
**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 4, 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 November 4, 2021, Codiak BioSciences, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended September 30, 2021. 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 4, 2021, 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 4, 2021

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 2021 Financial Results and Recent Operational Progress

- Announced strategic long-term exosome manufacturing collaboration with Lonza –
- Initial data readout from exoSTING™ clinical trial expected in Q4 2021; initial data from exoIL-12 trial in CTCL patients now anticipated in H1 2022 –
- Investigational New Drug (IND) application filing for exoASO™-STAT6 expected in Q4 2021 –
- Preclinical data showing new potential therapeutic applications for three engineered exosome candidates to be presented during SITC 2021 next week –

CAMBRIDGE, Mass., November 4, 2021 — 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 2021 financial results and recent operational progress.

“We made steady progress in the third quarter toward our goals for Codiak’s pipeline,” said Douglas E. Williams, Ph.D., President and Chief Executive Officer of Codiak. “Patient dosing and follow up in the Phase 1/2 trial of exoSTING has proceeded well, and we anticipate providing preliminary safety and pharmacologic data in patients from the initial dose escalation cohorts shortly. Enrollment in the CTCL portion of our exoIL-12 Phase 1 trial has ramped more slowly than anticipated due predominantly to COVID-related restrictions in the UK, and based on the latest correspondence with our sites, we now estimate that data will be available in the first half of next year. Our recently announced strategic collaboration with Lonza affirms that we are at the forefront of a promising new therapeutic modality. This partnership will expand and accelerate the creation of new exosome production technologies and secures a manufacturing partner for our later-stage clinical and potential commercial material.”

Third Quarter 2021 and Recent Highlights

- Entered into strategic exosome manufacturing collaboration with Lonza, which includes the pending acquisition of Codiak’s manufacturing site in Lexington, MA and the formation of a joint Center of Excellence for exosome manufacturing. Under terms of the agreement, Codiak will receive approximately \$65 million of in-kind manufacturing services for its clinical-stage programs, while retaining its core exosome engineering and loading expertise and pipeline. Lonza will assume operation of the Lexington facility.
- Continued to progress subject dosing and follow up in the Phase 1/2 clinical trial of exoSTING (CDK-002) for the treatment of advanced/metastatic, recurrent and injectable solid tumors
- Advanced cutaneous T cell lymphoma (CTCL) portion of Phase 1 trial of exoIL-12 (CDK-003)
- Completed IND-enabling studies for exoASO-STAT6 (CDK-004) for the intravenous treatment of myeloid-rich cancers
- Welcomed Lini Pandite, MBChB, MBA to Board of Directors

Anticipated Milestones and Events

- Three poster presentations at the 36th Annual Meeting of the Society for Immunotherapy of Cancer (SITC 2021) on November 12 and 13, including new preclinical data on exoASO-STAT6 in hepatocellular carcinoma, exoSTING in leptomeningeal disease and the combination of exoSTING and exoIL-12 in solid tumors
- Initial safety, PK, and PD data from dose escalation cohorts 1-3 on the Phase 1/2 trial of exoSTING in patients with advanced/metastatic solid tumors with injectable lesions expected in the fourth quarter of 2021

- IND filing for exoASO-STAT6 anticipated during the fourth quarter of 2021
- Initial safety, PK/PD and efficacy data in CTCL patients are now expected in the first half of next year due predominantly to COVID-related restrictions in the U.K. that are impacting the Phase 1 clinical trial sites for exoIL-12 (CDK-003)

Third Quarter 2021 Financial Results

Total revenues for the quarter ended September 30, 2021, were \$1.2 million, compared to \$1.0 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 September 30, 2021, was \$21.7 million, compared to a net loss of \$35.3 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 \$15.5 million for the quarter ended September 30, 2021, compared to \$30.6 million for the same period in 2020. The decrease in research and development expenses in the third quarter reflects a one-time payment to Kayla Therapeutics S.A.S. under a license agreement in the prior year, partially offset by increases in personnel costs and other engEx platform costs, including manufacturing and preclinical costs as we progressed Codiak's lead candidates into the clinic.

