Celldex Reports Fourth Quarter and Year End 2023 Financial Results and Provides Corporate Update

February 26, 2024

- Phase 3 CSU studies expected to initiate in summer 2024 -
- Positive Phase 2 CSU 12 week data reported in late breaking oral presentation at AAAAI 2024; 52 week data to be reported in 2H 2024 -
- Enrollment nearing completion in Phase 2 CIndU study; Data expected 2H 2024 -
- Phase 2 PN study expected to start in early 2024; Positive Phase 1 PN data reported in oral presentation at WCI 2023 -

HAMPTON, N.J., Feb. 26, 2024 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported financial results for the fourth quarter and year ended December 31, 2023 and provided a corporate update.

"In 2023, Celldex made transformational progress across the barzolvolimab development program, reporting multiple positive data sets across mast cell mediated diseases where patients desperately need better treatment options," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. "We carried this momentum into 2024, presenting positive 12 week data from our ongoing Phase 2 CSU study that directly support the planned initiation of registrational studies in CSU this summer, a major milestone for barzolvolimab and Celldex."

"This year we will continue to build on our leadership position in mast cell biology—reporting data from multiple barzolvolimab studies, expanding barzolvolimab into additional mast cell mediated diseases and introducing our first bispecific for inflammatory diseases. We look forward to an exciting year."

Recent Program Highlights

Barzolvolimab - KIT Inhibitor Program

Barzolvolimab is a humanized monoclonal antibody developed by Celldex that binds the KIT receptor with high specificity and potently inhibits its activity. The KIT receptor tyrosine kinase is expressed in a variety of cells, including mast cells, which mediate inflammatory responses such as hypersensitivity and allergic reactions. KIT signaling controls the differentiation, tissue recruitment, survival and activity of mast cells.

- Celldex is conducting Phase 2 clinical studies of barzolvolimab for the treatment of chronic spontaneous urticaria (CSU) and the two most common forms of chronic inducible urticaria (CIndU) - cold urticaria (ColdU) and symptomatic dermographism (SD). These randomized, double-blind, placebo-controlled Phase 2 studies are evaluating the efficacy and safety profile of multiple dose regimens of barzolvolimab in patients who remain symptomatic despite antihistamine therapy, to determine the optimal dosing strategies.
    - Celldex is currently planning two Phase 3 studies of barzolvolimab in CSU, which are expected to initiate this summer.
    - In November 2023, Celldex reported positive topline data from the Phase 2 CSU study and in February 2024, 12 week treatment results were reported at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting in a late breaking oral presentation. Barzolvolimab achieved the primary efficacy endpoint of the study, with a statistically significant mean change from baseline to week 12 of UAS7 (weekly urticaria activity score) compared to placebo across multiple dosing groups and was well tolerated. Secondary and exploratory endpoints in the study, including ISS7 (weekly itch severity score) and HSS7 (weekly hives severity score) and responder analyses strongly support the primary endpoint results. 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. 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. Patients on study will continue to receive barzolvolimab for 52 weeks and the Company plans to report 52 week data in the second half of 2024.
    - In October 2023, data on quality of life outcomes from the Phase 1b CSU study were presented at the European Academy of Dermatology & Venereology (EADV) Congress. The Dermatology Life Quality Index (DLQI) assesses patients' perceptions of the impact of their disease across different aspects of their health-related quality of life and includes questions on symptoms and feelings, daily activities, leisure, work and school performance, personal relationships and treatment. A rapid improvement in the DLQI was noted within 4 weeks in all barzolvolimab treated patients. DLQI improvement was sustained at doses ≥1.5mg/kg. Physician Global Assessment (PhysGA) for the treated cohorts also improved by week 1 and was sustained through week 24.

- Enrollment to the Phase 2 CIndU study is nearing completion and 12 week primary endpoint data from this study is expected to be reported in the second half of 2024. The study is designed to enroll approximately 180 patients with ColdU or SD.

