Curis Reports First Quarter 2022 Financial Results and Business Update

Strong balance sheet with $120.7 million in cash and investments at March 31, 2022; no change to cash guidance: cash runway into 2024

Potential opportunity for emavusertib in pancreatic cancer highlighted in a publication from Washington University in St. Louis

Management to host conference call today at 4:30 p.m. ET

LEXINGTON, Mass., May 5, 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 first quarter ended March 31, 2022 and provided business updates.

"During the first quarter of 2022, we continued to advance the clinical trials of emavusertib, previously referred to as CA-4948, our first-in-class, small molecule IRAK4 inhibitor in nine distinct patient populations across AML, MDS and B cell cancers. In January, we provided additional preliminary data showing early anti-cancer activity of emavusertib in AML/MDS patients with spliceosome or FLT3 mutation. In addition, we presented initial data from the dose escalation study of CI-8993, a monoclonal antibody targeting VISTA, in patients with relapsed/refractory solid tumors. We also would highlight that we have cleared the 0.3mg/kg dose level, which we believe is an important initial safety hurdle," said James Dentzer, President and Chief Executive Officer of Curis.

"Shortly after the close of the first quarter, our two TakeAim studies were put on partial clinical hold by the U.S. Food and Drug Administration ("FDA") as the agency is seeking additional data relating to emavusertib, including data related to rhabdomyolysis and our determination of the Recommended Phase 2 Dose. We are working collaboratively with the FDA and hope to resolve the partial hold on our studies quickly," continued Mr. Dentzer. "As we gain clarity on the timing of this resolution, we will provide updated guidance on our plan to discuss the potential for a rapid registrational path for emavusertib with the FDA."

First Quarter 2022 and Recent Operational Highlights

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

In January, the company hosted a conference call detailing updated data from the TakeAim Leukemia study.
The TakeAim Leukemia study is a Phase 1/2 dose escalation, dose expansion study examining emavusertib use as both monotherapy and in combination with azacitidine or venetoclax in patients with relapsed or refractory ("R/R") acute myeloid leukemia ("AML") or R/R high risk myelodysplastic syndrome ("MDS").

In patients with spliceosome-mutated R/R AML, key findings included:

CR/CRh rate of 40% (2 out of 5 patients)
Both patients who achieved CR/CRh have been on study > 6 months and achieved negative MRD (minimal residual disease) status
Consistent tumor burden reduction observed, 3 out of 5 patients with elevated blast counts achieving ≥ 50% reduction in blast counts

In patients with spliceosome-mutated R/R MDS, key findings included:

Objective response rate of 57% (4 out of 7 patients)
One of the patients who achieved a marrow CR ("mCR") proceeded to stem cell transplant after 1 cycle
Consistent tumor burden reduction observed, with 4 out of 6 patients with elevated baseline blast counts achieving ≥ 50% reduction in blast counts

In patients with a FLT3 mutated R/R AML, key findings included:

CR rate of 33% (1 out of 3 patients; this patient's AML also had a spliceosome mutation)
2 out of 3 patients showed eradication of FLT3 mutation following treatment, indicating potential for disease modification with emavusertib
Consistent tumor burden reduction observed; with 2 out of 3 patients with elevated blast counts achieving ≥ 50% reduction in blast counts

Curis collaborators at the Washington University School of Medicine in St. Louis, published research suggesting the potential use of emavusertib in solid tumors, such as pancreatic cancer, a setting with very limited therapeutic options.

The manuscript titled "*IRAK4 signaling drives resistance to checkpoint immunotherapy in pancreatic ductal*

adenocarcinoma" concluded that tumor IRAK4 drives T-cell exhaustion in pancreatic nonclinical ductal adenocarcinoma models and is a promising therapeutic target when combined with checkpoint immunotherapy. The manuscript is available online at https://www.gastrojournal.org/article/S0016-5085(22)00201-3/pdf.

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

Also discussed during the January update call were data from the Phase 1 study of CI-8993, Curis's first-in-class monoclonal anti-VISTA antibody, in patients with R/R solid tumors.

