

## Curis Provides Fourth Quarter 2024 Business Update

*FDA and EMA discussions completed to support a potential accelerated approval path in both US and EU*

*Orphan Drug Designation for PCNSL granted in both US and EU*

*Management to host conference call today at 8:30 a.m. ET*

LEXINGTON, Mass., March 31, 2025 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of emavusertib (CA-4948), an orally available, small molecule IRAK4 inhibitor, today reported its business update and financial results for the quarter ended December 31, 2024.

### Operational Highlights

#### Emavusertib (IRAK4 Inhibitor)

##### TakeAim Lymphoma

Curis successfully concluded meetings with both the U.S. Food and Drug Administration (FDA) and the Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA) on the suitability of using the ongoing TakeAim Lymphoma study (NCT 03328078) to support a potential accelerated approval path in PCNSL.

Curis also announced that emavusertib has been granted Orphan Drug Designation for PCNSL in both the US and Europe.

Curis provided a data update for 27 patients enrolled in the ongoing TakeAim Lymphoma study in relapsed/refractory (R/R) PCNSL as of January 2, 2025 (data cutoff).

In 20 BTKi-experienced patients:

13 patients had change in tumor burden data available as of data cutoff;

9 of these 13 patients demonstrated a reduction in tumor burden, including 6 objective responses, 4 complete responses (CR) and 2 partial responses (PR), with 3 of 4 CRs lasting more than six months.

In 7 BTKi-naïve patients:

6 patients had change in tumor burden data available as of data cutoff;

5 of these 6 patients demonstrated a reduction in tumor burden, including 5 objective responses, 1 CR and 4 PRs.

##### TakeAim Leukemia

In December 2024, the Company announced data from the TakeAim Leukemia study (NCT 04278768) in R/R Acute Myeloid Leukemia (AML) at the 66th ASH annual meeting for 21 patients with a FLT3 mutation who had received fewer than 3 lines of prior therapy and were treated with emavusertib as monotherapy at the Recommended Phase 2 Dose (RP2D) of 300 mg BID.

19 patients were response-evaluable:

10 of 19 patients achieved objective response, including 6 CRs, 2 CRs with incomplete hematological recovery or partial hematological recovery (CRi/CRh) and 2 morphologic leukemia-free state (MLFS);

7 of the 10 objective responses were reported at the first assessment.

2 patients were not response-evaluable, as they discontinued treatment prior to first disease assessment (death occurred at Day 8 and Day 13, respectively).

##### Ema-Ven-Aza Triplet Study in Frontline AML

The Company initiated a Phase 1 clinical study of emavusertib in combination with venetoclax and azacitidine (ema-ven-aza) in frontline AML (CA-4948-104, 2023-505828-58). The study is currently being conducted in Spain, Germany, and Italy to assess the safety and tolerability of different dosing regimens by adding emavusertib to a patient's ven-aza regimen after they have achieved a CR on ven-aza but remain positive for minimal residual disease. The first dosing cohort was completed and well tolerated, with no unexpected adverse events. As a result, the external Clinical Safety Review Committee recommended escalation to the next dosing cohort. Enrollment for this cohort is currently ongoing.

### Corporate

On March 28, 2025, Curis priced a registered direct offering of common stock and concurrent private placement of pre-funded warrants and warrants ("March 2025 Offerings") with gross proceeds of approximately \$10.0 million. The offerings are expected to close concurrently on March 31, 2025, subject to the satisfaction of customary closing conditions.

In October 2024, Curis completed a registered direct offering and concurrent private placement with net proceeds of approximately \$10.8 million.

"Curis had a very productive 2024. We started the year seeing early responses in our PCNSL trial. As more patients enrolled, and we continued to see positive data, we initiated discussions with the FDA and EMA to discuss the possibility of pursuing an accelerated approval path for emavusertib. We are pleased to announce today that we have received supportive feedback from both agencies. Over the next 12-18 months, we will be focused on enrolling 30-40 additional patients to support the regulatory filing for accelerated approval," said James Dentzer, Chief Executive Officer of Curis.

Additional details of the Company's discussions with EMA and FDA and the March 2025 Offerings were reported on Form 8-K filed by the Company with the SEC on March 28, 2025.

#### **Fourth Quarter 2024 Financial Results**

For the year ended December 31, 2024, Curis reported a net loss of \$43.4 million, or \$6.88 per share on both a basic and diluted basis, as compared to a net loss of \$47.4 million, or \$8.96 per share on both a basic and diluted basis in 2023. For the fourth quarter of 2024, Curis reported a net loss of \$9.6 million or \$1.25 per share on both a basic and diluted basis as compared to a net loss of \$11.7 million or \$2.03 on both a basic and diluted basis for the same period in 2023.

Revenues, net were \$10.9 million and \$10.0 million for the years ended December 31, 2024 and 2023, respectively. Revenues are comprised of royalty revenues related to Genentech and Roche's net sales of Erivedge<sup>®</sup>. Revenues were \$3.3 million and \$2.7 million for the fourth quarters of 2024 and 2023, respectively.

