidates, such events could prevent us from obtaining regulatory approval or achieving market acceptance of our drug candidates, and we may need to abandon or limit our development of some of our drug candidates.

If our drug candidates are associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected, such events could prevent us from obtaining regulatory approval or achieving market acceptance of our drug candidates, and we may need to abandon their development or limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In pharmaceutical development, many drugs that initially show promise in early-stage testing are later found to cause side effects that prevent further development of the drug. Currently marketed therapies for the treatment of inflammatory diseases are generally limited to some extent by their toxicity. In addition, some of our drug candidates would be chronic therapies or be used in pediatric populations, for which safety concerns may be particularly important. Use of our drug candidates as monotherapies may also result in adverse events consistent in nature with those associated with other marketed therapies. In addition, when used in combination with other marketed therapies, our drug candidates may exacerbate adverse events associated with the marketed therapy.

Our drug candidates, including barzolvolimab, are monoclonal antibodies, which are biologics. Side effects from biologics may include but are not limited to hypersensitivity; severe reactions such as anaphylaxis or cytokine release syndrome; immune-mediated adverse reactions that may occur in any organ system or tissue, such as pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, and dermatologic reactions; as well as infusion-related reactions, cellulitis, sepsis, pneumonia, urinary tract infection, fatigue, rash, and diarrhea.

Most biologics, including our drug candidates, are injected, either subcutaneously or intravenously. There are risks inherent in subcutaneous injections, such as injection-site reactions (including redness, itching, swelling, pain, and tenderness) and other side effects. In addition, there are risks inherent in intravenous administration such as infusion-related reactions (including nausea, pyrexia, rash, and dyspnea). These and other complications or side effects could harm further development and/or commercialization of our antibody-based products and product candidates utilizing this method of administration.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of biologics frequently causes an immune response, sometimes resulting in the creation of antibodies against the drug candidate which can impact the safety and/or efficacy associated with the treatment.

We may expend our resources to pursue a particular drug candidate or indication and forgo the opportunity to capitalize on drug candidates or indications that may ultimately be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we intend to focus on developing drug candidates for specific indications that we identify as most likely to succeed, in terms of both their potential for regulatory approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that may prove to have greater commercial potential.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable drug candidates. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the drug candidate.

We may be unable to manage multiple late-stage clinical trials for a variety of drug candidates simultaneously.

As our current clinical trials progress, we may need to manage multiple late-stage clinical trials simultaneously in order to continue developing all of our current products. The management of late-stage clinical trials is more complex and time consuming than early-stage trials. Typically, early-stage trials involve several hundred patients in no more than 10 to 30 clinical sites. Late-stage (Phase 3) trials may involve up to several thousand patients in up to several hundred clinical sites and may require facilities in several countries. Therefore, the project management required to supervise and control such an extensive program in a compliant manner is substantially larger than early-stage programs. As the need for these resources is not known until some months before the trials begin, it is necessary to recruit large numbers of experienced and talented individuals very quickly. If the labor market does not allow this team to be recruited quickly, we could be faced with a decision to delay the program or to initiate it with inadequate management resources. This may result in recruitment of inappropriate patients, inadequate monitoring of clinical investigators and inappropriate handling of data or data analysis. Consequently, it is possible that conclusions of efficacy or safety may not be acceptable to permit filing of a BLA or NDA for any one of the above reasons or a combination of several.

Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics for our drug candidates, if needed, could harm our drug development strategy and operational results.

As an element of our clinical development approach, we may seek to screen and identify subsets of patients that express a certain biomarker or that have a certain genetic alteration who may derive meaningful benefit from our development drug candidates. To achieve this, one or more of our drug development programs may be dependent on the development and commercialization of a companion diagnostic by us or by third-party collaborators. Companion diagnostics are developed in conjunction with clinical programs for the associated drug candidate. Companion diagnostics are subject to regulation as medical devices and must themselves be approved for marketing by the FDA or certain other foreign regulatory agencies before the related drug candidate may be commercialized. The approval of a companion diagnostic as part of the product label will limit the use of the drug candidate to only

those patients who express the specific biomarker it was developed to detect. We or our third-party collaborators may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners or negotiating insurance reimbursement for such companion diagnostic, all of which may prevent us from completing our clinical trials or commercializing our drugs on a timely or profitable basis, if at all.

We and our third-party collaborators may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval of our related drug candidates or, if regulatory approval is obtained, delay or limit our ability to commercialize our related drug candidates.

Any delay in obtaining regulatory approval would have an adverse impact on our ability to earn future revenues.

It is possible that none of the drug candidates that we develop will obtain the regulatory approvals necessary for us to begin commercializing them. The time required to obtain FDA and other approvals is unpredictable but in general takes years following the commencement of clinical trials, depending upon the nature of the drug candidate. Any analysis we perform of data from clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular drug candidate including, but not limited to, loss of patent term during the approval period. Furthermore, if we, or our partners, do not reach the market with our products before our competitors offer products for the same or similar uses, or if we, or our partners, are not effective in marketing our products, our revenues from product sales, if any, will be reduced.

We face intense competition in our development activities. We face competition from many companies in the United States and abroad, including a number of large pharmaceutical companies. Most of our competitors have substantially greater resources, more extensive experience in conducting preclinical studies and clinical testing and obtaining regulatory approvals for their products, greater operating experience, greater research and development and marketing capabilities and greater production capabilities than those of ours. These companies might succeed in obtaining regulatory approval for competitive products more rapidly than we can for our products, especially if we experience any delay in obtaining required regulatory approvals.

We may enter into collaboration agreements for the licensing, development and ultimate commercialization of some of our drug candidates including, where appropriate, for our lead drug candidates. In such cases, we will depend greatly on our third-party collaborators to license, develop and commercialize such drug candidates, and they may not meet our expectations.

We may enter into co-development and commercialization partnerships for our drug candidates where appropriate. The process of identifying collaborators and negotiating collaboration agreements for the licensing, development and ultimate commercialization of some of our drug candidates may cause delays and increased costs. We may not be able to enter into collaboration agreements on terms favorable to us or at all. Furthermore, some of those agreements may give substantial responsibility over our drug candidates to the collaborator. Some collaborators may be unable or unwilling to devote sufficient resources to develop our drug candidates as their agreements require. They often face business risks similar to ours, and this could interfere with their efforts. Also, collaborators may choose to devote their resources to products that compete with ours. If a collaborator does not successfully develop any one of our products, we will need to find another collaborator to do so. The success of our search for a new collaborator will depend on our legal right to do so at the time and whether the product remains commercially viable.

If we enter into collaboration agreements for one or more of our lead drug candidates, the success of such drug candidates will depend in great part upon our and our collaborators' success in promoting them as superior to other treatment alternatives. We believe that our drug candidates can be proven to offer disease treatment with notable advantages over drugs in terms of patient compliance and effectiveness. However, there can be no assurance that we will be able to prove these advantages or that the advantages will be sufficient to support the successful commercialization of our drug candidates.

Risks Related to Commercialization of Our Drug Candidates

We may face delays, difficulties or unanticipated costs in establishing sales, marketing and distribution capabilities or seeking a partnership for the commercialization of our drug candidates, even if regulatory approval is obtained.

We may retain full economic rights to our drug candidates or seek favorable economic terms through advantageous commercial partnerships. As a result, we may have full responsibility for commercialization of one or more of our drug candidates if and when they are approved for sale. We currently lack sufficient marketing, sales and distribution capabilities to carry out this strategy. If any of our drug candidates are approved by the FDA, we will need a drug sales force with technical expertise prior to the commercialization of any of our drug candidates. We may not succeed in developing such sales and distribution capabilities, the cost of establishing such sales and distribution capabilities may exceed any product revenue, or our direct marketing and sales efforts may be unsuccessful. We may find it necessary to enter into strategic partnerships, co-promotion or other licensing arrangements. To the extent we enter into such strategic partnerships, co- promotion or other licensing arrangements, our product revenues are likely to be lower than if we directly marketed and sold such drugs, and some or all of the revenues we receive will depend upon the efforts of third parties, which may not be successful and may not be within our control. If we are unable to enter into such strategic partnerships, co-promotion or other licensing arrangements on acceptable terms or at all, we may not be able to successfully commercialize our existing and future drug candidates. If we are not successful in commercializing any drug candidates for which we obtain regulatory approval, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may never achieve profitability or become unable to continue the operation of our business.

If our drug candidates for which we obtain regulatory approval do not achieve broad acceptance from physicians, patients and third-party payors, we may be unable to generate significant revenues, if any.

Even if we obtain regulatory approval for our drug candidates, our approved drugs may not gain market acceptance among physicians and patients. We believe that effectively marketing our drug candidates, if any of them are approved, will require substantial efforts, both prior to commercial launch and after approval. Physicians may elect not to prescribe our drugs, and patients may elect not to request or take them, for a variety of reasons, including:

- limitations or warnings contained in a drug's FDA-approved labeling;
- changes in the standard of care or the availability of alternative drugs for the targeted indications for any of our drug candidates;
- limitations in the approved indications for our drug candidates;
- the approval, availability, market acceptance and reimbursement for the companion diagnostic, where applicable;
- demonstrated clinical safety and efficacy compared to other drugs;
- significant adverse side effects;
- effectiveness of education, sales, marketing and distribution support;
- timing of market introduction and perceived effectiveness of competitive drugs;
- price and cost-effectiveness;
- adverse publicity about our drug candidates or favorable publicity about competitive drugs;
- convenience and ease of administration of our drug candidates; and
- willingness of third-party payors to reimburse for the cost of our drug candidates.

If our future drugs fail to achieve market acceptance, we will not be able to generate significant revenues and may never achieve profitability.

Even if any of our drug candidates receive FDA approval, the terms of the approval may limit such drug's commercial potential. Additionally, even after receipt of FDA approval, such drug would be subject to substantial, ongoing regulatory requirements.

The FDA has complete discretion over the approval of our drug candidates. If the FDA grants approval, the scope of the approval may limit our ability to commercialize such drug, and in turn, limit our ability to generate substantial product revenue. For example, the FDA may grant approval contingent on the performance of costly post-approval clinical trials or subject to warnings or contraindications or under a Risk Evaluation and Mitigation Strategy (REMS) drug safety program. Additionally, after approval, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for such drug will be subject to extensive and ongoing regulatory requirements. In addition, manufacturers of our drug candidates are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must inspect and approve these manufacturing facilities before they can be used to manufacture our drug candidates, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a third party discover previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the drug from the market or suspension of manufacturing. If we, our drug candidates or the manufacturing facilities for our drug candidates fail to comply with regulatory requirements of the FDA and/or other non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including the following:

- warning letters;
- civil or criminal penalties and fines;
- injunctions;
- consent decrees;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical studies;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new drugs;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of drugs or import bans.

The regulatory requirements and policies may change, and additional government regulations may be enacted with which we may also be required to comply. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we are not able to maintain regulatory compliance, we may not be permitted to market our future products and our business may suffer.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance of any of our drug candidates. If there is not sufficient reimbursement for our future drugs, it is less likely that such drugs will be widely used.

Market acceptance and sales of any of our drug candidates for which we obtain regulatory approval will depend on reimbursement policies and may be affected by future health care reform measures in both the United States and foreign jurisdictions. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. In addition, government authorities and these third-party payors are increasingly attempting to contain health care costs by demanding price discounts or rebates and limiting both the types and variety of drugs that they will cover and the amounts that they will pay for these drugs. In addition, we might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future drugs to such payors' satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources.

Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for drugs may be reduced by mandatory discounts or rebates required by government health care programs. Such programs, or regulatory changes or relaxation of laws that restrict imports of drugs from other countries, could reduce the net price we receive for any future marketed drugs. In addition, our future drugs might not ultimately be considered cost-effective.

We cannot be certain that reimbursement will be available for any drug candidates that we develop. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, any future drugs. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any drug candidates that we develop.

Other factors could affect the demand for and sales and profitability of any drug candidates that we may commercialize in the future.

In general, other factors that could affect the demand for and sales and profitability of our future drugs include, but are not limited to:

- the timing of regulatory approval, if any, of competitive drugs;
- our or any other of our partners' pricing decisions, as applicable, including a decision to increase or decrease the price of a drug, and the pricing decisions of our competitors;
- government and third-party payor reimbursement and coverage decisions that affect the utilization of our future drugs and competing drugs;
- negative safety or efficacy data from new clinical studies conducted either in the U.S. or internationally by any party, which could cause the sales of our future drugs to decrease or a future drug to be recalled;
- the degree of patent protection afforded our future drugs by patents granted to or licensed by us and by the outcome of litigation involving our or any of our licensor's patents;
- marketing exclusivity, if any, awarded by the FDA to our drugs;
- the outcome of litigation involving patents of other companies concerning our future drugs or processes related to production and formulation of those drugs or uses of those drugs;
- the increasing use and development of alternate therapies;
- the rate of market penetration by competing drugs; and
- the termination of, or change in, existing arrangements with our partners.

Any of these factors could have a material adverse effect on the sales of any drug candidates that we may commercialize in the future.

Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.

We may seek approval for our drug candidates outside the United States and may market future products in international markets. In order to market our future products in the European Economic Area, or EEA, and many other foreign jurisdictions, we must obtain separate regulatory approvals. Specifically, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA.

Before granting the MA, the European Medicines Agency or the competent authorities of the member states of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Clinical studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals, and even if we file, we may not receive necessary approvals to commercialize our products in any market.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If our drug candidates are approved for commercialization outside of the United States, we expect that we will be subject to additional risks related to international operations and entering into international business relationships, including:

- different regulatory requirements for drug approvals;
- reduced protection for intellectual property rights, including trade secret and patent rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, uncertain interest rate environments or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where employment regulations are different than, and labor unrest is more common than, in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters, including earthquakes, hurricanes, floods and fires; and
- difficulty in importing and exporting clinical trial materials and study samples.

The biopharmaceutical industry is subject to extensive regulatory obligations and policies that may be subject to change, including due to judicial challenges.

The U.S. biopharmaceutical industry is highly regulated and subject to frequent and substantial changes, including as a result of new judicial or government actions. Legislative and regulatory agendas as they relate to the biopharmaceutical industry are currently uncertain. Changes in the regulatory approval process, or substantial reductions in the personnel who oversee that process, could affect our ability to obtain regulatory approval for our product candidates or the timeline in which we can obtain that approval. We and our current and future third party collaborators may rely on government programs or agencies, such as the National Institutes for Health ("NIH"), as a source of grant funding for scientific research relevant to our product candidates. Funding from government agencies such as the NIH can fluctuate and is subject to the political process, which is often unpredictable. Reductions in NIH grants to us or our third-party collaborators may adversely impact our ability to develop our existing product candidates and our ability to identify new product candidates. In addition, on June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act ("APA") "must exercise their independent judgment" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." The decision could have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework may increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies could be subject to increased litigation and judicial scrutiny. We cannot predict how other future federal or state legislative or administrative changes relating to healthcare reform or the biopharmaceutical industry, or the regulatory agencies that oversee the biopharmaceutical industry, will affect our business.

Risks Related to Reliance on Third Parties

We rely on third parties to plan, conduct and monitor our clinical tests, and their failure to perform as required would interfere with our product development.

We rely on third parties to conduct a significant portion of our clinical development activities. These activities include clinical patient recruitment and observation, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. We conduct project management and medical and safety monitoring in-house for some of our programs and rely on third parties for the remainder of our clinical development activities. If any of these third parties is unable to perform in a quality and timely manner, and at a feasible cost, our clinical studies will face delays. Further, if any of these third parties fails to perform as we expect or if their work fails to meet regulatory standards, our testing could be delayed, cancelled or rendered ineffective.

We rely on CDMOs over whom we have limited control. Should the cost, delivery and quality of clinical materials manufactured by us in our Fall River facility or supplied by CDMOs vary to our disadvantage, our business operations could suffer significant harm.

We are a research and development company and have limited experience in commercial manufacturing. To conduct late-stage clinical trials, as well as manufacture and commercialize our drug candidates, we engage CDMOs in the U.S and outside the U.S. to manufacture our drug candidates on a large scale at a competitive cost and in accordance with cGMP and U.S. and foreign regulatory requirements, as applicable. We also rely on CDMOs for filling, labeling and storage for studies inside and outside the U.S. Any manufacturing failures or compliance issues at our CDMOs could cause delays in our clinical studies or commercialization of our drug candidates.

In order for us to establish our own commercial manufacturing facility, we would require substantial additional funds and would need to make facility modifications, hire and retain significant additional personnel and comply with extensive cGMP regulations applicable to such a facility. The commercial manufacturing facility would also need to be licensed for the production of our drug candidates by the FDA and meet other regulatory standards. We therefore work with CDMOs under established manufacturing arrangements that comply with the FDA's requirements and other regulatory standards, although there is no assurance that the manufacturing will be successful.

Prior to approval of any drug candidate, the FDA must review and approve validation studies for both drug substance and drug product. The manufacturing processes for our drug candidates and device delivery systems utilize known technologies. We believe that the products we currently have under development can be scaled up to permit manufacture in commercial quantities. However, there can be no assurance that we will not encounter difficulties in scaling up the manufacturing processes. Significant scale-up of

manufacturing may result in unanticipated technical challenges and may require additional validation studies that the FDA must review and approve. CDMOs may encounter difficulties in scaling up production, including problems involving supply chain, raw material suppliers, production yields, technical difficulties, scaled-up product characteristics, quality control and assurance, shortage of qualified personnel, capacity constraints, changing priorities within the CDMOs, compliance with FDA and foreign regulations, environmental compliance, production costs and development of advanced manufacturing techniques and process controls. Any of these difficulties, if they occur and are not overcome to the satisfaction of the FDA or other regulatory agency, could lead to significant delays and possibly the termination of the development program for such drug candidate. These risks become more acute as we scale up for commercial quantities, where reliable sources of drug substance and drug product become critical to commercial success. The commercial viability of any of our drug candidates, if approved, will depend on the ability of our CDMOs to produce drug substance and drug product on a large scale. Failure to achieve this level of supply can jeopardize and prevent the successful commercialization of the drug.

Our leading drug candidates require specialized manufacturing capabilities and processes. We may face difficulty in securing commitments from U.S. and foreign CDMOs as these manufacturers could be unwilling or unable to accommodate our needs. Relying on foreign manufacturers involves peculiar and increased risks, including the risk relating to the difficulty foreign manufacturers may face in complying with cGMP requirements as a result of language barriers, lack of familiarity with cGMP or the FDA regulatory process, supply chain issues or other causes, economic or political instability in or affecting the home countries of our foreign manufacturers, shipping delays, potential changes in foreign regulatory laws governing the sales of our product supplies, fluctuations in foreign currency exchange rates and the imposition or application of trade restrictions.

There can be no assurances that CDMOs will be able to meet our timetable and requirements. While we believe that there is currently sufficient capacity worldwide for the production of our potential products through CDMOs, establishing long-term relationships with CDMOs and securing multiple sources for the necessary quantities of clinical and commercial materials required can be a challenge due to increasing industry demand for CDMO services. Qualifying the initial source of clinical and ultimately commercial material is a time consuming and expensive process due to the highly regulated nature of the pharmaceutical/biotech industry. The key difficulty in qualifying more than one source for each product is the duplicated time and expense in doing so without the potential to mitigate these costs if the secondary source is never utilized. Further, CDMOs must operate in compliance with cGMP and failure to do so could result in, among other things, the disruption of product supplies.

Use of CDMOs also limits our control over and ability to monitor the manufacturing process. As a result, we may not be able to detect a variety of problems that may arise and may face additional costs in the process of interfacing with and monitoring the progress of our CDMOs. If CDMOs fail to meet our manufacturing needs in an acceptable manner or fail to comply with regulatory requirements, we would face delays and additional costs while we develop internal manufacturing capabilities or find alternate CDMOs. It may not be possible to have multiple CDMOs ready to supply us with needed material at all or without incurring significant costs. Our dependence upon CDMOs for the manufacture of our products may adversely affect our profit margins and our ability to develop, manufacture, sell and deliver products on a timely and competitive basis. Any manufacturing failures, supply chain delays or compliance issues at our Fall River facility or at our CDMOs could cause delays in our clinical studies for our drug candidates.

We may need to rely on third-party collaborators to develop and commercialize companion diagnostic tests for our drug candidates.

We do not have experience or capabilities in developing, administering, obtaining regulatory approval for, or commercializing companion diagnostic tests and will need to rely in large part on third-party collaborators to perform these functions. Companion diagnostic tests are subject to regulation by the FDA and similar regulatory authorities outside of the United States as medical devices and require separate regulatory approval prior to commercialization. We may need to rely on such third-party collaborators to obtain regulatory approval and commercialize such companion diagnostic tests. Such third-party collaborators:

- may not perform their obligations as expected or as required under our collaboration agreement;
- may encounter production difficulties that could constrain the supply of the companion diagnostic test;
- may have difficulties gaining acceptance of the use of the companion diagnostic test in the clinical community;
- may not pursue commercialization of the companion diagnostic test even if they receive any required regulatory approvals;

- may elect not to continue the development or commercialization of the companion diagnostic test based on changes in the third parties' strategic focus or available funding, or external factors such as an acquisition, that divert resources or create competing priorities;
- may be susceptible to third party cyber-attacks on our and their information security systems;
- may not commit sufficient resources to the marketing and distribution of the companion diagnostic test; and
- may terminate their relationship with us.

If such third-party collaborators fail to develop, obtain regulatory approval or commercialize the companion diagnostic test, we may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our drug candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our drug candidates.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them.

Because we rely on third parties to develop our drug candidates, we must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We also conduct joint research and development programs which may require us to share trade secrets under the terms of research and development partnership or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of our trade secrets would impair our competitive position.

Risks Related to Business Operations

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time we may consider strategic transactions, including acquisitions of companies, asset purchases and out-licensing or in-licensing of products, drug candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations, acquisitions of assets and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, drug candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;

- write-downs of assets or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may expand our clinical development, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect that if our drug candidates continue to progress in development, we may require significant additional investment in personnel, management systems and resources, particularly in the build out of our commercial capabilities. To date we have hired a core commercial team to plan for potential commercial launches if any of our drug candidates are approved. Over the next several years, we may experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. To manage this potential future growth, we may continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may not be able to successfully integrate our existing technology or to modify our technologies to create new immunotherapeutic drugs.

