

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

**Date of Report (date of earliest event reported)
November 3, 2022**

Codiak BioSciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-39615
(Commission
File Number)

47-4926530
(I.R.S. Employer
Identification Number)

**35 CambridgePark Drive, Suite 500
Cambridge, MA 02140**
(Address of principal executive offices and zip code)

(617) 949-4100
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	CDAK	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 - Results of Operations and Financial Condition

On November 3, 2022, Codiak BioSciences, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended September 30, 2022. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The information furnished under this Item 2.02 and in the accompanying Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference in such filing.

Item 9.01 - Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release, dated November 3, 2022, by Codiak BioSciences, Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 3, 2022

Codiak BioSciences, Inc.

By: /s/ Douglas E. Williams

Name: Douglas E. Williams, Ph.D.

Title: Chief Executive Officer and President



Codiak BioSciences Reports Third Quarter 2022 Financial Results and Operational Progress

- Patient enrollment continuing in Phase 1 clinical trial of exoASO™-STAT6 in patients with advanced hepatocellular carcinoma; preliminary data anticipated during 1H 2023 –
- Presented preclinical data showing exoVACC™ pan beta coronavirus vaccine, supported by CEPI, elicits broad protective immunity against variants of SARS-CoV-2 and other potentially human transmissible animal coronaviruses –
- Two preclinical abstracts accepted at SITC 2022 for exoASO-STAT6 and exoASO™-C/EBPβ–

CAMBRIDGE, Mass., Nov. 3, 2022 — 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 third quarter 2022 financial results and recent operational progress.

“During the third quarter we prioritized our pipeline to focus on the clinical trial underway with exoASO™-STAT6 in patients with certain liver, gastric and colorectal cancers, and on advancing our engEx® Platform and its potential in vaccine development and gene delivery,” said Douglas E. Williams, Ph.D., President and CEO of Codiak. “We are also grateful for the support of our existing shareholders and the new investors who participated in our recent financing and we remain focused on advancing our priority programs and delivering data from the exoASO-STAT6 clinical trial anticipated in the first half of 2023.”

Third Quarter 2022 and Recent Highlights

- Continued patient enrollment in the Phase 1 clinical trial of systemically administered exoASO-STAT6 in patients with advanced hepatocellular carcinoma, liver metastases from primary gastric cancer and colorectal cancer.
- Presented preclinical data at Vaccines Summit 2022 in October demonstrating Codiak’s exoVACC™ pan beta coronavirus vaccine elicits broad protective immunity against known variants of SARS-CoV-2 and seven SARS-related coronaviruses that are currently in bats and may have a high potential to jump into humans.
- Partnered with CEPI (Coalition for Epidemic Preparedness Innovations) in early Q3 to continue the advancement of vaccine candidates from the Company’s pan beta coronavirus program. 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.
- Announced financing, restructuring and re-prioritization to focus on delivering data from the ongoing clinical trial of exoASO-STAT6, advancing exoVACC, and supporting the engEx-AAV™ discovery program, a novel strategy that aims to enable repeat dosing of gene delivery constructs.

Anticipated Milestones and Events

- Continue enrollment in Phase 1 trial for exoASO-STAT6, with initial data expected in 1H 2023.
- Present new preclinical data for macrophage targeting programs exoASO-STAT6 and exoASO™-C/EBPβ at the Society for Immunotherapy of Cancer (SITC) in November 2022.

- Further validate engEx-AAV gene delivery platform, with *in vivo* proof of concept data expected later this year, to be presented in 1H 2023.
- Advance exoVACC pan beta coronavirus program toward identification of a clinical candidate through partnership with CEPI.
- Pursue partnership opportunities for select programs, the engEx Platform or at the corporate level to continue advancing this new modality of exosome-based therapeutics.

Third Quarter 2022 Financial Results

Total revenues for the quarter ended September 30, 2022 were \$0.5 million, compared to \$1.2 million for the same period in 2021. Revenues for the third quarter 2022 reflect grant revenue from the Company's agreement with CEPI.

