

Xencor Reports Third Quarter 2024 Financial Results

November 6, 2024

PASADENA, Calif.--(BUSINESS WIRE)--Nov. 6, 2024-- Xencor, Inc. (NASDAQ:XNCR), a clinical-stage biopharmaceutical company developing engineered antibodies for the treatment of cancer and other serious diseases, today reported financial results for the third quarter ended September 30, 2024 and provided a review of recent business and clinical-stage program updates.

"In September, we provided updates across our clinical pipeline of XmAb® bispecific T-cell engagers in oncology and introduced our new autoimmune programs, including the B-cell depleting bispecific antibodies plamotamab and XmAb657, and XmAb942, our high potency anti-TL1A antibody with extended half-life in development for patients with inflammatory bowel disease. This week, we announced that XmAb942 advanced into a Phase 1 dose-escalation study in healthy volunteers," said Bassil Dahiyat, Ph.D., president and chief executive officer at Xencor. "We have been rebalancing our broad portfolio to focus on programs that leverage our protein engineering strengths and reduce exposure to biological uncertainties to increase our overall opportunities for clinical success. We also remain highly encouraged by our partner Amgen's progress with developing xaluritamig, a STEAP1 x CD3 XmAb T-cell engager for patients with prostate cancer, which Amgen announced is starting a Phase 3 study later this year."

Recent Corporate Activities

New XmAb Drug Candidates in Autoimmune Disease: In September 2024, Xencor announced new clinical development plans for plamotamab (CD20 x CD3) and announced new XmAb drug candidates to be evaluated for the treatment of patients with autoimmune and inflammatory diseases. Plamotamab and XmAb657 (CD19 x CD3) could potentially address significant unmet needs for patients with a wide-range of autoimmune diseases that could be responsive to targeted B-cell depletion. XmAb942 (Xtend™ anti-TL1A) and a drug candidate to potentially emerge from the XmAb TL1A x IL-23 program could address significant unmet medical needs for patients with inflammatory bowel disease (IBD), such as Crohn's disease and ulcerative colitis, the two most common forms of IBD.

Public Offering Raised \$201.3 Million in Gross Proceeds: On September 12, 2024, Xencor announced the closing of an underwritten public offering of common stock and pre-funded warrants, and the gross proceeds to Xencor from the offering were \$201.3 million, before deducting underwriting discounts and commissions and offering expenses.

Internal Clinical-Stage Program Updates

XmAb942 (Xtend anti-TL1A): In the fourth quarter of 2024, <u>preclinical data</u> were presented during United European Gastroenterology (UEG) Week and a Phase 1 first-in-human study was initiated and <u>began dosing healthy volunteers</u>. XmAb942 is a high-potency, extended half-life, investigational anti-TL1A antibody in development for patients with IBD. Xencor expects to present initial data from the single-ascending dose portion of the Phase 1 study in the first half of 2025.

Plamotamab (CD20 x CD3): Xencor previously completed a Phase 1 clinical study of plamotamab in hematologic cancers. Data from subcutaneous dosing cohorts in patients with relapsed or refractory non-Hodgkin's lymphoma will be presented at the 66th American Society of Hematology Annual Meeting in a poster titled "First Presentation of Subcutaneous Administration in a Phase 1 Dose Escalation Study in Heavily Pretreated R/R NHL Patients Who Had Prior CAR-T Cell Therapy."

In September 2024, Xencor presented results from the study showing favorable tolerability and comparable preliminary efficacy data, when cross compared to results from studies of a competitor molecule within the class and with similar patient baseline characteristics. Based on these clinical outcomes, deep and durable B-cell depletion observed in preclinical studies, and the emergent biology supportive of B-cell targeted T cell engagers for the treatment of patients with autoimmune diseases, Xencor plans to evaluate plamotamab in rheumatoid arthritis, in which patients have progressed through prior standard-of-care treatment. Xencor plans to initiate a Phase 1b/2a proof-of-concept study in the first half of 2025.

