Codiak BioSciences Reports First Quarter 2022 Financial Results and Operational Progress

May 5, 2022

– Codiak to provide data from ongoing exoSTING™ and exoIL-12™ clinical trials in late 1H 2022 –

– Anticipate first patients dosed in exoASO™-STAT6 Phase 1 clinical trial in 1H 2022 –

– Data from preclinical engEx-AAV™ program to be presented at ASGCT 2022 showing potential applications for engineered exosomes in gene delivery –

CAMBRIDGE, Mass., May 05, 2022 (GLOBE NEWSWIRE) -- Codiak BioSciences, Inc. (NASDAQ: CDAK), a clinical-stage biopharmaceutical company focused on pioneering the development of exosome-based therapeutics as a new class of medicines, today reported first quarter 2022 financial results and operational progress.

“We are making exciting progress with our clinical and preclinical programs, which continue to generate further confirmatory evidence that our engEx™ Platform can harness exosomes for potent and selective delivery of therapeutics, not only in immuno-oncology, but in vaccines and gene therapy as well,” said Douglas E. Williams, Ph.D., President and Chief Executive Officer of Codiak. “We remain on track to deliver on several key milestones by the end of this quarter, including results from all five dose cohorts in our exoSTING trial, initial CTCL patient data from the exoIL-12 program, and commencement of dosing in the Phase 1 study of our third candidate to enter the clinic, exoASO-STAT6.”

First Quarter 2022 and Recent Highlights

- Completed enrollment and dose escalation in cohorts 4 and 5 in the Phase 1/2 clinical trial of exoSTING (CDK-002) for the treatment of advanced/metastatic, recurrent and injectable solid tumors; patient follow-up continues in all dose cohorts, as well as enrollment of enrichment cohorts
- Advanced cutaneous T cell lymphoma (CTCL) portion of Phase 1 trial of exoIL-12 (CDK-003); implemented plans for protocol amendment to include a broader range of CTCL patients, and developed plans to enroll patients with additional cutaneous malignancies responsive to rIL-12
- Activated sites for Phase 1 trial of exoASO-STAT6 (CDK-004) for the intravenous treatment of hepatocellular carcinoma in preparation for patient dosing
- Presented new preclinical data from the exoVACC™ pan-beta coronavirus vaccine program, as part of Codiak’s collaboration with the Ragon Institute, at the World Vaccine Congress 2022
- Presented preclinical data for exoASO™-C/EBPb, a proprietary engineered exosome loaded with antisense oligonucleotides targeting C/EBPβ, at the American Association for Cancer Research (AACR) Annual Meeting
- Published a manuscript describing the full exoASO-STAT6 preclinical program in the American Association for the Advancement of Science’s journal, *Science Advances*
- Named industry veteran oncology drug developer David Mauro, M.D., Ph.D. as Chief Medical Officer

Anticipated Milestones and Events

- First patients dosed in exoASO-STAT6 Phase 1 clinical trial in hepatocellular carcinomas anticipated during 1H 2022
- Safety, PK, PD, objective response rate (ORR), and efficacy data in injected and non-injected tumors from dose escalation cohorts 1-5 in the Phase 1/2 trial of exoSTING and recommended Phase 2 dose expected in late 1H 2022
- Initial safety, PK/PD and efficacy data from at least the first cohort of CTCL patients in the Phase 1 clinical trial of exoIL-12 anticipated in late 1H 2022
- Presentation of new data from engEx-AAV discovery program describing the generation of potent and high-yield exosome-associated AAV constructs as a strategy for improving gene therapy delivery at the American Society of Gene and Cell Therapy Annual Meeting to be held May 16-19, 2022

Dr. Williams added, “As we have noted in prior quarters, enrollment in the exoIL-12 study at trial sites in the UK has been challenging, and we have worked to pursue options for expediting enrollment. We’re looking forward to the positive impact of protocol enhancements for this trial to include a broader CTCL population (stage IIIa) and the potential to enroll patients with cutaneous malignancies responsive to rIL-12 in past studies – including Kaposi’s sarcoma, Merkel cell carcinoma, and Squamous cell carcinoma – each orphan cutaneous diseases treated by the same physicians, where local treatment is common.”

