
**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) May 6, 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
Common Stock, par value \$0.0001 per share

Trading symbol(s)
CDAK

Name of each exchange on which registered
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 May 6, 2021, Codiak BioSciences, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended March 31, 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 May 6, 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: May 6, 2021

Codiak BioSciences, Inc.

By: /s/ Douglas E. Williams

Name: Douglas E. Williams, Ph.D.

Title: Chief Executive Officer and President



Codiak BioSciences Reports First Quarter 2021 Financial Results and Operational Progress

- Key clinical data from first in-human studies of engineered exosome therapeutic candidates, exoIL-12™ and exoSTING™, expected this year –
- Data from multiple preclinical programs to be presented at ASGCT 2021 showing broad potential applications for engineered exosomes –

CAMBRIDGE, Mass., May 6, 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 first quarter 2021 financial results and operational progress.

“We are making excellent progress with our clinical and preclinical programs, which continue to generate further confirmatory evidence that our engEx exosome engineering and manufacturing platform can harness exosomes as delivery vehicles for potent and selective therapeutics, not only in immunology, but potentially in vaccines, gene therapy and neuro-oncology/neurology as well,” said Douglas E. Williams, Ph.D., President and Chief Executive Officer of Codiak. “We remain on track to deliver safety, biomarker and preliminary efficacy data from our exoIL-12 and exoSTING clinical programs in oncology and file an IND for our third program, exoASO-STAT6, later this year.”

First Quarter 2021 and Recent Highlights

- Reported positive Phase 1 results for exoIL-12 confirming local pharmacology and dose selection for safety and efficacy trial in patients with early-stage cutaneous T cell lymphoma (CTCL)
- Progressed with subject dosing in the Phase 1/2 clinical trial of exoSTING for the treatment of advanced/metastatic, recurrent and injectable solid tumors
- Continued to advance exoASO™-STAT6 for the intravenous treatment of myeloid-rich cancers through IND-enabling studies
- Detailed versatility of Codiak’s engEx™ Platform in manuscript published in *Molecular Therapeutics*, a Cell partner journal
- Presented pharmacokinetic/pharmacodynamic and tolerability 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, April 10-15
- Published manuscript highlighting the exoSTING preclinical program in *Communications Biology*, a Nature Research publication

Anticipated Milestones and Events

- Four poster presentations at the American Society of Gene and Cell Therapy (ASGCT) 24th Annual Meeting on May 11, including new preclinical data on exoAAV™, exoVACC™, exoASO-STAT6, and the ability of engineered exosomes to direct tropism to neuronal cells of interest
- Safety, biomarker and preliminary pharmacodynamics and efficacy data from the exoSTING Phase 1/2 clinical trial in patients with solid tumors continue to be expected mid-2021, within the third quarter
- Investigational New Drug (IND) application filing for exoASO-STAT6 anticipated during the second half of 2021 to enable initiation of clinical trials
- Safety, biomarker and preliminary pharmacodynamics and efficacy data in CTCL patients from the exoIL-12 Phase 1 trial expected by year-end 2021

First Quarter 2021 Financial Results

Total revenues for the quarter ended March 31, 2021 were \$13.2 million, compared to \$0.1 million for the same period in 2020. This increase was primarily due to the mutual agreement between the Company and Jazz Pharmaceuticals to discontinue their work on exoASO™-STAT3, one of five oncogene targets subject to the Collaboration and License Agreement by and between Codiak and Jazz Pharmaceuticals. The Company recognized the remaining \$10.9 million in deferred revenue allocated to this target as revenue during the three months ended March 31, 2021.

Net loss for the quarter ended March 31, 2021 was \$10.3 million, compared to a net loss of \$22.5 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, offset in part by the \$10.9 million in deferred revenue described above.

Research and development expenses were \$16.6 million for the quarter ended March 31, 2021 compared to \$18.4 million for the same period in 2020. The decrease in research and development expenses was driven primarily by lower manufacturing and preclinical costs as our lead assets progressed into the clinic during the second half of 2020.

General and administrative expenses were \$6.6 million for the quarter ended March 31, 2021 compared to \$4.2 million for the same period in 2020. The increase was driven primarily by an increase in personnel costs and costs associated with transitioning to a public company.

As of March 31, 2021, Codiak had cash, cash equivalents, and marketable securities of approximately \$130.3 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, statements concerning the development of exoASO-STAT6, including the timing of IND filing and initiation 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 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
(In thousands, except share and per share data)
(unaudited)

	<u>MARCH 31,</u> <u>2021</u>	<u>DECEMBER 31,</u> <u>2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 130,272	\$ 88,915
Prepaid expenses and other current assets	4,405	4,843
Total current assets	134,677	93,758
Property and equipment, net	30,885	31,410
Restricted cash, net of current portion	4,170	4,170
Operating right-of-use assets	21,767	22,003
Total assets	<u>\$ 191,499</u>	<u>\$ 151,341</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,162	\$ 2,018
Accrued expenses	6,805	8,870
Deferred revenue	4,345	5,281
Operating lease liabilities	2,230	1,482
Total current liabilities	<u>15,542</u>	<u>17,651</u>
Long-term liabilities:		
Deferred revenue, net of current portion	46,008	57,416
Note payable, net of discount	25,095	24,960
Operating lease liabilities, net of current portion	35,931	36,540
Other long-term liabilities	207	207
Total liabilities	<u>122,783</u>	<u>136,774</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.0001 par value; 150,000,000 shares authorized as of March 31, 2021 and December 31, 2020; 21,996,886 and 18,787,579 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	2	2
Additional paid-in capital	367,112	302,655
Accumulated deficit	(298,398)	(288,090)
Total stockholders' equity	<u>68,716</u>	<u>14,567</u>
Total liabilities and stockholders' equity	<u>\$ 191,499</u>	<u>\$ 151,341</u>

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,	
	2021	2020
Revenue:		
Collaboration revenue	\$ 13,191	\$ 134
Total revenue	13,191	134
Operating expenses:		
Research and development	16,550	18,391
General and administrative	6,588	4,233
Total operating expenses	23,138	22,624
Loss from operations	(9,947)	(22,490)
Other income (expense):		
Interest expense	(698)	(295)
Interest income	5	223
Other income	332	60
Total other expense, net	(361)	(12)
Net loss	\$ (10,308)	\$ (22,502)
Cumulative dividends on redeemable convertible preferred stock	—	(3,419)
Net loss attributable to common stockholders	\$ (10,308)	\$ (25,921)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.51)	\$ (8.64)
Weighted average common shares outstanding, basic and diluted	20,333,398	3,001,660
Comprehensive loss:		
Net loss	\$ (10,308)	\$ (22,502)
Other comprehensive loss:		
Unrealized loss on investments, net of tax of \$0	—	(41)
Total other comprehensive loss	—	(41)
Comprehensive loss	\$ (10,308)	\$ (22,543)

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