Dose escalation has proceeded to the 0.6mg/kg dose level, past the 0.15mg/kg dose level where toxicities were seen previously, namely cytokine release syndrome, or CRS. Dose escalation will continue until the Recommended Phase 2 Dose ("RP2D") has been determined
Pharmacodynamic data suggest CI-8993 has multiple anticancer mechanisms that may position it for combination with existing checkpoint inhibitors, in addition to monotherapy

Presentations at the 2022 American Society of Clinical Oncology Annual Meeting

Curis Presentations

TakeAim Lymphoma

Abstract Number: 7575
Abstract Title: *Open-label, dose-escalation, and expansion trial of CA-4948 in combination with ibrutinib in patients with relapsed or refractory hematologic malignancies.*
Session Type/Title: Poster Session/ Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia
Session Date and Time: Saturday, June 4, 2022, 8:00 AM-11:00 AM CDT

TakeAim Leukemia

Abstract Number: 7016
Abstract Title: *Phase 1/2a study of the IRAK4 inhibitor CA-4948 as monotherapy or in combination with azacitidine or venetoclax in patients with relapsed/refractory (R/R) acute myeloid leukemia or myelodysplastic syndrome.*
Session Type/Title: Poster Discussion Session/ Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant
Session Date and Time: Saturday, June 4, 2022, 1:15 PM-2:45 PM; 8:00 AM-11:00 AM CDT

Collaborator Presentations

Gastric and Esophageal Cancer

Abstract Number: TPS4168
Abstract Title: *Phase I trial of CA-4948, an IRAK4 inhibitor, in combination with FOLFOX/PD-1 inhibitor +/- trastuzumab for untreated unresectable gastric and esophageal cancer*
Session Type/Title: Poster Session/Gastrointestinal Cancer—Gastroesophageal, Pancreatic, and Hepatobiliary
Session Date and Time: Saturday, June 4, 2022, 8:00 AM-11:00 AM CDT

Melanoma Brain Metastases

Abstract Number: 2011
Abstract Title: *CA-4948 for the treatment of melanoma brain metastasis.*
Session Type/Title: Poster Discussion Session/ Central Nervous System Tumors
Session Date and Time: Sunday, June 5, 2022, 11:30 AM-1:00 PM; 8:00 AM-11:00 AM CDT

Upcoming Planned Milestones for 2022

Report data from the TakeAim Lymphoma study

In the first half of 2022, we plan to present new data for approximately 12 patients who have received treatment with the combination of emavusertib and ibrutinib at the upcoming American Society of Clinical Oncology ("ASCO") and European Hematology Association ("EHA") meetings in June 2022

Report data from the TakeAim Leukemia study

In the first half of 2022, we plan to present the monotherapy data released on our January update call in a peer-reviewed setting at the ASCO and EHA conferences
In the second half of 2022, we plan to present an update with additional monotherapy data

In the second half of 2022, we plan to present initial data for the study of emavusertib in combination with azacitadine or venetoclax

Report data from the CI-8993 (VISTA checkpoint inhibitor) study

In the second half of 2022, we plan to present an update with additional monotherapy data

First Quarter 2022 Financial Results

For the first quarter of 2022, Curis reported a net loss of $16.1 million or $0.18 per share on both a basic and diluted basis, as compared to a net loss of $9.9 million, or $0.11 per share on both a basic and diluted basis for the same period in 2021.

Revenues for the first quarter of 2022 and 2021 were $2.1 million and $2.2 million, respectively. Revenues for both periods comprise primarily royalty revenues recorded on Genentech and Roche's net sales of Erivedge®.

Operating expenses for the first quarter of 2022 were $17.2 million, as compared to $11.0 million for the same period in 2021, and comprised the following:

Cost of Royalty Revenues. Cost of royalty revenues, represents amounts due to third-party university patent licensors in connection with Genentech and Roche's Erivedge net sales, were $0.1 million for the first quarter of 2022 and 2021.

