CytomX Therapeutics, Inc. Logo

CytomX Therapeutics Reports 2023 Financial Results and Provides Business Update

March 11, 2024 at 4:10 PM EDT

- CX-904 (EGFRxCD3 T-cell engager) initial Phase 1a dose escalation data in solid tumors anticipated in the 2nd half of 2024 -

- CX-2051 (EpCAM ADC) Phase 1 clinical study initiation in solid tumors, including colorectal cancer (CRC) anticipated in the 1st half of 2024 -

- CX-801 (IFNα2b) Phase 1 clinical study initiation in solid tumors including melanoma, renal, and head and neck squamous cell carcinoma anticipated in 1st half of 2024 -

- Management to hold conference call today at 5 p.m. EDT / 2 p.m. PDT -

SOUTH SAN FRANCISCO, Calif., March 11, 2024 (GLOBE NEWSWIRE) -- CytomX Therapeutics, Inc. (Nasdaq: CTMX), a leader in the field of conditionally activated, localized biologics, today reported full year 2023 financial results and provided a business update.

“2023 was a year of sustained execution across our pipeline, highlighted by the continued progress of CX-904 in Phase 1 dose escalation and the parallel advancement of CX-2051 and CX-801 through successful IND enabling activities towards clinical initiation in the first half of 2024,” said Sean McCarthy, D.Phil., chief executive officer and chairman of CytomX. “We entered 2024 with a robust therapeutic pipeline based upon more than a decade of innovation with the PROBODY® platform. Our lead programs leverage validated oncology targets, potent effector mechanisms and tailored masking approaches. Our strategy is to address large oncology markets and major unmet needs to make a meaningful difference for patients, building on the strong company foundation we have laid with our comprehensive progress to date.”

McCarthy added, “Importantly, while advancing key programs throughout 2023, we maintained a consistently strong financial position through disciplined capital allocation and financing that included a strategic equity investment from our largest shareholder, BVF Partners, and ongoing funding from major collaborations.”

Fourth Quarter Business Highlights and Recent Developments

Pipeline

CX-904, PROBODY® T-cell-engager (TCE) targeted to EGFRxCD3 progressing in Phase 1, with dose escalation data anticipated in second half of 2024.

CX-904 is a conditionally activated PROBODY T-cell engager designed to target the epidermal growth factor receptor (EGFR) on cancer cells and the CD3 receptor on T cells within the tumor microenvironment. CX-904 is partnered with Amgen in a global co-development alliance and is being evaluated in an ongoing Phase 1 study in unselected patients with advanced solid tumors that are considered to have EGFR expression. Backfilling of certain dose escalation cohorts has been initiated and dose ranging continues.

- Initial Phase 1a dose escalation data is anticipated in the second half of 2024. The Phase 1a data is expected to focus primarily on identification of safe and tolerable doses and schedules and will include an evaluation of indicators of clinical activity, including pharmacokinetic-pharmacodynamic (PK-PD) data and assessment of anti-tumor activity.
- The CX-904 Phase 1a data will inform a potential decision during 2024 to initiate Phase 1b expansion cohorts in specific EGFR positive tumor types. The decision to potentially initiate Phase 1b expansion cohorts will be taken in conjunction with Amgen.

CX-2051, an EpCAM-directed PROBODY® antibody drug conjugate advancing to Phase 1 in the 1st half of 2024.

EpCAM is a high potential oncology target that is highly expressed across many indications including colorectal, gastric, endometrial, and ovarian cancers. EpCAM has been clinically validated by locally administered, previously approved cancer therapies. However, efforts to generate systemically administered anti-EpCAM therapeutics have, to date, been unsuccessful due to toxicities in certain epithelial tissues, notably in the gastrointestinal tract. As a conditionally activated ADC, CX-2051 is tailored to optimize the therapeutic index for EpCAM-expressing epithelial cancers. The cytotoxic payload utilized in CX-2051 is a derivative of camptothecin, a topoisomerase-1 inhibitor, a class of drug that has shown potent clinical anti-cancer activity in the ADC context for multiple targets and cancer types. CX-2051 has demonstrated a wide predicted therapeutic index in multiple preclinical models, constituting an opportunity for broad clinical use in large patient populations.

