# Curis Reports Fourth Quarter and Year End 2021 Financial Results

**- Presented positive updated data in Phase 1/2 TakeAim Leukemia study of CA-4948 Monotherapy in Targeted Patients with Relapsed or Refractory Acute Myeloid Leukemia or Myelodysplastic Syndromes -**
**- Presented initial clinical data from Phase 1 study of CI-8993 in Patients with Relapsed or Refractory Solid Tumors -**
**- Adopted "emavusertib" as the generic name for CA-4948 and introduced "TakeAim" as brand name for related clinical trials -**
**- Strong balance sheet with $139.8 million in cash, cash equivalents and investments at December 31, 2021; expected to maintain planned operations into 2024 -**
**- Management to host conference call today at 4:30 p.m. ET -**

LEXINGTON, Mass., Feb. 24, 2022 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, today reported its financial results for the fourth quarter ended December 31, 2021.

"2021 was a year marked by significant clinical progress across our pipeline of targeted cancer therapies, including our report of positive updated data from our ongoing Phase 1/2 TakeAim Leukemia study of emavusertib (CA-4948) demonstrating a favorable safety profile and encouraging anti-cancer activity, with expansion into multiple combination trials in R/R hematologic malignancies. We have also identified a potential registrational path for CA-4948 as a monotherapy in genetically-defined patient populations, and reported promising initial safety data highlighting the potential of CI-8993 to activate multiple anti-cancer immune mechanisms," said James Dentzer, President and Chief Executive Officer of Curis. "As we look ahead, we expect 2022 to be a year of meaningful clinical updates from across our ongoing clinical trials, as we plan on providing additional updates on expanded clinical data for emavusertib and an update on a potential rapid regulatory path to bring this novel therapy to a genetically-defined patient population in dire need. We will continue our dose-escalation study for CI-8993 to determine the recommended Phase 2 dose and to assess signs of anti-cancer activity. We also look forward to presenting data from both of our combination trials with emavusertib in AML/MDS and in B Cell Cancers this year.

"We are also pleased to have expanded our leadership with three new executives that will bring expertise to strengthen our internal capabilities. We are also delighted with the appointment of John Hohneker, M.D. to the Board of Directors as we continue to grow our team and build our capabilities to deliver a new class of therapies to our patients," added Mr. Dentzer.

**Full Year 2021 and Recent Operational Highlights**

**Precision oncology, emavusertib (IRAK4 Inhibitor; Aurigene collaboration):**

Today, Curis announced that it will be implementing the new name "emavusertib" for all future references of CA-4948, including in scientific publications and corporate materials. The Company also announced new branding of its existing clinical trials of emavusertib as TakeAim Leukemia and TakeAim Lymphoma to highlight the targeting mechanisms.
In January 2022, Curis presented an updated expanded data set supporting earlier preliminary efficacy data of emavusertib in R/R AML/MDS whose disease is characterized by spliceosome or FLT3 mutation, suggesting a favorable safety and anti-cancer activity profile compared to standard of care therapies for these patient populations. The safety profile observed showed emavusertib was well-tolerated across multiple dose levels, including at the Recommended Phase 2 Dose of 300 mg BID. Enrollment of the study is currently ongoing, and Curis expects to have discussions with the FDA in the first half of 2022 regarding the potential for a rapid registrational path for emavusertib as a monotherapy in genetically defined patient populations. Curis expects to provide additional data from the R/R AML/MDS study at a medical meeting in 2022.
In October 2021, Curis initiated dosing in the combination stage of the TakeAim Leukemia study of emavusertib plus azacitidine or venetoclax. The combination therapy portion includes two arms: emavusertib plus azacitidine, for patients naïve to HMA, and emavusertib plus venetoclax, for patients naïve to venetoclax.
In October 2021, Curis announced new preclinical data highlighting the potential of emavusertib in additional hematologic malignancies in two presentations at the AACR-NCI-EORTC Virtual Conference on Molecular Targets and Cancer Therapeutics. The preclinical data concluded emavusertib is synergistic with small molecule therapies targeted BCR signaling and suggest it can overcome or reduce secondary resistance to the therapies in marginal zone lymphoma.

**Immuno-oncology, CI-8993 (anti-VISTA antibody; ImmuNext collaboration):**

In January 2022, Curis announced that the ongoing Phase 1 dose escalation study of CI-8993 demonstrated a promising safety profile, with no dose-limiting toxicities observed, and encouraging PK/PD activity, suggesting the possibility that CI-8993 can activate multiple anti-cancer immune mechanisms, including mechanisms that are not addressed by currently approved checkpoint inhibitors. The initial safety data from this trial is based on 13 patients in the first two dose cohorts of 0.15mg/kg and 0.3mg/kg. Curis expects to report expanded safety and tolerability data, along with PK, PD, and anti-cancer data from the trial in the second half of 2022.

