Curis Provides Third Quarter 2025 Business Update

Management to host conference call and webcast today at4:30 p.m. ET

LEXINGTON, Mass., Nov. 6, 2025 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of emavusertib (CA-4948), an orally available, small molecule IRAK4 and FLT3 inhibitor, today reported its financial and operating results for the third quarter ended September 30, 2025.

"We made good progress advancing our clinical studies in PCNSL, CLL, and AML this quarter. We continue to enroll PCNSL patients in the TakeAim Lymphoma study in both the BTKi-experienced and BTKi-naïve cohorts to enable accelerated approval filings in the US and EU. We are presenting three posters at the SNO annual meeting later this month, two in PCNSL and one in SCNSL. We are presenting at the ASH annual meeting in December with initial data from the ongoing frontline AML triplet study evaluating different dosing regimens of emavusertib, venetoclax, and azacitidine. And, finally, we have filed the protocol with the FDA for our Phase 2 study of emavusertib + BTKi in CLL, we are working to activate clinical sites, and we expect to enroll our first patient in late Q4 or early Q1, with data expected at the ASH annual meeting in December 2026. I am very pleased with the progress we have made across multiple ongoing studies in PCNSL, CLL, and AML," said James Dentzer, President and Chief Executive Officer.

Operational Highlights

NHL/CLL

Curis will report clinical data in Primary CNS Lymphoma (PCNSL) and Secondary CNS Lymphoma (SCNSL) in three presentations at the 30th Annual Meeting of the Society for Neuro-Oncology (SNO) onNovember 19-23:

PCNSL

Rapid Oral Presentation + Poster
Dr. Christian Grommes, Memorial Sloan Kettering Cancer Center, NY, NY
Analysis of Genetic Mutation Profile and CNS Pharmacokinetics in Relapsed/Refractory Primary CNS Lymphoma Patients Responding to Novel Emavusertib (IRAK4i) and BTKi Combination

PCNSL

Poster Presentation
Dr. Lakshmi Nayak, Dana-Farber Cancer Institute, Boston, MA
Preliminary Safety and Efficacy of Emavusertib (CA-4948) in Combination with Ibrutinib in Relapsed/Refractory Primary Central Nervous System Lymphoma Patients

SCNSL

Poster Presentation
Dr. Cecilia A. Merrigan, Mayo Clinic, Rochester, MN
Promising Efficacy Signal in Secondary CNS Lymphoma Patients Treated with Emavusertib and Ibrutinib

Curis continued to enroll relapsed/refractory (R/R) PCSNL patients in the Company's TakeAim Lymphoma study which, as a result of discussions with the EMA and FDA, is intended to support filings for accelerated approval in PCNSL in the US and Europe. Emavusertib has been granted orphan drug designation by both the FDA and EMA in PCNSL.

Curis is initiating a Phase 2 clinical study of emavusertib in combination with a BTKi in patients with Chronic Lymphocytic Leukemia (CLL), with dosing of the first patient expected in late Q4 or early Q1. The goal of combining emavusertib with a BTKi is to improve upon the current standard of care (BTKi) with its limitations of partial responses and the need for chronic, life-long therapy. The combination of emavusertib with a BTKi has the potential to enable patients to achieve complete remission or undetectable minimal residual disease (uMRD) and the potential for time-limited treatment, which would be a paradigm shift in the management of CLL.

Leukemia

Curis will be presenting initial clinical data from the ongoing frontline AML triplet study in a poster presentation at the 67th ASH Annual Meeting in December:

AML

Poster Presentation
Dr. Christina Papayannidi,
IRCCS Azienda Ospedaliero Universitaria di Bologna
Preliminary pharmacokinetic and MRD results from AML patients treated with 7- and 14-day dosing schedule of emavusertib added to combination therapy with azacitidine and venetoclax

The AML triplet study is evaluating the addition of emavusertib to the combination of azacitidine and venetoclax (aza-ven) in AML patients who have achieved complete remission on aza-ven but remain MRD positive (MRD+). The first two cohorts in the study evaluate patients who received emavusertib for 7 or 14 days in a 28-day cycle, in addition to their azacitidine and venetoclax treatment. The abstract, published on November 3, 2025, showed data with a July 2, 2025 data cut-off for 4 patients in the 7-day cohort and 6 patients in the 14-day cohort:

MRD conversion (positive to undetectable) was observed in 4 of 8 patients (50%)
1 additional patient achieved a 40% reduction in MRD from baseline as of data cut-off
No patients who remained MRD+ progressed on study.
Two dose-limiting toxicities (CPK increase and neutropenia) were observed in the 14-day cohort and both resolved

Solid Tumors

Curis will be presenting initial clinical data from a Phase 1 Investigator Sponsored Study (IST) evaluating emavusertib in combination with gemcitabine and nab-paclitaxel in metastatic or unresectable pancreatic ductal adenocarcinoma at the American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium on January 8-10, 2026:

PDAC

Poster Presentation
Dr. Patrick Grierson,
Siteman Cancer Center, Washington University in St Louis
A phase I trial of emavusertib (CA-4948) in combination with gemcitabine and nab-paclitaxel in metastatic or unresectable pancreatic ductal adenocarcinoma (PDAC)

Corporate

Completed a registered direct offering and concurrent private placement extending cash runway into 2026.