- Celldex is currently planning for the initiation of a Phase 2 subcutaneous study in prurigo nodularis (PN) in early 2024. This randomized, double-blind, placebo-controlled, parallel group study will evaluate the efficacy and safety profile of barzolvolimab 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. Patients will 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.

  Data from the Phase 1b randomized, double-blind, placebo-controlled study in patients with prurigo nodularis were reported in an oral presentation at the 12th World Congress on Itch (WCI) in November 2023. 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 barzolvolimab was generally well tolerated.

- In July 2023, the first patient was dosed in the Phase 2 randomized, double-blind, placebo-controlled study in eosinophilic esophagitis (EoE); enrollment is ongoing. 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.

Bispecific Antibody Platform

CDX-585 – Bispecific ILT4 & PD-1

CDX-585 combines highly active PD-1 blockade with anti-ILT4 blockade to overcome immunosuppressive signals in T cells and myeloid cells. ILT4 is emerging as an important immune checkpoint on myeloid cells.

- In May 2023, the first patient was dosed in the Phase 1 study of CDX-585. This open-label, multi-center study of CDX-585 is evaluating patients with advanced or metastatic solid tumors that have progressed during or after standard of care therapy. Enrollment is ongoing in the dose-escalation portion of the study.

Fourth Quarter and Twelve Months 2023 Financial Highlights and 2024 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of December 31, 2023 were $423.6 million compared to $235.3 million as of September 30, 2023. The increase was primarily driven by net proceeds of $216.2 million from our November 2023 underwritten public offering, partially offset by cash used in operating activities of $32.5 million, which includes the $12.5 million payment to Shareholder Representative Services (SRS), the representative of the former stockholders of Kolltan Pharmaceuticals, Inc., pursuant to our settlement agreement. At December 31, 2023, Celldex had 55.9 million shares outstanding.

Revenues: Total revenue was $4.1 million in the fourth quarter of 2023 and $6.9 million for the year ended December 31, 2023, compared to $1.6 million and $2.4 million for the comparable periods in 2022. The increase in revenue was primarily due to an increase in services performed under our manufacturing and research and development agreements with Rockefeller University.

R&D Expenses: Research and development (R&D) expenses were $30.4 million in the fourth quarter of 2023 and $118.0 million for the year ended December 31, 2023, compared to $22.9 million and $82.3 million for the comparable periods in 2022. The increase in R&D expenses was primarily due to an increase in barzolvolimab clinical trial, barzolvolimab contract manufacturing, and personnel expenses.

G&A Expenses: General and administrative (G&A) expenses were $8.8 million in the fourth quarter of 2023 and $30.9 million for the year ended December 31, 2023, compared to $6.6 million and $27.2 million for the comparable periods in 2022. The increase in G&A expenses was primarily due to higher stock-based compensation, recruiting and barzolvolimab commercial planning expenses, partially offset by a decrease in legal expenses.

Changes in Fair Value Remeasurement of Contingent Consideration: The Company recorded a $6.9 million gain on fair value remeasurement of contingent consideration for the year ended December 31, 2022, primarily due to the Company's decision to deprioritize the CDX-1140 program in the second quarter of 2022.

Litigation Settlement Related Loss: The Company recorded a loss of $15.0 million in the second quarter of 2022 related to the $15.0 million initial payment made to SRS pursuant to our settlement agreement. During the fourth quarter of 2023, the Company announced positive topline results from our Phase 2 clinical trial of barzolvolimab in patients with moderate to severe CSU, satisfying the "Successful Completion" of a Phase 2 clinical trial of barzolvolimab milestone, thus triggering the payment of the $12.5 million milestone pursuant to the settlement agreement.