First Quarter 2022 Financial Results

Total revenues for the quarter ended March 31, 2022, were $12.7 million, compared to $13.2 million for the same period in 2021. These results reflect deferred revenue recognized under the Company’s collaboration with Jazz Pharmaceuticals.

Net loss for the quarter ended March 31, 2022, was $8.0 million, compared to a net loss of $10.3 million for the same period in 2021. The decrease in

net loss for the quarter was driven primarily by a reduction in research and development expenses, some of which were in connection with the Company's agreement with Lonza.

Research and development expenses were $14.2 million for the quarter ended March 31, 2022, compared to $16.6 million for the same period in 2021. The decrease in research and development expenses was driven primarily by decreases in lab expenses and personnel-related costs in connection with our agreement with Lonza.

General and administrative expenses were $6.7 million for the quarter ended March 31, 2022, compared to $6.6 million for the same period in 2021. The increase was driven primarily by an increase in personnel expenses.

As of March 31, 2022, Codiak had cash, cash equivalents, and marketable securities of approximately $56.5 million.

About Codiak BioSciences
Codiak is a clinical-stage biopharmaceutical company pioneering the development of exosome-based therapeutics, a new class of medicines with the potential to transform the treatment of a wide spectrum of diseases with high unmet medical need. By leveraging the biology of exosomes as natural intercellular transfer mechanisms, Codiak has developed its proprietary engEx Platform to expand upon the innate properties of exosomes to design, engineer and manufacture novel exosome therapeutic candidates. Codiak has utilized its engEx Platform to generate a deep pipeline of engineered exosomes aimed at treating a broad range of disease areas, spanning oncology, infectious disease and rare disease.

Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, among other things, statements concerning the development and therapeutic potential of exoSTING and exoIL-12, including timing of release of data, statements concerning the development of exoASO-STAT6, including the initiation timing of its clinical program, and statements regarding the capabilities and potential of Codiak's engEx Platform and engineered exosomes generally. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. For a discussion of these risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Codiak's Annual Report on Form 10-K for the year ended December 31, 2021, and in subsequent filings with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties and other important factors in Codiak's subsequent filings with the Securities and Exchange Commission. All information in this press release is current as of the date of this report, and Codiak undertakes no duty to update this information unless required by law.

- financial tables follow –

CODIAK BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(unaudited)

	MARCH 31, 2022	DECEMBER 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 56,494	$ 76,938
Prepaid manufacturing expenses	7,308	7,315
Prepaid expenses and other current assets	6,111	5,918
Total current assets	69,913	90,171
Property and equipment, net	22,456	23,479
Restricted cash	4,170	4,170
Operating right-of-use assets	21,638	21,957
Prepaid manufacturing expenses, net of current portion	31,893	31,893
Total assets	$ 150,070	$ 171,670
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,516	$ 1,838
Accrued expenses	6,808	9,703
Deferred revenue	442	12,963
Operating lease liabilities	2,775	2,661
Total current liabilities	11,541	27,165
Long-term liabilities:		
Deferred revenue, net of current portion	30,503	30,686
Note payable, net of discount	25,514	25,430
Operating lease liabilities, net of current portion	34,133	34,884
Other long-term liabilities	-	-
Total liabilities	101,691	118,165
Commitments and contingencies		
Stockholders' equity:		

Common stock, $0.0001 par value; 150,000,000 shares authorized as of March 31, 2022 and December 31, 2021; 22,493,867 and 22,383,830 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	2	2
Additional paid-in capital	381,652	378,750
Accumulated deficit	(333,275)	(325,247)
Total stockholders' equity	48,379	53,505
Total liabilities and stockholders' equity	$ 150,070	$ 171,670

CODIAK BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)
(unaudited)

	THREE MONTHS ENDED MARCH 31,	
	2022	**2021**
Revenue:		
Collaboration revenue	$ 12,704	$ 13,191
Total revenue	12,704	13,191
Operating expenses:		
Research and development	14,248	16,550
General and administrative	6,707	6,588
Total operating expenses	20,955	23,138
Loss from operations	(8,251)	(9,947)
Other income (expense):		
Interest expense	819	(698)
Interest income	4	5
Other income	(600)	332
Total other expense, net	223	(361)
Net loss	$ (8,028)	$ (10,308)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.36)	$ (0.51)
Weighted average common shares outstanding, basic and diluted	22,436,938	20,333,398

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