Codiak BioSciences Reports Second Quarter 2022 Financial Results and Operational Progress

August 4, 2022

– Reported platform-validating initial data from Phase 1 studies of exoSTING™ and exoIL-12™; plans to initiate Phase 2 studies for both programs in 1H 2023 –

– Initiated patient dosing in Phase 1 clinical trial of exoASO™-STAT6 in patients with advanced hepatocellular carcinoma, liver metastases from primary gastric cancer and colorectal cancer –

– Partnered with CEPI to advance pan *Betacoronavirus* candidate –

– Presented positive preclinical data on the Company's engEx-AAV™ discovery program –

CAMBRIDGE, Mass., Aug. 04, 2022 (GLOBE NEWSWIRE) -- Codiak BioSciences, Inc. (NASDAQ: CDAK), a clinical-stage biopharmaceutical company pioneering the development of exosome-based therapeutics as a new class of medicines, today reported second quarter 2022 financial results and recent operational progress.

"During the second quarter we made strong progress supporting our approach and making advancements across our pipeline. We reported Phase 1 data sets from both our exoSTING™ and exoIL-12™ programs, further validating our engEx® platform, and demonstrating we were able to deliver repeat doses of exoSTING™ and exoIL-12™ to the tumor with a high level of specificity. Importantly, we did so with no observed systemic exposure or associated toxicity, and an enhanced therapeutic index – while demonstrating tumor shrinkage in both injected and uninjected lesions," said Douglas E. Williams, Ph.D., President and CEO of Codiak. "We also initiated a Phase 1 study of exoASO™-STAT6, our third program to enter the clinic, in patients with certain liver, gastric and colorectal cancers. These updates, in combination with preclinical data showing the promise of our engEx-AAV ™ program and a partnership with CEPI to advance our pan *Betacoronavirus* program, show that Codiak is broadly advancing its portfolio programs in 2022, momentum we aim to carry through this year and into 2023."

Second Quarter 2022 and Recent Highlights

- Announced platform-validating data from Phase 1 trials of exoSTING™ and exoIL-12™; both candidates demonstrated potential for best-in-class profile; Codiak has identified a recommended Phase 2 dose for each program and intends to finalize study plans with the FDA during the second half of this year to prepare for initiation of Phase 2 trials for both candidates early next year.
    - In a Phase 1 trial, exoIL-12™ demonstrated a differentiating safety and tolerability profile, with no detectable systemic exposure of IL-12 and no treatment-related adverse events, which has not previously been reported by others with recombinant IL-12. The two patients with cutaneous T cell lymphoma (CTCL) who have been treated each received multiple (>20) injections of exoIL-12 and experienced tumor regressions in both injected and non-injected lesions, including a partial response in one patient.
    - In the Phase 1/2 clinical trial evaluating exoSTING™ as a single agent in patients with late-stage refractory solid tumors, data across all five dose cohorts showed repeat doses of exoSTING™ were well-tolerated, demonstrated tumor retention with no systemic exposure of the STING agonist, and in a subset of patients, tumor shrinkage was observed in injected and uninjected lesions.
- Initiated patient dosing in the Phase 1 clinical trial of exoASO™-STAT6 in patients with advanced hepatocellular carcinoma, liver metastases from primary gastric cancer and colorectal cancer; exoASO™-STAT6 is Codiak's third clinical program and the first to evaluate a systemically administered exosome-based drug candidate.
- Partnered with CEPI to continue the advancement of vaccine candidates from the Company's pan *Betacoronavirus* program; as part of the partnership, CEPI will provide seed funding of up to $2.5 million, which Codiak anticipates will fund the completion of preclinical development and identification of a clinical candidate.
- Presented preclinical data on the Company's engEx-AAV™ discovery program, a novel strategy that aims to leverage exosomes to improve adeno-associated virus (AAV) vector gene therapy, at the 25th Annual Meeting of the American Society of Gene and Cell Therapy (ASGCT); data demonstrated that exosome engineering generates significant increases in AAV yield compared to unmodified exosomes, while retaining the functionality to transduce cells with AAV and resist neutralizing antibodies that impair gene therapy efficacy.