If we are able to integrate our acquired assets and licensed assets with our immunotherapy technologies, we believe these assets will give our immunotherapeutic drugs a competitive advantage. However, if we are unable to successfully integrate licensed assets, or other technologies which we have acquired or may acquire in the future, with our existing technologies and potential products currently under development, we may be unable to realize any benefit from our acquisition of these assets, or other technologies which we have acquired or may acquire in the future, and we may face the loss of our investment of financial resources and time in the integration process.

We believe that our immunotherapy technology portfolio may offer opportunities to develop immunotherapeutic drugs that treat a variety of inflammatory and infectious diseases by stimulating a patient's immune system against those diseases. If our immunotherapy technology portfolio cannot be used to create effective immunotherapeutic drugs against a variety of diseases, we may lose all or portions of our investment in development efforts for new drug candidates.

Our internal computer systems, or those of our CROs, CDMOs, or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug development programs.

Our computer systems and those of our CROs, CDMOs, and other contractors and consultants are vulnerable to damage from cyberattacks, malicious intrusion, computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters, terrorism, war and telecommunication, electrical failures or other significant disruption even with a cybersecurity risk mitigation program developed by our enterprise. Such information technology systems are additionally vulnerable to security breaches from inadvertent or intentional actions by our employees, third-party vendors, contractors, consultants, business partners, and/or other third parties. The risks of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by traditional computer "hackers," threat actors, personnel (such as through theft, inadvertent mistake or misuse), sophisticated nation-state and

nation-state-supported actors, sovereign governments and cyber terrorists, have generally increased over time, including for geopolitical reasons and in conjunction with military conflicts and defense activities, along with the number, intensity and sophistication of attempted attacks and intrusions from around the world. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks that could materially disrupt our systems and operations, supply chain and ability to produce and distribute our products and product candidates. If any such events were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs and commercialization efforts. For example, the loss of clinical study data from completed or ongoing clinical studies for any of our drug candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Further, the risk of cyber-attacks or other privacy or data security incidents may be heightened due to common, external attempts to attack our information technology systems and data using means such as phishing, other social engineering and vulnerability exploitation. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development or commercialization of our drug candidates could be delayed.

While we have not experienced any material disruptions to our business, systems or operations as a result of a cybersecurity incident to date, if such an event were to occur and cause material interruptions in our operations, it could result in a material disruption of our independent drug development programs and our business overall. For example, the loss of clinical trial data from ongoing or future clinical trials for any of our product candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. Our information security systems are also subject to laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, HIPAA and its implementing regulations impose, among other requirements, certain regulatory and contractual requirements regarding the privacy and security of personal health information. In the European Union, the General Data Protection Regulation, or GDPR, further restricts all applicable personal data, including information masked by a coding system that is not considered deidentified data under applicable law. In addition to HIPAA and GDPR, numerous other federal and state laws, including, without limitation, state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure, protection and storage of personal information. To the extent that any disruption or security breach of our information technology systems were to result in a loss of or damage to data or applications, or inappropriate disclosure of third-party notifiable confidential or proprietary information, personal health information, personal information or personal data, we could incur substantial liability under laws that protect the privacy of personal information, our reputation would be damaged, and the further development of our product candidates could be delayed, any of which could adversely affect our business. The costs related to significant security breaches or disruptions could be material and exceed the limits of the cybersecurity insurance we maintain against such risks.

We cannot anticipate all possible types of security threats and we cannot guarantee that our data protection efforts and our investments in information technology will prevent significant breakdowns, data leakages, security breaches in our systems, or those of our third-party vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition.

Our business requires us to use hazardous materials, which increases our exposure to dangerous and costly accidents.

Our research and development activities involve the use of biological materials and small amounts of hazardous chemicals. The company has internal policies and procedures for the safe handling and disposal of these materials, in full compliance with applicable laws and regulations, including applicable OSHA, EPA, state and local regulations, and utilizing EPA licensed disposal companies and facilities. Although we believe we have reduced our risk and impacts from these materials through our safety procedures, we cannot completely eliminate the risk of accidental contamination or injury from these materials. The ongoing cost of complying with environmental laws and regulations is significant and may increase in the future. All risks of environmental damage inherent to our operations cannot be mitigated and failure to comply with applicable government regulations could result in the imposition of fines, restrictions, or increased operational costs, which could impact our ability to carry on with our operations.

We face the risk of product liability claims, which could exceed our insurance coverage, and product recalls, each of which could deplete our cash resources.

As a participant in the pharmaceutical, biotechnology and immunotherapeutic drug industries, we are exposed to the risk of product liability claims alleging that use of our drug candidates caused an injury or harm. These claims can arise at any point in the development, testing, manufacture, marketing or sale of our drug candidates and may be made directly by patients involved in clinical trials of our products, by consumers or health care providers or by individuals, organizations or companies selling our products.

Product liability claims can be expensive to defend, even if the drug or drug candidate did not actually cause the alleged injury or harm.

Insurance covering product liability claims becomes increasingly expensive as a drug candidate moves through the development pipeline to commercialization. However, there can be no assurance that such insurance coverage is or will continue to be adequate or available to us at a cost acceptable to us or at all. We may choose or find it necessary under our collaborative agreements to increase our insurance coverage in the future. We may not be able to secure greater or broader product liability insurance coverage on acceptable terms or at reasonable costs when needed. Any liability for damages resulting from a product liability claim could exceed the amount of our coverage, require us to pay a substantial monetary award from our own cash resources and have a material adverse effect on our business, financial condition and results of operations. Moreover, a product recall, if required, could generate substantial negative publicity about our products and business and inhibit or prevent development of our drug candidates and, if approval is obtained, commercialization of our future drugs.

Risks Related to Intellectual Property

We license technology from other companies to develop products, and those companies could influence research and development or restrict our use of it. In addition, if we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

Companies that license technologies to us that we use in our research and development programs may require us to achieve milestones or devote minimum amounts of resources to develop products using those technologies. They may also require us to make significant royalty and milestone payments, including a percentage of any sublicensing income, as well as payments to reimburse them for patent costs. The number and variety of our research and development programs require us to establish priorities and to allocate available resources among competing programs. From time to time, we may choose to slow down or cease our efforts on particular products. If in doing so we fail to fully perform our obligations under a license, the licensor can terminate the license or permit our competitors to use the technology. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms. Moreover, we may lose our right to market and sell any products based on the licensed technology. The occurrence of such events could materially harm our business.

Our ability to successfully develop and, if regulatory approval is obtained, commercialize our drug candidates may be materially adversely affected if we are unable to obtain and maintain effective intellectual property rights for our drug candidates and technologies.

Our success depends in part on our ability to obtain and maintain patent protection and other intellectual property protection for our drug candidates and proprietary technology. We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our drug candidates and technology that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing drugs and technologies. We may also be unable to obtain patent term adjustments or extensions (or similar rights, such as Supplementary Protection Certificates, in foreign countries) at the relevant times, or the duration of any such adjustments, extensions or the like may be less than requested.

Biotechnology patents involve complex legal, scientific and factual questions and are highly uncertain and may also result in different outcomes in different territories. To date, there is no consistent policy regarding the breadth of claims allowed in biotechnology patents, particularly in regard to patents for technologies for human uses like those we use in our business. We cannot predict whether the patents we or our licensors seek will issue. If such patents are issued, a competitor may challenge them and may potentially have them revoked or limit their scope, for example based on existing or newly identified prior art or other issues of validity. Moreover, our patents may not afford effective protection against competitors with similar technology. A successful challenge to any one of our patents could result in a third party's ability to use the technology covered by the patent. We also face the risk that others will infringe, avoid or circumvent our patents. Technology that we license from others is subject to similar risks and this could harm our ability to use that technology. If we, or a company that licenses technology to us, were not the first creator of an invention that we use, and/or if inventorship were to be decided against us (or our licensor) in any relevant litigation, our use of the underlying product or technology will face restrictions, including elimination, and our ability to defend and/or enforce any affected patent rights could also be materially harmed.

If we must defend against suits brought against us or prosecute suits against others involving intellectual property rights, we will incur substantial costs. In addition to any potential liability for significant monetary damages, a decision against us may require us to obtain licenses to patents or other intellectual property rights of others on potentially unfavorable terms. If those licenses from third parties are necessary but we cannot acquire them, we would attempt to design around the relevant technology, which would cause higher development costs and delays and may ultimately prove impracticable.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our drug candidates. It may be necessary for us to use the patented or proprietary technology of a third party to commercialize our own technology or drug candidates, in which case we would be required to obtain a license from such third party. A license to such intellectual property may not be available or may not be available on commercially reasonable terms, which could have a material adverse effect on our business and financial condition.

We may be unable to protect the confidentiality of our trade secrets, thus harming our business and competitive position.

We rely upon trade secrets, including unpatented know-how, technology and other proprietary information to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees that obligate them to assign their inventions to us. However, it is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees, consultants or collaborators that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. In addition, intellectual property laws in foreign countries may not protect our intellectual property to the same extent as the laws of the United States. If our trade secrets are disclosed or misappropriated, it would harm our ability to protect our rights and have a material adverse effect on our business.

We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time- consuming and unsuccessful.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our drug candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our drug candidates and technology. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing our drug candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease developing the infringing technology or product. In addition, we could be found liable for monetary damages. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed at universities or other diagnostic or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Regulatory Risks

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

We may seek orphan drug designation for some of our product candidates in the United States. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same indication for that drug during that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

We cannot assure you that any future application for orphan drug designation with respect to any product candidate will be granted. If we are unable to obtain orphan drug designation in the United States, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the financial incentives associated with orphan drug designation. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Any fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates. Additionally, our product candidates may treat indications that do not qualify for priority review vouchers.

We may seek fast track designation for some of our product candidates or priority review of applications for approval of our product candidates. If a drug is intended for the treatment of a serious or life- threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. If a product candidate offers major advances in treatment, the FDA may designate it eligible for priority review. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA would decide to grant them. Even if we do receive fast track designation or priority review, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

Any breakthrough therapy designation granted by the FDA for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek a breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval if the relevant criteria are met.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

If our processes and systems are not compliant with regulatory requirements, we could be subject to delays in submitting BLAs, NDAs or restrictions on marketing of drugs after they have been approved.

We currently are developing drug candidates for regulatory approval and are in the process of implementing regulated processes and systems required to obtain and maintain regulatory approval for our drug candidates. Certain of these processes and systems for conducting clinical trials and manufacturing material must be compliant with regulatory requirements before we can apply for regulatory approval for our drug candidates. These processes and systems will be subject to continual review and periodic inspection by the FDA and other regulatory bodies. If we are unable to achieve compliance in a timely fashion or if compliance issues are identified at any point in the development and approval process, we may experience delays in filing for regulatory approval for our drug candidates or delays in obtaining regulatory approval after filing. In addition, any later discovery of previously unknown problems or safety issues with approved drugs or manufacturing processes, or failure to comply with regulatory requirements may result in restrictions on such drugs or manufacturing processes, withdrawal of drugs from the market, the imposition of civil or criminal penalties or a refusal by the FDA and/or other regulatory bodies to approve pending applications for marketing approval of new drugs or supplements to approved applications, any of which could have a material adverse effect on our business. In addition, we are a party to agreements that transfer responsibility for complying with specified regulatory requirements, such as filing and maintenance of marketing authorizations and safety reporting or compliance with manufacturing requirements, to our collaborators and third-party manufacturers. If our collaborators or third-party manufacturers do not fulfill these regulatory obligations, any drugs for which we or they obtain approval may be subject to later restrictions on manufacturing or sale or may even risk withdrawal, which could have a material adverse effect on our business.

We have conducted and are conducting clinical trials outside the United States and anticipate conducting additional clinical trials outside the United States, and the FDA may not accept data from such trials.

We are currently conducting clinical trials for our product candidates in countries outside of the United States and we anticipate that we will conduct additional clinical trials in countries outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such study data by the FDA is subject to certain conditions. For example, the clinical trial must be conducted in accordance with GCP requirements and the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. Where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are considered applicable to the U.S. patient population and U.S. medical practice, the clinical trials were performed by clinical investigators of recognized competence, and the data is considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, such clinical trials would be subject to the applicable local laws of the foreign jurisdictions where the clinical trials are conducted. A description of any studies related to overdosage is also required, including information on

dialysis, antidotes, or other treatments, if known. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept any such data, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay aspects of our development plan.

Risks inherent in conducting international clinical trials include, but are not limited to:

- foreign regulatory requirements that could burden or limit our ability to conduct our clinical trials;
- administrative burdens of conducting clinical trials under multiple foreign regulatory schema;
- foreign currency fluctuations which could negatively impact our financial condition since certain payments are paid in local currencies;
- manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. During the course of a development program, sponsors may also change the contract manufacturers used to produce the product candidates. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of clinical trials. Such changes may also require additional testing, notification or approval by the FDA, EMA or other regulatory authorities. This could delay completion of clinical trials; require the conduct of bridging clinical trials or studies, or the repetition of one or more clinical trials; increase clinical trial costs; delay or prevent approval of our product candidates and jeopardize our ability to commence product sales and generate revenue.

Even if we receive regulatory approval for a drug candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.

Once regulatory approval has been granted, the approved product and its manufacturer are subject to continual review by the FDA and/or non-U.S. regulatory authorities. Any regulatory approval that we or our collaboration partners receive for our drug candidates may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies to monitor the safety and efficacy of the product. In addition, if the FDA and/or non-U.S. regulatory authorities approve any of our drug candidates, we will be subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products. In addition, manufacturers of our drug products are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must inspect and approve these manufacturing facilities before they can be used to manufacture our drug products, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a third party discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our drug candidates or the manufacturing facilities for our drug candidates fail to comply with regulatory requirements of the FDA and/or other non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including the following:

- warning letters;

- civil or criminal penalties and fines;
- injunctions;
- consent decrees;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical studies;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new drugs;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of drugs or import bans.

The regulatory requirements and policies may change and additional government regulations may be enacted with which we may also be required to comply. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we are not able to maintain regulatory compliance, we may not be permitted to market our future products, and our business may suffer.

We may be subject, directly or indirectly, to federal and state health care fraud and abuse laws, false claims laws, transparency and pricing laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our drug candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may affect, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal health care program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010 (“ACA”) requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;
- state law and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and

- state and federal laws, such as the Physician Sunshine Act, directed at generating transparency on financial issues, including drug prices and payments made by drug companies to various entities and individuals involved in healthcare.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including exclusion from payment by federal health care programs, civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Compliance with laws and regulations pertaining to the privacy and security of health information may be time consuming, difficult and costly, particularly in light of increased focus on privacy issues in countries around the world, including the U.S. and the EU.

We are subject to various domestic and international privacy and security regulations related to personal information, including health information, that are appliable to our business and associated data processing activities. The confidentiality, collection, use and disclosure of personal data, including clinical trial patient-specific information, are subject to governmental regulation generally in the country that the personal data was collected or used. In the United States, we are subject to various state and federal privacy and data security regulations, including but not limited to HIPAA and as amended by the HITECH Act. HIPAA imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information, and mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. We may also be subject to state security breach notification laws, state laws protecting the privacy and security of health and personal information, and federal and state consumer protections laws which regulate the collection, use, disclosure and transmission of personal information. These laws may overlap and conflict with each other, and each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. In the EU, personal data includes any information that relates to an identified or identifiable natural person with health information carrying additional obligations, including obtaining the explicit consent from the individual for collection, use or disclosure of the information. We are also subject to the EU General Data Protection Regulation 2016/679 (“GDPR”). Violations of the GDPR can carry hefty fines. In addition, we may be subject to additional national laws and regulations that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts. If we fail to comply with applicable data protection laws and regulations, we could be subject to penalties or sanctions, including criminal penalties. Furthermore, the legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues.

Compliance with these laws may be time-consuming, difficult and costly. If we fail to comply with applicable laws, regulations or duties relating to the use, privacy or security of personal data we could be subject to the imposition of significant civil and criminal penalties, be forced to alter our business practices and suffer reputational harm.

Changes in health care law and implementing regulations, including government restrictions on pricing and reimbursement, as well as health care policy and other health care payor cost-containment initiatives, may have a material adverse effect on us.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the regulatory system, health care system and efforts to control health care costs, including drug prices, that could have a significant negative impact on our business, including preventing, limiting or delay regulatory approval of our drug candidates and reducing the sales and profits derived from our products once they are approved. For example, in the United States, the ACA substantially changed the way health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Many provisions of ACA impact the biopharmaceutical industry, including that in order for a biopharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the drug pricing program under the Public Health Services Act, or PHS. Since its enactment, there have been judicial and Congressional challenges and amendments to certain aspects of ACA. There is continued uncertainty about the implementation of ACA, including the potential for further amendments to the ACA and legal challenges to or efforts to repeal the ACA.

In addition, the Inflation Reduction Act of 2022, enacted in August 2022, empowers the Centers for Medicare and Medicaid Services to negotiate directly with pharmaceutical companies to set the prices for a limited set of high-cost drugs covered by Medicare, and puts penalties in place for drug manufacturers who increase their Medicare prices by more than the rate of inflation.

Other examples of proposed changes include, but are not limited to, expanding post-approval requirements, changing the Orphan Drug Act, and restricting sales and promotional activities for pharmaceutical products.

We cannot be sure whether additional legislative changes will be enacted, or whether government regulations, guidance or interpretations will be changed, or what the impact of such changes would be on the marketing approvals, sales, pricing, or reimbursement of our drug candidates or products, if any, may be.

Risks Related to Our Capital Stock

Our history of losses and uncertainty of future profitability make our common stock a highly speculative investment.

We have had no commercial revenue to date from sales of our drug candidates. We had an accumulated deficit of $1.6 billion as of December 31, 2024. We expect to spend substantial funds to continue the research and development testing of our drug candidates.

In anticipation of FDA approval of these products, we will need to make substantial investments to establish sales, marketing, quality control, regulatory compliance capabilities and commercial manufacturing alliances. These investments will increase if and when any of these drug candidates receive FDA approval. We cannot predict how quickly our lead drug candidates will progress through the regulatory approval process. As a result, we may continue to lose money for several years.

We cannot be certain that we will achieve or sustain profitability in the future. Failure to achieve profitability could diminish our ability to sustain operations, pay dividends on our common stock, obtain additional required funds and make required payments on our present or future indebtedness.

Our share price has been and could remain volatile.

The market price of our common stock has historically experienced and may continue to experience significant volatility. From January 2023 through December 2024, the market price of our common stock has fluctuated from a high of $53.18 per share in the first quarter of 2024, to a low of $22.11 per share in the fourth quarter of 2023. Our progress in developing and commercializing our products, the impact of government regulations on our products and industry, the potential sale of a large volume of our common stock by stockholders, our quarterly operating results, changes in general conditions in the economy or the financial markets and other developments affecting us or our competitors could cause the market price of our common stock to fluctuate substantially with significant market losses. If our stockholders sell a substantial number of shares of common stock, especially if those sales are made during a short period of time, those sales could adversely affect the market price of our common stock and could impair our ability to raise capital. In addition, in recent years, the stock market has experienced significant price and volume fluctuations. This volatility has affected the market prices of securities issued by many companies for reasons unrelated to their operating performance and may adversely affect the price of our common stock. In addition, we could be subject to a securities class action litigation as a result of volatility in the price of our stock, which could result in substantial costs and diversion of management's attention and resources and could harm our stock price, business, prospects, results of operations and financial condition.

Our ability to use our net operating loss carryforwards will be subject to limitation and, under certain circumstances, may be eliminated.

As of December 31, 2024, we had net operating loss carryforwards, or NOLs, of approximately $566.0 million for federal income tax purposes, and $888.8 million for state income tax purposes. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. In addition, utilization of our net operating loss and research and development credit carryforwards may be subject to substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future provided by Section 382 of the Internal Revenue Code of 1986, or Section 382, as well as similar state provisions. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period.

In October 2007, June 2009, December 2009, December 2013, November 2016 and June 2020, we experienced a change in ownership as defined by Section 382. Historically, we have raised capital through the issuance of capital stock on several occasions which, combined with shareholders' subsequent disposition of those shares, has resulted in changes of control, as defined by Section 382. As a result of these ownership changes, utilization of at least some of our federal NOL carryforwards is subject to an annual limitation. We have not undertaken a study to assess whether an ownership change or multiple ownership changes have occurred for (i) acquired businesses with NOLs prior to being acquired by the Company, (ii) the Company on the state level, (iii) the Company since June 2024 or (iv) research and development credits. If, based on such a study, we were to determine that there has been an ownership change at any time, utilization of net operating loss or tax credit carryforwards would be subject to an annual limitation under Section 382 (or similar state provisions).

Any unused annual limitation may be carried over to later years, and the amount of the limitation may, under certain circumstances, be subject to adjustment if the fair value of our net assets is determined to be below or in excess of the tax basis of such assets at the time of the ownership change, and such unrealized loss or gain is recognized during the five-year period after the ownership change. Subsequent ownership changes, as defined in Section 382, could further limit the amount of net operating loss carryforwards and research and development credits that can be utilized annually to offset future taxable income.

Refer to Note 16, "Income Taxes," in the accompanying notes to the financial statements for additional discussion on income taxes.

General Risk Factors

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. We have designed, implemented and tested the internal control over financial reporting required to comply with this obligation, which was and is time consuming, costly, and complicated. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. Any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We have many competitors in our field, and they may develop technologies that make ours obsolete.

Biotechnology, pharmaceuticals and therapeutics are rapidly evolving fields in which scientific and technological developments are expected to continue at a rapid pace. We have many competitors in the U.S. and abroad. The following table is a summary of the competitors of which we are aware that have initiated a Phase 3 study or have obtained marketing approval for a potentially competitive drug to barzolvolimab for treatment of CSU, CIndU, PN, EoE and AD.

Competitor	Competitor Product	Indication(s)
Abbvie	Rinvoq	AD
Amgen	Tezpire	EoE
Amgen/Kiowa Kirin	Rocatinlimab	AD and PN
Celltrion	CT-P39, omalizumab biosimilar	CSU
Eli Lilly	Olumiant and Ebglyss	AD
Galderma/Chugai	Nemluvio	PN and AD
Incyte	Povorcitinib	PN
Kashiv Biosciences	ADL-018 omalizumab biosimilar	CSU
Leo Pharma	Adbry	AD
Medimetriks	Difamilast	AD
Novartis	Remibrutinib	CSU and CIndU
Pfizer	Cibinqo	AD
Regeneron/Sanofi	Dupixent	CSU, PN, EoE and AD
Regeneron/Sanofi	Amlitelimab	AD
Teva	Tev-45779, omalizumab biosimilar	CSU
Vanda Pharmaceuticals	Tradipitant	AD

Our success depends upon our ability to develop and maintain a competitive position in the product categories and technologies on which we focus. Many of our competitors have greater capabilities, experience and financial resources than we do. Competition is intense and is expected to increase as new products enter the market and new technologies become available. Our competitors may:

- develop technologies and products that are more effective than ours, making ours obsolete or otherwise noncompetitive;
- obtain regulatory approval for products more rapidly or effectively than us; and
- obtain patent protection or other intellectual property rights that would block our ability to develop competitive products.