- In January 2024, CytomX announced that the Investigational New Drug (IND) application for CX-2051 was allowed to proceed by the U.S. Food and Drug Administration (FDA).
- The Phase 1 dose escalation of CX-2051 in patients with solid tumors generally known to express EpCAM, including CRC, will be initiated in the first half of 2024. The Phase 1 dose escalation study will follow a Bayesian Optimal Interval (BOIN) design and is intended to demonstrate initial clinical proof of concept to inform a potential decision to move into dose expansion in 2025.

CX-801, a dually-masked PROBODY® interferon-alpha 2b advancing to Phase 1 in the 1st half of 2024.

Interferon-alpha 2b is an immunotherapeutic cytokine that has demonstrated clinical activity and gained regulatory approval previously in multiple cancer types, including locally advanced or metastatic melanoma, renal cancer and bladder cancer. IFNα2b provides a potentially superior approach to activating anti-tumor immune responses compared to other cytokines but its clinical benefit has been hindered by severe dose-limiting toxicity.

CX-801 is an optimized, dually masked, conditionally activated version of IFNα2b, with an expanded therapeutic index that has the potential to become a cornerstone of combination therapy for a wide range of tumor types.

- In January 2024, CytomX announced the Investigational New Drug (IND) application for CX-801 was allowed to proceed by the U.S. Food and Drug Administration (FDA).
- CX-801 is anticipated to initiate Phase 1 dose escalation in patients with solid tumors including melanoma, renal, and head and neck squamous cell carcinoma in the first half of 2024. The Phase 1 dose escalation will utilize a BOIN design to evaluate safety and signs of clinical activity for CX-801 monotherapy and for CX-801 in combination with immune checkpoint inhibition.

Focus of Bristol Myers Squibb (BMS) research collaboration evolves to ongoing research programs, including multiple T-cell engagers. The anti-CTLA-4 PROBODY® BMS-986288 will not be further advanced following a recent BMS internal portfolio review.

CytomX's research collaboration with Bristol Myers Squibb originated in 2014 and includes multiple PROBODY® therapeutic programs.

- Following a corporate portfolio prioritization process, Bristol Myers Squibb (BMS) notified CytomX on March 6th, 2024 that it does not intend to continue the development of BMS-986288 beyond the current Phase 2 study.
- CytomX's ongoing research collaboration with Bristol Myers Squibb includes multiple preclinical programs, including T-cell engagers.

CytomX continues to make progress in R&D partnerships.

CytomX has multiple active research and development partnerships and more than 10 ongoing research programs with major biotechnology and pharmaceutical companies (Amgen, Astellas, Bristol Myers Squibb, Moderna and Regeneron). Throughout 2023, CytomX made substantial progress across all research partnerships including the commencement of programs under its new alliances with Regeneron and Moderna. CytomX has a consistent track record of forming new strategic research and development alliances and achieving preclinical research and clinical milestones. Partnering is expected to remain an important part of the Company's strategy.

2024 Priorities and Key Milestones:

- **CX-904 (EGFRxCD3):** Continued enrollment into Phase 1a dose escalation with initial data expected in the second half of 2024. These data are expected to inform a potential 2024 decision, to be taken with Amgen, to initiate Phase 1b expansion cohorts in specific EGFR positive tumor types.
- **CX-2051 (EpCAM):** Initiation of Phase 1 dose escalation in solid tumors with known EpCAM expression, including locally advanced/metastatic colorectal cancer as a priority indication, is expected in the first half of 2024.
- **CX-801 (IFNα2b):** Initiation of Phase 1 dose escalation in solid tumors including melanoma, renal, and head and neck squamous cell carcinoma is expected in the first half of 2024.
- **Collaborations:** Continuation of drug discovery and development activities with Bristol Myers Squibb, Amgen, Astellas, Regeneron, and Moderna with potential pre-clinical and clinical milestones possible in 2024 and beyond.

Full Year and Q4 2023 Financial Results

Cash, cash equivalents and investments totaled $174.5 million as of December 31, 2023, compared to $193.7 million as of December 31, 2022. The cash balance as of December 31, 2023, included cash inflows during 2023 of a $35.0 million upfront payment received in January 2023 as a result of the collaboration with Moderna, a $5.0 million clinical candidate milestone from Astellas in February of 2023 and approximately $30.0 million of proceeds from the financing transaction with BVF Partners L.P. in July of 2023.

