
**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 19, 2020

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 19, 2020, Codiak BioSciences, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended September 30, 2020. 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 19, 2020, 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: November 20, 2020

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 2020 Financial Results and Operational Progress

– Human clinical testing now underway with Codiak’s first two candidates, exoIL-12™ and exoSTING™ –

- Initial safety results and preliminary systemic exposure/pharmacokinetics of exoIL-12 in healthy volunteers anticipated YE 2020—

- Biomarker, safety and clinical outcome results in cancer patients anticipated mid-2021 for both exoSTING and exoIL-12 –

CAMBRIDGE, Mass., November 19, 2020 — Codiak BioSciences, Inc. (NASDAQ: CDAK), a clinical-stage company focused on pioneering the development of exosome-based therapeutics, today reported third quarter 2020 financial results and operational progress.

“Codiak was founded to realize the potential of engineered exosomes as a new and important class of biologic medicines for the treatment of a broad range of diseases,” said Douglas E. Williams, Ph.D., President and Chief Executive Officer of Codiak. “The creativity, expertise, and execution of our team has enabled us to bring the field’s first two engineered exosome candidates into the clinic and we are on track to initiate a third clinical program next year. The recent successful completion of our initial public offering provides additional funding to progress our development programs, invest in our platform and sustain the positive momentum we have built.”

Third Quarter 2020 and Recent Highlights

- Closed initial public offering (IPO) in October 2020, raising \$74.4 million in net proceeds
- Initiated healthy volunteer dosing of exoIL-12 in a Phase 1 clinical trial designed to transition into patients with cutaneous T cell lymphoma (CTCL)
- Initiated subject dosing in a 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
- Presented preclinical data on exoIL-12 and the engEx™ Platform at the 35th Annual Meeting of the Society for Immunotherapy of Cancer (SITC)
- Expanded executive team with addition of Yalonda Howze as Executive Vice President, Chief Legal Officer
- Welcomed Jason Haddock to the Board of Directors and as Audit Committee Chairman

Anticipated Milestones and Events

- Initial safety, tolerability and systemic exposure/pharmacokinetics data from the healthy volunteer portion of the exoIL-12 Phase 1 clinical trial are expected by year-end, with biomarker, safety and preliminary pharmacodynamics and efficacy data in CTCL patients expected by mid-2021
- Safety and preliminary pharmacodynamics and efficacy data from exoSTING Phase 1/2 clinical trial in patients with solid tumors expected by mid-2021
- Evercore ISI HEALTHCONx Virtual Conference, December 2, 2020

Third Quarter 2020 Financial Results

Total revenues for the quarter ended September 30, 2020 were \$1.0 million, compared to \$0.2 million for the same period in 2019. This increase was primarily due to an increase in collaboration revenue driven primarily by activities in connection with the collaboration with Sarepta.

Net loss for the quarter ended September 30, 2020 was \$35.3 million, compared to a net loss of \$20.7 million for the same period in 2019. Net loss for the quarter ended September 30, 2020 was driven primarily by clinical development, general and administrative, and personnel expenses, and ongoing development of the engEx Platform. The current quarter net loss was inclusive of a \$15.0 million milestone payment to Kayla Therapeutics in connection with dosing of the first patient in the Phase 1/2 clinical trial of exoSTING.

Research and development expenses were \$30.7 million for the quarter ended September 30, 2020 compared to \$16.5 million for the same period in 2019. The increase was primarily driven by an increase in license milestones, personnel costs, and clinical development expenses related to the initiation of the exo-IL12 and exoSTING clinical trials in September 2020.

General and administrative expenses were \$5.3 million for the quarter ended September 30, 2020 compared to \$4.8 million for the same period in 2019. The increase was primarily driven by an increase in consulting and legal fees, personnel costs, and other administrative expenses in anticipation of operating as a public company.