Research and Development Expenses. Research and development expenses were $11.4 million for the first quarter of 2022 as compared to $6.8 million for the same period in 2021. The increase in direct research and development expenses for the quarter is primarily attributable to increased manufacturing costs for our programs and increased consulting services. Additionally, personnel related costs increased by $2.4 million and stock compensation increased $0.4 million, primarily as a result of additional headcount.

General and Administrative Expenses. General and administrative expenses were $5.7 million for the first quarter of 2022, as compared to $4.1 million for the same period in 2021. The increase in general and administrative expense was driven primarily by higher costs for personnel, stock-based compensation, and insurance costs.

Other Expense, Net. For the first quarter of 2022 and 2021, net other expense was $1.0 million and $1.1 million, respectively. Net other expense primarily consisted of imputed interest expense related to future royalty payments.

As of March 31, 2022, Curis's cash, cash equivalents and investments totaled $120.7 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, May 5, 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 hematologic malignancies, such as non-Hodgkins lymphoma and other B cell malignancies, both as a monotherapy and in combination with BTK inhibitor ibrutinib, and the Phase 1/2 TakeAim Leukemia trial in patients with acute myeloid leukemia and myelodysplastic syndrome, for which it has received Orphan Drug Designation from the U.S. Food and Drug Administration. The FDA has placed a partial clinical hold on the TakeAim Leukemia and TakeAim Lymphoma trials during which no new patients will be enrolled, and current study participants benefiting from treatment may continue to be treated with emavusertib at doses of 300mg BID or lower. 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.

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, any statements with respect to Curis's plans, strategies, objectives or financial results; statements concerning product research, development, clinical trials and studies and commercialization plans, timelines, anticipated results or the therapeutic potential of drug candidates including any statements regarding the initiation, progression, expansion, use, efficacy, dosage and potential benefits of CA-4948 in clinical trials as a monotherapy and/or as a combination therapy, the progression, use and potential benefits of CI-8993, Curis's plans and timelines to provide preliminary, interim and/or additional data from its ongoing or planned clinical trials, any statements concerning Curis's expectations regarding its interactions with the FDA or its ability to resolve the partial clinical hold of the TakeAim Leukemia study or the partial clinical hold of the TakeAim Lymphoma study, and statements with respect to mutations or potential biomarkers; 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, the FDA may not remove the partial clinical hold on the Phase 1/2 TakeAim Leukemia trial or the partial clinical hold on the Phase 1/2 TakeAim Lymphoma trial, or may take further regulatory action with regard to such trials; 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 will continue for their full terms, 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 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 March 31,	
	2022	**2021**
Revenues, net:		
Royalties	$ 2,060	$ 2,187

Contra revenue, net	(3)	2
Total revenues, net	2,057	2,189
Costs and expenses:		
Cost of royalty revenues	82	109
Research and development	11,435	6,757
General and administrative	5,673	4,123
Total costs and expenses	17,190	10,989
Loss from operations	(15,133)	(8,800)
Other expense:		
Interest income	80	46
Imputed interest expense related to the sale of future royalties	(1,056)	(1,173)
Total other expense	(976)	(1,127)
Net loss	$ (16,109)	$ (9,927)
Net loss per common share (basic and diluted)	$ (0.18)	$ (0.11)
Weighted average common shares (basic and diluted)	91,645,369	91,507,518

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	March 31, 2022	*December 31, 2021*
ASSETS		
Cash, cash equivalents and investments	$ 120,653	$ 139,848
Restricted cash	726	726
Accounts receivable	2,060	3,224
Property and equipment, net	479	505
Operating lease right-of-use asset	4,413	5,749
Goodwill	8,982	8,982
Prepaid expenses and other assets	3,426	3,267
Total assets	$ 140,739	$ 162,301
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued liabilities and other liabilities	$ 8,867	$ 12,756
Operating lease liability	3,765	5,040
Liability related to the sale of future royalties, net	52,133	53,798
Total liabilities	64,765	71,594
Total stockholders' equity	75,974	90,707
Total liabilities and stockholders' equity	$ 140,739	$ 162,301

SOURCE Curis, Inc.

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