Total revenue was $101.2 million for the year ended December 31, 2023, compared to $53.2 million in 2022. The increase in revenue was driven primarily by a higher percentage of completion for research programs in the Bristol Myers Squibb collaboration and the recent collaborations with Regeneron and Moderna. Revenue in the fourth quarter of 2023 was $26.6 million compared to $20.1 million in the corresponding period in 2022.

In 2023, CytomX remained focused on controlling costs and efficiently allocating capital towards its lead pipeline programs. Total operating expense in 2023 was $107.7 million compared to $154.5 million in 2022, a reduction of $46.8 million. The operating expense reduction was driven by the Company's workforce reduction in 2022, strategic pipeline prioritization, and primarily allocating early phase research efforts towards partnered programs. Operating expenses in the fourth quarter of 2023 were $27.2 million compared to $29.6 million in the corresponding period in 2022.

Research and development expenses decreased by $34.0 million during the year ended December 31, 2023, to $77.7 million compared to $111.6 million in 2022. The reduction in research and development expenses was primarily due to a decrease in personnel related expenses, as well as winding down of laboratory contract services and clinical study activities related to the CX-2009 and CX-2029 programs, partially offset by an increase in laboratory contract services related to IND-enabling activities for CX-2051 and CX-801 programs. Research and development expenses in the fourth quarter of 2023 were $19.4 million compared to $19.6 million in the corresponding period in 2022.

General and administrative expenses decreased by $12.8 million during the year ended December 31, 2023, to $30.0 million, compared to $42.8 million for the corresponding period in 2022. The reduction in general and administrative expenses was primarily due to a decrease in personnel related expenses as a result of the workforce reduction in 2022, reduced external vendor services, and lower occupancy costs as a result of a partial sublease of the Company's headquarters. General and administrative expenses in the fourth quarter of 2023 were $7.8 million compared to $10.1 million in the corresponding period in 2022.

Conference Call & Webcast

CytomX management will host a conference call and simultaneous webcast today at 5 p.m. EDT (2 p.m. PDT) to discuss the financial results and provide a business update. Participants may access the live webcast of the conference call from the Events and Presentations page of CytomX's website at https://ir.cytomx.com/events-and-presentations. Participants may register for the conference call here and are advised to do so at least 10 minutes prior to joining the call. An archived replay of the webcast will be available on the company's website.

About CytomX Therapeutics

CytomX is a clinical-stage, oncology-focused biopharmaceutical company focused on developing novel conditionally activated biologics designed to be localized to the tumor microenvironment. By pioneering a novel pipeline of localized biologics, powered by its PROBODY® therapeutic platform, CytomX's vision is to create safer, more effective therapies for the treatment of cancer. CytomX's robust and differentiated pipeline comprises therapeutic candidates across multiple treatment modalities including antibody-drug conjugates ("ADCs"), T-cell engagers, and immune modulators such as cytokines. CytomX's clinical-stage pipeline includes CX-904, CX-2051 and CX-801. CX-904 is a conditionally activated T-cell-engaging antibody targeting the epidermal growth factor receptor (EGFR) on tumor cells and the CD3 receptor on T cells and partnered with Amgen in a global co-development alliance. CX-2051 is a conditionally activated ADC directed toward epithelial cell adhesion molecule, EpCAM, with potential applicability across multiple EpCAM-expressing epithelial cancers. CX-801 is an interferon alpha-2b PROBODY® cytokine with broad potential applicability in traditionally immuno-oncology sensitive as well as insensitive (cold) tumors. CytomX has established strategic collaborations with multiple leaders in oncology, including Amgen, Astellas, Bristol Myers Squibb, Regeneron and Moderna. For more information about CytomX and how it is working to make conditionally activated treatments the new standard-of-care in the fight against cancer, visit **www.cytomx.com** and follow us on **LinkedIn** and **X** **(formerly Twitter)**.