Anticipated Milestones and Events

- Initiate Phase 2 study of exoIL-12™ in an expanded group of tumor types in 1H 2023; continue to monitor patients enrolled in Phase 1 study.
- Initiate Phase 2 study of exoSTING™ in bladder cancer in 1H 2023; continue to monitor patients enrolled in ongoing Phase 1/2 study, reporting additional data at an upcoming scientific conference.

- Continue enrollment for ongoing Phase 1 trial for exoASO™-STAT6, with initial data expected in 1H 2023.
- Advance exoVACC™ pan*Betacoronavirus* program toward identification of a clinical candidate through new partnership with CEPI.

Second Quarter 2022 Financial Results

Total revenues for the quarter ended June 30, 2022, were $13.1 million, compared to $0.9 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 June 30, 2022, was $6.8 million, compared to a net loss of $21.8 million for the same period in 2021. The decrease in net loss for the quarter was driven primarily by an increase in revenues in connection with the Company's agreement with Jazz Pharmaceuticals.

Research and development expenses were $12.8 million for the quarter ended June 30, 2022, compared to $15.4 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 the Company's agreement with Lonza.

General and administrative expenses were $7.4 million for the quarter ended June 30, 2022, compared to $6.9 million for the same period in 2021. The increase was due primarily to professional services driven by legal fees for intellectual property rights.

As of June 30, 2022, Codiak had cash, cash equivalents, and marketable securities of approximately $41.8 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 initiation of clinical trials, the release of data from clinical trials and the results of those trials, statements concerning the clinical development of exoASO™-STAT6, 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. In particular, the statements regarding the initiation and timing of clinical trials are dependent upon availability of sufficient cash resources, as to which the Company can make no assurance. 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 (SEC), as well as discussions of potential risks, uncertainties and other important factors in Codiak's subsequent filings with the SEC. 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)

	JUNE 30, 2022	DECEMBER 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 41,785	$ 76,938
Prepaid manufacturing expenses	9,063	7,315
Prepaid expenses and other current assets	5,161	5,918
Total current assets	56,009	90,171
Property and equipment, net	21,557	23,479
Restricted cash	4,170	4,170
Operating right-of-use assets	21,304	21,957
Prepaid manufacturing expenses, net of current portion	29,670	31,893
Total assets	$ 132,710	$ 171,670
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,131	$ 1,838
Accrued expenses	7,699	9,703
Deferred revenue	292	12,963
Operating lease liabilities	2,891	2,661
Total current liabilities	12,013	27,165

Long-term liabilities:		
Deferred revenue, net of current portion	17,341	30,686
Note payable, net of discount	25,596	25,430
Operating lease liabilities, net of current portion	33,362	34,884
Other long-term liabilities	-	-
Total liabilities	88,312	118,165
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value; 150,000,000 shares authorized as of June 30, 2022 and December 31, 2021; 22,545,531 and 22,383,830 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	2	2
Additional paid-in capital	384,446	378,750
Accumulated deficit	(340,050)	(325,247)
Total stockholders' equity	44,398	53,505
Total liabilities and stockholders' equity	$ 132,710	$ 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 JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2022	2021	2022	2021
Revenue:				
Collaboration revenue	$ 13,145	$ 890	$ 25,849	$ 14,081
Total revenue	13,145	890	25,849	14,081
Operating expenses:				
Research and development	12,798	15,419	27,045	31,969
General and administrative	7,364	6,937	14,071	13,525
Total operating expenses	20,162	22,356	41,116	45,494
Loss from operations	(7,017)	(21,466)	(15,267)	(31,413)
Other income (expense):				
Interest expense	(649)	(704)	(1,250)	(1,401)
Interest income	34	9	38	14
Other income	848	352	1,667	683
Realized gain	9	-	9	-
Total other income (expense), net	242	(343)	464	(704)
Net loss	$ (6,775)	$ (21,809)	$ (14,803)	$ (32,117)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.30)	$ (0.99)	$ (0.66)	$ (1.51)
Weighted average common shares outstanding, basic and diluted	22,493,879	22,117,593	22,444,799	21,230,424

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