Net Loss: Net loss was $43.3 million, or ($0.83) per share, for the fourth quarter of 2023, and $141.4 million, or ($2.92) per share, for the year ended December 31, 2023, compared to a net loss of $26.5 million, or ($0.56) per share, for the fourth quarter of 2022 and $112.3 million, or ($2.40) per share, for the year ended December 31, 2022. The litigation settlement related loss had a ($0.26) impact on net loss per share for the twelve months ended December 31, 2023.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at December 31, 2023 are sufficient to meet estimated working capital requirements and fund current planned operations into 2026.

About Celldex Therapeutics, Inc.
Celldex is a clinical stage biotechnology company leading the science at the intersection of mast cell biology and the development of transformative therapeutics for patients. Our pipeline includes antibody-based therapeutics which have the ability to engage the human immune system and/or directly affect critical pathways to improve the lives of patients with severe inflammatory, allergic, autoimmune and other devastating diseases. Visit www.celldex.com.

Forward Looking Statement
This release contains "forward-looking statements" made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are typically preceded by words such as "believes," "expects," "anticipates," "intends," "will," "may," "should," or similar expressions. These forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct or that those goals will be achieved, and you should be aware that actual results could differ materially from those contained in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to, our ability to successfully complete research and further development and commercialization of Company drug candidates, including barzolvolimab (also referred to as CDX-0159), in current or future indications; the uncertainties inherent in clinical testing and accruing patients for clinical trials; our limited experience in bringing programs through Phase 3 clinical trials; our ability to manage and successfully complete multiple clinical trials and the research and development efforts for our multiple products at varying stages of development; the effects of the outbreak of COVID-19 on our business and results of operations; the availability, cost, delivery and quality of clinical materials produced by our own manufacturing facility or supplied by contract manufacturers, who may be our sole source of supply; the timing, cost and uncertainty of obtaining regulatory approvals; the failure of the market for the Company's programs to continue to develop; our ability to protect the Company's intellectual property; the loss of any executive officers or key personnel or consultants; competition; changes in the regulatory landscape or the imposition of regulations that affect the Company's products; our ability to continue to obtain capital to meet our long-term liquidity needs on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials that we have initiated or plan to initiate; and other factors listed under "Risk Factors" in our annual report on Form 10-K and quarterly reports on Form 10-Q.

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 release. 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.

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CELLDEX THERAPEUTICS, INC.
(In thousands, except per share amounts)

Consolidated Statements of Operations Data	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
	(Unaudited)			
Revenues:				
Product development and licensing agreements	$ 259	$ 26	$ 278	$ 56
Contracts and grants	3,873	1,587	6,605	2,301
Total revenues	4,132	1,613	6,883	2,357
Operating expenses:				
Research and development	30,427	22,900	118,011	82,258
General and administrative	8,832	6,598	30,914	27,195
Gain on fair value remeasurement of contingent consideration	-	-	-	(6,862)
Litigation settlement related loss	12,500	-	12,500	15,000
Total operating expenses	51,759	29,498	161,425	117,591
Operating loss	(47,627)	(27,885)	(154,542)	(115,234)

Investment and other income, net	4,321	1,398	13,113	2,909
Net loss	$ (43,306)	$ (26,487)	$ (141,429)	$ (112,325)
Basic and diluted net loss per common share	$ (0.83)	$ (0.56)	$ (2.92)	$ (2.40)
Shares used in calculating basic and diluted net loss per share	52,028	47,132	48,449	46,888

Condensed Consolidated Balance Sheet Data	**December 31, 2023**	**December 31, 2022**
Assets		
Cash, cash equivalents and marketable securities	$ 423,598	$ 304,952
Other current assets	8,095	12,741
Property and equipment, net	4,060	3,747
Intangible and other assets, net	29,874	31,295
Total assets	$ 465,627	$ 352,735
Liabilities and stockholders' equity		
Current liabilities	$ 31,125	$ 18,610
Long-term liabilities	5,331	7,921
Stockholders' equity	429,171	326,204
Total liabilities and stockholders' equity	$ 465,627	$ 352,735
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Source: Celldex Therapeutics, Inc.