General and administrative expenses were \$7.2 million for the quarter ended September 30, 2021, compared to \$5.3 million for the same period in 2020. The increase was driven primarily by an increase in general business expenses, including corporate insurance costs, and additional general and administrative headcount to support our overall growth and our transition to becoming a public company.

As of September 30, 2021, Codiak had cash and cash equivalents of approximately \$98.6 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, neuro-oncology, neurology, 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 year 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)

	SEPTEMBER 30, 2021	DECEMBER 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 98,584	\$ 88,915
Prepaid expenses and other current assets	5,329	4,843
Total current assets	103,913	93,758
Property and equipment, net	29,384	31,410
Restricted cash, net of current portion	4,170	4,170
Operating right-of-use assets	21,258	22,003
Total assets	<u>\$ 158,725</u>	<u>\$ 151,341</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,998	\$ 2,018
Accrued expenses	9,315	8,870
Deferred revenue	9,352	5,281
Operating lease liabilities	2,438	1,482
Total current liabilities	23,103	17,651
Long-term liabilities:		
Deferred revenue, net of current portion	41,393	57,416
Note payable, net of discount	25,352	24,960
Operating lease liabilities, net of current portion	34,664	36,540
Other long-term liabilities	207	207
Total liabilities	<u>124,719</u>	<u>136,774</u>
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 150,000,000 shares authorized as of September 30, 2021 and December 31, 2020; 22,361,305 and 18,787,579 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	2	2
Additional paid-in capital	375,913	302,655
Accumulated deficit	(341,909)	(288,090)
Total stockholders' equity	34,006	14,567
Total liabilities and stockholders' equity	<u>\$ 158,725</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 SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2021	2020	2021	2020
Revenue:				
Collaboration revenue	\$ 1,157	\$ 954	\$ 15,238	\$ 1,275
Total revenue	<u>1,157</u>	<u>954</u>	<u>15,238</u>	<u>1,275</u>
Operating expenses:				
Research and development	15,467	30,640	47,436	60,653
General and administrative	7,186	5,342	20,711	13,933
Total operating expenses	<u>22,653</u>	<u>35,982</u>	<u>68,147</u>	<u>74,586</u>
Loss from operations	(21,496)	(35,028)	(52,909)	(73,311)
Other income (expense):				
Interest expense	(689)	(607)	(2,091)	(1,196)
Interest income	4	4	18	246
Other income	479	338	1,163	553
Total other expense, net	<u>(206)</u>	<u>(265)</u>	<u>(910)</u>	<u>(397)</u>
Net loss	\$ (21,702)	\$ (35,293)	\$ (53,819)	\$ (73,708)
Cumulative dividends on redeemable convertible preferred stock	—	(3,457)	—	(10,296)
Net loss attributable to common stockholders	\$ (21,702)	\$ (38,750)	\$ (53,819)	\$ (84,004)
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.97)</u>	<u>\$ (12.83)</u>	<u>\$ (2.49)</u>	<u>\$ (27.92)</u>
Weighted average common shares outstanding, basic and diluted	<u>22,325,334</u>	<u>3,020,055</u>	<u>21,599,405</u>	<u>3,008,576</u>
Comprehensive loss:				
Net loss	\$ (21,702)	\$ (35,293)	\$ (53,819)	\$ (73,708)
Other comprehensive loss:				
Unrealized loss on investments, net of tax of \$0	—	—	—	(43)
Total other comprehensive loss	<u>—</u>	<u>—</u>	<u>—</u>	<u>(43)</u>
Comprehensive loss	<u>\$ (21,702)</u>	<u>\$ (35,293)</u>	<u>\$ (53,819)</u>	<u>\$ (73,751)</u>

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