
**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) March 17, 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 March 17, 2021, Codiak BioSciences, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter and year ended December 31, 2020 and providing a business update. 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 March 17, 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: March 17, 2021

Codiak BioSciences, Inc.

By: /s/ Douglas E. Williams

Name: Douglas E. Williams, Ph.D.

Title: Chief Executive Officer and President



Codiak BioSciences Reports Fourth Quarter and Full Year 2020 Financial Results and Operational Progress

- First human proof-of-concept data from exoIL-12™ program confirmed desired product profile and enabled dose selection for further evaluation in patients –
- On track to report biomarker, safety and clinical anti-tumor efficacy results in cancer patients in mid-2021 for exoSTING™ and by year-end for exoIL-12 –
- Data from two novel engineered exosome therapeutic programs to be presented at AACR 2021, including initial clinical data for exoIL-12 accepted as late-breaking abstract –

CAMBRIDGE, Mass., March 17, 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 fourth quarter and full year 2020 financial results and operational progress.

“The past year was tremendously productive for Codiak as we brought our first two programs into the clinic, the first ever engineered exosome therapeutic candidates to be tested in humans, and completed a successful initial public offering,” said Douglas E. Williams, Ph.D., President and Chief Executive Officer of Codiak. “The early data from our exoIL-12 program have provided validation of our approach and propel us into what we anticipate will be an exciting year ahead, with multiple data read-outs and the initiation of a third clinical program expected.”

Fourth Quarter 2020 and Recent Highlights

- Reported initial pharmacokinetic/pharmacodynamic and tolerability data from randomized, placebo-controlled healthy volunteer portion of the exoIL-12 Phase 1 clinical trial and selected pharmacological dose and regimen to carry forward into assessment in patients with 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
- Closed IPO in October 2020, raising \$74.4 million in net proceeds
- Published manuscript detailing the exoIL-12 preclinical program in *Molecular Cancer Therapeutics*
- Published manuscript highlighting versatility of the engEx Platform in the online edition of *Molecular Therapy*
- Closed follow-on public offering in February 2021, raising \$62.0 million in net proceeds

Anticipated Milestones and Events

- Late-breaking abstract poster presentation of the full pharmacokinetic/pharmacodynamic and tolerability data from healthy volunteer portion of the exoIL-12 Phase 1 clinical trial at the American Association for Cancer Research (AACR) Annual Meeting, to be held April 10-15, 2021
- Poster presentation of preclinical data from the exoASO-STAT6 program at the AACR Annual Meeting, to be held April 10-15, 2021
- Safety and preliminary pharmacodynamics and efficacy data from exoSTING Phase 1/2 clinical trial in patients with solid tumors expected mid-2021
- Investigational New Drug (IND) application filing for exoASO-STAT6 program to enable initiation of clinical trials anticipated during the second half of 2021

- Biomarker, safety and preliminary pharmacodynamics and efficacy data in CTCL patients from exoIL-12 Phase 1 trial expected by year-end 2021

Fourth Quarter and Full Year 2020 Financial Results

Total revenues for the quarter ended December 31, 2020 were \$1.6 million, compared to \$0.2 million for the same period in 2019. Total revenues for the year ended December 31, 2020 were \$2.9 million, compared to \$0.4 million for the same period in 2019. These increases were primarily due to revenue recognized in connection with our collaboration with Sarepta Therapeutics.

Net loss for the quarter ended December 31, 2020 was \$18.0 million, compared to a net loss of \$21.6 million for the same period in 2019. Net loss for the year ended December 31, 2020 was \$91.7 million, compared to a net loss of \$78.0 million for the same period in 2019. Net loss for the quarter and year was driven primarily by clinical development, general and administrative, and personnel expenses, and ongoing development of the engEx Platform.

Research and development expenses were \$13.3 million for the quarter ended December 31, 2020 compared to \$17.7 million for the same period in 2019. The decrease in research and development expenses was driven primarily by the timing of external manufacturing expenditures in the prior year.

Research and development expenses were \$74.0 million for the year ended December 31, 2020 compared to \$59.5 million for the same period in 2019. The year-over-year increase was primarily driven by an increase in license milestones, personnel costs, and clinical development expenses related to the initiation of the exoIL-12 and exoSTING clinical trials in September 2020.

General and administrative expenses were \$5.9 million for the quarter ended December 31, 2020 compared to \$4.3 million for the same period in 2019. The increase was driven primarily by an increase in personnel costs and costs associated with transitioning to a public company.

General and administrative expenses were \$19.9 million for the year ended December 31, 2020 compared to \$21.0 million for the same period in 2019. The year-over-year decrease was primarily driven by a decrease in consulting, accounting and legal fees.