We or the third parties upon whom we depend may be adversely affected by natural disasters or other unforeseen events and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party CDMOs, could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. For example, our operations are located primarily on the east coast of the United States, and any adverse weather event or natural disaster, such as a hurricane or heavy snowstorm, could have a material adverse effect on a substantial portion of our operations. If any event occurred that prevented us from using all or a significant portion of our manufacturing and lab facilities, damaged critical infrastructure, such as third-party manufacturing facilities, or otherwise disrupted operations and travel, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

We face risks related to health epidemics and outbreaks, which could significantly disrupt our preclinical studies and clinical trials.

Disease outbreaks, epidemics and pandemics in regions where we have concentrations of clinical trial sites and other business operations, could adversely affect our business, including by causing significant disruptions in our operations and/or in the operations

of manufacturers and CROs upon whom we rely. Disease outbreaks, epidemics and pandemics may have negative impacts on our ability to initiate new clinical trial sites, enroll new patients and maintain existing patients who are participating in clinical trials, which may result in increased clinical trial costs, longer timelines and delay in our ability to obtain regulatory approvals of our product candidates, if at all. For example, patient enrollment and recruitment could be delayed due to local clinical trial site protocols designed to protect staff and patients from certain outbreaks, which could delay the expected timelines for data readouts of our preclinical studies and clinical trials. Additionally, general supply chain issues may be exacerbated during disease outbreaks, epidemics or pandemics and may also impact the ability of our clinical trial sites to obtain basic medical supplies used in our trials in a timely fashion, if at all. Moreover, the extent to which disease outbreaks, epidemics and pandemics may impact our business, results of operations and financial position will depend on future developments, which are highly uncertain and cannot be predicted with confidence. New health epidemics or pandemics may emerge that result in similar or more severe disruptions to our business. A future disease outbreak, epidemic or pandemic adversely affects our business, financial condition, results of operations and growth prospects.

The progression of an epidemic and the related effects on our business and operations are uncertain. A potential resurgence of an epidemic could pose the risk that we or our employees, suppliers, customers and others may be restricted or prevented from conducting business activities for indefinite or intermittent periods of time, including as a result of employee health and safety concerns, shutdowns, shelter in place orders, travel restrictions and other actions and restrictions that may be prudent or required by governmental authorities. This could disrupt our ability to operate our business, including producing drug product and administering our preclinical and clinical studies. In addition, fluctuations in demand and other implications associated with an epidemic could result in supply chain constraints and challenges.

Disruptions in the global economy and supply chains may have a material adverse effect on our business, financial condition and results of operations.

The disruptions to the global economy due to geopolitical events have impeded, and may continue to impede in the future, global supply chains, resulting in longer lead times and also increased critical component costs and freight expenses. We have taken steps to minimize the impact of these increased costs by working closely with our suppliers. Despite the actions we have undertaken to minimize the impacts from disruptions to the global economy, there can be no assurances that unforeseen future events in the global supply chain, and inflationary pressures, will not have a material adverse effect on our business, financial condition and results of operations.

We depend greatly on the intellectual capabilities and experience of our key executives and scientists, and the loss of any of them could affect our ability to develop our products.

The loss of any of our executive officers could harm us. We entered into employment agreements with each of our executive officers, although an employment agreement as a practical matter does not guarantee retention of an employee. We also depend on our scientific and clinical collaborators and advisors, all of whom have outside commitments that may limit their availability to us. In addition, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific, managerial and marketing personnel, particularly as we expand our activities in clinical trials, the regulatory approval process and sales and manufacturing. We routinely enter into consulting agreements with our scientific and clinical collaborators and advisors, key opinion leaders and heads of academic departments in the ordinary course of our business. We also enter into contractual agreements with physicians and institutions who recruit patients into our clinical trials on our behalf in the ordinary course of our business. Notwithstanding these arrangements, we face significant competition for this type of personnel from other companies, research and academic institutions, government entities and other organizations. We cannot predict our success in hiring or retaining the personnel we require for continued growth.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with applicable privacy laws, comply with manufacturing standards we have established, comply with federal and state health care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct

could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics and launched a Health Care Compliance program, but it is not always possible to identify and deter employee misconduct. The precautions we take and the investments we make to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant effect on our business and results of operations, including the imposition of significant fines or other sanctions.

We may not be able to maintain compliance with the Listing Rules of the NASDAQ Stock Exchange.

There can be no assurance that in the future we will be able to maintain compliance with the Nasdaq Listing Rules, including the minimum bid price requirement and other applicable corporate governance requirements. If we fail to maintain compliance with the minimum bid requirement or to meet the other applicable continued listing requirements for the NASDAQ Capital Market in the future and NASDAQ determines to delist our common stock, the delisting could adversely affect the market price and liquidity of our common stock and reduce our ability to raise additional capital. In addition, if our common stock is delisted from NASDAQ and the trading price remains below $5.00 per share, trading in our common stock might also become subject to the requirements of certain rules promulgated under the Exchange Act, which require additional disclosure by broker-dealers in connection with any trade involving a stock defined as a "penny stock" (generally, any equity security not listed on a national securities exchange or quoted on NASDAQ that has a market price of less than $5.00 per share, subject to certain exceptions).

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 1C. CYBERSECURITY

Cybersecurity Risk Management and Strategy

To effectively prevent, detect and respond to cybersecurity threats, we maintain a cyber risk management program under the responsibility of the head of the Information Technology ("IT") function. Our IT head has more than 25 years of IT experience in the biopharmaceutical industry where she has been responsible for technology leadership and digital transformation across core operations. Management and administration of cybersecurity systems and activities are primarily outsourced to consultants who have cross-functional expertise in cyber security and who perform the work under the supervision of the IT head. Our IT head, in turn reports to the Senior Vice-President and General Counsel who is responsible for and knowledgeable of legal and contractual cybersecurity risk for the organization. The program is comprised of policies, standards, architecture, and processes, which are reviewed and updated on a periodic basis. The program leverages a multilayered approach of utilizing different practices, technologies, vendors or techniques without an overreliance on a single vendor. We engage with consultants to help develop and evidence the policies, standards, and processes in a manner consistent with applicable legal requirements, and also evaluate and adopt cybersecurity software from reputable vendors in cybersecurity, some that provide software as a service solutions backed by a Security Operations Center. We also engage separate third parties to provide penetration testing, risk consulting, cybersecurity incident assessment and forensics, as necessary and in addition to IT's internal risk assessment processes. We work with many companies that provide hosted software or support for software systems. It is important for these companies to also have effective cybersecurity measures to protect data and systems. We have a self-attestation form to assess cybersecurity readiness that is sent to select vendors based on a risk assessment. For certain vendors, we request System and Organization Controls (SOC) reports or similar documents to provide assurance that the vendors have audited practices or practices in keeping with our legal requirements even if SOC audit documentation does not exist. We have also engaged legal counsel to advise on cybersecurity matters and we have developed an escalation protocol to report cybersecurity incidents as legally required. No material cybersecurity incidents have occurred to date.

The program also includes training that reinforces our policies, standards, and practices, as well as the expectation that employees comply with these policies. The training engages personnel on how to identify potential cybersecurity risks and protect our resources and information. This training is mandatory for all employees on a periodic basis, and it is supplemented by testing initiatives, including periodic phishing tests. We maintain a cybersecurity risk insurance policy.

Governance; Board Oversight

Our Audit Committee is responsible for reviewing our information security programs, including cybersecurity. Our IT team provides regular updates to the Audit Committee on our IT security strategy, secure score assessments, penetration testing results, and status of risk mitigation activities, where applicable. Our IT team also notifies the Audit Committee and Executive Committee of any cybersecurity incidents (suspected or actual) and provides updates on the incidents as well as cybersecurity risk mitigation activities, as appropriate.

Item 2. PROPERTIES

As of December 31, 2024, our significant leased properties are described below.

Property Location	Approximate Square Feet	Use	Lease Expiration Date
Hampton, New Jersey	33,400	Headquarters, Office and Laboratory	July 2027[1]
Fall River, Massachusetts	36,300	Manufacturing, Office and Laboratory	July 2027[2]
New Haven, Connecticut	17,700	Office and Laboratory	October 2026

(1) Lease includes two renewal options of two years.

(2) Lease includes one renewal option of three years.

Item 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

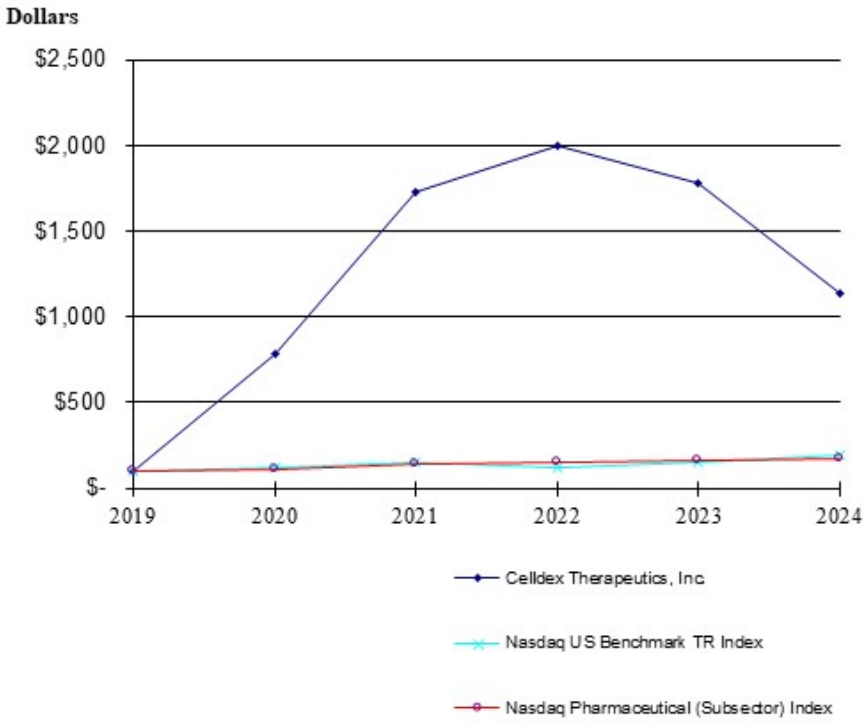
PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock currently trades on the Nasdaq Capital Market (NASDAQ) under the symbol "CLDX." As of February 14, 2025, there were approximately 136 shareholders of record of our common stock. On February 14, 2025 the closing price of our common stock, as reported by NASDAQ, was $22.70 per share. We have not paid any dividends on our common stock since our inception and do not intend to pay any dividends in the foreseeable future.

CELLDEX THERAPEUTICS, INC., NASDAQ MARKET INDEX — U.S. AND PEER GROUP INDICES

The graph below compares the cumulative total stockholder return on the common stock for the period from December 31, 2019 through December 31, 2024, with the cumulative return on (i) NASDAQ U.S. Benchmark TR Index and (ii) NASDAQ Pharmaceutical (Subsector) Index. The comparison assumes investment of $100 on December 31, 2019 in our common stock and in each of the indices and, in each case, assumes reinvestment of all dividends. The points on the graph are as of December 31 of the year indicated.



	2019	2020	2021	2022	2023	2024
Celldex Therapeutics, Inc.	$ 100	$ 786	$ 1,733	$ 1,999	$ 1,778	$ 1,133
NASDAQ U.S. Benchmark TR Index	$ 100	$ 121	$ 153	$ 123	$ 155	$ 193
NASDAQ Pharmaceutical (Subsector) Index	$ 100	$ 111	$ 137	$ 153	$ 159	$ 173

Item 6. [Reserved]

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

OVERVIEW

We are a biopharmaceutical company dedicated to exploring the science of mast cell biology and developing therapeutic antibodies which have the ability to engage the human immune system and/or directly affect critical pathways to improve the lives of patients with severe inflammatory, allergic, autoimmune and other devastating diseases. Our drug candidates include monoclonal and bispecific antibodies designed to address mast cell mediated diseases for which available treatments are inadequate.

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

- Barzolvolimab (also referred to as CDX-0159), a monoclonal antibody that specifically binds the KIT receptor and potently inhibits its activity, which is currently being studied across multiple mast cell driven diseases including
    - Chronic Urticarias: We initiated Phase 3 studies in chronic spontaneous urticaria (CSU) in July 2024. In November 2023, we announced that our Phase 2 study in CSU achieved the primary efficacy endpoint (statistically significant mean change from baseline to week 12 of urticaria activity score compared to placebo) and was well tolerated. Patients on study continued to receive barzolvolimab and, in September 2024, we reported data from 52 weeks of treatment—demonstrating sustained and deepening disease efficacy and a well tolerated long term safety profile. In July 2024, we announced that our Phase 2 study in chronic inducible urticaria (CIndU) 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 of 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 for 20 weeks of treatment;
    - Prurigo Nodularis (PN): In April 2024, we initiated a Phase 2 study in PN and enrollment is ongoing; positive data from a Phase 1b study in PN was reported in November 2023;
    - Eosinophilic Esophagitis (EoE): A Phase 2 study in EoE was initiated in June 2023 and is fully accrued; and
    - Atopic Dermatitis (AD): A Phase 2 study in AD was initiated in December 2024 and enrollment is ongoing.
- 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.
    - CDX-622 (TSLP & SCF): Our first bispecific candidate for inflammatory diseases is CDX-622 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 Phase 1a dose-escalation study in healthy volunteers was initiated and enrollment is ongoing.

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

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

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

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

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

- the number of patients that ultimately participate in the trial;
- the duration of patient follow-up that seems appropriate in view of results;
- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patient subjects; and
- the efficacy and safety profile of the drug candidate.

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

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

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

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, 2024, we incurred an aggregate of $459.7 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 years ended December 31, 2024, 2023 and 2022. 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.

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year Ended December 31, 2022
		(In thousands)	
Barzolvolimab/Anti-KIT Program	$ 123,750	$ 79,913	$ 51,220
CDX-622	17,341	16,299	5,613
CDX-585	2,813	6,357	9,793
Other Programs	19,646	15,442	15,632
Total R&D Expense	$ 163,550	$ 118,011	$ 82,258

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 July 2024, we initiated two Phase 3 studies in CSU. Phase 1 studies in CSU and CIndU were successfully completed and Phase 2 studies are ongoing. In July 2023, we announced that enrollment was complete in the ongoing Phase 2 CSU study. In November 2023, we reported that barzolvolimab achieved the primary efficacy endpoint in this study, with a statistically significant mean change from baseline to week 12 of UAS7 (weekly urticaria activity score) compared to placebo and was well tolerated. In September 2024, we presented 52 week treatment data from the CSU study, demonstrating sustained and deepening disease efficacy and a well tolerated long term safety profile. We plan to present follow up data from this study through week 76 in 2025. In April 2024, we announced enrollment was complete in the ongoing Phase 2 CIndU study. In July 2024, we announced that our Phase 2 study in chronic inducible urticaria (CIndU) 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 of 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 for 20 weeks of treatment and were then followed for up to 24 additional weeks without treatment. We plan to present data from this study through week 44 in 2025. Patients with resumption of symptoms were eligible to enroll into an open label extension.

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 ongoing Phase 2 studies in eosinophilic esophagitis (EoE), prurigo nodularis (PN) and atopic dermatitis (AD). We continue to assess potential opportunities for barzolvolimab in other diseases where mast cells play an important role, such as dermatologic, respiratory, allergic, gastrointestinal and ophthalmic conditions.

Chronic Spontaneous Urticaria (CSU) Summary of Phase 1 and Phase 2 Data Presented to Date; 76 week Phase 2 follow up data to be presented in 2025.

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. Omalizumab, an IgE inhibitor, provides relief for roughly half of the remaining antihistamine refractory patients. Consequently, there is a need for additional therapies.

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. Secondary and exploratory objectives included pharmacokinetic and pharmacodynamic assessments, clinical activity outcomes and quality of life assessments. Barzolvolimab was administered intravenously as add on treatment to H1-antihistamines, either alone or in combination with H2-antihistamines and/or leukotriene receptor agonists. 45 patients with moderate to severe CSU refractory to antihistamines were enrolled and treated [35 barzolvolimab (n=9 in 0.5 mg/kg; n=8 in 1.5 mg/kg; n=9 in 3.0 mg/kg; n=9 in 4.5 mg/kg) and 10 placebo].

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

Phase 1 CSU: Summary of Clinical Activity Assessments at Week 12 & 24			
	4.5 mg/kg Q8	3.0 mg/kg Q8	1.5 mg/kg Q4
Mean Reduction Baseline UAS7; % at Week 12	82% (n=9)	67% (n=9)	67% (n=8)
Mean Reduction Baseline UAS7; % at Week 24	77% (n=7)	70% (n=6)	80% (n=7)
UAS7=0 (Complete Control); % at Week 12	67%	44%	57%
UAS7=0 (Complete Control); % at Week 24	43%	67%	57%
UAS7≤6 (Well-controlled); % at Week 12	67%	67%	57%
UAS7≤6 (Well-controlled); % at Week 24	57%	67%	57%
UCT ≥ 12 (Well-controlled); % at Week 12	89%	63%	75%
UCT ≥ 12 (Well-controlled); % at Week 24	67%	67%	75%

During post-treatment follow up, 71% (10 of 14) of patients who had been treated with doses greater than or equal to 1.5 mg/kg and had a complete response (UAS7=0) at week 12, remained urticaria free at week 24 (patients received last dose of barzolvolimab at week 8). Profound and durable improvement in angioedema symptoms as measured through the weekly angioedema activity score (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. The most common treatment emergent adverse events were hair color changes, COVID-19, headache, neutropenia and urinary tract infections (UTIs). UTIs and COVID-19 were reported as unrelated to treatment. Generally transient, asymptomatic and mild changes in hematologic parameters were observed, consistent with observations from prior studies. No pattern of further decrease was observed with multiple dose administration.

Data from this study were reported across multiple medical meetings, including the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting in February 2023, the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress in June 2023 and the European Academy of Dermatology & Venereology (EADV) Congress in October 2023.

In June 2022, we initiated dosing in a Phase 2 study in patients with CSU who remained symptomatic despite antihistamine therapy; in July 2023, we announced that enrollment was complete. The study is being conducted at approximately 75 sites across 9 countries. The study is a randomized, double-blind, placebo-controlled, parallel group Phase 2 study evaluating the efficacy and safety profile of multiple dose regimens of barzolvolimab to determine the optimal dosing strategy. 208 patients have been randomly assigned on a 1:1:1:1 ratio to receive subcutaneous injections of barzolvolimab at 75 mg every 4 weeks, 150 mg every 4 weeks, 300 mg every 8 weeks or placebo during a 16-week placebo-controlled treatment phase. After 16 weeks, patients then enter a 36-week active treatment period, in which patients receiving placebo or the 75 mg dose are 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 remain on the same regimen as during the placebo-controlled treatment period. After 52 weeks, patients then enter a follow-up period for an additional 24 weeks. The primary endpoint of the study is mean change in baseline to week 12 in UAS7 (weekly urticaria activity score). Secondary endpoints include 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 of 2023 and 12 week treatment results were presented at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting in February 2024. Data from the 208 patients randomized in the study showed that barzolvolimab achieved the primary efficacy endpoint, with a statistically significant mean change from baseline to week 12 in UAS7 compared to placebo at all dose levels. Secondary and exploratory endpoints in the study were also achieved at week 12 and strongly support the primary endpoint results, including changes in ISS7 and HSS7 and responder analyses. Importantly, barzolvolimab demonstrated rapid, durable and clinically meaningful responses in patients with moderate to severe CSU refractory to antihistamines, including patients with prior omalizumab treatment. Demographics and baseline disease characteristics were well balanced across treatment groups. The majority of patients on study had severe disease (UAS7≥28).

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, 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 and these long term treatment data were presented in September at the European Academy of Dermatology & Venereology (EADV) Congress 2024. The data demonstrated a sustained and deepening disease efficacy and a well tolerated safety profile over a 52 week treatment period. Key highlighted 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.
- 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.

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. Both Phase 3 trials are randomized, double-blind, placebo-controlled, parallel group, global studies (approximately 40 countries; 250 sites per study) where approximately 915 patients per trial will be randomized evenly 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 will be re-randomized to active treatment across both dosing groups. The primary endpoint of the studies will evaluate 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. Enrollment is ongoing.

Chronic Inducible Urticaria (CIndU) Summary of Phase 1 and Phase 2 Data Presented to Date; 44 week Phase 2 follow up data to be presented in 2025.

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 are currently exploring cold-induced and dermographism (scratch-induced) urticarias in an ongoing Phase 2 study.

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.

In July 2022, we announced that the first patient had been dosed in a Phase 2 study in patients with CIndU who remain symptomatic despite antihistamine therapy; in April 2024, we announced that enrollment was complete. The study is being conducted at approximately 85 sites across approximately 12 countries. The randomized, double-blind, placebo-controlled, parallel group Phase 2 study is evaluating the efficacy and safety profile of multiple dose regimens of barzolvolimab in patients with CIndU to determine the optimal dosing strategy. 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 enter a follow-up phase for an additional 24 weeks. In addition, the study includes the option for patients who have symptoms following the treatment phase, including patients who were on placebo, to enroll in an open label extension where all patients receive 300 mg of barzolvolimab every 8 weeks. The primary endpoint of the study is the percentage of patients with a negative provocation test at week 12. Secondary endpoints include safety and other assessments of clinical activity including CTT (Critical Temperature Threshold), CFT (Critical Friction Threshold) and WI-NRS (Worst itch numeric rating scale).

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. 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 reflect 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.

We believe these results strongly support the further development of barzolvolimab in CIndU and plan to advance CIndU into Phase 3 registrational development.

Prurigo Nodularis (PN)

We have expanded clinical development of barzolvolimab into prurigo nodularis (PN). PN is a chronic skin disease characterized by the development of hard, intensely itchy (pruritic) nodules on the skin. Mast cells through their interactions with sensory neurons and other immune cells are believed to play an important role in amplifying chronic itch and neuroinflammation, both of which are a hallmark of PN. There is currently only one FDA approved therapy for PN, representing an area of significant unmet need. Industry sources estimate there are approximately 154,000 patients in the United States with PN who have undergone treatment within the last 12 months and, of these, approximately 75,000 would be biologic-eligible.