As of September 30, 2020, Codiak had cash, cash equivalents, and marketable securities of \$48.3 million. In October 2020, the completion of the IPO resulted in net proceeds of \$74.4 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 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

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

	SEPTEMBER 30, 2020	DECEMBER 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 48,339	\$ 10,316
Investments	—	73,065
Restricted cash	—	367
Prepaid expenses and other current assets	4,022	10,370
Total current assets	52,361	94,118
Property and equipment, net	31,544	17,626
Restricted cash, net of current portion	4,170	4,170
Operating lease right-of-use assets	22,226	—
Other non-current assets	50	48
Total assets	<u>\$ 110,351</u>	<u>\$ 115,962</u>
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 2,488	\$ 2,381
Accrued expenses	23,858	15,818
Deferred revenue	6,268	742
Deferred rent	—	814
Operating lease liabilities	1,778	—
Total current liabilities	34,392	19,755
Long-term liabilities:		
Deferred revenue, net of current portion	58,069	54,870
Note payable, net of discount	24,825	9,572
Deferred rent, net of current portion	—	9,814
Operating lease liabilities, net of current portion	37,102	—
Total liabilities	154,388	94,011
Commitments and contingencies (Note 10)		
Series A redeemable convertible preferred stock, \$0.0001 par value; 33,200,000 shares authorized as of September 30, 2020 and December 31, 2019; 33,200,000 shares issued and outstanding as of September 30, 2020 and December 31, 2019; liquidation value as of September 30, 2020 and December 31, 2019 of \$46,162 and \$44,169, respectively	46,162	44,169
Series B redeemable convertible preferred stock, \$0.0001 par value; 21,400,000 shares authorized as of September 30, 2020 and December 31, 2019; 20,583,328 and 20,520,828 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively; liquidation value as of September 30, 2020 and December 31, 2019 of \$84,769 and \$80,874, respectively	84,769	81,108
Series C redeemable convertible preferred stock, \$0.0001 par value; 20,204,100 shares authorized as of September 30, 2020 and December 31, 2019; 20,204,079 shares issued and outstanding as of September 30, 2020 and December 31, 2019; liquidation value as of September 30, 2020 and December 31, 2019 of \$94,102 and \$89,507, respectively	94,102	89,507
Stockholders' deficit:		
Common stock, \$0.0001 par value; 150,000,000 shares authorized as of September 30, 2020 and 120,000,000 shares authorized as of December 31, 2019; 3,195,355 and 2,997,040 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	—	—
Additional paid-in capital	1,063	2
Accumulated other comprehensive income	—	43
Accumulated deficit	(270,133)	(192,878)
Total stockholders' deficit	(269,070)	(192,833)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	<u>\$ 110,351</u>	<u>\$ 115,962</u>

CODIAK BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)
(Unaudited)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2020	2019	2020	2019
Revenue:				
Collaboration revenue	\$ 954	\$ 151	\$ 1,275	\$ 238
Total revenue	<u>954</u>	<u>151</u>	<u>1,275</u>	<u>238</u>
Operating expenses:				
Research and development	30,640	16,546	60,653	41,794
General and administrative	5,342	4,835	13,933	16,786
Total operating expenses	<u>35,982</u>	<u>21,381</u>	<u>74,586</u>	<u>58,580</u>
Loss from operations	(35,028)	(21,230)	(73,311)	(58,342)
Other income (expense):				
Interest income	4	344	246	1,145
Interest expense	(607)	(3)	(1,196)	(3)
Other income	338	226	553	878
Total other income (expense), net	<u>(265)</u>	<u>567</u>	<u>(397)</u>	<u>2,020</u>
Net loss	\$ (35,293)	\$ (20,663)	\$ (73,708)	\$ (56,322)
Cumulative dividends on redeemable convertible preferred stock	(3,457)	(3,454)	(10,296)	(10,247)
Net loss attributable to common stockholders	\$ (38,750)	\$ (24,117)	\$ (84,004)	\$ (66,569)
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (12.83)</u>	<u>\$ (8.05)</u>	<u>\$ (27.92)</u>	<u>\$ (22.29)</u>
Weighted average common shares outstanding, basic and diluted	<u>3,020,055</u>	<u>2,995,917</u>	<u>3,008,576</u>	<u>2,986,889</u>
Comprehensive income (loss):				
Net loss	\$ (35,293)	\$ (20,663)	\$ (73,708)	\$ (56,322)
Other comprehensive income (loss):				
Unrealized gain (loss) on investments, net of tax of \$0	—	(8)	(43)	72
Total other comprehensive income (loss)	<u>—</u>	<u>(8)</u>	<u>(43)</u>	<u>72</u>
Comprehensive loss	<u>\$ (35,293)</u>	<u>\$ (20,671)</u>	<u>\$ (73,751)</u>	<u>\$ (56,250)</u>