As of December 31, 2020, Codiak had cash and cash equivalents of approximately \$88.9 million. Subsequent to year end, Codiak closed a public offering in February 2021, raising \$62.0 million in net proceeds. Based on our current operating plan, we expect our cash and cash equivalents as of December 31, 2020, together with the net proceeds from our follow-on public offering in February 2021, will enable us to fund our operating expenses and capital expenditure requirements through the end of 2022.

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 initiation of its clinical program, statements regarding the capabilities and potential of Codiak’s engEx Platform and engineered exosomes generally and Codiak’s financial guidance

including cash runway . 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.

[tables to follow]

CODIAK BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	<u>DECEMBER 31,</u>	
	<u>2020</u>	<u>2019</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 88,915	\$ 10,316
Investments	—	73,065
Restricted cash	—	367
Prepaid expenses and other current assets	4,843	10,370
Total current assets	93,758	94,118
Property and equipment, net	31,410	17,626
Restricted cash, net of current portion	4,170	4,170
Operating right-of-use assets	22,003	—
Other non-current assets	—	48
Total assets	<u>\$ 151,341</u>	<u>\$ 115,962</u>
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 2,018	\$ 2,381
Accrued expenses	8,870	15,818
Deferred revenue	5,281	742
Deferred rent	—	814
Operating lease liability	1,482	—
Total current liabilities	17,651	19,755
Long-term liabilities:		
Deferred revenue, net of current portion	57,416	54,870
Note payable, net of discount	24,960	9,572
Deferred rent, net of current portion	—	9,814
Operating lease liability, net of current portion	36,540	—
Other long-term liabilities	207	—
Total liabilities	<u>136,774</u>	<u>94,011</u>
Commitments and contingencies (Note 10)		
Series A redeemable convertible preferred stock, \$0.0001 par value; No shares authorized, issued, or outstanding as of December 31, 2020; 33,200,000 shares authorized, issued and outstanding as of December 31, 2019; liquidation value as of December 31, 2019 of \$44,169	—	44,169
Series B redeemable convertible preferred stock, \$0.0001 par value; No shares authorized, issued, or outstanding as of December 31, 2020; 21,400,000 shares authorized; 20,520,828 shares issued and outstanding as of December 31, 2019; liquidation value as of December 31, 2019 of \$80,874	—	81,108
Series C redeemable convertible preferred stock, \$0.0001 par value; No shares authorized, issued, or outstanding as of December 31, 2020; 20,204,100 shares authorized; 20,204,079 shares issued and outstanding as of December 31, 2019; liquidation value as of December 31, 2019 of \$89,507	—	89,507
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized and no shares issued or outstanding as of December 31, 2020; no shares authorized, issued or outstanding as of December 31, 2019;	\$ —	\$ —
Common stock, \$0.0001 par value; 150,000,000 shares authorized as of December 31, 2020; 120,000,000 shares authorized as of December 31, 2019; 18,787,579, and 2,997,040 shares issued and outstanding as of December 31, 2020 and 2019, respectively	2	—
Additional paid-in capital	302,655	2
Accumulated other comprehensive income	—	43
Accumulated (deficit)	(288,090)	(192,878)
Total stockholders' equity (deficit)	14,567	(192,833)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 151,341</u>	<u>\$ 115,962</u>

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

	THREE MONTHS ENDED DECEMBER 31,		YEAR ENDED DECEMBER 31,	
	2020	2019	2020	2019
Revenue:				
Collaboration revenue	\$ 1,639	\$ 150	\$ 2,915	\$ 388
Total revenue	1,639	150	2,915	388
Operating expenses:				
Research and development	13,328	17,706	73,981	59,501
General and administrative	5,919	4,253	19,852	21,039
Total operating expenses	19,247	21,959	93,833	80,540
Loss from operations	(17,608)	(21,809)	(90,918)	(80,152)
Other (expense) income:				
Interest income	7	354	253	1,500
Interest expense	(710)	(297)	(1,906)	(300)
Other income	353	114	906	992
Total other (expense) income, net	(350)	171	(747)	2,192
Net loss	\$ (17,958)	\$ (21,638)	\$ (91,665)	\$ (77,960)
Cumulative dividends on redeemable convertible preferred stock	(534)	(3,454)	(10,831)	(13,701)
Net loss attributable to common stockholders	\$ (18,492)	\$ (25,092)	\$ (102,496)	\$ (91,661)
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.14)	\$ (8.37)	\$ (16.18)	\$ (30.66)
Weighted average common shares outstanding, basic and diluted	16,233,377	2,996,942	6,332,841	2,989,423
Comprehensive loss:				
Net loss	\$ (17,958)	\$ (21,638)	\$ (91,665)	\$ (77,960)
Other comprehensive (loss) income:				
Unrealized (loss) gain on investments, net of tax of \$0	—	(20)	(43)	52
Total other comprehensive (loss) income	—	(20)	(43)	52
Comprehensive loss	\$ (17,958)	\$ (21,658)	\$ (91,708)	\$ (77,908)

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