Net loss for the quarter ended September 30, 2022 was \$19.3 million, compared to a net loss of \$21.7 million for the same period in 2021. The decrease in net loss for the quarter was driven primarily by decreases in lab expenses and personnel-related costs in connection with the Company's agreement with Lonza.

Research and development expenses were \$10.8 million for the quarter ended September 30, 2022, compared to \$15.5 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 \$6.6 million for the quarter ended September 30, 2022, compared to \$7.2 million for the same period in 2021. The decrease was due primarily to reduced personnel costs, partially offset by an increase in legal fees for intellectual property rights.

As of September 30, 2022, Codiak had cash, cash equivalents, and marketable securities of approximately \$51.8 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 the Company's portfolio, the clinical development of exoASO-STAT6, statements regarding the capabilities and potential of Codiak's engEx Platform and engineered exosomes generally, and statements regarding the program reprioritization, plans to expand discussions related to potential strategic corporate and program-based partnerships, and the restructuring of operations. 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, and statements regarding the restructuring are dependent on Codiak's ability to successfully implement the restructuring and the impact of the restructuring on Codiak's business, as to which the Company can make no assurances. 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)

	SEPTEMBER 30, 2022	DECEMBER 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 51,762	\$ 76,938
Prepaid manufacturing services	6,727	7,315
Prepaid expenses and other current assets	2,744	5,918
Total current assets	61,233	90,171
Property and equipment, net of accumulated depreciation of \$14,990 and \$11,809	20,538	23,479
Restricted cash	4,170	4,170
Operating right-of-use assets	20,955	21,957
Prepaid manufacturing services, net of current portion	27,500	31,893
Total assets	<u>\$ 134,396</u>	<u>\$ 171,670</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,956	\$ 1,838
Accrued expenses	8,126	9,703
Deferred revenue	1,363	12,963
Operating lease liabilities	3,011	2,661
Total current liabilities	14,456	27,165
Long-term liabilities:		
Deferred revenue, net of current portion	17,317	30,686
Note payable, net of discount	25,693	25,430
Derivative liability - warrants	5,428	—
Operating lease liabilities, net of current portion	32,573	34,884
Total liabilities	95,467	118,165
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 150,000,000 shares authorized as of September 30, 2022 and December 31, 2021; 36,829,626 and 22,383,830 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	4	2
Additional paid-in capital	398,253	378,750
Accumulated deficit	(359,328)	(325,247)
Total stockholders' equity	38,929	53,505
Total liabilities and stockholders' equity	<u>\$ 134,396</u>	<u>\$ 171,670</u>

CODIAK BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

(unaudited)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021	2022	2021
Revenue:				
Collaboration revenue	\$ 28	\$ 1,157	\$ 25,877	\$ 15,238
Grant revenue	494	—	494	—
Total revenue	522	1,157	26,371	15,238
Operating expenses:				
Research and development	10,847	15,467	37,893	47,436
General and administrative	6,563	7,186	20,634	20,711
Impairment of prepaid manufacturing services	4,508	—	4,508	—
Total operating expenses	21,918	22,653	63,035	68,147
Loss from operations	(21,396)	(21,496)	(36,664)	(52,909)
Other income (expense):				
Interest expense	(758)	(689)	(2,007)	(2,091)
Interest income	119	4	157	18
Other income	35	479	1,711	1,163
Change in fair value of derivative liability - warrants	2,722	—	2,722	—
Total other income (expense), net	2,118	(206)	2,583	(910)
Net loss	\$ (19,278)	\$ (21,702)	\$ (34,081)	\$ (53,819)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.77)	\$ (0.97)	\$ (1.46)	\$ (2.49)
Weighted average common shares outstanding, basic and diluted	25,159,757	22,325,334	23,373,684	21,599,405

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