Research and development expenses were \$38.6 million and \$39.5 million for the years ended December 31, 2024 and 2023, respectively. The decrease was primarily attributable to lower clinical and consulting costs, partially offset by higher manufacturing costs. Research and development expenses were \$9.0 million and \$10.0 million for the fourth quarters of 2024 and 2023, respectively.

General and administrative expenses were \$16.8 million and \$18.6 million for the years ended December 31, 2024 and 2023, respectively. The decrease was primarily attributable to lower consulting, legal, facility, insurance and employee-related costs. General and administrative expenses were \$3.4 million and \$4.9 million for the fourth quarters of 2024 and 2023, respectively.

Other income, net was \$1.2 million and \$0.9 million for the years ended December 31, 2024 and 2023, respectively. The increase was attributable to a decrease in expense related to the sale of future royalties partially offset by a decrease in interest income. Other expense, net was \$0.6 million for the fourth quarter of 2024 and other income, net was \$0.5 million for the fourth quarter of 2023.

As of December 31, 2024, Curis's cash and cash equivalents totaled \$20.0 million, and the Company had approximately 8.5 million shares of common stock outstanding.

#### **Cash Runway Guidance**

Curis expects its cash and cash equivalents as of December 31, 2024, together with the expected proceeds from the March 2025 Offerings will enable the Company to fund its planned operations into the fourth quarter of 2025.

#### **Conference Call Information**

Curis management will host a conference call today, March 31, 2025, at 8:30 a.m. ET, to discuss the business update and these financial results.

To access the live conference call, please dial (800)-836-8184 from the United States or (646)-357-8785 from other locations, shortly before 8:30 a.m. ET. The conference call can also be accessed [here](#) on the Curis website in the Investors section.

#### **About Curis, Inc.**

Curis is a biotechnology company focused on the development of emavusertib, an orally available, small molecule IRAK4 inhibitor. Emavusertib is currently being evaluated in the Phase 1/2 TakeAim Lymphoma study (CA-4948-101) in patients with relapsed/refractory primary central nervous system lymphoma (PCNSL) in combination with the BTK inhibitor ibrutinib, as a monotherapy in the Phase 1/2 TakeAim Leukemia study (CA-4948-102) in patients with relapsed/refractory acute myeloid leukemia (AML) and relapsed/refractory high risk myelodysplastic syndrome (hrMDS), and as a frontline combination therapy with venetoclax and azacitidine in patients with AML (CA-4948-104). Emavusertib has received Orphan Drug Designation from the U.S. Food and Drug Administration for the treatment of PCNSL, AML and MDS and from the European Commission for the treatment of PCNSL. Curis, through its 2015 collaboration with Aurigene, has the exclusive license to emavusertib (CA-4948).

Curis licensed its rights to Erivedge® to Genentech, a member of the Roche Group, under which they are commercializing Erivedge® for the treatment of advanced basal cell carcinoma. For more information, visit Curis's website at [www.curis.com](http://www.curis.com).