We have completed a Phase 1b multi-center, randomized, double-blind, placebo-controlled intravenous study in PN. Data from the study, including 24 weeks of follow-up, were presented at the 12th World Congress on Itch (WCI) held in November 2023. 24 adults (evaluable: n=23 safety; n=22 efficacy) with moderate to severe PN were randomized across three arms: (1) barzolvolimab 3.0 mg/kg (n=9), barzolvolimab 1.5 mg/kg (n=7) and placebo (n=8). The primary endpoint of the study was safety; key secondary

endpoints include changes from baseline in Worst Itch-Numerical Rating Scale (WI-NRS) & Investigator Global Assessment (IGA). The primary timepoint for evaluation of clinical activity was 8 weeks; patients were followed for safety and efficacy endpoints to 24 weeks. Patients on study generally had moderate to severe disease with mean baselines scores across all arms of 8.6 for WI-NRS and 3.3 for IGA.

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

- At week 8, the percentage of patients with ≥4-point decrease in WI-NRS was 57% and 43% for the single dose 3.0 or 1.5 mg/kg barzolvolimab arms, respectively, and 25% for the placebo arm; this level of response generally persisted out to week 16. In the 3.0 mg/kg arm, a ≥4-point decrease in WI-NRS reduction was seen as early as the first week and reached a high of 71% of patients at week six which was distinct from both the 1.5 mg/kg barzolvolimab and placebo arms.

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

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

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

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

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

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

Eosinophilic Esophagitis (EoE)

In July of 2023, we announced that the first patient had been dosed in a Phase 2 study of eosinophilic esophagitis (EoE). EoE, the most common type of eosinophilic gastrointestinal disease, is a chronic inflammatory disease of the esophagus characterized by the infiltration of eosinophils. This chronic inflammation can result in trouble swallowing, chest pain, vomiting and impaction of food in the esophagus, a medical emergency. Several studies have suggested that mast cells may be an important driver in the disease, demonstrating that the number and activation state of mast cells are greatly increased in EoE biopsies and that mast cell signatures correlate with markers of inflammation, fibrosis, pain and disease severity. Currently, there is only one FDA approved therapy for EoE, representing an area of significant unmet need. Industry sources estimate there are approximately 160,000 patients in the United States with EoE who have undergone treatment within the last 12 months and, of these, approximately 48,000 would be biologic-eligible. Given the lack of effective therapies for EoE and barzolvolimab's potential as a mast cell depleting agent, we believe EoE is an important indication for future study.

The randomized, double-blind, placebo-controlled, parallel group Phase 2 study is evaluating the efficacy and safety profile of subcutaneous barzolvolimab in patients with active EoE. To optimize potential efficacy signal in this difficult to treat indication, we have recently amended the protocol to dose 300 mg every 4 weeks rather than 8 weeks. Approximately 75 patients will be enrolled in total. In the revised protocol, patients will be randomly assigned on a 1:1 ratio to receive subcutaneous injections of barzolvolimab at 300 mg every 4 weeks or placebo during a 16-week placebo-controlled treatment phase. Patients then enter a 12-week active treatment phase, in which all patients will receive barzolvolimab 300 mg every 4 weeks. Patients then enter a follow-up phase for an additional 16 weeks. The primary endpoint of the study is reducing esophageal intraepithelial infiltration of mast cells as assessed by peak esophageal intraepithelial mast cell count. Secondary endpoints include the reduction of symptoms of dysphagia and esophageal intraepithelial infiltration of eosinophils and safety. The study includes approximately 60 clinical trial centers across 8 countries, including the United States. The study is fully accrued and we plan to present data from the study in the second half of 2025.

Atopic Dermatitis (AD)

In December of 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 patienst 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. Approximately 120 patients will be 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 will be re-randomized at Week 16 into 1 of the 2 active treatment arms. Patients then enter 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. When all clinical trial sites are open, the study will include up to 50 clinical trial centers in the United States. Enrollment is ongoing.

Additional Barzolvolimab Development Activities

In 2023, we completed the transfer of our current barzolvolimab manufacturing process to a CDMO and successfully scaled up the drug substance manufacturing process to produce larger cGMP batches in support of late-stage trials and to prepare for potential commercialization. Drug product manufacturing into 1 mL pre-filled syringes has been completed and are actively being used in the ongoing Phase 3 CSU trials.

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.

CDX-622

CDX-622 is a bispecific antibody that 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. TSLP has been directly implicated in several respiratory and dermatological disorders, such as asthma, chronic obstructive pulmonary disease (COPD), eosinophilic esophagitis, atopic dermatitis and chronic spontaneous urticaria, and in fibrotic diseases such as systemic sclerosis and idiopathic pulmonary fibrosis. In these disorders, TSLP is often upregulated and associated with disease severity. Similarly, mast cells drive or contribute to the pathophysiology of allergic, inflammatory, autoimmune and fibrotic disorders and CDX-622 contains a unique SCF neutralizing function that is expected to inhibit and deplete mast cells. 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. In preclinical studies, CDX-622 inhibits TSLP and SCF with similar potency to both its respective parental mAbs and comparator mAbs *in vitro*. CDX-622 was well tolerated in a multi-dose 8 week toxicology study in non-human primates. The No Adverse Event Level (NOAEL) was established to be 75 mg/kg, the highest dose level tested.

In November 2024, we initiated a Phase 1 study of CDX-622 in healthy volunteers. The Phase 1a clinical trial is a two-part, randomized, double-blind, placebo-controlled, dose escalation study designed to assess the safety, pharmacokinetics, and pharmacodynamics of single ascending doses (Part 1) and multiple ascending doses (Part 2) of CDX-622 in up to 56 healthy participants. A single dose of CDX-622 or placebo will be administered intravenously once during Part 1. In Part 2, CDX-622 or placebo will be administered every 3 weeks (Q3W) for up to 6 weeks following the first dose, for a total of 3 doses. Participants will be followed for 12 weeks in both Parts 1 and 2 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. A subcutaneous formulation is currently being manufactured and will be added to this study in 2025

CDX-585 (development discontinued)

CDX-585 combined PD-1 blockade and anti-ILT4 blockade to overcome immunosuppressive signals in T cells and myeloid cells, respectively. We initiated a Phase 1 open-label, multi-center, multi-dose study in patients with advanced or metastatic solid tumors that had progressed during or after standard of care therapy. The dose-escalation phase of the study was completed and we announced in Q4 2024 that we would not advance CDX-585 given our expanding clinical development program in the inflammatory space.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our significant accounting policies are described in Note 2 to the financial statements included in Item 8 of this Form 10-K. 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.

The methods, estimates and judgments we use in applying our most critical accounting policies have a significant impact on the results we report in our financial statements. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Our experience and assumptions form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary from what we anticipate and different assumptions or estimates about the future could materially change our reported results. We believe the following accounting policies are the most critical to us in that they are important to the portrayal of our financial statements and they require our most difficult, subjective or complex judgments in the preparation of our financial statements:

Contingent Consideration

We record contingent consideration resulting from a business combination at its fair value on the acquisition date. We determine the fair value of the contingent consideration based primarily on the following factors:

- timing and probability of success of clinical events or regulatory approvals;
- timing and probability of success of meeting clinical and commercial milestones; and
- discount rates.

Our contingent consideration arose in connection with our acquisition of Kolltan. On a quarterly basis, we revalue these obligations and record increases or decreases in their fair value as an adjustment to operating earnings. As of December 31, 2024, the fair value of our contingent consideration was $0.0 million. Changes to contingent consideration obligations can result from adjustments to discount rates, accretion of the discount rates due to the passage of time, changes in our estimates of the likelihood or timing of achieving development or commercial milestones, changes in the probability of certain clinical events or changes in the assumed probability associated with regulatory approval.

The assumptions related to determining the 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.

Revenue Recognition

Revenues are recognized when performance obligations under agreements or contracts are satisfied, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those services.

The Company determines revenue recognition through the following steps:

- Identification of the contract, or contracts, with a customer;
- Identification of the performance obligations in the contract;
- Determination of the transaction price;
- Allocation of the transaction price to the performance obligations in the contract; and
- Recognition of revenue when, or as, the Company satisfies a performance obligation.

Revenue for the Company is derived from product development agreements with collaborative partners for the research and development of therapeutic drug candidates. The terms of the agreements may include nonrefundable signing and licensing fees, funding for research, development and manufacturing, milestone payments and royalties on any product sales derived from collaborations. The Company assesses the multiple obligations typically within product development contracts to determine the distinct performance obligations and how to allocate the arrangement consideration to each distinct performance obligation. Under product development agreements, revenue is generally recognized using a cost-to-cost measure of progress. Revenue is recognized based on the costs incurred to date as a percentage of the total estimated costs to fulfill the contract. Incurred cost represents work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer. Due to the nature of the work performed in these arrangements, the estimation of cost at completion is complex, subject to many variables, such as expected clinical trial costs, and requires significant judgements. Circumstances can arise that change original estimates of costs or progress toward completion. Any revisions to estimates are reflected in revenue on a cumulative catch-up basis in the period in which the change in circumstances became known.

Revenue for the Company is also derived from manufacturing and research and development arrangements. The Company operates a cGMP manufacturing facility in Fall River, Massachusetts, to produce drug substance for its current and planned early-stage clinical trials. In order to utilize excess capacity, the Company has, from time to time, entered into contract manufacturing and research and development arrangements in which services are provided on a time-and-material basis or at a negotiated fixed- price. Revenue from time-and-material contracts is generally recognized on an output basis as labor hours and/or direct expenses are incurred. Under fixed-price contracts, revenue is generally recognized on an output basis as progress is made toward completion of the performance obligations using surveys of performance completed to date.

Intangible and Long-Lived Assets

We evaluate the recoverability of our long-lived assets, including property and equipment when circumstances indicate that an event of impairment may have occurred. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values.

IPR&D assets acquired in a business combination initially are recorded at fair value and accounted for as indefinite-lived intangible assets. These assets are capitalized on our balance sheets until either the project underlying them is completed or the assets become impaired. If a project is completed, the carrying value of the related intangible asset is amortized over the remaining estimated life of the asset beginning in the period in which the project is completed. If a project becomes impaired or is abandoned, the carrying value of the related intangible asset is written down to its fair value and an impairment charge is taken in the period in which the impairment occurs. Discounted cash flow models are typically used in these tests, and the models require the use of significant estimates and assumptions including but not limited to:

- timing and costs to complete the in-process projects;
- timing and probability of success of clinical events or regulatory approvals;
- estimated future cash flows from product sales resulting from completed products and in-process projects; and
- discount rates

Each IPR&D asset is assessed for impairment at least annually or when impairment indicators are present. The Company has the option to assess qualitative factors to determine if it is more likely than not that the IPR&D asset is impaired and whether it is necessary to perform a quantitative impairment test.

Research and Development Expenses

Research and development costs, including internal and contract research costs, are expensed as incurred. Research and development expenses consist mainly of clinical trial costs, manufacturing of clinical material, toxicology and other preclinical studies, personnel costs, depreciation, license fees and funding of outside contracted research.

Clinical trial expenses include expenses associated with clinical research organization, or CRO, services. Contract manufacturing expenses include expenses associated with contract development & manufacturing organization, or CDMO, services. The invoicing from CROs and CDMOs for services rendered can lag several months. We accrue the cost of services rendered in connection with CRO and CDMO activities based on our estimate of costs incurred. We maintain regular communication with our CROs and CDMOs to assess the reasonableness of our estimates. Differences between actual expenses and estimated expenses recorded have not been material and are adjusted for in the period in which they become known.

Stock-Based Compensation Expense

We record stock-based compensation expense for all stock-based awards made to employees, consultants and non-employee directors based on the estimated fair values of the stock-based awards expected to vest at the grant date and adjust, if necessary, to reflect actual forfeitures. Our estimates of employee, consultant and non-employ director stock option values rely on estimates of future uncertain events. Significant assumptions include the use of historical volatility to estimate the expected stock price volatility. We also estimate expected term based on historical exercise patterns. For consultant and non-employee director grants, we may elect to use the contractual term as the expected term in the option-pricing model. Actual volatility and lives of options may be significantly different from our estimates. Compensation expense for all stock-based awards is recognized using the straight-line method over the term of vesting or performance.

RESULTS OF OPERATIONS

Year Ended December 31, 2024 compared with Year Ended December 31, 2023

	Year Ended December 31,		Increase/ (Decrease)	Increase/ (Decrease)
	2024	2023	$	%
	(In thousands)			
Revenues:				
Product development and licensing agreements	$ 13	$ 278	$ (265)	(95)%
Contracts and grants	7,007	6,605	402	6 %
Total revenues	$ 7,020	$ 6,883	$ 137	2 %
Operating expenses:				
Research and development	163,550	118,011	45,539	39 %
General and administrative	38,548	30,914	7,634	25 %
Litigation settlement related loss	—	12,500	(12,500)	(100)%
Total operating expenses	202,098	161,425	40,673	25 %
Operating loss	(195,078)	(154,542)	40,536	26 %
Investment and other income, net	37,215	13,113	24,102	184 %
Net loss	$ (157,863)	$ (141,429)	$ 16,434	12 %

Net Loss

The $16.4 million increase in net loss for the year ended December 31, 2024, as compared to the year ended December 31, 2023, was primarily due to increases in research and development and general and administrative expenses, partially offset by the $12.5 million litigation settlement related loss recorded in 2023 and an increase in investment and other income, net.

Revenue

The $0.4 million increase in contracts and grants revenue for the year ended December 31, 2024, as compared to the year ended December 31, 2023, was primarily due to an increase in services performed under our manufacturing and research and development agreements with Rockefeller University. We expect revenue to decrease over the next twelve months as a result of a decrease 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:

	Year Ended December 31,		Increase/ (Decrease)	
	2024	2023	$	%
	(In thousands)			
Personnel	$ 51,906	$ 40,121	$ 11,785	29 %
Laboratory supplies	5,611	5,358	253	5 %
Facility	5,094	4,970	124	2 %
Product development	90,604	59,319	31,285	53 %

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The $11.8 million increase in personnel expenses for the year ended December 31, 2024, as compared to the year ended December 31, 2023, was primarily due to higher stock-based compensation expense and an increase in employee headcount. We expect personnel expenses to increase over the next twelve months as a result of additional headcount to support the expanded development of barzolvolimab.

Laboratory supplies expenses include laboratory materials and supplies, services and other related expenses incurred in the development of our technology. The $0.3 million increase in laboratory supply expenses for the year ended December 31, 2024, as compared to the year ended December 31, 2023, was primarily due to higher laboratory services, 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 year ended December 31, 2024 were relatively consistent with the year ended December 31, 2023. We expect facility expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing. The $31.3 million increase in product development expenses for the year ended December 31, 2024, as compared to the year ended December 31, 2023, was primarily due to an increase in barzolvolimab clinical trial expenses, partially offset by a decrease in barzolvolimab contract manufacturing expenses. We expect product development expenses to increase over the next twelve months as a result of the expanded development of barzolvolimab, although there may be fluctuations on a quarterly basis.

General and Administrative Expense

The $7.6 million increase in general and administrative expenses for the year ended December 31, 2024, as compared to the year ended December 31, 2023, was primarily due to higher stock-based compensation and barzolvolimab commercial planning expenses. We expect general and administrative expenses to increase over the next twelve months as a result of the expanded development of barzolvolimab and an increase in commercial planning efforts, although there may be fluctuations on a quarterly basis.

Litigation Settlement Related Loss

During the fourth quarter of 2023, we announced positive topline results from our Phase 2 clinical trial of barzolvolimab in patients with moderate to severe CSU, which satisfied the requirement of "successful completion" of a Phase 2 Clinical Trial of barzolvolimab such that we were obligated to make the applicable milestone payment under the Settlement Agreement with SRS in the amount of $12.5 million. During the fourth quarter of 2023, we paid the $12.5 million milestone in cash and recorded a litigation settlement related loss of $12.5 million.

Investment and Other Income, Net

The $24.1 million increase in investment and other income, net for the year ended December 31, 2024, as compared to the year ended December 31, 2023, was primarily due to higher levels of cash as a result of our November 2023 and March 2024 underwritten public offerings. We expect investment and other income to decrease over the next twelve months due to lower levels of cash and investment balances, although there may be fluctuations on a quarterly basis.

Year Ended December 31, 2023 compared with Year Ended December 31, 2022

	Year Ended December 31,		Increase/ (Decrease)	Increase/ (Decrease)
	2023	2022	$	%
	(In thousands)			
Revenues:				
Product development and licensing agreements	$ 278	$ 56	$ 222	396 %
Contracts and grants	6,605	2,301	4,304	187 %
Total revenues	$ 6,883	$ 2,357	$ 4,526	192 %
Operating expenses:				
Research and development	118,011	82,258	35,753	43 %
General and administrative	30,914	27,195	3,719	14 %
Gain on fair value remeasurement of contingent consideration	—	(6,862)	(6,862)	(100)%
Litigation settlement related loss	12,500	15,000	(2,500)	(17)%
Total operating expenses	161,425	117,591	43,834	37 %
Operating loss	(154,542)	(115,234)	39,308	34 %
Investment and other income, net	13,113	2,909	10,204	351 %
Net loss	$ (141,429)	$ (112,325)	$ 29,104	26 %

Net Loss

The $29.1 million increase in net loss for the year ended December 31, 2023, as compared to the year ended December 31, 2022, was primarily due to an increase in research and development expenses and a decrease in the gain on fair value remeasurement of contingent consideration, partially offset by increases in contracts and grants revenue and investment and other income, net.

Revenue

The $4.3 million increase in contracts and grants revenue for the year ended December 31, 2023, as compared to the year ended December 31, 2022, was primarily related to an increase in services performed under our 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:

	Year Ended December 31,		Increase/ (Decrease)	
	2023	2022	$	%
	(In thousands)			
Personnel	$ 40,121	$ 32,674	$ 7,447	23 %
Laboratory supplies	5,358	6,310	(952)	(15)%
Facility	4,970	4,764	206	4 %
Product development	59,319	32,156	27,163	84 %

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The $7.4 million increase in personnel expenses for the year ended December 31, 2023, as compared to the year ended December 31, 2022, was primarily due to higher stock-based compensation expense and an increase in employee headcount.

Laboratory supplies expenses include laboratory materials and supplies, services and other related expenses incurred in the development of our technology. The $1.0 million decrease in laboratory supply expenses for the year ended December 31, 2023, as compared to the year ended December 31, 2022, was primarily due to lower laboratory services, materials and supplies purchases.

Facility expenses include depreciation, amortization, utilities, rent, maintenance and other related expenses incurred at our facilities. The $0.2 million increase in facility expenses for the year ended December 31, 2023, as compared to the year ended December 31, 2022, was primarily due to higher repairs and depreciation expense.

Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing. The $27.2 million increase in product development expenses for the year ended December 31, 2023, as compared to the year ended December 31, 2022, was primarily due to an increase in barzolvolimab clinical trial and contract manufacturing expenses.

General and Administrative Expense

The $3.7 million increase in general and administrative expenses for the year ended December 31, 2023, as compared to the year ended December 31, 2022, was primarily due to higher stock-based compensation, recruiting and barzolvolimab commercial planning expenses, partially offset by a decrease in legal expenses.

Gain on Fair Value Remeasurement of Contingent Consideration

The $6.9 million gain on fair value remeasurement of contingent consideration for the year ended December 31, 2022 was primarily due to our decision to deprioritize the CDX-1140 program.

Litigation Settlement Related Loss

We recorded a loss of $15.0 million in the second quarter of 2022 related to the Initial Payment due under the Settlement Agreement with SRS. During the fourth quarter of 2023, we announced positive topline results from our Phase 2 clinical trial of barzolvolimab in patients with moderate to severe CSU, which satisfied the requirement of "successful completion" of a Phase 2 Clinical Trial of barzolvolimab such that we were obligated to make the applicable milestone payment under the Settlement Agreement in the amount of $12.5 million. During the fourth quarter of 2023, we paid the $12.5 million milestone in cash and recorded a litigation settlement related loss of $12.5 million.

Investment and Other Income, Net

The $10.2 million increase in investment and other income, net for the year ended December 31, 2023, as compared to the year ended December 31, 2022, was primarily due to higher interest rates on fixed income investments and higher other income related to our sale of New Jersey tax benefits.

LIQUIDITY AND CAPITAL RESOURCES

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

The use of our cash flows for operations has primarily consisted of salaries and wages for our employees; facility and facility-related costs for our offices, laboratories and manufacturing facility; fees paid in connection with preclinical studies, clinical studies, contract manufacturing, laboratory supplies and services; and consulting, legal and other professional fees. We anticipate that our cash

flows from operations will continue to be focused in these areas as we progress our current drug candidates through the clinical trial process and develop additional drug candidates. To date, the primary sources of cash flows from operations have been payments received from our collaborative partners and from government entities and payments received for contract manufacturing and research and development services provided by us. The timing of any new contract manufacturing and research and development agreements, collaboration agreements, government contracts or grants and any payments under these agreements, contracts or grants cannot be easily predicted and may vary significantly from quarter to quarter.

At December 31, 2024, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of $725.3 million. We have had recurring losses and incurred a loss of $157.9 million for the year ended December 31, 2024. Net cash used in operations for the year ended December 31, 2024 was $157.8 million. We believe that the cash, cash equivalents and marketable securities at December 31, 2024 are sufficient to meet estimated working capital requirements and fund current planned operations through 2027. 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 financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business; and licensing or strategic collaborations may result in royalties or other terms which reduce our economic potential from products under development. Our ability to continue funding our planned operations into and beyond twelve months from the issuance date is also dependent on the timing and manner of payment of the future 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, 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 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 $157.8 million for the year ended December 31, 2024 compared to $107.3 million for the year ended December 31, 2023. The increase in net cash used in operating activities was primarily due to increases in research and development and general and administrative expenses and an increase in advance payments to clinical research and contract manufacturing organizations, partially offset by an increase in investment income as a result of higher levels of cash and a decrease in payments made under the Settlement Agreement with SRS. We expect that cash used in operating activities will increase over the next twelve months as a result of the expanded development of barzolvolimab.

Net cash used in operating activities was $107.3 million for the year ended December 31, 2023 compared to $103.7 million for the year ended December 31, 2022. The increase in net cash used in operating activities was primarily due to increases in research and development and general and administrative expenses, partially offset by an increase in revenue and a decrease in payments made under the Settlement Agreement with SRS.