**Corporate:**

Curis expanded its executive leadership capabilities, adding Felix Geissler, M.D., Ph.D., as Vice President of Medical Affairs, Kimberly Steinmann, M.D., as Vice President of Clinical Development, and Dora Ferrari, as Vice President of Clinical Operations. Drs. Geissler and Steinmann, and Ms. Ferrari are reporting directly to Dr. Reinhard von Roemeling, Senior Vice President, Clinical Development.
Curis expanded its Board of Directors with the appointment of John Hohneker, M.D. to the Board of Directors.

**Upcoming 2022 Planned Milestones**

In the first half of 2022, discuss potential for rapid registrational path for emavusertib with FDA
In the first half of 2022, report initial data for emavusertib in combination with ibrutinib in NHL
In 2022, report updated data for emavusertib in AML/MDS monotherapy
In the second half of 2022, report initial efficacy data for CI-8993 (VISTA)
In the second half of 2022, report initial data for emavusertib in combination with azacitadine or venetoclax in AML/MDS

**Full Year and Fourth Quarter 2021 Financial Results**

For the year ended December 31, 2021, Curis reported a net loss of $45.4 million, or $0.50 per share on both a basic and diluted basis, as compared to a net loss of $29.9 million, or $0.61 per share on both a basic and diluted basis in 2020. For the fourth quarter of 2021, Curis reported a net loss of $13.6 million or $0.15 per share on both a basic and diluted basis as compared to a net loss of $7.5 million, or $0.11 per share on both a basic and diluted basis, for the same period in 2020.

Revenues for the year ended December 31, 2021, were $10.6 million as compared to $10.8 million for the same period in 2020. Revenues for both periods comprise primarily royalty revenues recorded on Genentech and Roche's net sales of Erivedge®. Revenues for the fourth quarters of 2021 and 2020 were $3.1 million and $3.0 million, respectively.

Operating expenses for the year ended December 31, 2021, were $52.7 million, as compared to $35.7 million for the same period in 2020. Operating expenses for the fourth quarter of 2021 were $15.7 million, as compared to $9.3 million for the same period in 2020, and comprised the following:

*Costs of Royalty Revenues*. Costs of royalty revenues, primarily amounts due to third-party university patent licensors in connection with Genentech and Roche's Erivedge net sales, were $0.5 million for the years ended December 31, 2021 and 2020. Cost of royalty revenues were $0.2 million for the fourth quarter of 2021 and 2020.

*Research and Development Expenses*. Research and development expenses were $34.9 million for the year ended December 31, 2021, as compared to $23.1 million for the same period in 2020. Research and development expenses were $10.8 million for the fourth quarter of 2021 as compared to $5.6 million for the same period in 2020. The increase was primarily attributable to increased clinical and manufacturing costs for our programs and higher personnel counts as a result of additional headcount.

*General and Administrative Expenses.* General and administrative expenses were $17.3 million for the year ended December 31, 2021, as compared to $12.1 million for the same period in 2020. General and administrative expenses were $4.8 million for the fourth quarter of 2021, as compared to $3.5 million for the same period in 2020. The increase in general administrative expense was driven primarily by higher costs for stock-based compensation, professional and consulting services, personnel, and insurance as compared to the prior year.

*Other Expense, Net*. Net other expense was $3.4 million for the year ended December 31, 2021, as compared to $5.0 million for the same period in 2020. For the fourth quarter of 2021 and 2020, net other expense was $1.1 million and $1.2 million, respectively. Net other expense primarily consisted of imputed interest expense related to royalty payments.

As of December 31, 2021, Curis's cash, cash equivalents and investments totaled $139.8 million, and there were approximately 91.6 million shares of common stock outstanding. Curis expects that its existing cash, cash equivalents and investments should enable it to maintain its planned operations into 2024.

**Conference Call Information**

Curis management will host a conference call today, February 24, 2022, at 4:30 p.m. ET, to discuss these financial results, as well as provide a corporate update.

To access the live conference call, please dial 1-888-346-6389 from the United States or 1-412-317-5252 from other locations, shortly before 4:30 p.m. ET. The conference call can also be accessed on the Curis website at www.curis.com in the Investors section.

