
**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)
August 5, 2021**

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 August 5, 2021, Codiak BioSciences, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended June 30, 2021. The release also provided updated timing for announcement of data from the initial dose escalation cohorts in the Phase 1/2 trial of exoSTING. 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 August 5, 2021, by Codiak BioSciences, Inc.

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: August 5, 2021

Codiak BioSciences, Inc.

By: /s/ Douglas E. Williams

Name: Douglas E. Williams, Ph.D.

Title: Chief Executive Officer and President



Codiak BioSciences Reports Second Quarter 2021 Financial Results and Operational Progress

- Initial safety and PK/PD data from Phase 1/2 study of exoSTING™ now expected in the fourth quarter of 2021–
 - Initial safety and efficacy data from Phase 1 trial of exoIL-12™ in CTCL anticipated by year-end –
- IND filing for third clinical program, exoASO™-STAT6, planned for 2H 2021–

CAMBRIDGE, Mass., August 5, 2021 — 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 second quarter 2021 financial results and operational progress.

“We continue to be intensely focused on execution of our two lead clinical programs, with plans to deliver near-term data readouts from both the exoSTING and exoIL-12 trials. We anticipate sharing safety data and a differentiating pharmacologic profile from initial dose escalation cohorts in the Phase 1/2 trial of exoSTING in the fourth quarter of 2021, and we expect to report initial safety, PK/PD and efficacy data from CTCL patients in the exoIL-12 Phase 1 trial by year end,” said Douglas E. Williams, Ph.D., President and Chief Executive Officer of Codiak. “We are also prosecuting multiple preclinical programs that together demonstrate the versatility of our platform and we look forward to filing an IND this year for our third engineered exosome therapeutic candidate, exoASO-STAT6 for the treatment of myeloid-rich cancers.”

Second Quarter 2021 and Recent Highlights

- Presented new preclinical data on exoAAV™, exoVACC™, exoASO-STAT6, and the ability of engineered exosomes to direct tropism at the American Society of Gene and Cell Therapy (ASGCT) 24th Annual Meeting
- Published manuscript highlighting the exoSTING preclinical program in *Communications Biology*, a Nature Research publication
- Presented tolerability, pharmacokinetic (PK)/pharmacodynamic (PD) data from healthy volunteer portion of the exoIL-12 Phase 1 clinical trial and preclinical data from the exoASO-STAT6 program at the American Association for Cancer Research (AACR) Annual Meeting
- Appointed Jennifer Wheler, M.D., as Chief Medical Officer
- Added Anne-Virginie Eggimann, M.Sc., to Board of Directors

Anticipated Milestones and Events

- Initial safety, PK, and PD data from dose escalation cohorts 1-3 on the Phase 1/2 trial of exoSTING (CDK-002) in patients with advanced/metastatic solid tumors with injectable lesions expected in the fourth quarter of 2021
- IND filing for exoASO-STAT6 (CDK-004) anticipated during the second half of 2021
- Initial safety, PK/PD and efficacy data in CTCL patients from the Phase 1 trial of exoIL-12 (CDK-003) expected by year-end 2021

Second Quarter 2021 Financial Results

Total revenues for the quarter ended June 30, 2021, were \$0.9 million, compared to \$0.2 million for the same period in 2020. This increase was due to deferred revenue recognized from ongoing research and development collaborations.

Net loss for the quarter ended June 30, 2021, was \$21.8 million, compared to a net loss of \$15.9 million for the same period in 2020. Net loss for the quarter was driven primarily by clinical development, general and administrative, and personnel expenses, and ongoing development of the engEx Platform.

Research and development expenses were \$15.4 million for the quarter ended June 30, 2021, compared to \$11.6 million for the same period in 2020. The increase in research and development expenses was driven by an increase in engEx Platform expenses, partially offset by decreased manufacturing and preclinical costs as Codiak's lead candidates progressed into the clinic during the second half of 2020.

General and administrative expenses were \$6.9 million for the quarter ended June 30, 2021, compared to \$4.4 million for the same period in 2020. The increase was driven primarily by an increase in general and administrative headcount to support our overall growth and our transition to becoming a public company.

As of June 30, 2021, Codiak had cash and cash equivalents of approximately \$113.7 million.

About Codiak BioSciences

Codiak is a clinical-stage biopharmaceutical company focused on 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, neuro-oncology, neurology, neuromuscular disease and infectious 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 from clinical trials and the results of those trials, statements concerning the development of exoASO-STAT6, including the timing of IND filing and initiation of clinical trials, 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 quarter ended December 31, 2020, 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
(Unaudited, In thousands, except share and per share data)

	JUNE 30, 2021	DECEMBER 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 113,681	\$ 88,915
Prepaid expenses and other current assets	5,641	4,843
Total current assets	119,322	93,758
Property and equipment, net	30,263	31,410
Restricted cash, net of current portion	4,170	4,170
Operating right-of-use assets	21,519	22,003
Total assets	<u>\$ 175,274</u>	<u>\$ 151,341</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,782	\$ 2,018
Accrued expenses	7,689	8,870
Deferred revenue	9,117	5,281
Operating lease liabilities	2,333	1,482
Total current liabilities	20,921	17,651
Long-term liabilities:		
Deferred revenue, net of current portion	41,746	57,416
Note payable, net of discount	25,230	24,960
Operating lease liabilities, net of current portion	35,306	36,540
Other long-term liabilities	207	207
Total liabilities	123,410	136,774
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 150,000,000 shares authorized as of June 30, 2021 and December 31, 2020; 22,272,975 and 18,787,579 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	2	2
Additional paid-in capital	372,069	302,655
Accumulated deficit	(320,207)	(288,090)
Total stockholders' equity	51,864	14,567
Total liabilities and stockholders' equity	<u>\$ 175,274</u>	<u>\$ 151,341</u>

CODIAK BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited, in thousands, except share and per share data)

	THREE MONTHS ENDED		SIX MONTHS ENDED	
	JUNE 30,		JUNE 30,	
	2021	2020	2021	2020
Revenue:				
Collaboration revenue	\$ 890	\$ 187	\$ 14,081	\$ 321
Total revenue	890	187	14,081	321
Operating expenses:				
Research and development	15,419	11,622	31,969	30,013
General and administrative	6,937	4,358	13,525	8,591
Total operating expenses	22,356	15,980	45,494	38,604
Loss from operations	(21,466)	(15,793)	(31,413)	(38,283)
Other income (expense):				
Interest expense	(704)	(294)	(1,401)	(589)
Interest income	9	19	14	242
Other income	352	155	683	215
Total other expense, net	(343)	(120)	(704)	(132)
Net loss	\$ (21,809)	\$ (15,913)	\$ (32,117)	\$ (38,415)
Cumulative dividends on redeemable convertible preferred stock	—	(3,420)	—	(6,839)
Net loss attributable to common stockholders	\$ (21,809)	\$ (19,333)	\$ (32,117)	\$ (45,254)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.99)	\$ (6.44)	\$ (1.51)	\$ (15.07)
Weighted average common shares outstanding, basic and diluted	22,117,593	3,003,887	21,230,424	3,002,773
Comprehensive loss:				
Net loss	\$ (21,809)	\$ (15,913)	\$ (32,117)	\$ (38,415)
Other comprehensive loss:				
Unrealized loss on investments, net of tax of \$0	—	(2)	—	(43)
Total other comprehensive loss	—	(2)	—	(43)
Comprehensive loss	\$ (21,809)	\$ (15,915)	\$ (32,117)	\$ (38,458)

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