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 processes 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 $290.1 million for the year ended December 31, 2024 compared to $105.8 million for the year ended December 31, 2023. The increase in net cash used in investing activities was primarily due to net purchases of marketable

securities of $288.2 million for the year ended December 31, 2024 as compared to $104.0 million for the year ended December 31, 2023. We expect that cash provided by investing activities will increase over the next twelve months as we fund our operations through the combination of net proceeds from the sales and maturities of marketable securities, cash provided by financing activities and/or new partnerships, although there may be significant fluctuations on a quarterly basis based on the amount of cash provided by financing activities and/or new partnerships.

Net cash used in investing activities was $105.8 million for the year ended December 31, 2023 compared to net cash provided by investing activities of $89.9 million for the year ended December 31, 2022. The increase in net cash used in investing activities was primarily due to net purchases of marketable securities of $104.0 million for the year ended December 31, 2023 as compared to net sales and maturities of marketable securities of $91.7 million for the year ended December 31, 2022.

Financing Activities

Net cash provided by financing activities was $441.4 million for the year ended December 31, 2024 compared to $218.5 million for the year ended December 31, 2023. The increase in net cash provided by financing activities was primarily due to an increase in net proceeds from stock issuances.

Net cash provided by financing activities was $218.5 million for the year ended December 31, 2023 compared to $4.1 million for the year ended December 31, 2022. The increase in net cash provided by financing activities was primarily due to an increase in net proceeds from stock issuances.

Equity Offerings

In November 2023, we 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 our common stock. Also in November 2023, we issued 8,538,750 shares of our common stock in an underwritten public offering resulting in net proceeds of $216.2 million, after deducting underwriting fees and offering expenses.

On February 26, 2024, we entered into a controlled equity offering sales agreement ("ATM Agreement") with Cantor Fitzgerald & Co. ("Cantor") to allow us to issue and sell shares of our common stock from time to time through Cantor, acting as agent. At December 31, 2024, we had registered $300.0 million of our common stock to be sold pursuant to the ATM Agreement, all of which remained unsold as of that date.

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

Item 7A. 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 changes in interest rates is not material.

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

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Celldex Therapeutics, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Celldex Therapeutics, Inc. and its subsidiary (the "Company") as of December 31, 2024 and 2023, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2024, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance

regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Research and Development Expenses and Accruals Related to Clinical Research Organization and Contract Development and Manufacturing Organization Activities

As described in Notes 2 and 10 to the consolidated financial statements, research and development costs, including internal and contract research costs, are expensed as incurred. Research and development expenses consist mainly of clinical trial costs, manufacturing of clinical material, toxicology and other preclinical studies, personnel costs, depreciation, license fees and funding of outside contracted research. Clinical trial expenses include expenses associated with clinical research organization, or CRO, services. Contract manufacturing expenses include expenses associated with contract development & manufacturing organization, or CDMO, services. The invoicing from CROs and CDMOs for services rendered can lag several months. Management accrues the cost of services rendered in connection with CRO and CDMO activities based on their estimate of costs incurred. Management maintains regular communication with their CROs and CDMOs to assess the reasonableness of its estimates. Research and development expenses for the year ended December 31, 2024 were $163.6 million, the majority of which related to CRO and CDMO activities. Within accrued expenses, total accrued research and development contract costs as of December 31, 2024 amounted to $20.5 million, a majority of which related to CRO and CDMO activities.

The principal consideration for our determination that performing procedures relating to research and development expenses and accruals related to CRO and CDMO activities is a critical audit matter is a high degree of auditor effort in performing procedures related to the Company's research and development expenses and accruals.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's estimated research and development accruals, including those related to CRO and CDMO activities. These procedures also included, among others, (i) testing management's process for developing the estimate of research and development accruals related to CROs and CDMOs, (ii) evaluating the appropriateness of the methods used by management to develop the estimate, (iii) testing, on a sample basis, the completeness and accuracy of costs incurred for services that have been performed and for which the Company has been invoiced by comparing amounts to CRO and CDMO contracts and invoices, and evaluating the reasonableness of the cost incurred for the services for which the Company has not yet been invoiced by comparing estimated amounts to information received from the CROs and CDMOs, and (iv) testing, on a sample basis, classification of research and development expenses.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
February 27, 2025

We have served as the Company's auditor since 2008.

CELLDEX THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 28,356	$ 34,814
Marketable securities	696,925	388,784
Accounts and other receivables	700	2,628
Prepaid and other current assets	21,178	5,467
Total current assets	747,159	431,693
Property and equipment, net	4,346	4,060
Operating lease right-of-use assets, net	3,898	2,577
Intangible assets	27,190	27,190
Other assets	9,747	107
Total assets	$ 792,340	$ 465,627
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,265	$ 3,494
Accrued expenses	33,842	22,029
Current portion of operating lease liabilities	1,452	1,614
Current portion of long-term liabilities	942	3,988
Total current liabilities	39,501	31,125
Long-term portion of operating lease liabilities	2,361	928
Other long-term liabilities	3,473	4,403
Total liabilities	45,335	36,456
Commitments and contingent liabilities (Note 15)		
Stockholders' equity:		
Convertible preferred stock, $.01 par value; 3,000,000 shares authorized; no shares issued and outstanding at December 31, 2024 and 2023	—	—
Common stock, $.001 par value; 297,000,000 shares authorized; 66,374,549 and 55,883,377 shares issued and outstanding at December 31, 2024 and 2023, respectively	66	56
Additional paid-in capital	2,298,849	1,823,168
Accumulated other comprehensive income	3,314	3,308
Accumulated deficit	(1,555,224)	(1,397,361)
Total stockholders' equity	747,005	429,171
Total liabilities and stockholders' equity	$ 792,340	$ 465,627

The accompanying notes are an integral part of the consolidated financial statements.

CELLDEX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except per share amounts)

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year Ended December 31, 2022
Revenues:			
Product development and licensing agreements	$ 13	$ 278	$ 56
Contracts and grants	7,007	6,605	2,301
Total revenues	7,020	6,883	2,357
Operating expenses:			
Research and development	163,550	118,011	82,258
General and administrative	38,548	30,914	27,195
Gain on fair value remeasurement of contingent consideration	—	—	(6,862)
Litigation settlement related loss	—	12,500	15,000
Total operating expenses	202,098	161,425	117,591
Operating loss	(195,078)	(154,542)	(115,234)
Investment and other income, net	37,215	13,113	2,909
Net loss	$ (157,863)	$ (141,429)	$ (112,325)
Basic and diluted net loss per common share	$ (2.45)	$ (2.92)	$ (2.40)
Shares used in calculating basic and diluted net loss per share	64,395	48,449	46,888
Comprehensive loss:			
Net loss	$ (157,863)	$ (141,429)	$ (112,325)
Other comprehensive income (loss):			
Unrealized gain (loss) on marketable securities	6	2,048	(634)
Comprehensive loss	$ (157,857)	$ (139,381)	$ (112,959)

The accompanying notes are an integral part of the consolidated financial statements.

CELLDEX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share amounts)

	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2021	**46,730,198**	**$ 47**	**$ 1,561,142**	**$ 1,894**	**$ (1,143,607)**	**$ 419,476**
Shares issued under stock option and employee stock purchase plans	470,497	—	4,076	—	—	4,076
Stock-based compensation	—	—	15,611	—	—	15,611
Unrealized loss on marketable securities	—	—	—	(634)	—	(634)
Net loss	—	—	—	—	(112,325)	(112,325)
Balance at December 31, 2022	**47,200,695**	**$ 47**	**$ 1,580,829**	**$ 1,260**	**$ (1,255,932)**	**$ 326,204**
Shares issued under stock option and employee stock purchase plans	143,932	—	2,236	—	—	2,236
Shares issued in underwritten offering, net	8,538,750	9	216,213	—	—	216,222
Stock-based compensation	—	—	23,890	—	—	23,890
Unrealized gain on marketable securities	—	—	—	2,048	—	2,048
Net loss	—	—	—	—	(141,429)	(141,429)
Balance at December 31, 2023	**55,883,377**	**$ 56**	**$ 1,823,168**	**$ 3,308**	**$ (1,397,361)**	**$ 429,171**
Shares issued under stock option and employee stock purchase plans	693,172	—	9,151	—	—	9,151
Shares issued in underwritten offering, net	9,798,000	10	432,288	—	—	432,298
Stock-based compensation	—	—	34,242	—	—	34,242
Unrealized gain on marketable securities	—	—	—	6	—	6
Net loss	—	—	—	—	(157,863)	(157,863)
Balance at December 31, 2024	**66,374,549**	**$ 66**	**$ 2,298,849**	**$ 3,314**	**$ (1,555,224)**	**$ 747,005**

The accompanying notes are an integral part of the consolidated financial statements.

CELLDEX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year Ended December 31, 2022
Cash flows from operating activities:			
Net loss	$ (157,863)	$ (141,429)	$ (112,325)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,177	3,008	2,896
Amortization and premium of marketable securities, net	(15,749)	(6,222)	844
Loss on sale or disposal of assets	16	—	2
Gain on fair value remeasurement of contingent consideration	—	—	(6,862)
Stock-based compensation expense	34,242	23,890	15,611
Changes in operating assets and liabilities:			
Accounts and other receivables	1,928	(2,281)	(175)
Prepaid and other current assets	(19,887)	5,900	(9,572)
Other assets	(9,640)	(3)	—
Accounts payable and accrued expenses	11,634	9,384	3,123
Other liabilities	(5,636)	462	2,726
Net cash used in operating activities	(157,778)	(107,291)	(103,732)
Cash flows from investing activities:			
Sales and maturities of marketable securities	501,714	320,597	280,666
Purchases of marketable securities	(789,924)	(424,561)	(188,965)
Acquisition of property and equipment	(1,919)	(1,818)	(1,828)
Proceeds from sale or disposal of assets	—	—	69
Net cash (used in) provided by investing activities	(290,129)	(105,782)	89,942
Cash flows from financing activities:			
Net proceeds from stock issuances	432,298	216,222	—
Proceeds from issuance of stock from employee benefit plans	9,151	2,236	4,076
Net cash provided by financing activities	441,449	218,458	4,076
Net (decrease) increase in cash and cash equivalents	(6,458)	5,385	(9,714)
Cash and cash equivalents at beginning of period	34,814	29,429	39,143
Cash and cash equivalents at end of period	$ 28,356	$ 34,814	$ 29,429
Non-cash investing activities			
Accrued construction in progress	$ 27	$ 77	$ 113

The accompanying notes are an integral part of the consolidated financial statements.

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS

(1) Nature of Business and Overview

Celldex Therapeutics, Inc. (the "Company" or "Celldex") is a biopharmaceutical company dedicated to exploring the science of mast cell biology and developing therapeutic antibodies which have the ability to engage the human immune system and/or directly affect critical pathways to improve the lives of patients with severe inflammatory, allergic, autoimmune and other devastating diseases. Our drug candidates include monoclonal and bispecific antibodies designed to address mast cell mediated diseases for which available treatments are inadequate. The Company is primarily focusing its efforts and resources on the continued research and development of barzolvolimab (also referred to as CDX-0159) and CDX-622.

At December 31, 2024, the Company had cash, cash equivalents and marketable securities of $725.3 million. The Company has had recurring losses and incurred a loss of $157.9 million for the year ended December 31, 2024. Net cash used in operations for the year ended December 31, 2024 was $157.8 million. The Company believes that the cash, cash equivalents and marketable securities at the filing date of this Form 10-K will be sufficient to meet estimated working capital requirements and fund planned operations for at least the next twelve months from the date of issuance of these financial statements.

During the next twelve months and beyond, the Company may take further steps to raise additional capital to meet its long-term liquidity needs including, but not limited to, one or more of the following: the licensing of drug candidates with existing or new collaborative partners, possible business combinations, issuance of debt, or the issuance of common stock or other securities via private placements or public offerings. Although the Company has been successful in raising capital in the past, there can be no assurance that additional financing will be available on acceptable terms, if at all, and the Company's negotiating position in capital-raising efforts may worsen as existing resources are used. There is also no assurance that the Company will be able to enter into further collaborative relationships. Additional equity financings may be dilutive to the Company's stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict the Company's ability to operate as a business; and licensing or strategic collaborations may result in royalties or other terms which reduce the Company's economic potential from products under development. The Company's ability to continue funding its planned operations beyond twelve months from the issuance date is also dependent on the timing and manner of payment of amounts due under the Settlement Agreement with Shareholder Representative Services LLC ("SRS") (refer to Note 18), 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, 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 a significant discount or on other unfavorable terms, if at all, or sell all or a part of the Company.

(2) Summary of Significant Accounting Policies

Basis of Presentation

The balance sheets and statements of operations and comprehensive loss, stockholders' equity, and cash flows, are consolidated for the years ended December 31, 2024, 2023 and 2022. These consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

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.

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year Ended December 31, 2022
		(In thousands)	
Barzolvolimab/Anti-KIT Program	$ 123,750	$ 79,913	$ 51,220
CDX-622	17,341	16,299	5,613
CDX-585	2,813	6,357	9,793
Other Programs (a)	19,646	15,442	15,632
Total R&D Expense	$ 163,550	$ 118,011	$ 82,258

(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.

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year Ended December 31, 2022
		(In thousands)	
Personnel	$ 51,906	$ 40,121	$ 32,674
Laboratory Supplies	5,611	5,358	6,310
Facility	5,094	4,970	4,764
Product Development (b)	90,604	59,319	32,156
Other Expenses (c)	10,335	8,243	6,354
Total R&D Expense	$ 163,550	$ 118,011	$ 82,258

(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.

Use of Estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP) requires management to make estimates and use assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with a maturity date of 90 days or less at the date of purchase to be cash equivalents. Cash equivalents consist principally of money market funds and debt securities.

Marketable Securities

The Company invests its excess cash balances in marketable securities, including municipal bond securities, U.S. government agency securities, and highly rated corporate bonds. The Company classifies all of its marketable securities as current assets on the balance sheets because they are available-for-sale and available to fund current operations. Marketable securities are stated at fair value with unrealized gains and losses included as a component of accumulated other comprehensive income (loss), which is a separate component of stockholders' equity. Each reporting period, the Company evaluates its investment portfolio to determine if any security is impaired and if an allowance for credit losses should be recorded. As part of this evaluation, the Company considers whether it has the ability and intent to hold the investment until recovery of its amortized cost basis and whether the decline in fair

value is due to any credit related factors. If an impairment is the result of a credit loss, the Company recognizes an allowance for credit losses. Realized gains and losses are determined on the specific identification method and are included in investment and other income, net.

Concentration of Credit Risk and of Significant Customers and Suppliers

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash, cash equivalents, marketable securities and accounts receivable. The Company invests its cash, cash equivalents and marketable securities in debt instruments and interest-bearing accounts at major financial institutions in excess of insured limits. The Company mitigates credit risk by limiting the investment type and maturity to securities that preserve capital, maintain liquidity and have a high credit quality. The Company has not historically experienced credit losses from its accounts receivable and therefore has not established an allowance for doubtful accounts.

Revenue from Rockefeller University represented 100%, 95% and 75% of total Company revenue for the years ended December 31, 2024, 2023 and 2022, respectively.

The Company relies on contract development & manufacturing organizations (CDMOs) to manufacture drug substance and drug product as well as for future commercial supplies. The Company also relies on CDMOs for supply of raw materials as well as filling, packaging, storing and shipping our drug products.

Fair Value Measurements

The Company has certain assets and liabilities that are measured at fair value in the financial statements. The Company seeks to maximize the use of observable inputs (market data obtained from sources independent from the Company) and to minimize the use of unobservable inputs (the Company's assumptions about how market participants would price assets and liabilities) when measuring the fair value of its assets and liabilities. These assets and liabilities are classified into one of three levels of the following fair value hierarchy as defined by U.S. GAAP:

Level 1: Observable inputs such as quoted prices in active markets for identical assets or liabilities. An active market for an asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2: Observable inputs other than Level 1 prices, such as quoted prices in active markets for similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active.

Level 3: Unobservable inputs based on the Company's assessment of the assumptions that market participants would use in pricing the asset or liability.

Property and Equipment

Property and equipment are stated at cost and depreciated over the estimated useful lives of the related assets using the straight-line method. Laboratory equipment and office furniture and equipment are depreciated over five years, and computer equipment is depreciated over three years. Manufacturing equipment is depreciated over seven to ten years. Leasehold improvements are amortized over the shorter of the estimated useful life or the non-cancelable term of the related lease, including any renewals that are reasonably assured of occurring. Property and equipment under construction is classified as construction in progress and is depreciated or amortized only after the asset is placed in service. Expenditures for maintenance and repairs are charged to expense whereas the costs of significant improvements which extend the life of the underlying asset are capitalized. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are eliminated and any resulting gain or loss is reflected in the Company's statements of operations and comprehensive loss.

The treatment of costs to construct property and equipment depends on the nature of the costs and the stage of construction. Costs incurred in the project planning, design, construction and installation phases are capitalized as part of the cost of the asset. The Company stops capitalizing these costs when the asset is substantially complete and ready for its intended use. For manufacturing property and equipment, the Company also capitalizes the cost of validating these assets for the underlying manufacturing process. The Company completes the capitalization of validation costs when the asset is substantially complete and ready for its intended use. Costs capitalized include incremental labor and fringe benefits, and direct consultancy services.

Leases

The Company has operating leases of office, manufacturing and laboratory space, which have remaining lease terms of one to three years and may include one or more options to renew or terminate early.

The Company determines if an arrangement contains a lease at inception. Operating lease right-of-use assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. Certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued lease payments, initial direct costs paid or incentives received. The Company's leases do not contain an implicit rate, and therefore the Company uses an estimated incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. Options to extend or terminate the lease are reflected in the calculation when it is reasonably certain that the option will be exercised. The Company has elected to account for lease and non-lease components as a single lease component, however non-lease components that are variable, such as common area maintenance and utilities, are generally paid separately from rent based on actual costs incurred and therefore are not included in the right-of-use asset and operating lease liability and are reflected as an expense in the period incurred. Leases with an initial term of 12 months or less are not recorded on the balance sheet.

Contingent Consideration

The Company records contingent consideration resulting from a business combination at its fair value on the acquisition date. The Company determines the fair value of the contingent consideration based primarily on the (i) timing and probability of success of clinical events or regulatory approvals; (ii) timing and probability of success of meeting clinical and commercial milestones; and (iii) discount rates. The Company's contingent consideration liabilities arose in connection with its acquisition of Kolltan. On a quarterly basis, the Company revalues these obligations and records increases or decreases in their fair value as an adjustment to operating earnings. Changes to contingent consideration obligations can result from adjustments to discount rates, accretion of the discount rates due to the passage of time, changes in the Company's estimates of the likelihood or timing of achieving development or commercial milestones, changes in the probability of certain clinical events or changes in the assumed probability associated with regulatory approval. The assumptions related to determining the 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.

Intangible Assets

IPR&D assets acquired in a business combination initially are recorded at fair value and accounted for as indefinite-lived intangible assets. The valuation model used to measure the fair value of the Company's IPR&D assets was primarily a discounted cash flow approach. The assumptions used in determining the fair value of the Company's IPR&D assets include (i) probability of success; (ii) probability of partnership; (iii) partnership milestones; and (iv) discount rate. These assets are capitalized on the Company's balance sheets until either the project underlying them is completed or the assets become impaired. If a project is completed, the carrying value of the related intangible asset is amortized over the remaining estimated life of the asset beginning in the period in which the project is completed. If a project becomes impaired or is abandoned, the carrying value of the related intangible asset is written down to its fair value and an impairment charge is taken in the period in which the impairment occurs.

Each IPR&D asset is assessed for impairment at least annually or when impairment indicators are present. The Company has the option to assess qualitative factors to determine if it is more likely than not that the IPR&D asset is impaired and whether it is necessary to perform a quantitative impairment test.

Impairment of Intangible and Long-Lived Assets

The Company evaluates the recoverability of its long-lived assets, including property and equipment, right-of-use assets, and intangible assets when circumstances indicate that an event of impairment may have occurred. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their estimated fair values.

Revenue Recognition

Revenues are recognized when performance obligations under agreements or contracts are satisfied, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those services.

The Company determines revenue recognition through the following steps:

- Identification of the contract, or contracts, with a customer;
- Identification of the performance obligations in the contract;
- Determination of the transaction price;
- Allocation of the transaction price to the performance obligations in the contract; and
- Recognition of revenue when, or as, the Company satisfies a performance obligation.

Revenue for the Company is derived from product development agreements with collaborative partners for the research and development of therapeutic drug candidates. The terms of the agreements may include nonrefundable signing and licensing fees, funding for research, development and manufacturing, milestone payments and royalties on any product sales derived from collaborations. The Company assesses the multiple obligations typically within product development contracts to determine the distinct performance obligations and how to allocate the arrangement consideration to each distinct performance obligation. Under product development agreements, revenue is generally recognized using a cost-to-cost measure of progress. Revenue is recognized based on the costs incurred to date as a percentage of the total estimated costs to fulfill the contract. Incurred cost represents work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer. Due to the nature of the work performed in these arrangements, the estimation of cost at completion is complex, subject to many variables, such as expected clinical trial costs, and requires significant judgements. Circumstances can arise that change original estimates of costs or progress toward completion. Any revisions to estimates are reflected in revenue on a cumulative catch-up basis in the period in which the change in circumstances became known.

Revenue for the Company is also derived from manufacturing and research and development arrangements. The Company operates a cGMP manufacturing facility in Fall River, Massachusetts, to produce drug substance for its current and planned early-stage clinical trials. In order to utilize excess capacity, the Company has, from time to time, entered into contract manufacturing and research and development arrangements in which services are provided on a time-and-material basis or at a negotiated fixed price. Revenue from time-and-material contracts is generally recognized on an output basis as labor hours and/or direct expenses are incurred. Under fixed-price contracts, revenue is generally recognized on an output basis as progress is made toward completion of the performance obligations using surveys of performance completed to date.

Contract Assets and Liabilities

The Company classifies the right to consideration in exchange for products or services transferred to a client as either a receivable or a contract asset. A receivable is a right to consideration that is unconditional as compared to a contract asset which is a right to consideration that is conditional upon factors other than the passage of time.

The Company’s contract liabilities result from arrangements where the Company has received payment in advance of performance under the contract. These amounts are included as deferred revenue within current portion of long-term liabilities on the consolidated balance sheets.