XmAb808 (B7-H3 x CD28): In the ongoing Phase 1 study's highest dose cohort to date, within the range of expected active doses, two patients experienced dose-limiting toxicities as defined in the study protocol. One patient experienced an infusion-related reaction during administration of the first dose of XmAb808. A second patient experienced immune-related hepatitis with Grade 4 elevation of transaminases and Grade 3 elevation of bilirubin, after the second dose. The patient with liver toxicity was asymptomatic, and the laboratory abnormalities are resolving. The maximum tolerated dose has not been defined per protocol. As the data from these recent events are analyzed, back-fill enrollment is proceeding in the next lower dose cohort, a dose within the range of target doses, which was determined to be tolerable. Xencor anticipates that dose escalation will continue per protocol if the currently enrolling cohort continues to be tolerable.

In September 2024, Xencor announced that most patients enrolled into the Phase 1 dose-escalation study were men with metastatic castration-resistant prostate cancer (mCRPC), and in this group, prostate specific antigen (PSA) declines had been observed during the four-week monotherapy safety run-in period. Xencor plans to provide a clinical update around initiation of dose expansion cohorts during the first half of 2025.

XmAb819 (ENPP3 x CD3): In September 2024, Xencor announced that initial evidence of anti-tumor activity was observed in the ongoing Phase 1 dose-escalation study in patients with advanced clear cell renal cell carcinoma, including RECIST responses, and the duration of treatment for several patients in earlier dose cohorts had extended beyond one year. Cytokine release syndrome remained manageable, no maximum tolerated dose had been reached and the tolerability profile from recent dose cohorts supported continued dose escalation toward target dose levels. Xencor continues to anticipate reaching target dose levels by year end and plans to provide a clinical update around initiation of the first dose expansion cohort during the first half of 2025.

Collaboration Partner Amgen's Xaluritamig Advancing into Phase 3 Development

Results from a Phase 1 study evaluating xaluritamig, a first-in-class STEAP1 x CD3 XmAb 2+1 bispecific T-cell engager, in patients with mCRPC were presented at the European Society for Medical Oncology (ESMO) Congress in September 2024. With a median follow-up time of 27.9 months, the median overall survival (OS) was 17.7 months across all cohorts. A PSA90 rate of 45.1% was also observed in high-dose cohorts, and PSA90 response was associated with survival (p = 0.0044), which Amgen believes could potentially serve as an early indicator for benefit in these patients. Amgen has indicated that a Phase 3 study in patients with post-taxane mCRPC will be initiated in the fourth quarter of 2024. Multiple Phase 1 studies evaluating xaluritamig as a monotherapy or in combination are enrolling patients with earlier prostate cancer.

Financial Results for the Third Quarter Ended September 30, 2024

Cash, cash equivalents and marketable debt securities totaled \$754.3 million as of September 30, 2024, compared to \$697.0 million as of December 31, 2023. Net proceeds from Xencor's September 2024 underwritten public offering were \$189.2 million.

Revenues for the third quarter ended September 30, 2024 were \$10.7 million, compared to \$59.2 million for the same period in 2023. Revenues earned in the third quarter of 2024 were primarily non-cash royalty revenue from Alexion and Incyte, compared to the same period in 2023, which were primarily royalty and milestone revenue from Alexion and milestone revenue from Janssen, Gilead and Omeros.

Research and development (R&D) expenses for the third quarter ended September 30, 2024 were \$58.2 million, compared to \$64.9 million for the same period in 2023. Decreased R&D spending for the third quarter of 2024 compared to 2023 is primarily due to decreased spending on wind down costs of terminated programs, partially offset by increased spending on programs such as XmAb942, XmAb819 and plamotamab.

General and administrative (G&A) expenses for the third quarter ended September 30, 2024 were \$14.8 million, compared to \$12.5 million for the same period in 2023. Increased G&A spending for the third quarter of 2024 compared to 2023 is primarily due to increased spending on professional fees.

Other income, net, for the third quarter ended September 30, 2024 was \$16.0 million, compared to other expense, net of \$6.0 million for the same period in 2023. Other income, net, for the third quarter of 2024, compared to other expense, net, for the same period in 2023, is primarily due to unrealized and realized gains from the change in fair value and sale of equity investments and interest income from investments.

Net loss attributable to Xencor for the third quarter ended September 30, 2024 was \$45.1 million, or \$(0.71) on a fully diluted per share basis, compared to net loss of \$24.3 million, or \$(0.40) on a fully diluted per share basis, for the same period in 2023.

Financial Guidance

Based on current operating plans, Xencor expects to end 2024 with between \$690 million and \$710 million in cash, cash equivalents and marketable debt securities, and to have cash to fund research and development programs and operations into 2028.