Upcoming Presentations and Conferences

Updated PCNSL and SCNSL data will be reported in poster presentations at the 30th Annual Meeting of the Society for Neuro-Oncology on November 19-23, 2026

Initial clinical data in the frontline AML triplet study of emavusertib with azacitidine and venetoclax will be reported in a poster presentation at the 67th ASH Annual Meeting on December 6-9, 2025

Initial clinical data from an Investigator Sponsored Study (IST) in pancreatic ductal adenocarcinoma (PDAC) will be reported at the ASCO Gastrointestinal Cancers Symposium on January 8-10, 2026

Third Quarter 2025 Financial Results

For the third quarter of 2025, Curis reported a net loss of $7.7 million or $0.49 per share on both a basic and diluted basis as compared to $10.1 million or $1.70 per share on both a basic and diluted basis, for the same period in 2024. Curis reported a net loss of $26.9 million or $2.19 per share on both a basic and diluted basis, for the nine months ended September 30, 2025, as compared to a net loss of $33.8 million or $5.77 per share on both a basic and diluted basis for the same period in 2024.

Revenues were $3.2 million for third quarter of 2025, as compared to $2.9 million for the same period in 2024. Revenues were $8.3 million for the nine months ended September 30, 2025, as compared to $7.6 million for the same period in 2024. Revenues consist of royalty revenues from Genentech/Roche's sales of Erivedge®.

Research and development expenses were $6.4 million for the third quarter of 2025, as compared to $9.7 million for the same period in 2024. The decrease was primarily attributable to lower clinical, employee related, manufacturing, research, and consulting costs. Research and development expenses were $22.4 million for the nine months ended September 30, 2025, as compared to $29.6 million for the same period in 2024.

General and administrative expenses were $3.7 million for the third quarter of 2025, as compared to $3.8 million for the same period in 2024. The decrease was primarily attributable to lower employee related costs. General and administrative expenses were $11.2 million for the nine months ended September 30, 2025, as compared to $13.4 million for the same period in 2024.

Other expense was $0.8 million for the third quarter of 2025, as compared to other income of $0.5 million for the same period in 2024. The decrease was primarily attributable to an increase in the expense related to the sale of future royalties and a decrease in interest income. Other expense was $1.6 million for the nine months ended September 30, 2025, as compared to other income of $1.8 million for the same period in 2024.

Curis's cash and cash equivalents totaled $9.1 million as of September 30, 2025, and the Company had approximately 12.7 million shares of common stock outstanding. We believe that our existing cash and cash equivalents, should enable us to fund our existing operations into the first quarter of 2026.

Conference Call and Webcast Information

Curis management will host a conference call today, November 6, 2025, at 4:30 p.m. ET, to discuss the business update and these financial results.

To access the live conference call, please dial 1-800-836-8184 from the United States or 1-646-357-8785 from other locations. To access the webcast login here shortly before 4:30 p.m. ET. The webcast can also be accessed on the Curis website at the Events and Presentations section of the Investors page.

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 TakeAim Lymphoma Phase 1/2 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 TakeAim Leukemia Phase 1/2 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 patents 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 Discovery Technologies Limited, 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.

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 Curis's expectations with respect to initiating a frontline study of emavusertib in combination with a BTK inhibitor in Chronic Lymphocytic Leukemia (CLL), the dosing of the first patient in such study, and the therapeutic potential of emavusertib in combination with a BTKi to improve treatment outcomes, achieve complete remissions and/or MRD negativity, and/or reduce time on treatment for patients with CLL; Curis's expectations with respect to enrollment of BTKi naïve and BTKi experienced populations in the TakeAim Lymphoma study; statements regarding updated PCNSL data and the timing of such data from the TakeAim Lymphoma study, and the therapeutic potential and tolerability of emavusertib in patients with PCNSL; statements regarding data from the AML triplet study and the timing of such data; 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 in current and/or potential new studies; any statements concerning the design of a head-to-head registrational trial of emavusertib vs. gilteritinib in R/R AML, and the design of a Phase 1/2 study in frontline high-risk MDS (hrMDS) in combination with azacitidine; 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. 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 enroll patients and submit regulatory filings for emavusertib in PCNSL and/or other potential indications. 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 will be extended, 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 or generic versions may compete with 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, including its ability to regain and maintain its listing on the Nasdaq Capital Market, 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 Form 10-Q and 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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenues, net	$ 3,176	$ 2,931	$ 8,305	$ 7,563
Operating expenses:				
Cost of royalties	15	22	45	81
Research and development	6,432	9,723	22,429	29,594
General and administrative	3,653	3,753	11,163	13,436
Total operating expenses	10,100	13,498	33,637	43,111
Loss from operations	(6,924)	(10,567)	(25,332)	(35,548)
Total other income (expense)	(805)	475	(1,606)	1,777
Net loss	$ (7,729)	$ (10,092)	$ (26,938)	$ (33,771)
Net loss per common share (basic and diluted)	$ (0.49)	$ (1.70)	$ (2.19)	$ (5.77)
Weighted average common shares (basic and diluted)	15,680,178	5,940,924	12,293,558	5,847,982

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	September 30, 2025	*December 31, 2024*
ASSETS		
Cash and cash equivalents	$ 9,051	$ 19,997
Restricted cash	544	544
Accounts receivable	3,243	3,349
Prepaid expenses and other assets	3,502	4,999
Property and equipment, net	98	231
Operating lease right-of-use asset	2,221	3,163
Goodwill	8,982	8,982
Total assets	$ 27,641	$ 41,265
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Accounts payable and accrued liabilities	$ 11,733	$ 10,135
Operating lease liability	1,968	2,954
Liability related to the sale of future royalties, net	28,631	34,174
Total liabilities	42,332	47,263
Total stockholders' deficit	(14,691)	(5,998)
Total liabilities and stockholders' deficit	$ 27,641	$ 41,265

SOURCE Curis, Inc.

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

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https://investors.curis.com/2025-11-06-Curis-Provides-Third-Quarter-2025-Business-Update