Research and Development Expenses

Research and development costs, including internal and contract research costs, are expensed as incurred. Research and development expenses consist mainly of clinical trial costs, manufacturing of clinical material, toxicology and other preclinical studies, personnel costs, depreciation, license fees and funding of outside contracted research.

Clinical trial expenses include expenses associated with clinical research organization, or CRO, services. Contract manufacturing expenses include expenses associated with contract development & manufacturing organization, or CDMO, services. The invoicing from CROs and CDMOs for services rendered can lag several months. The Company accrues the cost of services rendered in connection with CRO and CDMO activities based on our estimate of costs incurred. The Company maintains regular communication with our CROs and CDMOs to assess the reasonableness of its estimates. Differences between actual expenses and estimated expenses recorded have not been material and are adjusted for in the period in which they become known.

Patent Costs

Patent costs are expensed to general and administrative expense as incurred. Certain patent costs are reimbursed by the Company's product development and licensing partners. Any reimbursed patent costs are recorded as product development and licensing agreement revenues in the Company's consolidated financial statements.

Stock-Based Compensation

The Company records stock-based compensation expense for all stock-based awards made to employees, consultants and non-employee directors based on the estimated fair values of the stock-based awards expected to vest at the grant date and adjusts, if necessary, to reflect actual forfeitures. Compensation expense for all stock-based awards is recognized using the straight-line method over the term of vesting or performance.

Foreign Currency Translation

Net unrealized gains and losses resulting from foreign currency translation are included in accumulated other comprehensive income. At December 31, 2024 and 2023, accumulated other comprehensive income includes a net unrealized gain related to foreign currency translation of $2.6 million.

Income Taxes

The Company uses the asset and liability method to account for income taxes, including the recognition of deferred tax assets and deferred tax liabilities for the anticipated future tax consequences attributable to differences between financial statement amounts and their respective tax basis. Quarterly, the Company reviews its deferred tax assets for recovery. A valuation allowance is established when the Company believes that it is more likely than not that its deferred tax assets will not be realized. Changes in valuation allowances from period to period are included in the Company's tax provision in the period of change.

The Company records uncertain tax positions in the financial statements only if it is more likely than not that the uncertain tax position will be sustained upon examination by the taxing authorities. The Company records interest and penalties related to uncertain tax positions in income tax expense.

Comprehensive Loss

Comprehensive loss is comprised of net loss and certain changes in stockholders' equity that are excluded from net loss. The Company includes foreign currency translation adjustments and unrealized gains and losses on marketable securities in other comprehensive loss. The statements of operations and comprehensive loss reflect total comprehensive loss for the years ended December 31, 2024, 2023 and 2022.

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:

	Year Ended December 31,		
	2024	2023	2022
Stock options	7,540,109	6,378,924	5,085,662

Newly-Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07 *Segment Reporting - Improvements to Reportable Segment Disclosures*, which improves reportable segment disclosure requirements, primarily through enhanced disclosure of significant segment expenses. The amendments in ASU 2023-07 apply to public entities, including those with a single reportable segment. The Company retrospectively adopted this ASU for its fiscal year ended December 31, 2024.

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

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

(3) Accumulated Other Comprehensive Income

The changes in accumulated other comprehensive income, which is reported as a component of stockholders' equity, for the year ended December 31, 2024 are summarized below:

	Unrealized Gain (Loss) on Marketable Securities	Foreign Currency Items	Total
		(In thousands)	
Balance at December 31, 2023	$ 712	$ 2,596	$ 3,308
Other comprehensive gain	6	—	6
Balance at December 31, 2024	$ 718	$ 2,596	$ 3,314

No amounts were reclassified out of accumulated other comprehensive income during the years ended December 31, 2024, 2023 and 2022.

(4) Fair Value Measurements

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

	As of December 31, 2024	Level 1	Level 2	Level 3
		(In thousands)		
Assets:				
Money market funds and cash equivalents	$ 9,927	—	$ 9,927	—
Marketable securities	696,925	—	696,925	—
	$ 706,852	—	$ 706,852	—

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

The Company's financial assets consist mainly of 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 December 31, 2024 and December 31, 2023. The valuation technique used to measure fair value of the Company's Level 3 liabilities, which consist of contingent consideration related to the acquisition of Kolltan Pharmaceuticals, Inc. ("Kolltan") in 2016, is primarily an income approach. The significant unobservable inputs used in the fair value measurement of the contingent consideration are estimates including probability of success, discount rates and amount of time until the conditions of the milestone payment are met.

During the year ended December 31, 2022, the Company recorded a $6.9 million gain on fair value remeasurement of contingent consideration primarily due to the Company's decision to deprioritize the CDX-1140 program. The assumptions related to determining the 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 of assets or liabilities between the fair value measurement classifications during the years ended December 31, 2024 and 2023.

(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)		
December 31, 2024				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	$ 185,388	$ 467	$ —	$ 185,855
Maturing after one year through three years	102,331	316	(144)	102,503
Total U.S. government and municipal obligations	$ 287,719	$ 783	$ (144)	$ 288,358
Corporate debt securities				
Maturing in one year or less	$ 336,350	$ 350	$ (54)	$ 336,646
Maturing after one year through three years	72,139	36	(254)	71,921
Total corporate debt securities	$ 408,489	$ 386	$ (308)	$ 408,567
Total marketable securities	$ 696,208	$ 1,169	$ (452)	$ 696,925
December 31, 2023				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	$ 132,459	$ 143	$ (53)	$ 132,549
Maturing after one year through three years	26,009	77	—	26,086
Total U.S. government and municipal obligations	$ 158,468	$ 220	$ (53)	$ 158,635
Corporate debt securities				
Maturing in one year or less	$ 183,625	$ 300	$ (10)	$ 183,915
Maturing after one year through three years	45,977	257	—	46,234
Total corporate debt securities	$ 229,602	$ 557	$ (10)	$ 230,149
Total marketable securities	$ 388,070	$ 777	$ (63)	$ 388,784

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 December 31, 2024 and December 31, 2023 was $142.5 million and $80.4 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 December 31, 2024.

Marketable securities include $6.1 million and $1.9 million in accrued interest at December 31, 2024 and 2023, respectively.

(6) Property and Equipment, Net

Property and Equipment, net includes the following:

	December 31, 2024	December 31, 2023
	(In thousands)	
Laboratory equipment	$ 10,411	$ 9,848
Manufacturing equipment	3,010	2,419
Office furniture and equipment	3,965	3,738
Leasehold improvements	10,285	9,653
Construction in progress	139	787
Total property and equipment	27,810	26,445
Less: accumulated depreciation and amortization	(23,464)	(22,385)
Property and equipment, net	$ 4,346	$ 4,060

Depreciation and amortization expense related to property and equipment was $1.6 million, $1.5 million and $1.4 million for the years ended December 31, 2024, 2023 and 2022, respectively.

(7) Leases

The Company has operating leases of office, manufacturing and laboratory space, which have remaining lease terms of one to three years and may include one or more options to renew.

During the years ended December 31, 2024, 2023 and 2022, the Company recorded right of use assets and lease liabilities of $2.9 million, $0.1 million and $2.5 million related to new leases and lease extensions, respectively.

Operating lease expense was $2.0 million, $1.9 million and $1.9 million for years ended December 31, 2024, 2023 and 2022, respectively. Variable lease expense was $0.8 million, $0.8 million and $0.8 million for years ended December 31, 2024, 2023 and 2022, respectively. Cash paid for amounts included in the measurement of operating lease liabilities was $2.0 million, $2.0 million and $1.9 million for the years ended December 31, 2024, 2023 and 2022, respectively. As of December 31, 2024, the weighted-average remaining lease term was 2 years and the weighted-average discount rate was 10.0%, compared to a weighted-average remaining lease term of 2 years and weighted average discount rate of 10.0% as of December 31, 2023.

Future minimum lease payments under non-cancellable leases as of December 31, 2024 were as follows:

2025	$	1,761
2026		1,779
2027		742
Total lease payments		4,282
Less imputed interest		(469)
Present value of operating lease liabilities	$	3,813

(8) Intangible Assets

At December 31, 2024 and 2023, the carrying value of the Company's indefinite-lived intangible assets was $27.2 million. Indefinite-lived intangible assets consist of acquired in-process research and development ("IPR&D") related to the development of the anti-KIT program (including barzolvolimab). Barzolvolimab is in Phase 3 development. As of December 31, 2024, the IPR&D asset related to the anti-KIT program had not reached technological feasibility nor did the asset have alternative future uses.

The Company performs an impairment test on IPR&D assets at least annually, or more frequently if events or changes in circumstances indicate that IPR&D assets may be impaired.

The Company performed its annual impairment test of the IPR&D asset related to the development of the anti-KIT program (including barzolvolimab) during the fourth quarter of 2024 and concluded that the IPR&D asset was not 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.

(9) 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 $9.6 million and $0.0 million at December 31, 2024 and December 31, 2023, respectively.

(10) Accrued Expenses

Accrued expenses include the following:

	December 31, 2024	December 31, 2023
	(In thousands)	
Accrued payroll and employee benefits	$ 11,568	$ 9,348
Accrued research and development contract costs	20,544	10,864
Accrued professional fees	1,392	1,439
Other accrued expenses	338	378
	$ 33,842	$ 22,029

(11) Other Long-Term Liabilities

Other long-term liabilities include the following:

	December 31, 2024	December 31, 2023
	(In thousands)	
Net deferred tax liabilities related to IPR&D (Note 16)	$ 1,613	$ 1,613
Deferred income from sale of tax benefits	2,790	3,720
Deferred revenue (Note 14)	12	3,058
Total	4,415	8,391
Less current portion	(942)	(3,988)
Long-term portion	$ 3,473	$ 4,403

In March 2022, the Company received approval from the New Jersey Economic Development Authority and agreed to sell New Jersey tax benefits of $5.0 million to an independent third party for $4.7 million. Under the agreement, the Company must maintain a base of operations in New Jersey for five years or the tax benefits must be paid back on a pro-rata basis based on the number of years completed. The Company recognized $0.9 million in other income related to the sale of these tax benefits during the years ended December 31, 2024 and 2023.

(12) Stockholders' Equity

Common Stock

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. Also in November 2023, the Company issued 8,538,750 shares of its common stock in an underwritten public offering resulting in net proceeds to the Company of $216.2 million, after deducting underwriting fees and offering expenses.

On February 26, 2024, the Company entered into a controlled equity offering sales agreement ("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 December 31, 2024, 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.

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

Convertible Preferred Stock

At December 31, 2024, the Company had authorized 3,000,000 shares of preferred stock all of which have been designated Class C Preferred Stock including 350,000 shares which have been designated Series C-1 Junior Participating Cumulative Preferred Stock (the "Series C-1 Preferred Stock"). No shares of Series C-1 Preferred Stock were outstanding at December 31, 2024 or 2023.

(13) Stock-Based Compensation

The Company has the following stock-based compensation plans: the 2004 Employee Stock Purchase Plan (the "2004 ESPP Plan"), the 2008 Stock Option and Incentive Plan (the "2008 Plan") and the 2021 Omnibus Equity Incentive Plan (the "2021 Plan"). There are no shares available for future grant under the 2008 Plan. Outstanding options under the 2008 Plan will be rolled into the 2021 Plan if canceled.

Employee Stock Purchase Plan

At December 31, 2024, a total of 276,666 shares of common stock are reserved for issuance under the 2004 ESPP Plan. Under the 2004 ESPP Plan, each participating employee may purchase shares of common stock through payroll deductions at a purchase price equal to 85% of the lower of the fair market value of the common stock at either the beginning of the offering period or the applicable exercise date. During the years ended December 31, 2024, 2023 and 2022, the Company issued 13,187, 12,729 and 12,243 shares under the 2004 ESPP Plan, respectively. At December 31, 2024, 150,316 shares were available for issuance under the 2004 ESPP Plan.

Employee Stock Option Plan

The 2021 Plan permits the granting of incentive stock options (intended to qualify as such under Section 422A of the Internal Revenue Code of 1986, as amended), non-qualified stock options, stock appreciation rights, performance share units, restricted stock and other awards of restricted stock to employees, consultants and non-employee directors.

The 2021 Plan allows for grants of new awards until April 19, 2031. As of December 31, 2024, there were 1,513,850 shares outstanding under the 2008 Plan that will be rolled into the 2021 Plan if canceled. The Company's Board of Directors determines the term of each option, option price, and number of shares for which each option is granted and the rate at which each option vests. Options generally vest over a period not to exceed four years. The term of each option cannot exceed ten years (five years for options granted to holders of more than 10% of the voting stock of the Company), and the exercise price of stock options cannot be less than the fair market value of the common stock at the date of grant (110% of fair market value for incentive stock options granted to holders of more than 10% of the voting stock of the Company). Vesting of all employee and non-employee director stock option awards may accelerate upon a change in control as defined in the 2021 Plan.

A summary of stock option activity for the year ended December 31, 2024 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In Years)
Options outstanding at December 31, 2023	6,378,924	$ 29.69	7.5
Granted	1,959,320	$ 36.22	—
Exercised	(679,985)	$ 12.98	—
Canceled	(118,150)	$ 120.67	—
Options outstanding at December 31, 2024	7,540,109	$ 31.47	7.5
Options vested and expected to vest at December 31, 2024	7,416,025	$ 31.41	7.4
Options exercisable at December 31, 2024	3,980,565	$ 29.17	6.3
Shares available for grant under the Celldex Therapeutics, Inc. 2021 Omnibus Equity Incentive Plan (as amended, effective as of June 13, 2024) at December 31, 2024	2,372,333	—	—

The total intrinsic value of stock options exercised during the years ended December 31, 2024, 2023 and 2022 was $17.2 million, $2.7 million and $12.8 million, respectively. The weighted average grant-date fair value of stock options granted during the years ended December 31, 2024, 2023 and 2022 was $26.21, $28.15 and $17.60, respectively. The total fair value of stock options vested during the years ended December 31, 2024, 2023 and 2022 was $32.4 million, $20.4 million and $15.6 million, respectively.

The aggregate intrinsic value of stock options outstanding at December 31, 2024 was $24.4 million. The aggregate intrinsic value of stock options vested and expected to vest at December 31, 2024 was $24.4 million. The aggregate intrinsic value of stock options exercisable at December 31, 2024 was $23.0 million. As of December 31, 2024, total compensation cost related to non-vested employee and non-employee director stock options not yet recognized was approximately $77.1 million, net of estimated forfeitures, which is expected to be recognized as expense over a weighted average period of 2.6 years.

Valuation and Expenses Information

Stock-based compensation expense for the years ended December 31, 2024, 2023 and 2022 was recorded as follows:

	2024	2023	2022
		(In thousands)	
Research and development	$ 17,442	$ 11,948	$ 8,082
General and administrative	16,800	11,942	7,529
Total stock-based compensation expense	$ 34,242	$ 23,890	$ 15,611

The fair values of employee and director stock options granted during the years ended December 31, 2024, 2023 and 2022 were valued using the Black-Scholes option pricing model with the following assumptions:

	2024	2023	2022
Expected stock price volatility	82 -93%	92%	90 - 97%
Expected option term	6.0 Years	6.0 Years	6.0 Years
Risk-free interest rate	3.5 - 4.5%	3.5 - 4.7%	1.7 - 4.2%
Expected dividend yield	None	None	None

The Company estimates expected term based on historical exercise patterns. The Company uses its historical stock price volatility consistent with the expected term of grant as the basis for its expected volatility assumption. The risk-free interest rate is based upon the yield of U.S. Treasury securities consistent with the expected term of the option. The dividend yield assumption is based on the Company's history of zero dividend payouts and expectation that no dividends will be paid in the foreseeable future.

(14) 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 $7.0 million, $6.6 million and $1.8 million in revenue under the agreements with Rockefeller during the years ended December 31, 2024, 2023 and 2022, respectively.

Contract Assets and Liabilities

At December 31, 2024 and 2023, the Company's right to consideration under all contracts was considered unconditional, and as such, there were no recorded contract assets. At December 31, 2024, the Company had no material contract liabilities recorded. At December 31, 2023, the Company had $3.1 million in contract liabilities recorded. Revenue recognized from contract liabilities as of December 31, 2023 during the year ended December 31, 2024 was $3.1 million.

(15) Collaboration Agreements

The Company has entered into license agreements whereby the Company has received licenses or options to license technology, specified patents and/or patent applications. These license and collaboration agreements generally provide for royalty payments equal to specified percentages of product sales, annual license maintenance fees, continuing patent prosecution costs and potential future milestone payments to third parties upon the achievement of certain development, regulatory and/or commercial milestones. Nonrefundable license fee expense of $0.2 million, $0.3 million and $0.1 million was recorded to research and development expense for the years ended December 31, 2024, 2023 and 2022, respectively.

Yale University (Yale)

Under a license agreement with Yale, the Company may be required to make a one-time payment to Yale of $3.0 million with respect to barzolvolimab upon achievement of a specified commercial milestone. In addition, the Company may be required to pay a low single-digit royalty on annual worldwide net sales of barzolvolimab. Unless earlier terminated by us or Yale, the Yale license agreement is due to expire no later than May 2038 but may expire earlier on a country-by-country basis under specified circumstances.

(16) Income Taxes

The components of income tax benefit (provision) are as follows:

	Year Ended December 31,		
	2024	2023	2022
		(In thousands)	
Income tax benefit (provision):			
Federal	$ 39,821	$ 36,067	$ 17,484
State	15,375	13,691	9,606
Expiration of NOLs and R&D credit	(82,825)	(15,141)	(16,862)
	(27,629)	34,617	10,228
Deferred tax valuation allowance	27,629	(34,617)	(10,228)
	$ —	$ —	$ —

A reconciliation between the amount of reported income tax and the amount computed using the U.S. statutory rate is as follows:

	2024	2023	2022
		(In thousands)	
Pre-tax loss	$ (157,863)	$ (141,429)	$ (112,325)
Loss at statutory rates	(33,151)	(29,700)	(23,588)
Research and development credits	(7,332)	(5,237)	(3,876)
State taxes	(15,375)	(13,691)	(9,606)
Other	662	(1,130)	11,421
Change in fair value remeasurement of contingent consideration	—	—	(1,441)
Expiration of Federal and State NOLs and R&D credits	82,825	15,141	16,862
Change in valuation allowance	(27,629)	34,617	10,228
Income tax (benefit) provision	$ —	$ —	$ —

Deferred tax assets and liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using future expected enacted rates. The principal components of the deferred tax assets and liabilities at December 31, 2024 and 2023 are as follows:

	December 31, 2024	December 31, 2023
	(In thousands)	
Gross deferred tax assets		
Net operating loss carryforwards	$ 176,816	$ 197,618
Tax credit carryforwards	24,718	56,830
Deferred research and development expenses	101,047	82,077
Stock-based compensation	20,940	14,671
Fixed assets	1,033	1,019
Accrued expenses and other	429	398
	324,983	352,613
Gross deferred tax liabilities		
IPR&D intangibles	(6,840)	(6,840)
Total deferred tax assets and liabilities	318,143	345,773
Valuation allowance	(319,756)	(347,386)
Net deferred tax liability	$ (1,613)	$ (1,613)

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.

The net deferred tax liability of $1.6 million at December 31, 2024 and 2023, relates to the temporary differences associated with the IPR&D intangible assets acquired in previous business combinations and are not deductible for tax purposes.

As of December 31, 2024, the Company had federal and state net operating loss carryforwards of $566.0 million and $888.8 million, respectively, which may be available to offset certain future income tax liabilities. State net operating loss carryforwards begin to expire in 2024. The federal net operating loss carryforwards of $566.0 million are from 2005 through 2024 and begin to expire in 2024. As of December 31, 2024, the Company also had federal and state research and development tax credit carryforwards of $19.8 million and $6.3 million, respectively, which may be available to offset future income tax liabilities and begin to expire in 2040 and 2029, respectively.

Utilization of the net operating loss carryforwards and research and credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, or Section 382, due to ownership changes that occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has performed a study under Internal Revenue Code Section 382 as of June 30, 2024, and concluded that a change in ownership following stock issuances in 2016 and 2020 triggered Section 382 limitations and approximately $758.7 million of federal NOL carryforwards and $48.7 million of federal tax credit carryforwards that were generated through June 30, 2020 will expire unutilized due to Section 382 and 383 limitations. The Company also estimated the amounts of State net operating loss and research and development tax credit carryforwards which will expire unutilized as a result of its annual limitations under Section 382 and has excluded those amounts from the carryforward amounts disclosed above and in the deferred tax assets and liabilities table included in this footnote.

As of December 31, 2024 and 2023, the Company did not have any unrecognized tax benefits.

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. Generally, in U.S. federal and state taxing jurisdictions, all years which generated net operating losses and/or tax credit carryforwards remain subject to examination to the extent those carryforwards are utilized in a subsequent period.

(17) Retirement Savings Plan

The Company maintains a 401(k) Plan which is available to substantially all employees. Under the terms of the 401(k) Plan, participants may elect to contribute up to 60% of their compensation or the statutory prescribed limits. The Company may make 50% matching contributions on up to 4% of a participant's annual salary. Benefit expense for the 401(k) Plan was $0.5 million, $0.5 million and $0.4 million for the years ended December 31, 2024, 2023 and 2022, respectively.

(18) 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 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of December 31, 2024, our management 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 December 31, 2024. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within time periods specified by the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with the authorizations of management and directors; and
- provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework provided in *Internal Control — Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2024.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2024, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears in Item 8 above.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

(a) None.

(b) During the three months ended December 31, 2024, no director or officer of the Company adopted or terminated a "Rule 10b5 - 1 trading agreement" or "non - Rule 10b5 - 1 trading agreement," as each term is defined in Item 408 (a) of Regulation S - K.

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 will be included in the definitive Proxy Statement for our 2025 Annual Meeting of Stockholders, or the 2025 Proxy Statement, under "Information Regarding Our Current Directors and Executive Officers," "Delinquent Section 16(a) Reports," "Code of Business Conduct and Ethics," "Insider Trading Policy" and "The Board of Directors and Its Committees" and is incorporated herein by reference. If the 2025 Proxy Statement is not filed with the SEC within 120 days after the end of our most recent fiscal year, we will provide such information by means of an amendment to this Annual Report on Form 10-K.

