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 30, 2021

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 7.01 - Regulation FD Disclosure

On November 30, 2021, Codiak BioSciences, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has cleared the Company's Investigational New Drug Application for exoASO-STAT6. 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 under this Item 7.01 is being furnished herewith and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 - Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	Description
99.1	Press release, dated November 30, 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 30, 2021

Codiak BioSciences, Inc.

By: /s/ Douglas E. Williams
Name: Douglas E. Williams, Ph.D.
Title: Chief Executive Officer and President

Exhibit 99.1

Codiak BioSciences Announces FDA Clearance of IND for exoASO™-STAT6;
Patient Dosing Expected 1H 2022

– Codiak's first engineered exosome therapeutic candidate for systemic administration –

– Single agent anti-tumor effect observed in preclinical models via macrophage reprogramming –

– Phase 1 trial will evaluate safety, tolerability, biomarkers and preliminary antitumor activity of exoASO-STAT6 in hepatocellular carcinomas –

CAMBRIDGE, Mass., November 30, 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 announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug Application (IND) for exoASO-STAT6. exoASO-STAT6 is Codiak's third engineered exosome therapeutic candidate to be cleared for clinical evaluation, and the first intended for systemic (intravenous) administration. It is designed to silence the transcription factor STAT6 selectively in tumor associated macrophages (TAMs). Preclinical studies of exoASO-STAT6 showed single agent antitumor activity in models of aggressive hepatocellular carcinoma.

"This is an important milestone for Codiak and we are excited to be advancing exoASO-STAT6 into clinical development. This program is our first systemically administered exosome therapeutic candidate, our first antisense oligonucleotide payload, our first candidate showing cell specific targeting of a transcription factor, and the first macrophage targeting candidate to show single agent anti-tumor activity of this magnitude in preclinical models," said Douglas E. Williams, Ph.D., CEO of Codiak. "We are eager to confirm this biological profile in the clinic and expect to begin enrolling patients in this Phase 1 study in the first half of 2022."

In data recently presented at the 36th Annual Meeting of the Society for Immunotherapy of Cancer (SITC 2021), exoASO-STAT6 was observed to induce significant and prolonged reduction of STAT6 mRNA in hepatocellular carcinoma models, attenuate tumor growth, and induce complete remission of tumor lesions in 50% of mice. This response rate was further enhanced (75% complete remissions) when exoASO-STAT6 was administered in combination with anti-PD1 antibodies. This monotherapy activity seen in preclinical models was accompanied by considerable remodeling of the tumor model microenvironment, including significant expansion of M1-like, immune stimulatory macrophages, ultimately resulting in tumor elimination.

About exoASO™-STAT6

exoASO-STAT6 is an exosome engineered to deliver antisense oligonucleotides and selectively target uptake in M2 polarized tumor-associated macrophages via overexpression of the exosomal protein, PTGFRN. Targeting STAT6 acts as an effective switch of the polarization of TAMs from an M2 tumor permissive/anti-inflammatory phenotype to an M1 T cell attractive, anti-tumor/inflammatory phenotype. Codiak plans to initially develop exoASO-STAT6 for primary cancers of the liver.

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 exoASO-STAT6, including future development plans and regulatory filings and timing with respect thereto. 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.

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