CytomX Therapeutics Forward-Looking Statements

This press release includes forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors that are difficult to predict, may be beyond our control, and may cause the actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied in such statements, including those related to the future potential of partnerships or collaboration agreements. Accordingly, you should not rely on any of these forward-looking statements, including those relating to the potential benefits, safety and efficacy or progress of CytomX's or any of its collaborative partners' product candidates, including CX-2051, CX-801, and CX-904, the potential benefits or applications of CytomX's PROBODY ® therapeutic platform, CytomX's or its collaborative partners' ability to develop and advance product candidates into and successfully complete clinical trials, including the ongoing and planned clinical trials of CX-904, and the timing of the commencement of clinical trials or initial and ongoing data availability for CX-801 and CX-2051, and other development milestones. Risks and uncertainties that contribute to the uncertain nature of the forward-looking statements include: the unproven nature of CytomX's novel PROBODY ® therapeutic technology; CytomX's clinical trial product candidates are in the initial stages of clinical development and its other product candidates are currently in preclinical development, and the process by which preclinical and clinical development could potentially lead to an approved product is long and subject to significant risks and uncertainties, including the possibility that the results of preclinical research and early clinical trials may not be predictive of future results; the possibility that CytomX's clinical trials will not be successful; the possibility that current preclinical research may not result in additional product candidates; CytomX's dependence on the success of CX-904, CX-801, and CX-2051; CytomX's reliance on third parties for the manufacture of the Company's product candidates; possible regulatory developments in the United States and foreign countries; and the risk that we may incur higher costs than expected for research and development or unexpected costs and expenses. Additional applicable risks and uncertainties include those relating to our preclinical research and development, clinical development, and other risks identified under the heading "Risk Factors" included in CytomX's Annual Report on Form 10-K filed with the SEC on March 11, 2024. The forward-looking statements contained in this press release are based on information currently available to CytomX and speak only as of the date on which they are made. CytomX does not undertake and specifically disclaims any obligation to update any forward-looking statements, whether as a result of any new information, future events, changed circumstances or otherwise.

PROBODY is a U.S. registered trademark of CytomX Therapeutics, Inc.

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CYTOMX THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Year Ended December 31,	
	2023	**2022**
Revenues	$ 101,214	$ 53,163
Operating expenses:		
Research and development	77,680	111,649
General and administrative	30,018	42,849
Total operating expenses	107,698	154,498
Loss from operations	(6,484)	(101,335)
Interest income	9,837	1,678
Other income (expense), net	(30)	340
Income (Loss) before income taxes	3,323	(99,317)

Provision for income taxes	3,892	—
Net loss	(569)	(99,317)
Other comprehensive loss:		
Unrealized gain on available-for-sale investments, net of tax	85	252
Total comprehensive loss	$ (484)	$ (99,065)
Net loss per share, basic and diluted	$ (0.01)	$ (1.51)
Shares used to compute net loss per share, basic and diluted	73,808,237	65,739,844

CYTOMX THERAPEUTICS, INC.
BALANCE SHEETS
(in thousands)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 17,171	$ 193,650
Short-term investments	157,338	—
Accounts receivable	3,432	35,986
Prepaid expenses and other current assets	4,995	7,466
Total current assets	182,936	237,102
Property and equipment, net	3,958	5,072
Intangible assets, net	729	875
Goodwill	949	949
Restricted cash	917	917
Operating lease right-of-use asset	12,220	15,949
Other assets	83	27
Total assets	$ 201,792	$ 260,891
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 1,458	$ 2,809
Accrued liabilities	17,599	24,450
Operating lease liabilities - short term	4,589	4,082
Deferred revenues, current portion	132,267	121,267
Total current liabilities	155,913	152,608
Deferred revenue, net of current portion	80,048	180,059
Operating lease liabilities - long term	9,385	13,975
Other long-term liabilities	3,893	—
Total liabilities	249,239	346,642
Commitments and contingencies		
Stockholders' deficit		
Convertible preferred stock	—	—
Common stock	1	1
Additional paid-in capital	675,905	637,117
Accumulated other comprehensive income	95	10
Accumulated deficit	(723,448)	(722,879)
Total stockholders' deficit	(47,447)	(85,751)
Total liabilities and stockholders' deficit	$ 201,792	$ 260,891

CYTOMX THERAPEUTICS

Source: CytomX Therapeutics Inc.