Item 11. EXECUTIVE COMPENSATION

The information required by this Item 11 will be included in the 2025 Proxy Statement under "Executive Compensation," and "Compensation Committee Interlocks and Insider Participation," and is incorporated herein by reference. If the 2025 Proxy Statement is not filed with the SEC within 120 days after the end of our most recent fiscal year, we will provide such information by means of an amendment to this Annual Report on Form 10-K.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 will be included in the 2025 Proxy Statement under "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" and is incorporated herein by reference. If the 2025 Proxy Statement is not filed with the SEC within 120 days after the end of our most recent fiscal year, we will provide such information by means of an amendment to this Annual Report on Form 10-K.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item 13 will be included in the 2025 Proxy Statement under "Election of Directors" and "Approval of Related Person Transactions and Transactions with Related Persons" and is incorporated herein by reference. If the 2025 Proxy Statement is not filed with the SEC within 120 days after the end of our most recent fiscal year, we will provide such information by means of an amendment to this Annual Report on Form 10-K.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item 14 will be included in the 2025 Proxy Statement under "Independent Registered Public Accounting Firm" and is incorporated herein by reference. If the 2025 Proxy Statement is not filed with the SEC within 120 days after the end of our most recent fiscal year, we will provide such information by means of an amendment to this Annual Report on Form 10-K.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(A) The following documents are filed as part of this Form 10-K:

(1) Financial Statements:

The Financial Statements and Supplementary Data are included in Part II Item 8 of this report.

(2) Financial Statement Schedules:

Schedules are omitted since the required information is not applicable or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the Financial Statements or Notes thereto.

(3) Exhibits:

		Incorporated by Reference to		
No.	**Description**	**Form and SEC File No.**	**Exhibit No.**	**SEC Filing Date**
Plan of Acquisition, Reorganization, Arrangement, Liquidation or Succession				
1.1	Sales Agreement, dated February 26, 2024, by and between Celldex Therapeutics, Inc. and Cantor Fitzgerald & Co.	10 – K (000 - 15006)	1.1	2/26/24
2.1	Agreement and Plan of Merger, dated as of November 1, 2016, by and among Kolltan Pharmaceuticals, Inc., Celldex Therapeutics, Inc., Connemara Merger Sub 1 Inc. and Connemara Merger Sub 2 LLC.	8-K (000-15006)	2.1	11/1/16
Articles of Incorporation and By-Laws				
3.1	Third Restated Certificate of Incorporation	S-4 (333-59215)	3.1	7/16/98
3.2	Certificate of Amendment of Third Restated Certificate of Incorporation	S-4 (333-59215)	3.1	7/16/98
3.3	Second Certificate of Amendment of Third Restated Certificate of Incorporation	S-4 (333-59215)	3.2	7/16/98
3.4	Third Certificate of Amendment of Third Restated Certificate of Incorporation	10-Q (000-15006)	3.1	5/10/02
3.5	Fourth Certificate of Amendment of Third Restated Certificate of Incorporation	8-K (000-15006)	3.1	3/11/08
3.6	Fifth Certificate of Amendment of Third Restated Certificate of Incorporation	8-K (000-15006)	3.2	3/11/08
3.7	Sixth Certificate of Amendment of Third Restated Certificate of Incorporation	10-Q (000-15006)	3.7	11/10/08
3.8	Seventh Certificate of Amendment of Third Restated Certificate of Incorporation	8-K (000-15006)	3.1	2/8/19
3.9	Second Amended and Restated By-Laws of Celldex Therapeutics, Inc., dated November 3, 2022	10-Q (000-15006)	3.1	11/9/22
Instruments Defining the Rights of Security Holders				
4.1	Specimen of Common Stock Certificate	8-K (000-15006)	4.1	2/8/19
4.2	Certificate of Designations, Preferences and Rights of a Series of Preferred Stock classifying and designating the	8-A (000-15006)	3.1	11/8/04

	Series C-1 Junior Participating Cumulative Preferred Stock			
4.3	Description of Securities	10-K (000-15006)	4.3	2/28/23
Material Contracts-Leases				
*10.1	Lease Agreement, by and between the Company and the Massachusetts Development Finance Agency, dated as of December 22, 2003	10-Q (000-15006)	10.1	4/30/04
10.2	First Amendment to Lease between Massachusetts Development Finance Agency and the Company dated March 17, 2005	10-K/A (000-15006)	10.6	12/23/10
10.3	Second Amendment to Lease by and between the Company and the Massachusetts Development Finance Agency dated as of November 4, 2005	10-K (000-15006)	10.41	3/16/06
10.4	Third Amendment to Lease between Massachusetts Development Finance Agency and the Company dated December 20, 2006	10-K/A (000-15006)	10.7	12/23/10
10.5	Fifth Amendment to Lease between Massachusetts Development Finance Agency and the Company dated October 3, 2008	10-K/A (000-15006)	10.8	12/23/10
10.6	Sixth Amendment to Lease between Massachusetts Development Finance Agency and the Company dated August 20, 2009	10-K/A (000-15006)	10.9	12/23/10
10.7	Seventh Amendment to Lease by and between the Company and the Massachusetts Development Finance Agency dated as of June 22, 2010	10-Q (000-15006)	10.1	8/5/10
10.8	Eighth Amendment to Lease by and between the Company and University of Massachusetts Dartmouth dated as of November 1, 2015	10-K/A (000-15006)	10.12	2/25/16
10.9	Ninth Amendment to Lease by and between the Company and University of Massachusetts Dartmouth dated as of October 1, 2019	10-K (000-15006)	10.13	3/26/20
10.10	Extension of Lease Agreement between the Company and University of Massachusetts Dartmouth dated as of July 1, 2020	10-Q (000-15006)	10.1	8/6/20
10.11	Tenth Amendment to Lease by and between the Company and University of Massachusetts Dartmouth dated as of August 1, 2022	10-Q (000-15006)	10.2	11/9/22
10.12	Eleventh Amendment to Lease by and between the Company and University of Massachusetts Dartmouth dated as of December 1, 2024	Filed herewith		
10.13	Lease Agreement dated as of May 1, 2013 by and between Crown Perryville, LLC and the Company.	10-Q (000-15006)	10.1	5/03/13
10.14	First Amendment to Lease between Company and Crown Perryville, LLC dated as of June 17, 2015	10-Q (000-15006)	10.2	8/10/15
10.15	Second Amendment to Lease Agreement between the Company and Crown Perryville, LLC dated as of March 8, 2019	10-Q (000-15006)	10.1	5/7/19
10.16	Third Amendment to Lease Agreement between the Company and Perryville SPE LLC (successor-in-interest) to Crown Perryville, LLC dated as of May 23, 2022	10-Q (000-15006)	10.3	8/8/22
10.17	Fourth Amendment to Lease Agreement between the Company and Perryville SPE LLC (successor-in-interest) to Crown Perryville, LLC dated as of October 30, 2024	Filed herewith		

Material Contracts-License, Collaboration, Supply and Distribution Agreements

*10.18	Amended and Restated License Agreement by and between the Company and Yale University dated as of July 26, 2022	10-Q (000-15006)	10.1	11/9/22

Material Contracts-Other

10.19	Confidential Settlement Agreement and Mutual Release, dated July 15, 2022, by and between Shareholder Representatives Services LLC, solely in its capacity as Stockholders Representative, and Celldex Therapeutics, Inc.	8-K (000-15006)	10.1	7/18/22

Material Contracts- Management Contracts and Compensatory Plans

†10.20	Amendment No. 2 to Celldex Therapeutics, Inc. 2021 Omnibus Equity Incentive Plan	8-K (000-15006)	10.1	6/14/24
†10.21	Celldex Therapeutics, Inc. 2021 Omnibus Equity Incentive Plan (as amended June 15, 2023)	8-K (000-15006)	10.1	6/15/23
†10.22	Celldex Therapeutics, Inc. 2021 Omnibus Equity Incentive Plan	8-K (000-15006)	10.1	6/17/21
†10.23	Celldex Therapeutics, Inc. Amended and Restated 2008 Stock Option and Incentive Plan (as amended, effective June 18, 2020).	8-K (000-15006)	10.1	6/18/20
†10.24	Celldex Therapeutics, Inc. Amended and Restated 2004 Employee Stock Purchase Plan (effective as of June 19, 2019)	8-K (000-15006)	10.2	6/19/19
†10.25	Amended and Restated Employment Agreement, dated as of July 1, 2021, by and between Celldex Therapeutics, Inc. and Anthony S. Marucci	8-K (000-15006)	10.1	7/1/21
†10.26	Amended and Restated Employment Agreement, dated as of July 1, 2021, by and between Celldex Therapeutics, Inc. and Sam Martin	8-K (000-15006)	10.2	7/1/21
†10.27	Amended and Restated Employment Agreement, dated as of July 1, 2021, by and between Celldex Therapeutics, Inc. and Tibor Keler, Ph.D.	8-K (000-15006)	10.3	7/1/21
†10.28	Amended and Restated Employment Agreement, dated as of July 1, 2021, by and between Celldex Therapeutics, Inc. and Ronald Pepin, Ph.D.	8-K (000-15006)	10.4	7/1/21
†10.29	Amended and Restated Employment Agreement, dated as of July 1, 2021, by and between Celldex Therapeutics, Inc. and Sarah Cavanaugh	8-K (000-15006)	10.5	7/1/21
†10.30	Amended and Restated Employment Agreement, dated as of July 1, 2021, by and between Celldex Therapeutics, Inc. and Margo Heath-Chiozzi, M.D.	8-K (000-15006)	10.6	7/1/21
†10.31	Amended and Restated Employment Agreement, dated as of July 1, 2021, by and between Celldex Therapeutics, Inc. and Elizabeth Crowley	8-K (000-15006)	10.7	7/1/21
†10.32	Amended and Restated Employment Agreement, dated as of July 1, 2021, by and between Celldex Therapeutics, Inc. and Richard Wright, Ph.D.	8-K (000-15006)	10.8	7/1/21
†10.33	Amended and Restated Employment Agreement, dated as of July 1, 2021, by and between Celldex Therapeutics, Inc. and Diane Young, M.D.	8-K (000-15006)	10.9	7/1/21
†10.34	Amended and Restated Employment Agreement, dated as of July 1, 2021, by and between Celldex Therapeutics, Inc. and Freddy Jimenez	8-K (000-15006)	10.10	7/1/21

†10.35	Celldex Therapeutics, Inc. 2021 Plan Form of Restricted Stock Award Agreement	8-K (000-15006)	10.2	6/17/21
†10.36	Celldex Therapeutics, Inc. 2021 Plan Form of Incentive Stock Option Grant Agreement	8-K (000-15006)	10.3	6/17/21
†10.37	Celldex Therapeutics, Inc. 2021 Plan Form of Nonqualified Stock Option Grant Agreement	8-K (000-15006)	10.4	6/17/21
†10.38	Celldex Therapeutics, Inc. 2021 Plan Form of Restricted Stock Unit Award Agreement	8-K (000-15006)	10.5	6/17/21
†10.39	2008 Plan Form of Stock Option Agreement	10-Q (000-15006)	10.1	8/08/18
†10.40	2008 Plan Form of Restricted Stock Award	10-K (000-15006)	10.42	3/12/10
19.1	Celldex Therapeutics, Inc. Insider Trading Policy	Filed herewith		
21.1	Subsidiaries of Celldex Therapeutics, Inc.	Filed herewith		
23.1	Consent of PricewaterhouseCoopers LLP, an Independent Registered Public Accounting Firm	Filed herewith		
31.1	Certification of President and Chief Executive Officer	Filed herewith		
31.2	Certification of Senior Vice President and Chief Financial Officer	Filed herewith		
32	Section 1350 Certifications	Furnished herewith		
†97	Celldex Therapeutics, Inc. Compensation Recovery Policy	10-K (000-15006)	97	2/26/24
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	Filed herewith		
101.SCH	Inline XBRL Taxonomy Extension Schema Document	Filed herewith		
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith		
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith		
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	Filed herewith		
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith		
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)			

* Certain confidential portions of this exhibit were redacted. Celldex Therapeutics, Inc. agrees to furnish supplementally to the U.S. Securities and Exchange Commission a copy of any omitted schedule and/or exhibit upon request. The confidential portions of this exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material, (ii) would be competitively harmful if publicly disclosed and (iii) contain information that Celldex Therapeutics, Inc, customarily and actually treats as private or confidential.

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

Item 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CELLDEX THERAPEUTICS, INC.

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

Date
February 27, 2025

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ ANTHONY S. MARUCCI Anthony S. Marucci	President, Chief Executive Officer, and Director (Principal Executive Officer)	February 27, 2025
/s/ SAM MARTIN Sam Martin	Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	February 27, 2025
/s/ KAREN L. SHOOS Karen L. Shoos	Director, Chair of the Board of Directors	February 27, 2025
/s/ KEITH L. BROWNLIE Keith L. Brownlie	Director	February 27, 2025
/s/ CHERYL L. COHEN Cheryl L. Cohen	Director	February 27, 2025
/s/ HERBERT J. CONRAD Herbert J. Conrad	Director	February 27, 2025
/s/ RITA I. JAIN, M.D, Rita I. Jain, M.D.	Director	February 27, 2025
/s/ JAMES J. MARINO James J. Marino	Director	February 27, 2025
/s/ GARRY A. NEIL, M.D. Garry A. Neil, M.D.	Director	February 27, 2025
/s/ HARRY H. PENNER, JR. Harry H. Penner, Jr.	Director	February 27, 2025

ELEVENTH AMENDMENT TO LEASE

This ELEVENTH AMENDMENT TO LEASE (this "**Amendment**") is made as of the 1st day of December, 2024, (the "**Effective Date**") by and between **UNIVERSITY OF MASSACHUSETTS DARTMOUTH**, an institution of Higher Education of the Commonwealth of Massachusetts, with an address of 285 Old Westport Rd. North Dartmouth Massachusetts 02747 ("**Landlord**") and **CELLDEX THERAPEUTICS, IN**C. (formerly AVANT Immunotherapeutic, Inc.), a Delaware corporation, with an address of 53 Frontage Road, Hampton NJ 08827 ("**Tenant**").

RECITALS

WHEREAS, Tenant and the Massachusetts Development Finance Agency ("MDFA") entered into a certain Lease dated effective December 22, 2003 (the "Lease), as amended by that certain First Amendment to Lease dated as of March 17, 2005 (the "**First Amendment**"), that certain Second Amendment to Lease dated as of November 4, 2005 (the "**Second Amendment**"), that certain Third Amendment To Lease dated as of December 20, 2006 (the "**Third Amendment**"), that certain Fourth Amendment to Lease dated as of July 18, 2008 (the "**Fourth Amendment**"), that certain Fifth Amendment to Lease dated as of October 3, 2008 (the "**Fifth Amendment**"), that certain Sixth Amendment to Lease dated as of August 20, 2009 (the "**Sixth Amendment**"), that certain Seventh Amendment to Lease dated June 22, 2010 (the "**Seventh Amendment**"), that certain Eight Amendment to lease dated November 15, 2015 (the "**Eight Amendment**"), that certain Ninth Amendment to lease dated, October 1, 2019 (the "**Ninth Amendment**"), and that certain Tenth Amendment to the lease dated August 1, 2022 (the "**Tenth Amendment**") of certain premises consisting of approximately 33,931 rentable square feet of space (the "**Premises**") in the building (the "**Building**") located at 151 Martine Street,

Fall River, Massachusetts (the "**Property**") in the South Coast Research & Technology Park (the "**Park**"); and

WHEREAS, on June 24, 2014, MDFA conveyed all of its rights, title and interest in the Building and assigned the Lease to Landlord; and

WHEREAS, the Premises is comprised of: (i) the original premises demised by the Lease, as amended through the Third Amendment, being 11,756 rentable square feet on the second (2nd) floor of the Building, (ii) the Additional Space (as defined in the First Amendment) demised by the First Amendment, being 71 rentable square feet on the first (1st) floor of the Building, (iii) the Expansion Premises (as defined in the Second Amendment), being 2,487 rentable square feet on the second (2nd) floor of the Building; (iv) the Second Expansion Premises (as defined in the Third Amendment), being 1,853 rentable square feet on the second (2nd) floor of the Building; (v) the Substitute Third Expansion Premises (as defined in the Fifth Amendment), being 4,864 rentable square feet of space on the second floor of the Building (referred to therein as the "Third Expansion Premises"); (vi) the Fourth Expansion Premises (as defined in the Sixth Amendment), being 2,382 rentable square feet on the second (2nd) floor of the Building; (vii) the Fifth Expansion Premises (as defined in the Eight Amendment), being 5,511 rentable square feet on the second (2^{nd}) floor of the Building, and (viii) the Sixth Expansion Premises (as defined in the Ninth Amendment), being 5,007 rentable square feet - 4,686 rentable square feet on the first (1st) floor of the building and 321 rentable square feet on the second (2nd) floor of the Building such that the "Premises Square Footage" (as stated in the Ninth Amendment) is defined to be 33,931 rentable square feet; and

WHEREAS, Landlord and Tenant agree to enter into this Eleventh Amendment to the Lease to extend the term of the lease and to amend certain additional provisions of the Lease,

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby mutually acknowledged, Landlord and Tenant agree as follows:

1. Capitalized Terms. Unless otherwise defined herein, all capitalized terms used in this Amendment shall have the meanings ascribed to them in the Lease, and all references in the Lease to the "Lease" or "this Lease" or "herein" or "hereunder" or similar terms or to any Section thereof shall, after the Effective Date, mean the Lease, or such Section thereof, as amended by this Amendment.

2. Section 2.2. Term. Section 2.2 of the Lease shall be amended as of December 1, 2024 to read as follows:"Section 2.2 Term. TO HAVE AND TO HOLD for a term (the "Term") beginning on the Term Commencement Date which shall be August 1, 2022 and expiring on July 31, 2027 (the "Term Expiration Date"), unless earlier terminated as provided for in section 2.4"

3. Annual Fixed Rental Rate. Section 1.1 as of December 1, 2024 the Lease is amended by deleting the provisions regarding the "Annual Fixed Rental Rate" and inserting, the following language:

Annual Fixed Rental Rate:	As of December 1, 2024 and through July 31, 2025: 19.91 per square foot. As of August 1, 2025 and through July 31, 2026: $21.00 per rentable square foot. As of August 1, 2026 through July 31, 2027: $21.50 per rentable square foot.

4. Demise of Seventh Expansion Premises. Commencing on December 1, 2024 (“The Seventh Expansion Premise Commencement Date”), Landlord does hereby lease to Tenant and Tenant does lease from Landlord the approximately 2418 rentable square feet - 1,333 rentable square feet on the first (1st) floor of the building and 1,085 rentable square feet on the second (2nd) floor of the Building, as shown on the floor plan attached hereto as Exhibit A-10 (the “Seventh Expansion Premises”) to have and to hold for the remainder of the Lease Term as set forth in the Lease. Tenant shall have access to the Seventh Expansion Premises as of December 1, 2024. Rental fee shall commence on December 1, 2024. Any delay in access to all Seventh Expansion Premises will result in similar delay in rent commencement. Except as otherwise expressly provided herein, Tenant’s lease of the Seventh Expansion Premises shall be on all of the terms and conditions of the Lease (including, without limitation, extension rights of Tenant for Extension Terms) and the term of the Lease with respect to the Seventh Expansion Premises shall be coterminous with the Term (and, if exercised, Extension Terms) of the Lease for the Existing Premises. As of the Seventh Expansion Premises Commencement Date, all references in the Lease to (i) the “Premises” and/or premises demised by the Lease shall mean the Existing Premises and the Seventh Expansion Premises collectively as shown on Exhibit A to the Lease, Exhibit A-1, attached to the First Amendment , Exhibit A-2, attached to the Second Amendment, Exhibit A-3, attached to the Third Amendment, and on Exhibit A-5, attachead to the Fifth Amendment, Exhibit A-6, attached to the Sixth Amendment, Exhibit A-7, attached to the Seventh Amendment, Exhibit A-8 attached to the Eight Amendment, Exhibit A-9 attached to 9th Amendment and Exhibit A-10 attached to this amendment; (ii) the “Tenant’s Proportionate Fraction” as set forth in Section 1.1, “Reference Information”, of the Lease shall mean 63.24% which is calculated by adding the Premises Square Footage as set forth in the

Eight Amendment and the Seventh Expansion Premises and dividing the Building's rentable square foot into that sum; and (iii) the "Premises Square Footage shall mean 36,349 rentable square feet.

5. The parties agree that License agreement dated July 13, 2020 is terminated as of December 1, 2024.

6. Landlord Representation Regarding Environmental Hazards. To its knowledge, Landlord represents that there are no environmental hazards or violations of any environmental laws, regulations or ordinances in or around the Building which violations might pose a present danger to health, life or safety.

7. Non-disturbance of Tenancy. Landlord represents that it has no financing on the Building whereby Landlord's lender would be entitled to disturb the tenancy of Tenant upon a default therein Landlord. Landlord further represents that it shall not enter into any such financing, but rather shall negotiate with any such lender so as to permit Tenant to remain in possession of the Premises on a direct rental relationship with such lender so long as Tenant is not in default of its obligations under this Lease.

8. Ratification. Except as expressly modified by this Amendment, the Lease shall remain in full force and effect, and as further modified by this Amendment, is expressly ratified and confirmed by the parties hereto. This Amendment shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns, subject to the provisions of the Lease regarding assignment and subletting.

9. Governing Law; Interpretation; and Partial Invalidity. This Amendment shall be governed and construed in accordance with the laws of the Commonwealth of Massachusetts. If any term of this Amendment, or the application thereof to any person or circumstances, shall

to any extent be invalid or unenforceable, the remainder of this Amendment, or the application of such term to persons or circumstances other than those as to which it is invalid or unenforceable, shall not be affected thereby, and each term of this Amendment shall be valid and enforceable to the fullest extent permitted by law. The titles for the paragraphs are for convenience only and not to be considered in construing this Amendment. This Amendment contains all of the agreements of the parties with respect to the subject matter hereof, and supersedes all prior dealings between them with respect to such subject matter. No delay or omission on the part of either party to this Amendment in requiring performance by the other party or exercising any right hereunder shall operate as a waiver of any provision hereof or any rights hereunder, and no waiver, omission or delay in requiring performance or exercising any right hereunder on any one occasion shall be construed as a bar to or waiver of such performance or right on any future occasion.

10. Counterparts and Authority, This Amendment may be executed in multiple counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same document. Landlord and Tenant each warrant to the other that the person or persons executing this Amendment on its behalf has or have authority to do so and that such execution has fully obligated and bound such party to all terms and provisions of this Amendment.

IN WITNESS WHEREOF, the undersigned executed this Amendment as of the date and year first written above.