### **Cautionary Note Regarding Forward-Looking Statements:**

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, including, without limitation, statements concerning the offerings and the expected closing of the offerings; regulatory guidance on potential Conditional Marketing Authorization (CMA) from the EMA and potential NDA for Accelerated Approval from the FDA for emavusertib in the treatment of PCNSL, and Curis's expectations with respect to regulatory objectives; Curis's expectations with respect to enrollment of BTKi naïve and BTKi experienced populations in the TakeAim Lymphoma study; statements regarding updated PCNSL data from the TakeAim Lymphoma study, the potential use thereof for regulatory submissions to support CMA and/or Accelerated Approval, and the therapeutic potential and tolerability of emavusertib in patients with PCNSL; statements concerning research, development, clinical trials and commercialization plans, timelines, anticipated results, use, safety, efficacy, rates and duration of responses, mutations or potential biomarkers, and potential benefits of emavusertib as a monotherapy and/or as a combination therapy; statements regarding Curis's anticipated cash runway; and statements of assumptions underlying any of the foregoing. Forward-looking statements may contain the words "believes," "expects," "anticipates," "plans," "intends," "seeks," "estimates," "assumes," "predicts," "projects," "targets," "will," "may," "would," "could," "should," "likelihood", "continue," "potential," "opportunity," "focus," "strategy," "mission," or similar expressions. These forward-looking statements are not guarantees of future performance and involve risks, uncertainties, assumptions and other important factors that may cause actual results to be materially different from those indicated by such forward-looking statements. Customary closing conditions related to the offerings may not be satisfied. Curis may experience adverse results, delays and/or failures in its drug development programs and may not be able to successfully advance the development of its drug candidates in the time frames it projects, if at all. Curis's drug candidates may cause unexpected toxicities, fail to demonstrate sufficient safety and efficacy in clinical studies and/or may never achieve the requisite regulatory approvals needed for commercialization. Notably, Curis may not achieve its project timeline to fully enroll patients and submit regulatory filings for emavusertib within the next 18-24 months, and the safety and efficacy data results from the TakeAim Lymphoma study of emavusertib in PCNSL may not be sufficient for Curis to successfully achieve conditional marketing authorization from the EMA or accelerated approval from the FDA for emavusertib. Favorable results seen in preclinical studies and early clinical trials of Curis's drug candidates may not be replicated in later trials. Curis is dependent on the success of emavusertib and any delays in the development of emavusertib could have a material adverse effect on its business. There can be no guarantee that the collaboration agreement with Aurigene will continue for its full term, or the CRADA with NCI, that Curis or its collaborators will each maintain the financial and other resources necessary to continue financing its portion of the research, development and commercialization costs, or that the parties will successfully discover, develop or commercialize drug candidates under the collaboration. Regulatory authorities may determine to delay or restrict Genentech's and/or Roche's ability to continue to commercialize Erivedge in basal cell carcinoma. Competing drugs may be developed that are superior to Erivedge. In connection with its agreement with Oberland Capital, Curis faces risks relating to the transfer and encumbrance of certain royalty and royalty-related payments on commercial sales of Erivedge, including the risk that, in the event of a default by Curis or its wholly-owned subsidiary, Curis could lose all retained rights to future royalty and royalty-related payments, Curis could be required to repurchase such future royalty and royalty-related payments at a price that is a multiple of the payments it has received, and its ability to enter into future arrangements may be inhibited, all of which could have a material adverse effect on its business, financial condition and stock price. Curis will require substantial additional capital to fund its business. Based on its available cash resources, it does not have sufficient cash on hand to support current operations within the next 12 months from the date of this press release. Curis will require substantial additional funding in the immediate term to fund the development of emavusertib through regulatory approval and commercialization, and to support its continued operations. If it is not able to obtain sufficient funding, it will be forced to delay, reduce in scope or eliminate the development emavusertib, including related clinical trials and operating expenses, potentially delaying the time to market for, or preventing the marketing of, emavusertib, which could adversely affect its business prospects and its ability to continue operations, and would have a negative impact on its financial condition and its ability to pursue its business strategies. Curis faces substantial competition. Curis and its collaborators face the risk of potential adverse decisions made by the FDA, EMA and other regulatory authorities, investigational review boards, and publication review bodies. Curis may not obtain or maintain necessary patent protection and could become involved in expensive and time-consuming patent litigation and interference proceedings. Unstable market and economic conditions, natural disasters, public health crises, political crises and other events outside of Curis's control could significantly disrupt its operations or the operations of third parties on which Curis depends and could adversely impact Curis's operating results and its ability to raise capital. Other important factors that may cause or contribute to actual results being materially different from those indicated by forward-looking statements include the factors set forth under the captions "Risk Factor Summary" and "Risk Factors" in our most recent Form 10-K, and the factors that are discussed in other filings that we periodically make with the Securities and Exchange Commission. In addition, any forward-looking statements represent the views of Curis only as of today and should not be relied upon as representing Curis's views as of any subsequent date. Curis disclaims any intention or obligation to update any of the forward-looking statements after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by law.

**CURIS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(UNAUDITED)  
(In thousands, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
Revenues, net	\$ 3,345	\$ 2,696	\$ 10,908	\$ 10,023
Operating expenses:				
Cost of royalties	17	54	98	212
Research and development	8,968	9,964	38,562	39,496
General and administrative	3,354	4,877	16,790	18,647
Total operating expenses	12,339	14,895	55,450	58,355
Loss from operations	(8,994)	(12,199)	(44,542)	(48,332)
Total other income (expense)	(624)	487	1,153	919
Net loss	\$ (9,618)	\$ (11,712)	\$ (43,389)	\$ (47,413)
Net loss per common share (basic and diluted)	\$ (1.25)	\$ (2.03)	\$ (6.88)	\$ (8.96)
Weighted average common shares (basic and diluted)	7,671,226	5,772,201	6,306,284	5,293,294

**CURIS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

(UNAUDITED)  
(In thousands)

	December 31, 2024	December 31, 2023
<b>ASSETS</b>		
Cash, cash equivalents and investments	\$ 19,997	\$ 56,334
Restricted cash	544	544
Accounts receivable	3,349	2,794
Prepaid expenses and other assets	4,999	5,138
Property and equipment, net	231	434
Operating lease right-of-use asset	3,163	3,056
Goodwill	8,982	8,982
Total assets	\$ 41,265	\$ 77,282
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Accounts payable and accrued liabilities	\$ 10,135	\$ 12,212
Operating lease liability	2,954	2,794
Liability related to the sale of future royalties, net	34,174	42,606
Total liabilities	47,263	57,612
Total stockholders' equity (deficit)	(5,998)	19,670
Total liabilities and stockholders' equity (deficit)	\$ 41,265	\$ 77,282

SOURCE Curis, Inc.

For further information: Investor Relations: IR@curis.com

<https://investors.curis.com/2025-03-31-Curis-Provides-Fourth-Quarter-2024-Business-Update>