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 10, 2022

Codiak BioSciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39615**	**47-4926530**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(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 10, 2022, Codiak BioSciences, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter and year ended December 31, 2021 and describing recent operational progress. 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

Exhibit Number	Description
99.1	Press release, dated March 10, 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: March 10, 2022

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 2021 Financial Results and Recent Operational Progress

– Reported positive initial data from exoSTING™ clinical trial; on track to provide data from all dose escalation cohorts in late 1H 2022 –

– Investigational New Drug (IND) application cleared for exoASO™-STAT6, with clinical trial initiation expected 1H 2022 –

– Initial safety, PK/PD and efficacy data for exoIL-12™ in CTCL patients anticipated late 1H 2022 –

– Progressed preclinical pan-beta coronavirus vaccine program –

CAMBRIDGE, Mass., March 10, 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 fourth quarter and full year 2021 financial results and recent operational progress.

“We are making a strong start in 2022 thanks to progress with our development programs in 2021 and into this year, and plan to report clinical data for two of our engineered exosome therapeutic candidates and initiate clinical development for a third candidate all in the first half of the year,” said Douglas E. Williams, Ph.D., President and CEO of Codiak. “The platform we’ve developed at Codiak allows us to deliver multiple classes of therapeutics with a high degree of precision to specific cells and our clinical data from two programs has already shown promising safety and predictable PK/PD relationships. The emergence of programs in vaccines and gene delivery highlight the breadth of opportunity across multiple therapeutic areas with the engEx™ platform.”

Fourth Quarter 2021 and Recent Highlights

- Reported positive initial data from dose cohorts 1-3 in the Phase 1/2 clinical trial of exoSTING (CDK-002) for the treatment of advanced/metastatic, recurrent and injectable solid tumors; progressed subject dosing to cohorts 4 and 5 and follow up in all dose cohorts
- Advanced cutaneous T cell lymphoma (CTCL) portion of Phase 1 trial of exoIL-12 (CDK-003)
- Filed and received U.S. FDA clearance of Investigational New Drug (IND) application for exoASO-STAT6 (CDK-004) for the intravenous treatment of hepatocellular carcinoma
- Presented three abstracts at the 36th Annual Meeting of the Society for Immunotherapy of Cancer (SITC 2021), 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
- Announced new preclinical data from the exoVACC™ exosome-based vaccine platform at the World Vaccine & Immunotherapy Congress (WVIC) 2021
- Published a manuscript describing the full exoASO-STAT6 preclinical program in the American Association for the Advancement of Science’s journal, *Science Advances*

Anticipated Milestones and Events

- Safety, PK, PD, and objective response rate (ORR) data from dose escalation cohorts 1-5 in the Phase 1/2 trial of exoSTING and recommended Phase 2 dose expected in late 1H 2022
- First-in-human dosing for exoASO-STAT6 in a Phase 1 clinical trial in hepatocellular carcinomas anticipated in 1H 2022

- Initial safety, PK/PD and efficacy data in CTCL patients in the Phase 1 clinical trial of exoIL-12 anticipated in late 1H 2022. While COVID-related restrictions in the UK that impacted clinical trial sites last year are abating, Codiak continues to work with those sites to explore options to facilitate enrollment.
- Poster presentation of preclinical data for exoASO-C/EBPß, a proprietary engineered exosome loaded with antisense oligonucleotides targeting C/EBPß, at the American Association for Cancer Research (AACR) Annual Meeting, to be held April 8-13, 2022
- Presentation of new preclinical data from the exoVACC pan-beta coronavirus vaccine program, as part of Codiak's collaboration with the Ragon Institute, at the World Vaccine Congress, to be held April 18-21, 2022

Fourth Quarter and Full Year 2021 Financial Results

Total revenues for the quarter ended December 31, 2021 were $7.7 million, compared to $1.6 million for the same period in 2020. Total revenues for the year ended December 31, 2021 were $22.9 million, compared to $2.9 million for the same period in 2020. These increases were primarily driven by revenue recognized from the Jazz collaboration for $10.9 million as a result of the mutual decision to discontinue work on STAT3 in Q1 2021 and the early termination of the research agreement with Sarepta, for $7.0 million in Q4 2021.