About Xencor

Xencor is a clinical-stage biopharmaceutical company developing engineered antibodies for the treatment of patients with cancer and other serious diseases. More than 20 candidates engineered with Xencor's XmAb® technology are in clinical development, and multiple XmAb medicines are marketed by partners. Xencor's XmAb engineering technology enables small changes to a protein's structure that result in new mechanisms of therapeutic action. For more information, please visit www.xencor.com.

Forward-Looking Statements

Certain statements contained in this press release may constitute forward-looking statements within the meaning of applicable securities laws. Forward-looking statements include statements that are not purely statements of historical fact, and can generally be identified by the use of words such as "potential," "can," "will," "plan," "may," "could," "would," "expect," "anticipate," "seek," "look forward," "believe," "committed," "investigational," and similar terms, or by express or implied discussions relating to Xencor's business, including, but not limited to, statements regarding statements regarding expectations for clinical progress, planned receipt and presentations of clinical data, including timing thereof, new XmAb candidates and programs, planned and ongoing clinical trials, projected financial resources and financial guidance, including estimated cash at year end and cash runway, the quotations from Xencor's chief executive officer, and other statements that are not purely statements of historical fact. Such statements are made on the basis of the current beliefs, expectations, and assumptions of the management of Xencor and are subject to significant known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements and the timing of events to be materially different from those implied by such statements, and therefore these statements should not be read as guarantees of future performance or results. Such risks include, without limitation, the risks associated with the process of discovering, developing, manufacturing and commercializing drugs that are safe and effective for use as human therapeutics and other risks, including the ability of publicly disclosed preliminary clinical trial data to support continued clinical development and regulatory approval for specific treatments, in each case as described in Xencor's public securities filings. For a discussion of these and other factors, please refer to Xencor's annual report on Form 10-K for the year ended December 31, 2023 as well as Xencor's subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements. which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended to date. All forward-looking statements are qualified in their entirety by this cautionary statement and Xencor undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof, except as required by law.

(in thousands)

	September 30, 2024	December 31, 2023	
Cash, cash equivalents and marketable debt securities - current	(Unaudited)		
	\$ 464,074	\$	551,515
Other current assets	109,254		71,645
Marketable debt securities - long term	290,274		145,512
Other long-term assets	120,033		184,020
Total assets	\$ 983,635	\$	952,692
Total current liabilities	91,972		84,709
Deferred income - long term	94,107		125,183
Other long term liabilities	76,658		73,667
Total liabilities	262,737		283,559
Total stockholders' equity	720,898		669,133
Total liabilities and stockholders' equity	\$ 983,635	\$	952,692

Xencor, Inc.

Consolidated Statements of Comprehensive Loss (in thousands, except share and per share data)

	Three Months Ended September 30,			Nine Months Ended September 30,				
		2024		2023		2024		2023
	(Unaudited)							
Revenue	\$	10,710	\$	59,164	\$	40,475	\$	123,649
Operating expenses								
Research and development		58,226		64,941		176,630		190,553
General and administrative		14,767		12,493		46,300		38,107
Total operating expenses		72,993		77,434		222,930		228,660
Loss from operations		(62,283)		(18,270)		(182,455)		(105,011)
Other income (expense), net		15,986		(5,999)		158		(1,975)
Loss before income tax		(46,297)		(24,269)		(182,297)		(106,986)
Income tax expense		_		_		117		_
Net loss		(46,297)		(24,269)		(182,414)		(106,986)
Net loss attributable to non-controlling interest		(1,154)		_		(3,275)		_
Net loss attributable to Xencor, Inc.		(45,143)		(24,269)		(179,139)		(106,986)
Other comprehensive income								
Net unrealized gain on marketable debt securities		2,452		1,151		510		6,244
Comprehensive loss attributable to Xencor, Inc.	\$	(42,691)	\$	(23,118)	\$	(178,629)	\$	(100,742)
Net loss per common share attributable to Xencor, Inc.:								
Basic and Diluted	\$	(0.71)	\$	(0.40)	\$	(2.87)	\$	(1.77)
Weighted average common shares used to compute net loss per share attributable to Xencor, Inc.								
Basic and Diluted	64	4,022,547	60	0,621,534	6	2,310,045	6	0,387,163

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