**About Curis, Inc.**

Curis is a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer. In 2015, Curis entered into a collaboration with Aurigene in the areas of immuno-oncology and precision oncology. As part of this collaboration, Curis has exclusive licenses to oral small molecule antagonists of immune checkpoints including the VISTA/PDL1

antagonist CA-170, and the TIM3/PDL1 antagonist CA-327, as well as the IRAK4 kinase inhibitor, emavusertib (CA-4948). Emavusertib is currently undergoing testing in the Phase 1/2 TakeAim Lymphoma trial, in patients with non-Hodgkin's lymphoma both as a monotherapy and in combination with BTK inhibitor ibrutinib. Curis is also evaluating emavusertib in the Phase 1/2 TakeAim Leukemia trial in patients with acute myeloid leukemia and myelodysplastic syndromes, for which it has received Orphan Drug Designation from the U.S. Food and Drug Administration. In addition, Curis is engaged in a collaboration with ImmuNext for development of CI-8993, a monoclonal anti-VISTA antibody, which is currently undergoing testing in a Phase 1 trial in patients with solid tumors. Curis is also party to a collaboration with Genentech, a member of the Roche Group, under which Genentech and Roche are commercializing Erivedge® for the treatment of advanced basal cell carcinoma. For more information, visit Curis's website at www.curis.com.

**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, any statements with respect to Curis's capabilities, plans, strategies, objectives or advancement of its drug candidates, including anticipated results, potential regulatory and commercialization timelines, and providing additional clinical data updates; 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," "continue," "potential," "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. For example, 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. Favorable results seen in preclinical studies and early clinical trials of Curis's drug candidates may not be replicated in later trials. There can be no guarantee that the collaboration agreements with Aurigene and ImmuNext, or the CRADA with NCI, will continue for their full terms, 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 develop or commercialize Erivedge in BCC. Erivedge may not demonstrate sufficient or any activity to merit its further development in disease indications other than BCC. 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. If it is not able to obtain sufficient funding, it will be forced to delay, reduce in scope or eliminate some of its research and development programs, including related clinical trials and operating expenses, potentially delaying the time to market for, or preventing the marketing of, any of its product candidates, 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 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. For example, the COVID-19 pandemic may result in closures of third-party facilities, impact enrollment in clinical trials or impact sales of Erivedge by Genentech and/or Roche. The extent to which the COVID-19 pandemic may impact Curis's business or operating results is uncertain. 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 Form 10-Q, and the factors that are discussed in other filings that we periodically make with the Securities and Exchange Commission ("SEC"). 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, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Revenues, net: | | | | |
| Royalties | $ 3,156 | $ 3,043 | $ 10,749 | $ 10,724 |
| Other revenue | — | 4 | 1 | 214 |
| Contra revenue | (21) | (23) | (101) | (103) |
| Total revenues, net | 3,135 | 3,024 | 10,649 | 10,835 |
| Operating expenses: | | | | |
| Cost of royalties | 157 | 151 | 533 | 534 |
| Research and development | 10,772 | 5,609 | 34,884 | 23,068 |
| General and administrative | 4,773 | 3,539 | 17,297 | 12,131 |
| Total costs and expenses | 15,702 | 9,299 | 52,714 | 35,733 |
| Loss from operations | (12,567) | (6,275) | (42,065) | (24,898) |
| Other expense: | | | | |
| Interest income | 53 | 4 | 211 | 63 |
| Imputed interest expense related to the sale of future royalty payments | (1,106) | (1,246) | (4,472) | (5,095) |
| Other income (expense), net | — | — | 890 | 22 |
| Total other expense | (1,053) | (1,242) | (3,371) | (5,010) |
| Net loss | (13,620) | (7,517) | (45,436) | (29,908) |
| Basic and diluted net loss per common share | $ (0.15) | $ (0.11) | $ (0.50) | $ (0.61) |
| Basic and diluted weighted average common shares outstanding | 91,618,770 | 66,363,229 | 91,569,154 | 48,670,381 |

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

**(UNAUDITED)**
**(In thousands)**

| | December 31, 2021 | December 31, 2020 |
|---|---|---|
| **ASSETS** | | |
| Cash, cash equivalents and investments | $ 139,848 | $ 183,058 |
| Restricted cash | 726 | 816 |
| Accounts receivable | 3,224 | 3,043 |
| Property and equipment, net | 505 | 663 |
| Operating lease right-of-use asset | 5,749 | 6,578 |
| Goodwill | 8,982 | 8,982 |
| Prepaid expenses and other assets | 3,267 | 1,218 |
| Total assets | $ 162,301 | $ 204,358 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Accounts payable, accrued liabilities and other liabilities | $ 12,756 | $ 7,791 |
| Operating lease liability | 5,040 | 6,771 |
| Debt obligations | — | 891 |
| Liability related to the sale of future royalties, net | 53,798 | 58,235 |
| Total liabilities | 71,594 | 73,688 |
| Total stockholders' equity | 90,707 | 130,670 |
| Total liabilities and stockholders' equity | $ 162,301 | $ 204,358 |

SOURCE Curis, Inc.

For further information: Stephanie Ascher, Stern Investor Relations, Inc., 212-362-1200, Stephanie.Ascher@sternir.com

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https://investors.curis.com/2022-02-24-Curis-Reports-Fourth-Quarter-and-Year-End-2021-Financial-Results