Net income for the quarter ended December 31, 2021 was $16.7 million, compared to a net loss of $18.0 million for the same period in 2020. Net loss for the year ended December 31, 2021, was $37.2 million, compared to a net loss of $91.7 million for the same period in 2020. The decrease in net loss for the fourth quarter and year was driven primarily by a gain on disposition of $33.3 million related to the agreement with Lonza, as well as collaboration revenue recognition in 2021.

Research and development expenses were $17.4 million for the quarter ended December 31, 2021, compared to $13.3 million for the same period in 2020. The increase in research and development expenses for the quarter was driven primarily by an increase in personnel-related costs and ongoing development of the engEx Platform.

Research and development expenses were $64.9 million for the year ended December 31, 2021, compared to $74.0 million for the same period in 2020. The year-over-year decrease was primarily driven by a licensing payment to Kayla Therapeutics in September 2020, offset by increases in clinical development costs for exoIL-12, exoSTING, and exoASO-STAT6 in 2021.

General and administrative expenses were $6.9 million for the quarter ended December 31, 2021, compared to $5.9 million for the same period in 2020. General and administrative expenses were $27.6 million for the year ended December 31, 2021, compared to $19.9 million for the same period in 2020. These increases were driven primarily by an increase in personnel costs and costs associated with transitioning to a public company.

As of December 31, 2021, Codiak had cash and cash equivalents of approximately $76.9 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, 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.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

	YEAR ENDED DECEMBER 31,	
	2021	2020
Assets		
Current assets:		
Cash and cash equivalents	$ 76,938	$ 88,915
Prepaid manufacturing services	7,315	101
Prepaid expenses and other current assets	5,918	4,742
Total current assets	90,171	93,758
Property and equipment, net	23,479	31,410
Restricted cash	4,170	4,170
Operating right-of-use assets	21,957	22,003
Prepaid manufacturing services, net of current portion	31,893	—
Total assets	$ 171,670	$ 151,341
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,838	$ 2,018
Accrued expenses	9,703	8,870
Deferred revenue	12,963	5,281
Operating lease liabilities	2,661	1,482
Total current liabilities	27,165	17,651
Long-term liabilities:		
Deferred revenue, net of current portion	30,686	57,416
Note payable, net of discount	25,430	24,960
Operating lease liabilities, net of current portion	34,884	36,540
Other long-term liabilities	—	207
Total liabilities	118,165	136,774
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, $0.0001 par value; 150,000,000 shares authorized as of December 31, 2021 and December 31, 2020; 22,383,830 and 18,787,579 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	2	2
Additional paid-in capital	378,750	302,655
Accumulated deficit	(325,247)	(288,090)
Total stockholders' equity	53,505	14,567
Total liabilities and stockholders' equity	$ 171,670	$ 151,341

CODIAK BIOSCIENCES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	THREE MONTHS ENDED DECEMBER 31,		YEAR ENDED DECEMBER 31,	
	2021	2020	2021	2020
Revenue:				
Collaboration revenue	$ 7,697	$ 1,639	$ 22,935	$ 2,915
Total revenue	7,697	1,639	22,935	2,915
Operating expenses:				
Research and development	17,419	13,328	64,855	73,981
General and administrative	6,919	5,919	27,629	19,852
Total operating expenses	24,338	19,247	92,484	93,833
Loss from operations	(16,641)	(17,608)	(69,549)	(90,918)
Other income (expense):				
Gain on disposition	33,286	—	33,286	—
Other income	618	353	1,780	906
Interest income	4	7	22	253
Interest expense	(605)	(710)	(2,696)	(1,906)
Total other income (expense), net	33,303	(350)	32,392	(747)
Net income (loss)	$ 16,662	$ (17,958)	$ (37,157)	$ (91,665)
Cumulative dividends on redeemable convertible preferred stock	—	(534)	—	(10,831)
Net income (loss) attributable to common stockholders	$ 16,662	$ (18,492)	$ (37,157)	$ (102,496)
Net income (loss) per share attributable to common stockholders, basic and diluted	$ 0.74	$ (1.14)	$ (1.70)	$ (16.18)
Weighted average common shares outstanding, basic and diluted	22,373,607	16,233,377	21,794,546	6,332,841
Comprehensive income (loss):				
Net income (loss)	$ 16,662	$ (17,958)	$ (37,157)	$ (91,665)
Other comprehensive loss:				
Unrealized loss on investments, net of tax of $0	—	—	—	(43)
Total other comprehensive loss	—	—	—	(43)
Comprehensive income (loss)	$ 16,662	$ (17,958)	$ (37,157)	$ (91,708)

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