LANDLORD:

University Of Massachusetts Dartmouth

By: /s/ Mark Fuller
Name: Mark Fuller
Title: Chancellor

TENANT:

CELLDEX THERAPEUTICS, INC.,

By: /s/ Anthony S. Marucci
Name: Anthony S. Marucci
Title: President and CEO

FOURTH AMENDMENT TO LEASE AGREEMENT

This Fourth Amendment to Lease Agreement (this "Amendment") is made and entered into as of October 30, 2024 ("Effective Date"), by and between **PERRYVILLE SPE, LLC**, a limited liability company ("Landlord"), and **CELLDEX THERAPEUTICS, INC**. ("Tenant").

W I T N E S S E T H:

WHEREAS, Landlord's predecessor-in-interest, Crown Perryville, LLC., and Tenant entered into that certain Lease dated as of May 1, 2013 (the "Original Lease") in the building known as Perryville Ill at Perryville Corporate Park located at 53 Frontage Road, Hampton, New Jersey 08827 (the "Building) , as amended by a First Amendment of Lease, dated as of June 17, 2015 (the "First Amendment"), and as further amended by a Second Amendment of Lease, dated as of March 8, 2019 (the "Second Amendment"), and as further amended by a Third Amendment of Lease, dated as of May 22, 2022 (the "Third Amendment"), pursuant to which Tenant is currently leasing premises (the "Premises") consisting of approximately 3,539 rentable square feet located on a portion of the first (1st) floor and approximately 29,824 rentable square feet located on a portion of the second (2nd) floor (the Original Lease, as amended by the First Amendment, Second Amendment, and Third Amendment is hereinafter collectively referred to as the "Lease"); and

WHEREAS, Landlord and Tenant desire to further amend the Lease on the terms and conditions set forth herein, all as provided in this Fourth Amendment;

NOW, THEREFORE, for valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree to amend the Lease as follows:

1. **Incorporation of Recitals**: The above Recitals are hereby incorporated into this Amendment as if fully set forth herein. Except as otherwise defined herein, the capitalized terms used in this Amendment shall have the definitions as set forth in the Lease.

2. **Extension Term and Renewal Option**:

    A. **Extension Term**: As of the Effective Date, the New Extension Term of the Lease commencing on August 1, 2020, and ending on July 31, 2025, shall be extended by two years to end on July 31, 2027.

    B. **Base Rent**:

        - **Year 1** (August 1, 2025 - July 31, 2026): $17.42 per Rentable Square Foot (RSF) plus Tenant Electric (hereinafter defined).

- **Year 2** (August 1, 2026 - July 31, 2027): $17.86 per RSF plus Tenant Electric (hereinafter defined).

C. **Tenant Electric**: Due to increased utility rates, Tenant Electric shall be $2.25 per RSF during the Extension Term.

D. **Additional Renewal Options**: Tenant shall have two (2) additional two-year renewal options under the same terms as Section 4.B. of the Third Amendment, except that the first Renewal Term shall be for the period commencing August 1, 2027 through July 31, 2029 and the second Renewal Term shall be for the period commencing August 1, 2029 through July 31, 2031. The rent shall be increased by 102.5% of the Base Rent for the last year of the prior term and will increase 2.5% annually thereafter.

3. **Right of First Refusal (ROFR)**:

A. As long as Tenant is not in default under the Lease (subject to applicable notice and cure periods), if Landlord receives or issues a proposal for leasing any space on the third (3rd) floor of the Building (the "ROFR Space"), which Landlord is willing to accept, Landlord will notify Tenant within seven (7) business days of the receipt of the offer.

B. Tenant will have seven (7) business days to respond to Landlord if they wish to accept the ROFR Space at the terms contained in the offer.

C. If Tenant accepts the ROFR Space offer, the parties shall execute a lease amendment within thirty (30) days of receiving the draft amendment from Landlord. Failure, on the part of Tenant, to execute the draft amendment within 30 days of receipt shall a rejection of the ROFR Space.

D. If not specified in the offer, the commencement date for the ROFR Space shall be 180 days following the date the ROFR Space is delivered to Tenant vacant and in broom-clean condition.

4. **Right of First Offer (ROFO)**:

Tenant retains a Right of First Offer, consistent with Section 19.29 of the Lease.

5. **Brokerage Representation**:

A. Tenant represents and warrants that they have dealt solely with Rv3 Solutions as their exclusive broker.

B. Landlord has engaged Jones Lang LaSalle (JLL**)** as its broker.

C. If a lease amendment is executed, a market commission based on the aggregate Base Rent will be paid by Landlord to Rv3 Solutions and JLL pursuant to separate written agreements.

6. **No Further Modification**: Except as specifically amended hereby, the Lease shall remain in full force and effect in accordance with its terms. In the event of any conflict between this Amendment and the Lease, the terms of this Amendment shall prevail.

7. **Counterparts**: This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

8. **Non-Binding Until Execution**: Submission by Landlord of the within Amendment for execution by Tenant shall confer no rights nor impose any obligation on Landlord unless and until both Landlord and Tenant shall have executed this Amendment and duplicate originals thereof shall have been delivered by Landlord and Tenant to each other.

9. **Binding Effect**: This Amendment shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and assigns.

10. **Miscellaneous**: Except as expressly amended hereby, all of the terms, covenants, conditions and provisions of the Lease shall remain and continue unmodified, in full force and effect. This Amendment sets forth the entire agreement between the parties regarding the subject matter hereof, superseding all prior agreements and understandings, written and oral, and may not be altered or modified except by a writing signed by both parties. Landlord and Tenant each represent and warrant to the other that it has not relied upon any representation or warranty, express or implied, in entering into this Amendment, except those which are set forth herein

[Signature on following page]

IN WITNESS WHEREOF, the parties hereto have executed this Fourth Amendment to Lease Agreement as of the date first above written.

LANDLORD:
Shelbourne Spring, LLC

By:/s/ BERNARD S. BERTRAM
Name: Bernard Bertram
Title: Managing Member

TENANT:
Celldex Therapeutics, Inc.

By:/s/ ANTHONY S. MARUCCI

INSIDER TRADING POLICY (Revised February 12, 2025)

This Insider Trading Policy (this "Policy") of Celldex Therapeutics, Inc. (the "Company" or "Celldex") is designed to prevent insider trading or allegations of insider trading, protect the Company's reputation for integrity and ethical conduct and to assist Insiders (as defined below) in complying with their obligations under the federal securities laws. You must read, sign and retain a copy of this Policy and, upon request by the Company, re-acknowledge it. Please address questions to the Company's Chief Financial Officer, who has initially been designated as the "Compliance Officer" for this Policy, or such other person who is designated by the Board of Directors of the Company.

WHO IS SUBJECT TO THIS POLICY?

This Policy applies to employees and directors of Celldex, their family members[1] who reside with them, any other individuals who reside with them, any Family Members who do not reside with them but whose transactions in the Company's Securities (as defined herein) would be directed by or are subject to the influence of the employee or director, any entity controlled by the employee or director or any of the related individuals listed above ("Controlled Entities"), any nonemployees whom the Compliance Officer may designate as "Insiders" because they have access to material non-public information concerning the Company, and any other persons to whom any of the foregoing have communicated material nonpublic information. All such persons are referred to herein as "Insiders". The use of "you" and "your" throughout this Policy speaks directly to Insiders.

Compliance Officer

The Company has designated the Chief Financial Officer as its Compliance Officer. The Compliance Officer is responsible for administering this Policy and monitoring and enforcing compliance. Any Insider who violates this Policy or knows of any such violation by any other Insiders, must report the violation immediately to the Compliance Officer. The Compliance Officer will maintain as Company records all documents required by the provisions of this Policy and all required Securities and Exchange Commission ("SEC") reports related to insider trading including Forms 3, 4, 5 and 144 and Schedules 13D and 13G. As described more fully in the "Pre-Clearance" section below, the Compliance Officer will designate and announce Special Blackout Periods (as defined herein) during which no Insider may Trade (as defined herein) in Company Securities. The Compliance Officer will review and either approve or prohibit in his or her sole discretion all proposed Trades by the Insiders specified in this Policy with advice from the Company's outside legal counsel, if needed. In the event the Compliance Officer is unavailable, all proposed Trades shall be approved by the President and Chief Executive Officer. The Compliance Officer may not Trade in Company Securities unless the President and Chief Executive Officer with advice from the Company's outside legal counsel, if needed, has previously approved the Trade.

WHAT TRANSACTIONS ARE SUBJECT TO THIS POLICY?

The policy applies to any and all transactions in (including gifts of) the Company's securities ("Trades"). Company securities include common stock and options to purchase common stock, securities that are convertible into common stock and any other type of securities that the Company may issue, such as preferred stock, securities that are convertible into preferred stock, convertible debentures, warrants and exchange-traded options or other derivative securities, and any other

[1] Family members include any relatives, such as a child, stepchild, grandchild, parent, stepparent, aunt, uncle, niece, nephew, grandparent, spouse, sibling and in-law, and any other person typically considered a relative ("Family Members").

"security" defined under the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder (collectively referred to herein as "Securities").

Gifts

For purposes of this Policy, gifts or other transfers to Family Members, whether for estate planning or otherwise, or to charities or other third parties, are considered "Trades" within the meaning of this Policy. Gifts are subject to the requirements and restrictions outlined in this Policy and require pre-clearance in accordance with the "Pre-Clearance" section of this Policy.

WHAT IS ILLEGAL AND PROHIBITED INSIDER TRADING?

Generally, illegal and prohibited insider trading occurs when a person who is aware of **material nonpublic information** about a company buys or sells, or engages in transactions with (e.g. buying, selling, hedging, shorting, swaps, etc.), that company's securities or provides material nonpublic information to another person who may trade on the basis of that information.

Material Information

Information about the Company is "material" if it would be expected to affect the investment decision (i.e., a decision to buy, hold, or sell securities) of the reasonable shareholder or investor, or if the disclosure of the information would be expected to significantly alter the total mix of the information in the marketplace about the Company. In simple terms, material information is any type of information, positive or negative, which could reasonably be expected to affect the price of Company Securities. Material information is not limited to information of a financial nature; rather, material information can relate to virtually any aspect of the Company's business. Material information is also not limited to historical facts. Insiders can be in possession of material information with respect to a future event, such as a merger, acquisition or introduction of a new product.

There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances, and is often evaluated by enforcement authorities with the benefit of hindsight. While it is not possible to identify all information that would be "material", some examples of information that ordinarily would be regarded as material are: information about the status of FDA filings, status and results of clinical trials, financing efforts, new business deals or collaborations, potential mergers and acquisitions, status of product development, product launches, ability to commercialize products, actual or threatened major litigation, or the resolution of such litigation, significant changes in senior management, cybersecurity incidents or quarterly and year-end earnings.

Nonpublic Information

Material information is "non-public" if it has not been widely disseminated to the public through major newswire services, national news services and financial news services; through a broadcast on widely available internet, radio or television programs; or through public disclosure documents filed with the SEC. By contrast, information would likely not be considered widely disseminated if it is available only to the Company's employees, or if it is only available to a select group of analysts, brokers, institutional investors or industry participants.

For purposes of this policy, information will be considered public, i.e., no longer "non-public", after the close of trading on the second full trading day following the Company's widespread release of the information. If, for example, the Company were to make an announcement before market hours on a Monday morning, the information typically would not be considered digested until pre-market on

Wednesday morning. As a general rule, no Trade should take place prior to the completion of this two full trading-day period.

PRE-CLEARANCE

Before engaging in any Trades involving the Company's Securities, all employees and directors must obtain prior written approval (including email) from the Compliance Officer. This will enable you to consult with the Compliance Officer for guidance as to whether you are in possession of any material non-public information about the Company. Note that while pre-clearance is not required for trading in securities issued by other companies, you are cautioned to comply with our policy as well as applicable law when making trades in other securities issued by other companies.

PROHIBITION ON ILLEGAL INSIDER TRADING

No Trading on Material Nonpublic Information

If you are aware of material nonpublic information about the Company or Company Securities, you may not Trade Company Securities, except as otherwise specified in this Policy (see "Exempt Transactions" below). In addition, it is the policy of Celldex that no Insider who, in the course of working for Celldex, learns of material nonpublic information about a company, (including, but not limited to, a customer or supplier of Celldex) may trade in that company's securities until the information becomes public or is no longer material.

No Tipping

If you are aware of material nonpublic information about the Company, or if you are aware of material nonpublic information about another company learned in the course of performing your work duties for the Company, you may not communicate or pass ("Tip") that information on to persons within the Company whose jobs do not require them to have that information, or to persons outside the Company, including Family Members, Controlled Entities, friends or anyone else. The federal securities laws impose liability on any person who Tips or communicates (the "Tipper") material nonpublic information to another person or entity (the "Tippee") who then Trades on the basis of the information. Penalties may apply regardless of whether or not the Tipper Trades or derives any benefits from the Tippee's Trading activities.

Blackout Periods

From time to time, the Compliance Officer will notify Insiders in writing (including by email) of a commencement of a quarterly Blackout Period. Trading is prohibited during Blackout Periods or Special Blackout Periods, as described in more detail in the "Quarterly Trading Windows for All Insiders" and "Special Blackout Periods" sections below.

BLACKOUT PERIODS

Quarterly Trading Windows for All Insiders

All Insiders who are NOT in possession of material non-public information concerning the Company may Trade in Company Securities only during the quarterly Trading Window (as defined herein). Each quarter, the window opens beginning at the close of trading on the second full trading day following the Company's widespread public release of quarterly or year-end earnings and ends on the fifteenth day of the last month of the quarter (the "Trading Window"). All other times are considered "Blackout Periods". Even if there is a Trading Window open, persons who are in possession of material non-

public information may not Trade in Company Securities. No Insider may Trade in Company Securities outside of the applicable trading windows or during any Special Blackout Periods that the Compliance Officer may designate, as described in more detail in the "Special Blackout Periods" section below. No Insider may disclose to any outside third party that a Special Blackout Period has been designated.

Special Blackout Periods

From time to time, an event may occur that is material to the Company. So long as the event remains material and nonpublic, certain Insiders, in the discretion of the Compliance Office, may be restricted from Trading in Company Securities (a "Special Blackout Period"). In that situation, the Compliance Officer will notify those Insiders in writing (including by email) of the commencement of the Special Blackout Period and that they are prohibited from Trading in Company Securities, whether or not the Compliance Officer discloses the reason for the restriction. The Compliance Officer will also notify those Insiders in writing (including by email) of the termination of the Special Blackout Period. Until the Compliance Officer has notified those Insiders of the termination of the Special Blackout Period, they may not Trade in Company Securities. The existence of a Special Blackout Period or extension of a Blackout Period should not be communicated to any other person. Even if the Compliance Officer has not designated a Special Blackout Period, an Insider should not Trade in Company Securities while aware of material nonpublic information. Exceptions will not be granted during a Special Blackout Period.

ADDITIONAL RESTRICTIONS

Stock Option Exercises

The Trading prohibitions and restrictions of this Policy apply to all sales of Securities acquired through the exercise of stock options granted by the Company – including, but not limited to, sales made in order to effectuate broker-assisted "cashless" exercise arrangements. The Trading prohibitions and restrictions of this Policy do not, however, apply to acquisitions of Securities pursuant to the exercise of such options so long as cash proceeds are used.

Short Sales

Insiders may not sell any Company Securities that are not owned by such person at the time of the sale (a "short sale"), including a sale with delayed delivery (a "sale or short against the box").

Hedging Transactions

Certain forms of hedging or monetization transactions, such as zero-cost collars and forward sale contracts, allow investors to lock in much of the value of their stock holdings, often in exchange for all or part of the potential for upside appreciation in the stock. These transactions allow an investor to continue to own the covered securities, but without the full risks and rewards of ownership. When that occurs, the investor may no longer have the same objectives as the Company's other stockholders. Therefore, Insiders may not engage in any such transactions.

Margin Accounts and Pledges

Securities held in a margin account may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. A margin sale or foreclosure sale may occur at a time when the pledgor is aware of material non-public information or otherwise is not permitted to trade in Company Securities.

Consequently, Insiders of the Company are prohibited from holding Company Securities in a margin account or pledging Company Securities as collateral for a loan.

EXEMPT TRANSACTIONS

Employee Stock Purchase Plan

The trading prohibitions and restrictions of this Policy do not apply to periodic contributions by the Company or employees to employee benefit plans (e.g., ESPP, pension or 401(k) plans) which are used to purchase Company Securities pursuant to the employees' advance instructions. However, no employee may alter their instructions regarding the purchase or sale of Company Securities in such plans when in possession of material non-public information.

Restricted Stock Awards.

This Policy does not apply to the vesting of restricted stock (if, as and when issued by the Company), or of a tax withholding right pursuant to which you elect to have the Company withhold shares of stock to satisfy tax withholding requirements upon the vesting of any restricted stock. This Policy, however, would apply to any market sale of restricted stock (if any becomes issued).

Rule 10b5-1 Trading Plans

A Rule 10b5-1 trading plan is a trading plan adopted pursuant to Rule 10b5-1 ("Rule 10b5-1") promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Trades in the Company's Securities that are executed pursuant to a Rule 10b5-1 trading plan are not subject to the prohibition on Trading while in possession of material non-public information (i.e. pre-clearance procedures and Trading Windows) contained in this Policy.

Insiders are prohibited from entering into a 10b5-1 Plan during (i) a Blackout Period, (ii) during a Special Blackout Period, or (iii) at any time when they are aware of material, nonpublic information about the Company. Pre-clearance is required prior to entry into a 10b5-1 Plan, termination of a 10b5-1 Plan, or a modification of a 10b5-1 Plan. A copy of a 10b5-1 Plan must be submitted to the Compliance Officer for review and pre-clearance at least three (3) business days prior to the anticipated entry into a 10b5-1 Plan. The 10b5-1 Plan document must be reviewed and pre-cleared by the Compliance Officer prior to being signed by the Insider. The Company has discretion to refuse approval of any 10b5-1 Plan document for any reason and need not provide any reason for such refusal to the Insider. Once a 10b5-1 Plan is adopted, the Insider must not exercise any influence over the amount, price or the date of any Trade. The 10b5-1 Plan must include a cooling-off period consistent with applicable SEC rules before Trades can commence.

In addition, the Rule 10b5-1 trading plan must be in full compliance with the Company's Rule 10b5-1 trading plan guidelines and policies, as in effect from time to time.

POST-TRADE REPORTING

If you are required to file reports under Section 16 of the Exchange Act, including Forms 3, 4 and 5, you are required to report to the Compliance Officer any Trade in Company Securities by you, your Family Members and Controlled Entities no later than the end of business day in which you made the Trade. Each report made should include the date of the Trade, quantity, price, and broker through which the Trade was effected. This reporting requirement may be satisfied by sending (or having your broker send) duplicate confirmations of Trades to the Compliance Officer if such information is received by the required date.

The foregoing reporting requirement is designed to help monitor compliance with these procedures and to enable the Company to help those persons who are subject to reporting obligations under Section 16 of the Exchange Act to comply with such reporting obligations. Each officer and director, however, and not the Company, is personally responsible for ensuring that his or her Trades do not give rise to "short swing" liability under Section 16 and for filing timely reports of Trades with the SEC.

THE CONSEQUENCES OF VIOLATING THIS POLICY

Trading of Company Securities while aware of material nonpublic information, or the disclosure of material nonpublic information to others who then Trade in Company Securities, is prohibited by the federal and state laws. Insider trading violations are pursued vigorously by the SEC, U.S. Attorneys, and state enforcement authorities as well as the laws of foreign jurisdictions. Punishment for insider trading violations is severe, and could include significant fines and imprisonment. While the regulatory authorities concentrate their efforts on the individuals who Trade, or who Tip information to others who Trade, the federal securities laws also impose potential liability on companies and other "controlling persons" (such as directors, officers and other supervisory personnel) if they fail to take reasonable steps to prevent insider trading by company personnel.

In addition, you would also be in violation of Company policy and subject to termination for cause, whether or not your failure to comply results in a violation of law. Needless to say, a violation of law, or even an SEC investigation that does not result in prosecution, can tarnish your reputation and irreparably damage a career.

POST-TERMINATION TRADES

This Policy continues to apply to Insiders even after the Insider ceases to be an Insider. If an Insider is aware of material, nonpublic information when their employment or service relationship terminates, they may not Trade in Company Securities until that information has become public or is no longer material.

REPORTING OF VIOLATIONS

If any person knows or has reason to believe that this Policy has been or may be violated, the person should bring the actual or potential violation to the attention of the Compliance Officer.

MODIFICATIONS AND WAIVERS

The Company reserves the right to amend or modify the procedures set forth herein at any time. Waiver

of any provision of this Policy in a specific instance may be authorized in writing by the Compliance Officer.

This document states a policy of the Company and is not intended to be regarded as the rendering of legal advice. This Policy is intended to promote compliance with existing law and is not intended to create or impose liability that would not exist in the absence of this Policy.

If you have any questions about this Policy, or about matters relating to the Company's Securities, please contact the Compliance Officer.

ACKNOWLEDGMENT AND CERTIFICATION

The undersigned does hereby acknowledge receipt of this Policy. The undersigned has read and understands (or has had explained) this Policy and agrees to be governed by this Policy at all times and the confidentiality of nonpublic information.

_____

(Signature)

_____

(Please print name)

Date:

_____

Exhibit 21.1

SUBSIDIARIES OF CELLDEX THERAPEUTICS, INC.

Name	Jurisdiction of Organization	Ownership Percentage
Celldex Therapeutics Switzerland GmbH	Switzerland	100%

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-280207, 333-272804, 333-257137, 333-239463, 333-232253, 333-232255, 333-219867, 333-219869, 333-205694, 333-189336, 333-182142, 333-151728 and 333-117602) and on Form S-3 (Nos. 333-275300 and 333-215747) of Celldex Therapeutics, Inc. of our report dated February 27, 2025 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
February 27, 2025

Exhibit 31.1

CERTIFICATION

I, Anthony S. Marucci, certify that:

1. I have reviewed this annual report on Form 10-K 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 the 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: February 27, 2025

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 annual report on Form 10-K 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 the 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: February 27, 2025

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

Exhibit 32

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Each of the undersigned hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in his capacity as an officer of Celldex Therapeutics, Inc. (the "Company"), that, to his knowledge, the Annual Report of the Company on Form 10-K for the period ended December 31, 2024 (the "Form 10-K"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §78m or 78o(d)) and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to the Form 10-K. A signed original of this statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: February 27, 2025

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

Date: February 27, 2025

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.